20. APPENDIX

表 33： 治療下で発現した有害事象：器官別大分類別及び基本語別（コホート 1）（BGB-3111-302 試験、安全性解析対象集団）

	Treatment Naive		Relapsed/Refractory		Overall	
System Organ Class Preferred Term	**Ibrutinib (N = 18) n (%)**	**Zanubrutinib (N = 19) n (%)**	**Ibrutinib (N = 80) n (%)**	**Zanubrutinib (N = 82) n (%)**	**Ibrutinib (N = 98) n (%)**	**Zanubrutinib (N = 101) n (%)**
Patients with at least 1 TEAE	18 (100.0)	19 (100.0)	80 (100.0)	82 (100.0)	98 (100.0)	101 (100.0)
感染症および寄生虫症	14 (77.8)	13 (68.4)	66 (82.5)	68 (82.9)	80 (81.6)	81 (80.2)
上気道感染	5 (27.8)	4 (21.1)	27 (33.8)	29 (35.4)	32 (32.7)	33 (32.7)
尿路感染	3 (16.7)	2 (10.5)	16 (20.0)	14 (17.1)	19 (19.4)	16 (15.8)
上咽頭炎	0 (0.0)	3 (15.8)	9 (11.3)	11 (13.4)	9 (9.2)	14 (13.9)
COVID-19	0 (0.0)	1 (5.3)	6 (7.5)	9 (11.0)	6 (6.1)	10 (9.9)
下気道感染	2 (11.1)	0 (0.0)	8 (10.0)	10 (12.2)	10 (10.2)	10 (9.9)
気道感染	0 (0.0)	2 (10.5)	3 (3.8)	6 (7.3)	3 (3.1)	8 (7.9)
鼻炎	0 (0.0)	1 (5.3)	7 (8.8)	6 (7.3)	7 (7.1)	7 (6.9)
蜂巣炎	2 (11.1)	1 (5.3)	6 (7.5)	5 (6.1)	8 (8.2)	6 (5.9)
胃腸炎	0 (0.0)	1 (5.3)	5 (6.3)	5 (6.1)	5 (5.1)	6 (5.9)
帯状疱疹	1 (5.6)	2 (10.5)	3 (3.8)	4 (4.9)	4 (4.1)	6 (5.9)
インフルエンザ	1 (5.6)	1 (5.3)	1 (1.3)	5 (6.1)	2 (2.0)	6 (5.9)
副鼻腔炎	2 (11.1)	0 (0.0)	8 (10.0)	6 (7.3)	10 (10.2)	6 (5.9)
肺炎	3 (16.7)	0 (0.0)	18 (22.5)	5 (6.1)	21 (21.4)	5 (5.0)
気管支炎	0 (0.0)	1 (5.3)	4 (5.0)	3 (3.7)	4 (4.1)	4 (4.0)
皮膚真菌感染	0 (0.0)	1 (5.3)	2 (2.5)	2 (2.4)	2 (2.0)	3 (3.0)
敗血症	1 (5.6)	0 (0.0)	3 (3.8)	3 (3.7)	4 (4.1)	3 (3.0)
皮膚感染	1 (5.6)	0 (0.0)	6 (7.5)	3 (3.7)	7 (7.1)	3 (3.0)
歯膿瘍	1 (5.6)	0 (0.0)	0 (0.0)	3 (3.7)	1 (1.0)	3 (3.0)
歯感染	1 (5.6)	0 (0.0)	4 (5.0)	3 (3.7)	5 (5.1)	3 (3.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
COVID-19 肺炎	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
結膜炎	1 (5.6)	0 (0.0)	6 (7.5)	2 (2.4)	7 (7.1)	2 (2.0)
耳感染	0 (0.0)	0 (0.0)	3 (3.8)	2 (2.4)	3 (3.1)	2 (2.0)
眼感染	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
毛包炎	2 (11.1)	0 (0.0)	3 (3.8)	2 (2.4)	5 (5.1)	2 (2.0)
ウイルス性胃腸炎	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
歯肉炎	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
B 型肝炎再活性化	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
迷路炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
限局性感染	3 (16.7)	0 (0.0)	8 (10.0)	2 (2.4)	11 (11.2)	2 (2.0)
口腔カンジダ症	2 (11.1)	1 (5.3)	0 (0.0)	1 (1.2)	2 (2.0)	2 (2.0)
爪囲炎	1 (5.6)	0 (0.0)	3 (3.8)	2 (2.4)	4 (4.1)	2 (2.0)
咽頭炎	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
細菌性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
細菌尿	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
ブドウ球菌性蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
慢性副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
コロナウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
クリプトコッカス性真菌血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
感染性下痢	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
憩室炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
出血性腸憩室炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
細菌性心内膜炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
大腸菌性菌血症	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
大腸菌性敗血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
細菌性眼感染	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
ロタウイルス胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
サルモネラ菌性胃腸炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
陰部ヘルペス	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
歯肉膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ヘルペスウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
麦粒腫	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
膿痂疹	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
咬傷感染	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
感染性皮膚潰瘍	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
口唇感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
好中球減少性敗血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
爪真菌症	2 (11.1)	0 (0.0)	3 (3.8)	1 (1.2)	5 (5.1)	1 (1.0)
口腔真菌感染	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
口腔ヘルペス	2 (11.1)	0 (0.0)	3 (3.8)	1 (1.2)	5 (5.1)	1 (1.0)
口腔感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
骨髄炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
中耳炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
パルボウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
処置後感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
急性 COVID-19 後症候群	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
術後膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肺結核	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
RS ウイルス感染	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ライノウイルス感染	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
軟部組織感染	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
レンサ球菌性菌血症	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
レンサ球菌性心内膜炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
レンサ球菌性敗血症	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
真菌性舌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
細菌性尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外陰腟真菌感染	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
肛門カンジダ症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
肛門感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
細菌性下痢	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
細菌性敗血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ブラストシスティス感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
脳膿瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
クロストリジウム・ディフィシレ感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
角膜膿瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
膀胱炎	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
感染性皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
医療機器関連感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
感染性腸炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
丹毒	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
大腸菌性尿路感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
せつ	1 (5.6)	0 (0.0)	3 (3.8)	0 (0.0)	4 (4.1)	0 (0.0)
消化管感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
帯状疱疹再燃	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
感染性胸水	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
喉頭炎	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
乳様突起炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
爪感染	2 (11.1)	0 (0.0)	4 (5.0)	0 (0.0)	6 (6.1)	0 (0.0)
鼻ヘルペス	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
神経クリプトコッカス症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
食道カンジダ症	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
パラインフルエンザウイルス感染	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
軟骨膜炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
眼窩周囲蜂巣炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ウイルス性肺炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
処置後敗血症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
腎盂腎炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
膿疱性皮疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
敗血症性ショック	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ブドウ球菌感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
皮下組織膿瘍	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
腸球菌性尿路感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
真菌性尿路感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
尿路性敗血症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
水痘帯状疱疹ウイルス感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ウイルス感染	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
創傷感染	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
真菌性創感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ブドウ球菌性創感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
胃腸障害	13 (72.2)	15 (78.9)	50 (62.5)	55 (67.1)	63 (64.3)	70 (69.3)
下痢	7 (38.9)	5 (26.3)	29 (36.3)	18 (22.0)	36 (36.7)	23 (22.8)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
便秘	4 (22.2)	5 (26.3)	8 (10.0)	15 (18.3)	12 (12.2)	20 (19.8)
悪心	4 (22.2)	7 (36.8)	11 (13.8)	12 (14.6)	15 (15.3)	19 (18.8)
嘔吐	4 (22.2)	3 (15.8)	11 (13.8)	12 (14.6)	15 (15.3)	15 (14.9)
消化不良	1 (5.6)	0 (0.0)	6 (7.5)	6 (7.3)	7 (7.1)	6 (5.9)
口内乾燥	1 (5.6)	1 (5.3)	3 (3.8)	4 (4.9)	4 (4.1)	5 (5.0)
直腸出血	2 (11.1)	1 (5.3)	0 (0.0)	4 (4.9)	2 (2.0)	5 (5.0)
腹痛	1 (5.6)	0 (0.0)	5 (6.3)	4 (4.9)	6 (6.1)	4 (4.0)
上腹部痛	1 (5.6)	1 (5.3)	5 (6.3)	3 (3.7)	6 (6.1)	4 (4.0)
胃食道逆流性疾患	2 (11.1)	1 (5.3)	3 (3.8)	3 (3.7)	5 (5.1)	4 (4.0)
口内炎	1 (5.6)	2 (10.5)	4 (5.0)	2 (2.4)	5 (5.1)	4 (4.0)
嚥下障害	0 (0.0)	0 (0.0)	3 (3.8)	3 (3.7)	3 (3.1)	3 (3.0)
口腔血性水疱	1 (5.6)	1 (5.3)	0 (0.0)	2 (2.4)	1 (1.0)	3 (3.0)
腹部膨満	0 (0.0)	1 (5.3)	3 (3.8)	1 (1.2)	3 (3.1)	2 (2.0)
肛門失禁	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
口角口唇炎	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
歯肉出血	4 (22.2)	0 (0.0)	1 (1.3)	2 (2.4)	5 (5.1)	2 (2.0)
歯肉痛	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
痔出血	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
痔核	0 (0.0)	1 (5.3)	4 (5.0)	1 (1.2)	4 (4.1)	2 (2.0)
口腔内出血	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
口腔内潰瘍形成	0 (0.0)	1 (5.3)	5 (6.3)	1 (1.2)	5 (5.1)	2 (2.0)
歯の障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
腹部不快感	1 (5.6)	0 (0.0)	4 (5.0)	1 (1.2)	5 (5.1)	1 (1.0)
腹部ヘルニア	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腹部腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
下腹部痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
肛門の炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
齲歯	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
歯不快感	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
憩室	1 (5.6)	1 (5.3)	1 (1.3)	0 (0.0)	2 (2.0)	1 (1.0)
腸憩室	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
鼓腸	2 (11.1)	1 (5.3)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.0)
胃出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
単径ヘルニア	0 (0.0)	1 (5.3)	3 (3.8)	0 (0.0)	3 (3.1)	1 (1.0)
過敏性腸症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
大腸ポリープ	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
下部消化管出血	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
膵臓障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
耳下腺腫大	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
舌潰瘍	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
歯痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
肛門出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
大腸炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血性下痢	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
十二指腸炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
糞塊	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
食中毒	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
排便回数増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胃潰瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
出血性胃潰瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胃炎	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
胃腸障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
胃腸ポリープ出血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
歯肉障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
吐血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血便排泄	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
裂孔ヘルニア	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
口の感覚鈍麻	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
口唇痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
口唇腫脹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
メレナ	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
食道炎	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
口腔粘膜水疱形成	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
舌腫脹	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
舌乾燥	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
舌異形成	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
歯の侵食	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
上部消化管出血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
一般・全身障害および投与部位の状態	11 (61.1)	14 (73.7)	47 (58.8)	45 (54.9)	58 (59.2)	59 (58.4)
疲労	5 (27.8)	5 (26.3)	14 (17.5)	21 (25.6)	19 (19.4)	26 (25.7)
末梢性浮腫	5 (27.8)	4 (21.1)	17 (21.3)	15 (18.3)	22 (22.4)	19 (18.8)
発熱	0 (0.0)	4 (21.1)	15 (18.8)	14 (17.1)	15 (15.3)	18 (17.8)
無力症	0 (0.0)	0 (0.0)	6 (7.5)	9 (11.0)	6 (6.1)	9 (8.9)
インフルエンザ様疾患	1 (5.6)	2 (10.5)	4 (5.0)	4 (4.9)	5 (5.1)	6 (5.9)
薬剤離脱症候群	0 (0.0)	1 (5.3)	2 (2.5)	4 (4.9)	2 (2.0)	5 (5.0)
末梢腫脹	3 (16.7)	1 (5.3)	9 (11.3)	4 (4.9)	12 (12.2)	5 (5.0)
胸痛	1 (5.6)	2 (10.5)	4 (5.0)	2 (2.4)	5 (5.1)	4 (4.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
歩行障害	0 (0.0)	3 (15.8)	0 (0.0)	1 (1.2)	0 (0.0)	4 (4.0)
悪寒	1 (5.6)	1 (5.3)	3 (3.8)	2 (2.4)	4 (4.1)	3 (3.0)
非心臓性胸痛	0 (0.0)	1 (5.3)	0 (0.0)	2 (2.4)	0 (0.0)	3 (3.0)
疼痛	0 (0.0)	1 (5.3)	1 (1.3)	2 (2.4)	1 (1.0)	3 (3.0)
医薬品副作用	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
異常感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ヘルニア	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
治癒不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
埋込み部位潰瘍	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
倦怠感	1 (5.6)	0 (0.0)	2 (2.5)	1 (1.2)	3 (3.1)	1 (1.0)
浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ワクチン接種部位発疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
腋窩痛	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
カテーテル留置部位疼痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胸部不快感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
死亡	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
不快感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
注入部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
体調不良	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
分泌物分泌	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
顔面腫脹	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血管穿刺部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
筋骨格系および結合組織障害	11 (61.1)	11 (57.9)	52 (65.0)	48 (58.5)	63 (64.3)	59 (58.4)
関節痛	4 (22.2)	4 (21.1)	20 (25.0)	20 (24.4)	24 (24.5)	24 (23.8)
背部痛	5 (27.8)	3 (15.8)	13 (16.3)	15 (18.3)	18 (18.4)	18 (17.8)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
四肢痛	2 (11.1)	1 (5.3)	8 (10.0)	14 (17.1)	10 (10.2)	15 (14.9)
筋痙縮	7 (38.9)	3 (15.8)	21 (26.3)	9 (11.0)	28 (28.6)	12 (11.9)
筋肉痛	0 (0.0)	3 (15.8)	3 (3.8)	4 (4.9)	3 (3.1)	7 (6.9)
関節腫脹	2 (11.1)	1 (5.3)	2 (2.5)	3 (3.7)	4 (4.1)	4 (4.0)
筋力低下	0 (0.0)	2 (10.5)	1 (1.3)	2 (2.4)	1 (1.0)	4 (4.0)
滑液包炎	0 (0.0)	1 (5.3)	0 (0.0)	2 (2.4)	0 (0.0)	3 (3.0)
側腹部痛	0 (0.0)	0 (0.0)	1 (1.3)	3 (3.7)	1 (1.0)	3 (3.0)
筋骨格系胸痛	1 (5.6)	1 (5.3)	2 (2.5)	2 (2.4)	3 (3.1)	3 (3.0)
頚部痛	1 (5.6)	1 (5.3)	5 (6.3)	2 (2.4)	6 (6.1)	3 (3.0)
変形性関節症	0 (0.0)	0 (0.0)	3 (3.8)	3 (3.7)	3 (3.1)	3 (3.0)
肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	3 (3.8)	3 (3.7)	3 (3.1)	3 (3.0)
関節炎	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
骨痛	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
筋攣縮	1 (5.6)	0 (0.0)	0 (0.0)	2 (2.4)	1 (1.0)	2 (2.0)
筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
筋炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
足底筋膜炎	1 (5.6)	1 (5.3)	1 (1.3)	1 (1.2)	2 (2.0)	2 (2.0)
脊椎痛	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
尾骨痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肋軟骨炎	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腱付着部症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外骨腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
骨折痛	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
鼡径部痛	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
筋骨格不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
筋骨格硬直	0 (0.0)	1 (5.3)	2 (2.5)	0 (0.0)	2 (2.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
頚部腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
神経障害性関節症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
骨粗鬆症	0 (0.0)	1 (5.3)	3 (3.8)	0 (0.0)	3 (3.1)	1 (1.0)
骨粗鬆症性骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
滑液嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
腱鞘炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
痛風結節	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
関節滲出液	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
関節硬直	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
筋骨格障害	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
骨壊死	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
側弯症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
脊柱管狭窄症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
滑膜炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
腱痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
腱炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
椎間孔狭窄	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚および皮下組織障害	10 (55.6)	9 (47.4)	48 (60.0)	49 (59.8)	58 (59.2)	58 (57.4)
発疹	4 (22.2)	3 (15.8)	15 (18.8)	16 (19.5)	19 (19.4)	19 (18.8)
そう痒症	0 (0.0)	5 (26.3)	6 (7.5)	10 (12.2)	6 (6.1)	15 (14.9)
点状出血	2 (11.1)	2 (10.5)	3 (3.8)	5 (6.1)	5 (5.1)	7 (6.9)
皮膚病変	0 (0.0)	2 (10.5)	3 (3.8)	4 (4.9)	3 (3.1)	6 (5.9)
紅斑	0 (0.0)	1 (5.3)	3 (3.8)	4 (4.9)	3 (3.1)	5 (5.0)
紅斑性皮疹	1 (5.6)	0 (0.0)	0 (0.0)	5 (6.1)	1 (1.0)	5 (5.0)
紫斑	1 (5.6)	1 (5.3)	5 (6.3)	3 (3.7)	6 (6.1)	4 (4.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
斑状丘疹状皮疹	0 (0.0)	0 (0.0)	2 (2.5)	4 (4.9)	2 (2.0)	4 (4.0)
光線角化症	0 (0.0)	0 (0.0)	5 (6.3)	3 (3.7)	5 (5.1)	3 (3.0)
湿疹	1 (5.6)	1 (5.3)	1 (1.3)	2 (2.4)	2 (2.0)	3 (3.0)
多汗症	0 (0.0)	0 (0.0)	1 (1.3)	3 (3.7)	1 (1.0)	3 (3.0)
皮膚潰瘍	0 (0.0)	1 (5.3)	4 (5.0)	2 (2.4)	4 (4.1)	3 (3.0)
アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
接触皮膚炎	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
皮膚乾燥	2 (11.1)	1 (5.3)	5 (6.3)	1 (1.2)	7 (7.1)	2 (2.0)
酒さ	1 (5.6)	1 (5.3)	4 (5.0)	1 (1.2)	5 (5.1)	2 (2.0)
脱毛症	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
皮膚炎	1 (5.6)	1 (5.3)	4 (5.0)	0 (0.0)	5 (5.1)	1 (1.0)
ざ瘡様皮膚炎	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
薬疹	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
斑状出血	0 (0.0)	0 (0.0)	4 (5.0)	1 (1.2)	4 (4.1)	1 (1.0)
貨幣状湿疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
汗腺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
苔癬様角化症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
爪の障害	1 (5.6)	1 (5.3)	2 (2.5)	0 (0.0)	3 (3.1)	1 (1.0)
寝汗	1 (5.6)	1 (5.3)	1 (1.3)	0 (0.0)	2 (2.0)	1 (1.0)
爪破損	2 (11.1)	0 (0.0)	8 (10.0)	1 (1.2)	10 (10.2)	1 (1.0)
皮膚疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
光線性皮膚症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
そう痒性皮疹	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
皮膚亀裂	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.2)	3 (3.1)	1 (1.0)
皮膚出血	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
皮膚腫瘤	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
皮膚毒性	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.2)	3 (3.1)	1 (1.0)
うっ滞性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
一過性棘融解性皮膚症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
蕁麻疹	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
血管炎性皮疹	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
水疱	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
血性水疱	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚嚢腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
アレルギー性皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
逆むけ	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
嵌入爪	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
斑	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
丘疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
陰茎潰瘍形成	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
乾癬	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
老人性紫斑	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
毛孔性皮疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
斑状皮疹	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
丘疹性皮疹	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
皮膚灼熱感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
神経系障害	9 (50.0)	14 (73.7)	39 (48.8)	41 (50.0)	48 (49.0)	55 (54.5)
頭痛	2 (11.1)	4 (21.1)	13 (16.3)	14 (17.1)	15 (15.3)	18 (17.8)
浮動性めまい	3 (16.7)	4 (21.1)	11 (13.8)	12 (14.6)	14 (14.3)	16 (15.8)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
末梢性感覚ニューロパチー	0 (0.0)	4 (21.1)	5 (6.3)	4 (4.9)	5 (5.1)	8 (7.9)
失神	3 (16.7)	3 (15.8)	5 (6.3)	2 (2.4)	8 (8.2)	5 (5.0)
錯感覚	1 (5.6)	0 (0.0)	7 (8.8)	4 (4.9)	8 (8.2)	4 (4.0)
健忘	1 (5.6)	1 (5.3)	1 (1.3)	2 (2.4)	2 (2.0)	3 (3.0)
平衡障害	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
認知障害	0 (0.0)	2 (10.5)	2 (2.5)	0 (0.0)	2 (2.0)	2 (2.0)
注意力障害	0 (0.0)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)
感覚鈍麻	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
失神寸前の状態	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
下肢静止不能症候群	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
失語症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
運動失調	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
脳血管発作	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
脱髄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
体位性めまい	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
嗜眠	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
記憶障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
筋痙直	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
脊髄症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
パーキンソニズム	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
末梢性感覚運動ニューロパチー	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
腓骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ヘルペス後神経痛	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
神経根痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
坐骨神経痛	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.2)	3 (3.1)	1 (1.0)
痙攣発作	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
感覚消失	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
傾眠	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
一過性全健忘	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
灼熱感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
手根管症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
意識消失	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
神経痛	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
パーキンソン病	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
末梢性運動ニューロパチー	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
くも膜下出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
味覚障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
振戦	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
傷害、中毒および処置合併症	11 (61.1)	13 (68.4)	37 (46.3)	38 (46.3)	48 (49.0)	51 (50.5)
挫傷	5 (27.8)	7 (36.8)	23 (28.8)	12 (14.6)	28 (28.6)	19 (18.8)
転倒	4 (22.2)	3 (15.8)	7 (8.8)	7 (8.5)	11 (11.2)	10 (9.9)
四肢損傷	1 (5.6)	2 (10.5)	4 (5.0)	3 (3.7)	5 (5.1)	5 (5.0)
皮膚裂傷	4 (22.2)	1 (5.3)	4 (5.0)	4 (4.9)	8 (8.2)	5 (5.0)
処置による疼痛	0 (0.0)	2 (10.5)	0 (0.0)	2 (2.4)	0 (0.0)	4 (4.0)
頭部損傷	0 (0.0)	2 (10.5)	0 (0.0)	1 (1.2)	0 (0.0)	3 (3.0)
眼窩周囲出血	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
脊椎圧迫骨折	0 (0.0)	2 (10.5)	1 (1.3)	1 (1.2)	1 (1.0)	3 (3.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
動物咬傷	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
肉離れ	0 (0.0)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)
処置後出血	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
肋骨骨折	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
脊椎骨折	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
歯牙破折	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
術後貧血	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
動物による引っかき傷	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
足関節部骨折	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
脳振盪	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
上顆炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼挫傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
大腿骨骨折	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
足骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
手骨折	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
注入に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
関節脱臼	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
関節損傷	0 (0.0)	0 (0.0)	4 (5.0)	1 (1.2)	4 (4.1)	1 (1.0)
靭帯断裂	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腰椎骨折	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
筋損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
膝蓋骨骨折	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
眼窩周囲血腫	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
処置後合併症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
処置後腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外傷後疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
引っかき傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
皮膚創傷	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
軟部組織損傷	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
硬膜下血腫	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
硬膜下出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
サンバーン	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腱損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
胸椎骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外傷性血腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外傷性頭蓋内出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
創傷出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
手首関節骨折	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
節足動物咬傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼瞼損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
顔面損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
大腿骨頚部骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
靱帯捻挫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
口唇損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
下肢骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
筋骨格内異物	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
筋骨格系損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
口腔挫傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
骨盤骨折	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
処置後血腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
反応性胃障害	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚擦過傷	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
ストーマ部出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ストレス骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
創傷	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
創部分泌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	9 (50.0)	13 (68.4)	42 (52.5)	37 (45.1)	51 (52.0)	50 (49.5)
咳嗽	2 (11.1)	4 (21.1)	18 (22.5)	16 (19.5)	20 (20.4)	20 (19.8)
鼻出血	4 (22.2)	6 (31.6)	17 (21.3)	12 (14.6)	21 (21.4)	18 (17.8)
呼吸困難	3 (16.7)	2 (10.5)	6 (7.5)	15 (18.3)	9 (9.2)	17 (16.8)
湿性咳嗽	2 (11.1)	1 (5.3)	2 (2.5)	5 (6.1)	4 (4.1)	6 (5.9)
口腔咽頭痛	0 (0.0)	0 (0.0)	10 (12.5)	4 (4.9)	10 (10.2)	4 (4.0)
胸水	0 (0.0)	1 (5.3)	3 (3.8)	3 (3.7)	3 (3.1)	4 (4.0)
喘鳴	1 (5.6)	2 (10.5)	0 (0.0)	2 (2.4)	1 (1.0)	4 (4.0)
発声障害	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
労作性呼吸困難	0 (0.0)	1 (5.3)	3 (3.8)	1 (1.2)	3 (3.1)	2 (2.0)
間質性肺疾患	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
鼻閉	1 (5.6)	0 (0.0)	2 (2.5)	2 (2.4)	3 (3.1)	2 (2.0)
アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
鼻漏	0 (0.0)	0 (0.0)	5 (6.3)	2 (2.4)	5 (5.1)	2 (2.0)
急性呼吸不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
慢性閉塞性肺疾患	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
喀血	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
血胸	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
過換気	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
喉頭の炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
喉頭浮腫	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
喉頭強皮症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肺硬化	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
肺陰影	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
鼻部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
副鼻腔の炎症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
誤嚥性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肺臓炎	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.2)	3 (3.1)	1 (1.0)
肺線維症	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
肺痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
呼吸不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
鼻痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
副鼻腔うっ血	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
咽喉刺激感	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
上気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
急性肺水腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
アレルギー性咳嗽	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
咽喉乾燥	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
喉頭障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肺浸潤	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
鼻乾燥	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
鼻茸	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
鼻そう痒症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
口腔咽頭不快感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
咽頭紅斑	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
咽頭腫脹	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
咽頭潰瘍	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
胸膜炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胸膜痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肺腫瘤	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
逆流性喉頭炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
呼吸障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
上気道咳症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血液およびリンパ系障害	6 (33.3)	12 (63.2)	35 (43.8)	37 (45.1)	41 (41.8)	49 (48.5)
好中球減少症	1 (5.6)	7 (36.8)	15 (18.8)	23 (28.0)	16 (16.3)	30 (29.7)
貧血	2 (11.1)	6 (31.6)	20 (25.0)	12 (14.6)	22 (22.4)	18 (17.8)
血小板減少症	0 (0.0)	3 (15.8)	16 (20.0)	12 (14.6)	16 (16.3)	15 (14.9)
発熱性好中球減少症	0 (0.0)	0 (0.0)	1 (1.3)	4 (4.9)	1 (1.0)	4 (4.0)
リンパ節症	0 (0.0)	0 (0.0)	1 (1.3)	4 (4.9)	1 (1.0)	4 (4.0)
内出血発生の増加傾向	3 (16.7)	0 (0.0)	2 (2.5)	3 (3.7)	5 (5.1)	3 (3.0)
鉄欠乏性貧血	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
出血性素因	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
過粘稠度症候群	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
白血球減少症	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
赤血球増加症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
特発性血腫	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
後天性フォンウィルブランド病	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
溶血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
溶血性貧血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
出血性障害	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
リンパ球減少症	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
代謝および栄養障害	6 (33.3)	9 (47.4)	32 (40.0)	29 (35.4)	38 (38.8)	38 (37.6)
鉄欠乏	2 (11.1)	3 (15.8)	5 (6.3)	4 (4.9)	7 (7.1)	7 (6.9)
低ナトリウム血症	0 (0.0)	3 (15.8)	1 (1.3)	2 (2.4)	1 (1.0)	5 (5.0)
ビタミン D 欠乏	0 (0.0)	0 (0.0)	2 (2.5)	5 (6.1)	2 (2.0)	5 (5.0)
食欲減退	2 (11.1)	0 (0.0)	2 (2.5)	4 (4.9)	4 (4.1)	4 (4.0)
高尿酸血症	0 (0.0)	1 (5.3)	9 (11.3)	3 (3.7)	9 (9.2)	4 (4.0)
脱水	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
痛風	2 (11.1)	1 (5.3)	3 (3.8)	2 (2.4)	5 (5.1)	3 (3.0)
高血糖	0 (0.0)	1 (5.3)	4 (5.0)	2 (2.4)	4 (4.1)	3 (3.0)
低カルシウム血症	0 (0.0)	1 (5.3)	1 (1.3)	2 (2.4)	1 (1.0)	3 (3.0)
低カリウム血症	1 (5.6)	1 (5.3)	5 (6.3)	2 (2.4)	6 (6.1)	3 (3.0)
高カリウム血症	1 (5.6)	1 (5.3)	0 (0.0)	1 (1.2)	1 (1.0)	2 (2.0)
低マグネシウム血症	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
低リン血症	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
水分過負荷	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
葉酸欠乏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
高カルシウム血症	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
高コレステロール血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
高マグネシウム血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
低アルブミン血症	0 (0.0)	1 (5.3)	3 (3.8)	0 (0.0)	3 (3.1)	1 (1.0)
栄養障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ビタミン B12 欠乏	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
異常体重減少	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
アシドーシス	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
グルテン過敏症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
高脂血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
高リン血症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
低血糖	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
ビタミン B 群欠乏	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心臓障害	9 (50.0)	8 (42.1)	31 (38.8)	29 (35.4)	40 (40.8)	37 (36.6)
心房細動	5 (27.8)	1 (5.3)	16 (20.0)	6 (7.3)	21 (21.4)	7 (6.9)
動悸	2 (11.1)	2 (10.5)	8 (10.0)	4 (4.9)	10 (10.2)	6 (5.9)
洞性徐脈	2 (11.1)	1 (5.3)	1 (1.3)	5 (6.1)	3 (3.1)	6 (5.9)
狭心症	3 (16.7)	2 (10.5)	1 (1.3)	2 (2.4)	4 (4.1)	4 (4.0)
心不全	1 (5.6)	0 (0.0)	1 (1.3)	3 (3.7)	2 (2.0)	3 (3.0)
急性心筋梗塞	3 (16.7)	1 (5.3)	0 (0.0)	1 (1.2)	3 (3.1)	2 (2.0)
大動脈弁狭窄	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
右脚ブロック	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
僧帽弁閉鎖不全症	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
上室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
急性左室不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
大動脈弁疾患	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
大動脈弁閉鎖不全症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
心房粗動	0 (0.0)	0 (0.0)	4 (5.0)	1 (1.2)	4 (4.1)	1 (1.0)
完全房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
第二度房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
徐脈	3 (16.7)	0 (0.0)	0 (0.0)	1 (1.2)	3 (3.1)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
うっ血性心不全	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
心タンポナーデ	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心拡大	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
慢性左室不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
冠動脈疾患	2 (11.1)	1 (5.3)	1 (1.3)	0 (0.0)	3 (3.1)	1 (1.0)
心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
洞結節機能不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
洞性頻脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
上室性頻脈	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
収縮機能障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
頻脈性不整脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
頻脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
上室性不整脈	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
冠動脈硬化症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
急性心不全	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心粗動	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
心血管不全	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心嚢液貯留	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心嚢内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心膜炎	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
心室性不整脈	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心室性期外収縮	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
眼障害	7 (38.9)	5 (26.3)	21 (26.3)	22 (26.8)	28 (28.6)	27 (26.7)
結膜出血	1 (5.6)	2 (10.5)	5 (6.3)	3 (3.7)	6 (6.1)	5 (5.0)
白内障	2 (11.1)	1 (5.3)	4 (5.0)	2 (2.4)	6 (6.1)	3 (3.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
霧視	0 (0.0)	2 (10.5)	6 (7.5)	1 (1.2)	6 (6.1)	3 (3.0)
ドライアイ	1 (5.6)	0 (0.0)	2 (2.5)	2 (2.4)	3 (3.1)	2 (2.0)
眼瞼紅斑	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
黄斑変性	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
硝子体剥離	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
霰粒腫	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
複視	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
眼の障害	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
眼血腫	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
眼出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
眼球浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
眼部腫脹	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
眼瞼出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼瞼発疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼瞼そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼充血	2 (11.1)	0 (0.0)	1 (1.3)	1 (1.2)	3 (3.1)	1 (1.0)
視神経症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
網膜剥離	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
視力障害	1 (5.6)	1 (5.3)	1 (1.3)	0 (0.0)	2 (2.0)	1 (1.0)
眼瞼炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
嚢下白内障	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
後天性涙道狭窄	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
糖尿病網膜症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
眼刺激	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
眼そう痒症	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
眼瞼障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼瞼浮腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
流涙増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼窩嚢胞	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼窩周囲浮腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
網膜出血	1 (5.6)	0 (0.0)	3 (3.8)	0 (0.0)	4 (4.1)	0 (0.0)
視力低下	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
視野欠損	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
硝子体浮遊物	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
腎および尿路障害	8 (44.4)	6 (31.6)	18 (22.5)	21 (25.6)	26 (26.5)	27 (26.7)
血尿	4 (22.2)	3 (15.8)	9 (11.3)	9 (11.0)	13 (13.3)	12 (11.9)
慢性腎臓病	1 (5.6)	2 (10.5)	1 (1.3)	2 (2.4)	2 (2.0)	4 (4.0)
尿閉	0 (0.0)	1 (5.3)	0 (0.0)	3 (3.7)	0 (0.0)	4 (4.0)
夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
急性腎障害	0 (0.0)	1 (5.3)	4 (5.0)	1 (1.2)	4 (4.1)	2 (2.0)
腎結石症	1 (5.6)	0 (0.0)	1 (1.3)	2 (2.4)	2 (2.0)	2 (2.0)
蛋白尿	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
腎臓痛	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
非感染性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
糖尿病性腎症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
白血球尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
頻尿	0 (0.0)	1 (5.3)	3 (3.8)	0 (0.0)	3 (3.1)	1 (1.0)
尿管結石症	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
膀胱刺激症状	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
排尿困難	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
腎不全	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
膀胱出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血管障害	7 (38.9)	7 (36.8)	31 (38.8)	19 (23.2)	38 (38.8)	26 (25.7)
高血圧	3 (16.7)	4 (21.1)	21 (26.3)	12 (14.6)	24 (24.5)	16 (15.8)
血腫	1 (5.6)	1 (5.3)	8 (10.0)	4 (4.9)	9 (9.2)	5 (5.0)
低血圧	1 (5.6)	2 (10.5)	1 (1.3)	2 (2.4)	2 (2.0)	4 (4.0)
起立性低血圧	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
末梢静脈疾患	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
出血性静脈瘤	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
深部静脈血栓症	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
間欠性跛行	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
リンパ嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
リンパ浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
末梢冷感	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
末梢血管障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
白衣性高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
出血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血栓後症候群	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血栓性静脈炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
表在性血栓性静脈炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
四肢静脈血栓症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
臨床検査	5 (27.8)	5 (26.3)	21 (26.3)	20 (24.4)	26 (26.5)	25 (24.8)
好中球数減少	2 (11.1)	0 (0.0)	2 (2.5)	8 (9.8)	4 (4.1)	8 (7.9)
血中クレアチニン増加	1 (5.6)	1 (5.3)	1 (1.3)	2 (2.4)	2 (2.0)	3 (3.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
体重減少	0 (0.0)	2 (10.5)	2 (2.5)	1 (1.2)	2 (2.0)	3 (3.0)
アラニンアミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	3 (3.8)	2 (2.4)	3 (3.1)	2 (2.0)
血中ビリルビン増加	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	3 (3.8)	2 (2.4)	3 (3.1)	2 (2.0)
血小板数減少	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
血中葉酸減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
血中免疫グロブリン G 減少	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
血中鉄減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
C-反応性蛋白増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
カンジダ検査陽性	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心拍数増加	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
心拍数不整	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
インターフェロンγ応答測定陽性	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
酸素飽和度低下	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
前立腺特異性抗原増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
血沈亢進	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
血清フェリチン減少	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
トロポニン増加	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
体重増加	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
血中アルカリホスファターゼ減少	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血中アルカリホスファターゼ増加	1 (5.6)	0 (0.0)	3 (3.8)	0 (0.0)	4 (4.1)	0 (0.0)
血中乳酸脱水素酵素増加	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
血中カリウム減少	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血圧上昇	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼圧上昇	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive Ibrutinib (N = 18) n (%)	Treatment Naive Zanubrutinib (N = 19) n (%)	Relapsed/Refractory Ibrutinib (N = 80) n (%)	Relapsed/Refractory Zanubrutinib (N = 82) n (%)	Overall Ibrutinib (N = 98) n (%)	Overall Zanubrutinib (N = 101) n (%)
磁気共鳴画像異常	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
膵酵素減少	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
尿細胞診異常	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (22.2)	3 (15.8)	15 (18.8)	18 (22.0)	19 (19.4)	21 (20.8)
基底細胞癌	0 (0.0)	1 (5.3)	5 (6.3)	5 (6.1)	5 (5.1)	6 (5.9)
皮膚有棘細胞癌	1 (5.6)	0 (0.0)	4 (5.0)	3 (3.7)	5 (5.1)	3 (3.0)
ボーエン病	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
皮膚癌	0 (0.0)	1 (5.3)	2 (2.5)	1 (1.2)	2 (2.0)	2 (2.0)
良性骨巨細胞腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
乳癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
慢性骨髄単球性白血病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
遠隔転移を伴う結腸直腸癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
子宮内膜腺癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
外耳の悪性新生物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
ケラトアカントーマ	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肺の悪性新生物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
リンパ腫の転化	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
悪性黒色腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
悪性黒色腫第 1 期	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
メラノサイト性母斑	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
遠隔転移を伴う悪性黒色腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
骨髄異形成症候群	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
結節性黒色腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
形質細胞性骨髄腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
腫瘍出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
膀胱移行上皮癌	3 (16.7)	0 (0.0)	1 (1.3)	0 (0.0)	4 (4.1)	0 (0.0)
慢性骨髄性白血病	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
神経膠芽細胞腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚血管腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
化膿性肉芽腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
脂漏性角化症	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
精神障害	4 (22.2)	9 (47.4)	15 (18.8)	8 (9.8)	19 (19.4)	17 (16.8)
不安	0 (0.0)	2 (10.5)	7 (8.8)	3 (3.7)	7 (7.1)	5 (5.0)
うつ病	1 (5.6)	2 (10.5)	3 (3.8)	1 (1.2)	4 (4.1)	3 (3.0)
不眠症	3 (16.7)	2 (10.5)	6 (7.5)	1 (1.2)	9 (9.2)	3 (3.0)
抑うつ気分を伴う適応障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
アルコール離脱症候群	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
反社会的行動	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
錯乱状態	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
譫妄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
抑うつ気分	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
幻覚	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
神経過敏	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
睡眠の質低下	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
睡眠障害	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
激越	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
気分変化	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
耳および迷路障害	0 (0.0)	2 (10.5)	9 (11.3)	12 (14.6)	9 (9.2)	14 (13.9)
耳鳴	0 (0.0)	1 (5.3)	3 (3.8)	5 (6.1)	3 (3.1)	6 (5.9)
回転性めまい	0 (0.0)	1 (5.3)	4 (5.0)	2 (2.4)	4 (4.1)	3 (3.0)
耳不快感	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
耳痛	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
難聴	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
片耳難聴	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
耳閉	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
耳出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
耳垢分泌過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
中耳の炎症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
耳漏	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
生殖系および乳房障害	6 (33.3)	1 (5.3)	10 (12.5)	9 (11.0)	16 (16.3)	10 (9.9)
女性化乳房	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
血精液症	2 (11.1)	0 (0.0)	0 (0.0)	2 (2.4)	2 (2.0)	2 (2.0)
腟脱	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
後天性陰嚢水瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
後天性包茎	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
良性前立腺肥大症	1 (5.6)	0 (0.0)	2 (2.5)	1 (1.2)	3 (3.1)	1 (1.0)
勃起不全	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
陰茎浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
陰嚢浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
精巣腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
精巣痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
乳房腫瘤	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
生殖器病変	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
閉経後出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
前立腺障害	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
前立腺炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
腟分泌物	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
外陰部障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
免疫系障害	2 (11.1)	2 (10.5)	7 (8.8)	5 (6.1)	9 (9.2)	7 (6.9)
季節性アレルギー	0 (0.0)	2 (10.5)	2 (2.5)	2 (2.4)	2 (2.0)	4 (4.0)
造影剤アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
薬物過敏症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
節足動物咬傷アレルギー	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
アミロイドーシス	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
造影剤反応	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
低γグロブリン血症	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
免疫再構築炎症反応症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
免疫反応	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
肝胆道系障害	3 (16.7)	2 (10.5)	2 (2.5)	1 (1.2)	5 (5.1)	3 (3.0)
胆石症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
薬物性肝障害	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
門脈拡張	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
胆嚢炎	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
肝硬変	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肝炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
内分泌障害	1 (5.6)	1 (5.3)	2 (2.5)	1 (1.2)	3 (3.1)	2 (2.0)
甲状腺機能亢進症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
甲状腺機能低下症	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
副甲状腺機能亢進症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
甲状腺腫瘤	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

Source: Table 14.3.1.2.2.1 in BGB-3111-302 clinical study report (final database lock date: [redacted] 20[redacted]). Data cutoff: 21JUN2022; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE.
Abbreviation(s): TEAE, treatment-emergent adverse event.
Cohort 1 includes patients with activating mutations in MYD88.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
MedDRA Version: 24.0.

表 34： 治療下で発現した有害事象：器官別大分類別及び基本語別（ザヌブルチニブを投与した被験者全例）（BGB-3111-302 試験、安全性解析対象集団）

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
Patients with at least 1 TEAE	101 (100.0)	27 (96.4)	128 (99.2)
感染症および寄生虫症	81 (80.2)	24 (85.7)	105 (81.4)
上気道感染	33 (32.7)	7 (25.0)	40 (31.0)
尿路感染	16 (15.8)	5 (17.9)	21 (16.3)
上咽頭炎	14 (13.9)	4 (14.3)	18 (14.0)
COVID-19	10 (9.9)	6 (21.4)	16 (12.4)
気道感染	8 (7.9)	5 (17.9)	13 (10.1)
下気道感染	10 (9.9)	2 (7.1)	12 (9.3)
帯状疱疹	6 (5.9)	3 (10.7)	9 (7.0)
肺炎	5 (5.0)	4 (14.3)	9 (7.0)
気管支炎	4 (4.0)	4 (14.3)	8 (6.2)
蜂巣炎	6 (5.9)	2 (7.1)	8 (6.2)
胃腸炎	6 (5.9)	2 (7.1)	8 (6.2)
鼻炎	7 (6.9)	1 (3.6)	8 (6.2)
インフルエンザ	6 (5.9)	1 (3.6)	7 (5.4)
副鼻腔炎	6 (5.9)	0 (0.0)	6 (4.7)
眼感染	2 (2.0)	2 (7.1)	4 (3.1)
ウイルス性胃腸炎	2 (2.0)	2 (7.1)	4 (3.1)
限局性感染	2 (2.0)	2 (7.1)	4 (3.1)
口腔カンジダ症	2 (2.0)	2 (7.1)	4 (3.1)
歯膿瘍	3 (3.0)	1 (3.6)	4 (3.1)
歯感染	3 (3.0)	1 (3.6)	4 (3.1)
ウイルス性上気道感染	3 (3.0)	1 (3.6)	4 (3.1)
結膜炎	2 (2.0)	1 (3.6)	3 (2.3)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
毛包炎	2 (2.0)	1 (3.6)	3 (2.3)
皮膚真菌感染	3 (3.0)	0 (0.0)	3 (2.3)
敗血症	3 (3.0)	0 (0.0)	3 (2.3)
皮膚感染	3 (3.0)	0 (0.0)	3 (2.3)
細菌性関節炎	1 (1.0)	1 (3.6)	2 (1.6)
COVID-19 肺炎	2 (2.0)	0 (0.0)	2 (1.6)
膀胱炎	0 (0.0)	2 (7.1)	2 (1.6)
耳感染	2 (2.0)	0 (0.0)	2 (1.6)
歯肉炎	2 (2.0)	0 (0.0)	2 (1.6)
B 型肝炎再活性化	2 (2.0)	0 (0.0)	2 (1.6)
迷路炎	2 (2.0)	0 (0.0)	2 (1.6)
口腔ヘルペス	1 (1.0)	1 (3.6)	2 (1.6)
爪囲炎	2 (2.0)	0 (0.0)	2 (1.6)
咽頭炎	2 (2.0)	0 (0.0)	2 (1.6)
レンサ球菌性菌血症	1 (1.0)	1 (3.6)	2 (1.6)
細菌尿	1 (1.0)	0 (0.0)	1 (0.8)
体部白癬	0 (0.0)	1 (3.6)	1 (0.8)
ブドウ球菌性蜂巣炎	1 (1.0)	0 (0.0)	1 (0.8)
慢性副鼻腔炎	1 (1.0)	0 (0.0)	1 (0.8)
コロナウイルス感染	1 (1.0)	0 (0.0)	1 (0.8)
クリプトコッカス性真菌血症	1 (1.0)	0 (0.0)	1 (0.8)
感染性下痢	1 (1.0)	0 (0.0)	1 (0.8)
憩室炎	1 (1.0)	0 (0.0)	1 (0.8)
出血性腸憩室炎	1 (1.0)	0 (0.0)	1 (0.8)
細菌性心内膜炎	1 (1.0)	0 (0.0)	1 (0.8)
大腸菌性菌血症	1 (1.0)	0 (0.0)	1 (0.8)
大腸菌感染	0 (0.0)	1 (3.6)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
大腸菌性敗血症	1 (1.0)	0 (0.0)	1 (0.8)
細菌性眼感染	1 (1.0)	0 (0.0)	1 (0.8)
ノロウイルス性胃腸炎	0 (0.0)	1 (3.6)	1 (0.8)
ロタウイルス胃腸炎	1 (1.0)	0 (0.0)	1 (0.8)
サルモネラ菌性胃腸炎	1 (1.0)	0 (0.0)	1 (0.8)
陰部ヘルペス	1 (1.0)	0 (0.0)	1 (0.8)
陰部単純ヘルペス	0 (0.0)	1 (3.6)	1 (0.8)
歯肉膿瘍	1 (1.0)	0 (0.0)	1 (0.8)
ヘリコバクター感染	0 (0.0)	1 (3.6)	1 (0.8)
B 型肝炎	0 (0.0)	1 (3.6)	1 (0.8)
ヘルペスウイルス感染	1 (1.0)	0 (0.0)	1 (0.8)
麦粒腫	1 (1.0)	0 (0.0)	1 (0.8)
膿痂疹	1 (1.0)	0 (0.0)	1 (0.8)
咬傷感染	1 (1.0)	0 (0.0)	1 (0.8)
感染性皮膚潰瘍	1 (1.0)	0 (0.0)	1 (0.8)
喉頭炎	0 (0.0)	1 (3.6)	1 (0.8)
口唇感染	1 (1.0)	0 (0.0)	1 (0.8)
乳腺炎	0 (0.0)	1 (3.6)	1 (0.8)
好中球減少性敗血症	1 (1.0)	0 (0.0)	1 (0.8)
爪真菌症	1 (1.0)	0 (0.0)	1 (0.8)
口腔真菌感染	1 (1.0)	0 (0.0)	1 (0.8)
口腔感染	1 (1.0)	0 (0.0)	1 (0.8)
骨髄炎	1 (1.0)	0 (0.0)	1 (0.8)
中耳炎	1 (1.0)	0 (0.0)	1 (0.8)
パルボウイルス感染	1 (1.0)	0 (0.0)	1 (0.8)
ウイルス性肺炎	0 (0.0)	1 (3.6)	1 (0.8)
処置後感染	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
急性 COVID-19 後症候群	1 (1.0)	0 (0.0)	1 (0.8)
術後膿瘍	1 (1.0)	0 (0.0)	1 (0.8)
肺結核	1 (1.0)	0 (0.0)	1 (0.8)
歯髄炎	0 (0.0)	1 (3.6)	1 (0.8)
RS ウイルス感染	1 (1.0)	0 (0.0)	1 (0.8)
ウイルス性気道感染	1 (1.0)	0 (0.0)	1 (0.8)
ライノウイルス感染	1 (1.0)	0 (0.0)	1 (0.8)
軟部組織感染	1 (1.0)	0 (0.0)	1 (0.8)
ブドウ球菌感染	0 (0.0)	1 (3.6)	1 (0.8)
レンサ球菌性心内膜炎	1 (1.0)	0 (0.0)	1 (0.8)
レンサ球菌性敗血症	1 (1.0)	0 (0.0)	1 (0.8)
真菌性舌感染	1 (1.0)	0 (0.0)	1 (0.8)
細菌性尿路感染	1 (1.0)	0 (0.0)	1 (0.8)
尿路性敗血症	0 (0.0)	1 (3.6)	1 (0.8)
外陰腟真菌感染	1 (1.0)	0 (0.0)	1 (0.8)
胃腸障害	70 (69.3)	15 (53.6)	85 (65.9)
下痢	23 (22.8)	9 (32.1)	32 (24.8)
便秘	20 (19.8)	6 (21.4)	26 (20.2)
悪心	19 (18.8)	2 (7.1)	21 (16.3)
嘔吐	15 (14.9)	4 (14.3)	19 (14.7)
消化不良	6 (5.9)	3 (10.7)	9 (7.0)
腹痛	4 (4.0)	2 (7.1)	6 (4.7)
上腹部痛	4 (4.0)	1 (3.6)	5 (3.9)
口内乾燥	5 (5.0)	0 (0.0)	5 (3.9)
胃食道逆流性疾患	4 (4.0)	1 (3.6)	5 (3.9)
直腸出血	5 (5.0)	0 (0.0)	5 (3.9)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
腹部膨満	2 (2.0)	2 (7.1)	4 (3.1)
口内炎	4 (4.0)	0 (0.0)	4 (3.1)
嚥下障害	3 (3.0)	0 (0.0)	3 (2.3)
歯肉出血	2 (2.0)	1 (3.6)	3 (2.3)
口腔血性水疱	3 (3.0)	0 (0.0)	3 (2.3)
肛門失禁	2 (2.0)	0 (0.0)	2 (1.6)
口角口唇炎	2 (2.0)	0 (0.0)	2 (1.6)
歯肉痛	2 (2.0)	0 (0.0)	2 (1.6)
痔出血	2 (2.0)	0 (0.0)	2 (1.6)
痔核	2 (2.0)	0 (0.0)	2 (1.6)
口腔内出血	2 (2.0)	0 (0.0)	2 (1.6)
口腔内潰瘍形成	2 (2.0)	0 (0.0)	2 (1.6)
歯の障害	2 (2.0)	0 (0.0)	2 (1.6)
歯痛	1 (1.0)	1 (3.6)	2 (1.6)
腹部不快感	1 (1.0)	0 (0.0)	1 (0.8)
腹部ヘルニア	1 (1.0)	0 (0.0)	1 (0.8)
腹部腫瘤	1 (1.0)	0 (0.0)	1 (0.8)
下腹部痛	1 (1.0)	0 (0.0)	1 (0.8)
肛門の炎症	1 (1.0)	0 (0.0)	1 (0.8)
クローン病	0 (0.0)	1 (3.6)	1 (0.8)
齲歯	1 (1.0)	0 (0.0)	1 (0.8)
歯不快感	1 (1.0)	0 (0.0)	1 (0.8)
憩室	1 (1.0)	0 (0.0)	1 (0.8)
腸憩室	1 (1.0)	0 (0.0)	1 (0.8)
十二指腸潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
変色便	0 (0.0)	1 (3.6)	1 (0.8)
鼓腸	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
胃出血	1 (1.0)	0 (0.0)	1 (0.8)
胃潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
出血性胃潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
胃炎	0 (0.0)	1 (3.6)	1 (0.8)
血便排泄	0 (0.0)	1 (3.6)	1 (0.8)
単径ヘルニア	1 (1.0)	0 (0.0)	1 (0.8)
過敏性腸症候群	1 (1.0)	0 (0.0)	1 (0.8)
大腸ポリープ	1 (1.0)	0 (0.0)	1 (0.8)
口唇乾燥	0 (0.0)	1 (3.6)	1 (0.8)
下部消化管出血	1 (1.0)	0 (0.0)	1 (0.8)
膵臓障害	1 (1.0)	0 (0.0)	1 (0.8)
耳下腺腫大	1 (1.0)	0 (0.0)	1 (0.8)
舌乾燥	0 (0.0)	1 (3.6)	1 (0.8)
舌潰瘍	1 (1.0)	0 (0.0)	1 (0.8)
皮膚および皮下組織障害	58 (57.4)	17 (60.7)	75 (58.1)
発疹	19 (18.8)	4 (14.3)	23 (17.8)
そう痒症	15 (14.9)	7 (25.0)	22 (17.1)
紅斑	5 (5.0)	2 (7.1)	7 (5.4)
点状出血	7 (6.9)	0 (0.0)	7 (5.4)
皮膚病変	6 (5.9)	1 (3.6)	7 (5.4)
紅斑性皮疹	5 (5.0)	1 (3.6)	6 (4.7)
光線角化症	3 (3.0)	2 (7.1)	5 (3.9)
紫斑	4 (4.0)	0 (0.0)	4 (3.1)
斑状丘疹状皮疹	4 (4.0)	0 (0.0)	4 (3.1)
皮膚炎	1 (1.0)	2 (7.1)	3 (2.3)
湿疹	3 (3.0)	0 (0.0)	3 (2.3)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
多汗症	3 (3.0)	0 (0.0)	3 (2.3)
酒さ	2 (2.0)	1 (3.6)	3 (2.3)
皮膚潰瘍	3 (3.0)	0 (0.0)	3 (2.3)
脱毛症	1 (1.0)	1 (3.6)	2 (1.6)
アトピー性皮膚炎	2 (2.0)	0 (0.0)	2 (1.6)
接触皮膚炎	2 (2.0)	0 (0.0)	2 (1.6)
皮膚乾燥	2 (2.0)	0 (0.0)	2 (1.6)
斑状出血	1 (1.0)	1 (3.6)	2 (1.6)
皮膚腫瘤	1 (1.0)	1 (3.6)	2 (1.6)
血管炎性皮疹	1 (1.0)	1 (3.6)	2 (1.6)
褥瘡性潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
ざ瘡様皮膚炎	1 (1.0)	0 (0.0)	1 (0.8)
薬疹	1 (1.0)	0 (0.0)	1 (0.8)
貨幣状湿疹	1 (1.0)	0 (0.0)	1 (0.8)
汗腺炎	1 (1.0)	0 (0.0)	1 (0.8)
嵌入爪	0 (0.0)	1 (3.6)	1 (0.8)
硬化性苔癬	0 (0.0)	1 (3.6)	1 (0.8)
苔癬様角化症	1 (1.0)	0 (0.0)	1 (0.8)
爪の障害	1 (1.0)	0 (0.0)	1 (0.8)
寝汗	1 (1.0)	0 (0.0)	1 (0.8)
爪破損	1 (1.0)	0 (0.0)	1 (0.8)
皮膚疼痛	1 (1.0)	0 (0.0)	1 (0.8)
光線性皮膚症	1 (1.0)	0 (0.0)	1 (0.8)
光線過敏性反応	0 (0.0)	1 (3.6)	1 (0.8)
斑状皮疹	0 (0.0)	1 (3.6)	1 (0.8)
そう痒性皮疹	1 (1.0)	0 (0.0)	1 (0.8)
皮膚剥脱	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
皮膚亀裂	1 (1.0)	0 (0.0)	1 (0.8)
皮膚出血	1 (1.0)	0 (0.0)	1 (0.8)
皮膚毒性	1 (1.0)	0 (0.0)	1 (0.8)
うっ滞性皮膚炎	1 (1.0)	0 (0.0)	1 (0.8)
一過性棘融解性皮膚症	1 (1.0)	0 (0.0)	1 (0.8)
蕁麻疹	1 (1.0)	0 (0.0)	1 (0.8)
筋骨格系および結合組織障害	59 (58.4)	15 (53.6)	74 (57.4)
関節痛	24 (23.8)	5 (17.9)	29 (22.5)
背部痛	18 (17.8)	6 (21.4)	24 (18.6)
四肢痛	15 (14.9)	3 (10.7)	18 (14.0)
筋痙縮	12 (11.9)	4 (14.3)	16 (12.4)
筋肉痛	7 (6.9)	1 (3.6)	8 (6.2)
筋骨格系胸痛	3 (3.0)	2 (7.1)	5 (3.9)
側腹部痛	3 (3.0)	1 (3.6)	4 (3.1)
関節腫脹	4 (4.0)	0 (0.0)	4 (3.1)
筋力低下	4 (4.0)	0 (0.0)	4 (3.1)
変形性関節症	3 (3.0)	1 (3.6)	4 (3.1)
滑液包炎	3 (3.0)	0 (0.0)	3 (2.3)
頚部痛	3 (3.0)	0 (0.0)	3 (2.3)
肩回旋筋腱板症候群	3 (3.0)	0 (0.0)	3 (2.3)
関節炎	2 (2.0)	0 (0.0)	2 (1.6)
骨痛	2 (2.0)	0 (0.0)	2 (1.6)
筋攣縮	2 (2.0)	0 (0.0)	2 (1.6)
筋骨格痛	2 (2.0)	0 (0.0)	2 (1.6)
筋炎	2 (2.0)	0 (0.0)	2 (1.6)
骨粗鬆症	1 (1.0)	1 (3.6)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
足底筋膜炎	2 (2.0)	0 (0.0)	2 (1.6)
脊椎痛	2 (2.0)	0 (0.0)	2 (1.6)
腱鞘炎	1 (1.0)	1 (3.6)	2 (1.6)
腋窩腫瘤	0 (0.0)	1 (3.6)	1 (0.8)
軟骨石灰化症	0 (0.0)	1 (3.6)	1 (0.8)
尾骨痛	1 (1.0)	0 (0.0)	1 (0.8)
肋軟骨炎	1 (1.0)	0 (0.0)	1 (0.8)
腱付着部症	1 (1.0)	0 (0.0)	1 (0.8)
外骨腫	1 (1.0)	0 (0.0)	1 (0.8)
骨折痛	1 (1.0)	0 (0.0)	1 (0.8)
鼡径部痛	1 (1.0)	0 (0.0)	1 (0.8)
筋骨格不快感	1 (1.0)	0 (0.0)	1 (0.8)
筋骨格硬直	1 (1.0)	0 (0.0)	1 (0.8)
頚部腫瘤	1 (1.0)	0 (0.0)	1 (0.8)
神経障害性関節症	1 (1.0)	0 (0.0)	1 (0.8)
骨粗鬆症性骨折	1 (1.0)	0 (0.0)	1 (0.8)
乾癬性関節症	0 (0.0)	1 (3.6)	1 (0.8)
滑液嚢腫	1 (1.0)	0 (0.0)	1 (0.8)
腱炎	0 (0.0)	1 (3.6)	1 (0.8)
一般・全身障害および投与部位の状態	59 (58.4)	14 (50.0)	73 (56.6)
疲労	26 (25.7)	5 (17.9)	31 (24.0)
末梢性浮腫	19 (18.8)	5 (17.9)	24 (18.6)
発熱	18 (17.8)	6 (21.4)	24 (18.6)
無力症	9 (8.9)	3 (10.7)	12 (9.3)
末梢腫脹	5 (5.0)	2 (7.1)	7 (5.4)
薬剤離脱症候群	5 (5.0)	1 (3.6)	6 (4.7)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
インフルエンザ様疾患	6 (5.9)	0 (0.0)	6 (4.7)
胸痛	4 (4.0)	0 (0.0)	4 (3.1)
歩行障害	4 (4.0)	0 (0.0)	4 (3.1)
悪寒	3 (3.0)	0 (0.0)	3 (2.3)
非心臓性胸痛	3 (3.0)	0 (0.0)	3 (2.3)
疼痛	3 (3.0)	0 (0.0)	3 (2.3)
医薬品副作用	1 (1.0)	0 (0.0)	1 (0.8)
胸部不快感	0 (0.0)	1 (3.6)	1 (0.8)
異常感	1 (1.0)	0 (0.0)	1 (0.8)
ヘルニア	1 (1.0)	0 (0.0)	1 (0.8)
治癒不良	1 (1.0)	0 (0.0)	1 (0.8)
埋込み部位潰瘍	1 (1.0)	0 (0.0)	1 (0.8)
倦怠感	1 (1.0)	0 (0.0)	1 (0.8)
浮腫	1 (1.0)	0 (0.0)	1 (0.8)
体調不良	0 (0.0)	1 (3.6)	1 (0.8)
ワクチン接種部位発疹	1 (1.0)	0 (0.0)	1 (0.8)
神経系障害	55 (54.5)	10 (35.7)	65 (50.4)
頭痛	18 (17.8)	4 (14.3)	22 (17.1)
浮動性めまい	16 (15.8)	2 (7.1)	18 (14.0)
末梢性感覚ニューロパチー	8 (7.9)	3 (10.7)	11 (8.5)
失神	5 (5.0)	1 (3.6)	6 (4.7)
錯感覚	4 (4.0)	1 (3.6)	5 (3.9)
健忘	3 (3.0)	0 (0.0)	3 (2.3)
感覚鈍麻	2 (2.0)	1 (3.6)	3 (2.3)
平衡障害	2 (2.0)	0 (0.0)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
認知障害	2 (2.0)	0 (0.0)	2 (1.6)
注意力障害	2 (2.0)	0 (0.0)	2 (1.6)
失神寸前の状態	2 (2.0)	0 (0.0)	2 (1.6)
下肢静止不能症候群	2 (2.0)	0 (0.0)	2 (1.6)
坐骨神経痛	1 (1.0)	1 (3.6)	2 (1.6)
痙攣発作	1 (1.0)	1 (3.6)	2 (1.6)
感覚障害	2 (2.0)	0 (0.0)	2 (1.6)
失語症	1 (1.0)	0 (0.0)	1 (0.8)
運動失調	1 (1.0)	0 (0.0)	1 (0.8)
灼熱感	0 (0.0)	1 (3.6)	1 (0.8)
頚動脈硬化症	0 (0.0)	1 (3.6)	1 (0.8)
脳血管発作	1 (1.0)	0 (0.0)	1 (0.8)
頚髄神経根障害	1 (1.0)	0 (0.0)	1 (0.8)
脱髄	1 (1.0)	0 (0.0)	1 (0.8)
体位性めまい	1 (1.0)	0 (0.0)	1 (0.8)
嗜眠	1 (1.0)	0 (0.0)	1 (0.8)
記憶障害	1 (1.0)	0 (0.0)	1 (0.8)
片頭痛	1 (1.0)	0 (0.0)	1 (0.8)
筋痙直	1 (1.0)	0 (0.0)	1 (0.8)
脊髄症	1 (1.0)	0 (0.0)	1 (0.8)
パーキンソニズム	1 (1.0)	0 (0.0)	1 (0.8)
末梢性感覚運動ニューロパチー	1 (1.0)	0 (0.0)	1 (0.8)
腓骨神経麻痺	1 (1.0)	0 (0.0)	1 (0.8)
ヘルペス後神経痛	1 (1.0)	0 (0.0)	1 (0.8)
外傷後頭痛	0 (0.0)	1 (3.6)	1 (0.8)
神経根痛	1 (1.0)	0 (0.0)	1 (0.8)
神経根障害	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
感覚消失	1 (1.0)	0 (0.0)	1 (0.8)
傾眠	1 (1.0)	0 (0.0)	1 (0.8)
一過性全健忘	1 (1.0)	0 (0.0)	1 (0.8)
傷害、中毒および処置合併症	51 (50.5)	13 (46.4)	64 (49.6)
挫傷	19 (18.8)	7 (25.0)	26 (20.2)
転倒	10 (9.9)	3 (10.7)	13 (10.1)
四肢損傷	5 (5.0)	3 (10.7)	8 (6.2)
皮膚裂傷	5 (5.0)	3 (10.7)	8 (6.2)
頭部損傷	3 (3.0)	1 (3.6)	4 (3.1)
処置による疼痛	4 (4.0)	0 (0.0)	4 (3.1)
関節損傷	1 (1.0)	2 (7.1)	3 (2.3)
眼窩周囲出血	3 (3.0)	0 (0.0)	3 (2.3)
脊椎圧迫骨折	3 (3.0)	0 (0.0)	3 (2.3)
歯牙破折	2 (2.0)	1 (3.6)	3 (2.3)
動物咬傷	2 (2.0)	0 (0.0)	2 (1.6)
眼挫傷	1 (1.0)	1 (3.6)	2 (1.6)
靭帯断裂	1 (1.0)	1 (3.6)	2 (1.6)
肉離れ	2 (2.0)	0 (0.0)	2 (1.6)
眼窩周囲血腫	1 (1.0)	1 (3.6)	2 (1.6)
処置後出血	2 (2.0)	0 (0.0)	2 (1.6)
外傷後疼痛	1 (1.0)	1 (3.6)	2 (1.6)
肋骨骨折	2 (2.0)	0 (0.0)	2 (1.6)
軟部組織損傷	1 (1.0)	1 (3.6)	2 (1.6)
脊椎骨折	2 (2.0)	0 (0.0)	2 (1.6)
硬膜下血腫	1 (1.0)	1 (3.6)	2 (1.6)
硬膜下出血	1 (1.0)	1 (3.6)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
術後貧血	1 (1.0)	0 (0.0)	1 (0.8)
動物による引っかき傷	1 (1.0)	0 (0.0)	1 (0.8)
足関節部骨折	1 (1.0)	0 (0.0)	1 (0.8)
脳振盪	1 (1.0)	0 (0.0)	1 (0.8)
上顆炎	1 (1.0)	0 (0.0)	1 (0.8)
大腿骨骨折	1 (1.0)	0 (0.0)	1 (0.8)
腓骨骨折	0 (0.0)	1 (3.6)	1 (0.8)
足骨折	1 (1.0)	0 (0.0)	1 (0.8)
手骨折	1 (1.0)	0 (0.0)	1 (0.8)
注入に伴う反応	1 (1.0)	0 (0.0)	1 (0.8)
関節脱臼	1 (1.0)	0 (0.0)	1 (0.8)
腰椎骨折	1 (1.0)	0 (0.0)	1 (0.8)
筋損傷	1 (1.0)	0 (0.0)	1 (0.8)
膝蓋骨骨折	1 (1.0)	0 (0.0)	1 (0.8)
処置後合併症	1 (1.0)	0 (0.0)	1 (0.8)
処置後腫脹	1 (1.0)	0 (0.0)	1 (0.8)
引っかき傷	1 (1.0)	0 (0.0)	1 (0.8)
皮膚創傷	1 (1.0)	0 (0.0)	1 (0.8)
サンバーン	1 (1.0)	0 (0.0)	1 (0.8)
腱損傷	1 (1.0)	0 (0.0)	1 (0.8)
胸椎骨折	1 (1.0)	0 (0.0)	1 (0.8)
外傷性血腫	1 (1.0)	0 (0.0)	1 (0.8)
外傷性頭蓋内出血	1 (1.0)	0 (0.0)	1 (0.8)
創傷	0 (0.0)	1 (3.6)	1 (0.8)
創傷出血	1 (1.0)	0 (0.0)	1 (0.8)
手首関節骨折	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
血液およびリンパ系障害	49 (48.5)	14 (50.0)	63 (48.8)
好中球減少症	30 (29.7)	5 (17.9)	35 (27.1)
貧血	18 (17.8)	6 (21.4)	24 (18.6)
血小板減少症	15 (14.9)	3 (10.7)	18 (14.0)
内出血発生の増加傾向	3 (3.0)	2 (7.1)	5 (3.9)
発熱性好中球減少症	4 (4.0)	0 (0.0)	4 (3.1)
リンパ節症	4 (4.0)	0 (0.0)	4 (3.1)
過粘稠度症候群	1 (1.0)	1 (3.6)	2 (1.6)
鉄欠乏性貧血	2 (2.0)	0 (0.0)	2 (1.6)
出血性素因	1 (1.0)	0 (0.0)	1 (0.8)
白血球減少症	1 (1.0)	0 (0.0)	1 (0.8)
リンパ節痛	0 (0.0)	1 (3.6)	1 (0.8)
赤血球増加症	1 (1.0)	0 (0.0)	1 (0.8)
特発性血腫	1 (1.0)	0 (0.0)	1 (0.8)
呼吸器、胸郭および縦隔障害	50 (49.5)	13 (46.4)	63 (48.8)
咳嗽	20 (19.8)	6 (21.4)	26 (20.2)
鼻出血	18 (17.8)	1 (3.6)	19 (14.7)
呼吸困難	17 (16.8)	1 (3.6)	18 (14.0)
湿性咳嗽	6 (5.9)	2 (7.1)	8 (6.2)
胸水	4 (4.0)	1 (3.6)	5 (3.9)
口腔咽頭痛	4 (4.0)	0 (0.0)	4 (3.1)
喘鳴	4 (4.0)	0 (0.0)	4 (3.1)
労作性呼吸困難	2 (2.0)	1 (3.6)	3 (2.3)
喀血	1 (1.0)	2 (7.1)	3 (2.3)
慢性閉塞性肺疾患	1 (1.0)	1 (3.6)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
発声障害	2 (2.0)	0 (0.0)	2 (1.6)
間質性肺疾患	2 (2.0)	0 (0.0)	2 (1.6)
鼻閉	2 (2.0)	0 (0.0)	2 (1.6)
肺臓炎	1 (1.0)	1 (3.6)	2 (1.6)
呼吸不全	1 (1.0)	1 (3.6)	2 (1.6)
アレルギー性鼻炎	2 (2.0)	0 (0.0)	2 (1.6)
鼻漏	2 (2.0)	0 (0.0)	2 (1.6)
急性呼吸不全	1 (1.0)	0 (0.0)	1 (0.8)
喘息	0 (0.0)	1 (3.6)	1 (0.8)
声門機能不全	0 (0.0)	1 (3.6)	1 (0.8)
血胸	1 (1.0)	0 (0.0)	1 (0.8)
過換気	1 (1.0)	0 (0.0)	1 (0.8)
喉頭の炎症	1 (1.0)	0 (0.0)	1 (0.8)
喉頭浮腫	1 (1.0)	0 (0.0)	1 (0.8)
喉頭強皮症	1 (1.0)	0 (0.0)	1 (0.8)
肺硬化	1 (1.0)	0 (0.0)	1 (0.8)
肺陰影	1 (1.0)	0 (0.0)	1 (0.8)
鼻部不快感	1 (1.0)	0 (0.0)	1 (0.8)
鼻閉塞	0 (0.0)	1 (3.6)	1 (0.8)
器質化肺炎	0 (0.0)	1 (3.6)	1 (0.8)
副鼻腔の炎症	1 (1.0)	0 (0.0)	1 (0.8)
誤嚥性肺炎	1 (1.0)	0 (0.0)	1 (0.8)
肺線維症	1 (1.0)	0 (0.0)	1 (0.8)
肺痛	1 (1.0)	0 (0.0)	1 (0.8)
鼻痛	1 (1.0)	0 (0.0)	1 (0.8)
副鼻腔うっ血	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
咽喉刺激感	1 (1.0)	0 (0.0)	1 (0.8)
上気道うっ血	1 (1.0)	0 (0.0)	1 (0.8)
代謝および栄養障害	38 (37.6)	10 (35.7)	48 (37.2)
食欲減退	4 (4.0)	4 (14.3)	8 (6.2)
低ナトリウム血症	5 (5.0)	2 (7.1)	7 (5.4)
鉄欠乏	7 (6.9)	0 (0.0)	7 (5.4)
高尿酸血症	4 (4.0)	2 (7.1)	6 (4.7)
痛風	3 (3.0)	2 (7.1)	5 (3.9)
ビタミン D 欠乏	5 (5.0)	0 (0.0)	5 (3.9)
脱水	3 (3.0)	0 (0.0)	3 (2.3)
高血糖	3 (3.0)	0 (0.0)	3 (2.3)
高カリウム血症	2 (2.0)	1 (3.6)	3 (2.3)
低カルシウム血症	3 (3.0)	0 (0.0)	3 (2.3)
低カリウム血症	3 (3.0)	0 (0.0)	3 (2.3)
低マグネシウム血症	2 (2.0)	1 (3.6)	3 (2.3)
水分過負荷	1 (1.0)	1 (3.6)	2 (1.6)
葉酸欠乏	1 (1.0)	1 (3.6)	2 (1.6)
低リン血症	2 (2.0)	0 (0.0)	2 (1.6)
高カルシウム血症	1 (1.0)	0 (0.0)	1 (0.8)
高コレステロール血症	1 (1.0)	0 (0.0)	1 (0.8)
高マグネシウム血症	1 (1.0)	0 (0.0)	1 (0.8)
高トリグリセリド血症	1 (1.0)	0 (0.0)	1 (0.8)
低アルブミン血症	1 (1.0)	0 (0.0)	1 (0.8)
低血糖	0 (0.0)	1 (3.6)	1 (0.8)
低蛋白血症	0 (0.0)	1 (3.6)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
栄養障害	1 (1.0)	0 (0.0)	1 (0.8)
ビタミン B12 欠乏	1 (1.0)	0 (0.0)	1 (0.8)
心臓障害	37 (36.6)	5 (17.9)	42 (32.6)
心房細動	7 (6.9)	2 (7.1)	9 (7.0)
動悸	6 (5.9)	2 (7.1)	8 (6.2)
洞性徐脈	6 (5.9)	0 (0.0)	6 (4.7)
狭心症	4 (4.0)	0 (0.0)	4 (3.1)
心不全	3 (3.0)	0 (0.0)	3 (2.3)
急性心筋梗塞	2 (2.0)	0 (0.0)	2 (1.6)
大動脈弁狭窄	2 (2.0)	0 (0.0)	2 (1.6)
右脚ブロック	2 (2.0)	0 (0.0)	2 (1.6)
うっ血性心不全	1 (1.0)	1 (3.6)	2 (1.6)
期外収縮	2 (2.0)	0 (0.0)	2 (1.6)
僧帽弁閉鎖不全症	2 (2.0)	0 (0.0)	2 (1.6)
上室性期外収縮	2 (2.0)	0 (0.0)	2 (1.6)
頻脈	1 (1.0)	1 (3.6)	2 (1.6)
急性左室不全	1 (1.0)	0 (0.0)	1 (0.8)
大動脈弁疾患	1 (1.0)	0 (0.0)	1 (0.8)
大動脈弁閉鎖不全症	1 (1.0)	0 (0.0)	1 (0.8)
心房粗動	1 (1.0)	0 (0.0)	1 (0.8)
完全房室ブロック	1 (1.0)	0 (0.0)	1 (0.8)
第二度房室ブロック	1 (1.0)	0 (0.0)	1 (0.8)
徐脈	1 (1.0)	0 (0.0)	1 (0.8)
心停止	0 (0.0)	1 (3.6)	1 (0.8)
心タンポナーデ	1 (1.0)	0 (0.0)	1 (0.8)
心拡大	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
慢性左室不全	1 (1.0)	0 (0.0)	1 (0.8)
冠動脈疾患	1 (1.0)	0 (0.0)	1 (0.8)
心筋虚血	1 (1.0)	0 (0.0)	1 (0.8)
洞結節機能不全	1 (1.0)	0 (0.0)	1 (0.8)
洞性頻脈	1 (1.0)	0 (0.0)	1 (0.8)
上室性頻脈	1 (1.0)	0 (0.0)	1 (0.8)
収縮機能障害	1 (1.0)	0 (0.0)	1 (0.8)
頻脈性不整脈	1 (1.0)	0 (0.0)	1 (0.8)
心室性期外収縮	0 (0.0)	1 (3.6)	1 (0.8)
血管障害	26 (25.7)	8 (28.6)	34 (26.4)
高血圧	16 (15.8)	3 (10.7)	19 (14.7)
血腫	5 (5.0)	1 (3.6)	6 (4.7)
低血圧	4 (4.0)	1 (3.6)	5 (3.9)
リンパ浮腫	1 (1.0)	1 (3.6)	2 (1.6)
起立性低血圧	2 (2.0)	0 (0.0)	2 (1.6)
末梢静脈疾患	2 (2.0)	0 (0.0)	2 (1.6)
白衣性高血圧	1 (1.0)	1 (3.6)	2 (1.6)
出血性静脈瘤	1 (1.0)	0 (0.0)	1 (0.8)
深部静脈血栓症	1 (1.0)	0 (0.0)	1 (0.8)
潮紅	0 (0.0)	1 (3.6)	1 (0.8)
出血	0 (0.0)	1 (3.6)	1 (0.8)
間欠性跛行	1 (1.0)	0 (0.0)	1 (0.8)
リンパ嚢腫	1 (1.0)	0 (0.0)	1 (0.8)
末梢冷感	1 (1.0)	0 (0.0)	1 (0.8)
末梢血管障害	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
血栓性静脈炎	0 (0.0)	1 (3.6)	1 (0.8)
腎および尿路障害	27 (26.7)	6 (21.4)	33 (25.6)
血尿	12 (11.9)	1 (3.6)	13 (10.1)
尿閉	4 (4.0)	1 (3.6)	5 (3.9)
急性腎障害	2 (2.0)	2 (7.1)	4 (3.1)
慢性腎臓病	4 (4.0)	0 (0.0)	4 (3.1)
夜間頻尿	3 (3.0)	0 (0.0)	3 (2.3)
腎結石症	2 (2.0)	0 (0.0)	2 (1.6)
蛋白尿	2 (2.0)	0 (0.0)	2 (1.6)
腎臓痛	2 (2.0)	0 (0.0)	2 (1.6)
非感染性膀胱炎	1 (1.0)	0 (0.0)	1 (0.8)
糖尿病性腎症	1 (1.0)	0 (0.0)	1 (0.8)
排尿困難	0 (0.0)	1 (3.6)	1 (0.8)
白血球尿	1 (1.0)	0 (0.0)	1 (0.8)
頻尿	1 (1.0)	0 (0.0)	1 (0.8)
多尿	0 (0.0)	1 (3.6)	1 (0.8)
腎動脈狭窄症	0 (0.0)	1 (3.6)	1 (0.8)
尿管結石症	1 (1.0)	0 (0.0)	1 (0.8)
眼障害	27 (26.7)	5 (17.9)	32 (24.8)
結膜出血	5 (5.0)	0 (0.0)	5 (3.9)
霧視	3 (3.0)	1 (3.6)	4 (3.1)
白内障	3 (3.0)	0 (0.0)	3 (2.3)
眼充血	1 (1.0)	2 (7.1)	3 (2.3)
ドライアイ	2 (2.0)	0 (0.0)	2 (1.6)
眼瞼紅斑	2 (2.0)	0 (0.0)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
黄斑変性	2 (2.0)	0 (0.0)	2 (1.6)
視力障害	1 (1.0)	1 (3.6)	2 (1.6)
硝子体剥離	2 (2.0)	0 (0.0)	2 (1.6)
眼瞼炎	0 (0.0)	1 (3.6)	1 (0.8)
霰粒腫	1 (1.0)	0 (0.0)	1 (0.8)
複視	1 (1.0)	0 (0.0)	1 (0.8)
眼の障害	1 (1.0)	0 (0.0)	1 (0.8)
眼血腫	1 (1.0)	0 (0.0)	1 (0.8)
眼出血	1 (1.0)	0 (0.0)	1 (0.8)
眼球浮腫	1 (1.0)	0 (0.0)	1 (0.8)
眼痛	1 (1.0)	0 (0.0)	1 (0.8)
眼部腫脹	1 (1.0)	0 (0.0)	1 (0.8)
眼瞼出血	1 (1.0)	0 (0.0)	1 (0.8)
眼瞼嚢胞	0 (0.0)	1 (3.6)	1 (0.8)
眼瞼発疹	1 (1.0)	0 (0.0)	1 (0.8)
眼瞼そう痒症	1 (1.0)	0 (0.0)	1 (0.8)
流涙増加	0 (0.0)	1 (3.6)	1 (0.8)
瞼板腺炎	0 (0.0)	1 (3.6)	1 (0.8)
視神経症	1 (1.0)	0 (0.0)	1 (0.8)
網膜剥離	1 (1.0)	0 (0.0)	1 (0.8)
臨床検査	25 (24.8)	7 (25.0)	32 (24.8)
好中球数減少	8 (7.9)	1 (3.6)	9 (7.0)
血中クレアチニン増加	3 (3.0)	1 (3.6)	4 (3.1)
体重減少	3 (3.0)	1 (3.6)	4 (3.1)
アラニンアミノトランスフェラーゼ増加	2 (2.0)	0 (0.0)	2 (1.6)
アスパラギン酸アミノトランスフェラーゼ増加	1 (1.0)	1 (3.6)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
血中ビリルビン増加	2 (2.0)	0 (0.0)	2 (1.6)
γ－グルタミルトランスフェラーゼ増加	2 (2.0)	0 (0.0)	2 (1.6)
血小板数減少	2 (2.0)	0 (0.0)	2 (1.6)
血中アルカリホスファターゼ増加	0 (0.0)	1 (3.6)	1 (0.8)
血中葉酸減少	1 (1.0)	0 (0.0)	1 (0.8)
血中ブドウ糖増加	0 (0.0)	1 (3.6)	1 (0.8)
血中免疫グロブリン G 減少	1 (1.0)	0 (0.0)	1 (0.8)
血中鉄減少	1 (1.0)	0 (0.0)	1 (0.8)
C-反応性蛋白増加	1 (1.0)	0 (0.0)	1 (0.8)
カンジダ検査陽性	1 (1.0)	0 (0.0)	1 (0.8)
心拍数増加	1 (1.0)	0 (0.0)	1 (0.8)
心拍数不整	1 (1.0)	0 (0.0)	1 (0.8)
インターフェロン γ 応答測定陽性	1 (1.0)	0 (0.0)	1 (0.8)
酸素飽和度低下	1 (1.0)	0 (0.0)	1 (0.8)
前立腺特異性抗原増加	1 (1.0)	0 (0.0)	1 (0.8)
血沈亢進	1 (1.0)	0 (0.0)	1 (0.8)
SARS-CoV-2 検査陽性	0 (0.0)	1 (3.6)	1 (0.8)
血清フェリチン減少	1 (1.0)	0 (0.0)	1 (0.8)
トロポニン増加	1 (1.0)	0 (0.0)	1 (0.8)
体重増加	1 (1.0)	0 (0.0)	1 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	21 (20.8)	6 (21.4)	27 (20.9)
基底細胞癌	6 (5.9)	3 (10.7)	9 (7.0)
皮膚有棘細胞癌	3 (3.0)	0 (0.0)	3 (2.3)
ボーエン病	2 (2.0)	0 (0.0)	2 (1.6)
リンパ腫の転化	1 (1.0)	1 (3.6)	2 (1.6)
皮膚癌	2 (2.0)	0 (0.0)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
良性骨巨細胞腫	1 (1.0)	0 (0.0)	1 (0.8)
乳癌	1 (1.0)	0 (0.0)	1 (0.8)
慢性骨髄単球性白血病	1 (1.0)	0 (0.0)	1 (0.8)
遠隔転移を伴う結腸直腸癌	1 (1.0)	0 (0.0)	1 (0.8)
子宮内膜腺癌	1 (1.0)	0 (0.0)	1 (0.8)
外耳の悪性新生物	1 (1.0)	0 (0.0)	1 (0.8)
ケラトアカントーマ	1 (1.0)	0 (0.0)	1 (0.8)
脂肪腫	1 (1.0)	0 (0.0)	1 (0.8)
肺の悪性新生物	1 (1.0)	0 (0.0)	1 (0.8)
悪性黒色腫	1 (1.0)	0 (0.0)	1 (0.8)
悪性黒色腫第 1 期	1 (1.0)	0 (0.0)	1 (0.8)
メラノサイト性母斑	1 (1.0)	0 (0.0)	1 (0.8)
遠隔転移を伴う悪性黒色腫	1 (1.0)	0 (0.0)	1 (0.8)
骨髄異形成症候群	1 (1.0)	0 (0.0)	1 (0.8)
結節性黒色腫	1 (1.0)	0 (0.0)	1 (0.8)
形質細胞性骨髄腫	1 (1.0)	0 (0.0)	1 (0.8)
ケーラー紅色肥厚症	0 (0.0)	1 (3.6)	1 (0.8)
肺扁平上皮癌	0 (0.0)	1 (3.6)	1 (0.8)
腫瘍出血	1 (1.0)	0 (0.0)	1 (0.8)
精神障害	17 (16.8)	3 (10.7)	20 (15.5)
不安	5 (5.0)	1 (3.6)	6 (4.7)
不眠症	3 (3.0)	1 (3.6)	4 (3.1)
うつ病	3 (3.0)	0 (0.0)	3 (2.3)
譫妄	1 (1.0)	1 (3.6)	2 (1.6)
抑うつ気分を伴う適応障害	1 (1.0)	0 (0.0)	1 (0.8)
アルコール離脱症候群	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
反社会的行動	1 (1.0)	0 (0.0)	1 (0.8)
錯乱状態	1 (1.0)	0 (0.0)	1 (0.8)
抑うつ気分	1 (1.0)	0 (0.0)	1 (0.8)
幻覚	1 (1.0)	0 (0.0)	1 (0.8)
神経過敏	1 (1.0)	0 (0.0)	1 (0.8)
睡眠の質低下	1 (1.0)	0 (0.0)	1 (0.8)
睡眠障害	1 (1.0)	0 (0.0)	1 (0.8)
耳および迷路障害	14 (13.9)	4 (14.3)	18 (14.0)
耳鳴	6 (5.9)	1 (3.6)	7 (5.4)
回転性めまい	3 (3.0)	1 (3.6)	4 (3.1)
耳痛	2 (2.0)	1 (3.6)	3 (2.3)
難聴	1 (1.0)	1 (3.6)	2 (1.6)
耳不快感	2 (2.0)	0 (0.0)	2 (1.6)
片耳難聴	1 (1.0)	0 (0.0)	1 (0.8)
耳閉	1 (1.0)	0 (0.0)	1 (0.8)
耳出血	1 (1.0)	0 (0.0)	1 (0.8)
耳垢分泌過多	1 (1.0)	0 (0.0)	1 (0.8)
生殖系および乳房障害	10 (9.9)	2 (7.1)	12 (9.3)
女性化乳房	3 (3.0)	0 (0.0)	3 (2.3)
血精液症	2 (2.0)	0 (0.0)	2 (1.6)
腟脱	2 (2.0)	0 (0.0)	2 (1.6)
後天性陰嚢水瘤	1 (1.0)	0 (0.0)	1 (0.8)
後天性包茎	1 (1.0)	0 (0.0)	1 (0.8)
良性前立腺肥大症	1 (1.0)	0 (0.0)	1 (0.8)
勃起不全	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
骨盤痛	0 (0.0)	1 (3.6)	1 (0.8)
陰茎不快感	0 (0.0)	1 (3.6)	1 (0.8)
陰茎浮腫	1 (1.0)	0 (0.0)	1 (0.8)
陰嚢浮腫	1 (1.0)	0 (0.0)	1 (0.8)
精巣腫瘤	1 (1.0)	0 (0.0)	1 (0.8)
精巣痛	1 (1.0)	0 (0.0)	1 (0.8)
免疫系障害	7 (6.9)	1 (3.6)	8 (6.2)
季節性アレルギー	4 (4.0)	0 (0.0)	4 (3.1)
造影剤アレルギー	2 (2.0)	0 (0.0)	2 (1.6)
薬物過敏症	1 (1.0)	0 (0.0)	1 (0.8)
免疫反応	0 (0.0)	1 (3.6)	1 (0.8)
肝胆道系障害	3 (3.0)	1 (3.6)	4 (3.1)
胆石症	1 (1.0)	0 (0.0)	1 (0.8)
胆汁うっ滞	0 (0.0)	1 (3.6)	1 (0.8)
薬物性肝障害	1 (1.0)	0 (0.0)	1 (0.8)
門脈拡張	1 (1.0)	0 (0.0)	1 (0.8)
内分泌障害	2 (2.0)	0 (0.0)	2 (1.6)
甲状腺機能亢進症	1 (1.0)	0 (0.0)	1 (0.8)
甲状腺機能低下症	1 (1.0)	0 (0.0)	1 (0.8)

Source: Table 14.3.1.2.2.2 in BGB-3111-302 clinical study report (final database lock date: [redacted] 20[redacted]). Data cutoff: 21JUN2022; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE.
Abbreviation(s): TEAE, treatment-emergent adverse event.
Cohort 1 includes patients with activating mutations in MYD88; Cohort 2 includes patients with wild type and unknown MYD88.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
MedDRA Version: 24.0.

表 35： 投与と関連のある TEAE：器官別大分類別及び基本語別（コホート 1）（BGB-3111-302 試験、安全性解析対象集団）

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
Patients with at least 1 Treatment-Related TEAE	16 (88.9)	16 (84.2)	72 (90.0)	67 (81.7)	88 (89.8)	83 (82.2)
胃腸障害	11 (61.1)	10 (52.6)	31 (38.8)	26 (31.7)	42 (42.9)	36 (35.6)
下痢	6 (33.3)	0 (0.0)	21 (26.3)	11 (13.4)	27 (27.6)	11 (10.9)
悪心	2 (11.1)	2 (10.5)	5 (6.3)	6 (7.3)	7 (7.1)	8 (7.9)
便秘	0 (0.0)	2 (10.5)	0 (0.0)	5 (6.1)	0 (0.0)	7 (6.9)
胃食道逆流性疾患	1 (5.6)	1 (5.3)	2 (2.5)	2 (2.4)	3 (3.1)	3 (3.0)
口腔血性水疱	0 (0.0)	1 (5.3)	0 (0.0)	2 (2.4)	0 (0.0)	3 (3.0)
口内炎	1 (5.6)	2 (10.5)	1 (1.3)	1 (1.2)	2 (2.0)	3 (3.0)
嘔吐	0 (0.0)	0 (0.0)	4 (5.0)	3 (3.7)	4 (4.1)	3 (3.0)
腹痛	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
口内乾燥	1 (5.6)	1 (5.3)	2 (2.5)	1 (1.2)	3 (3.1)	2 (2.0)
歯肉出血	4 (22.2)	0 (0.0)	1 (1.3)	2 (2.4)	5 (5.1)	2 (2.0)
歯肉痛	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
口腔内出血	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肛門の炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
鼓腸	2 (11.1)	1 (5.3)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.0)
胃出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
痔出血	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
口腔内潰瘍形成	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
耳下腺腫大	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
直腸出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腹部不快感	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
上腹部痛	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
肛門出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
大腸炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血性下痢	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
消化不良	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
嚥下障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胃潰瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胃炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
胃腸障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
血便排泄	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
口の感覚鈍麻	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
メレナ	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
食道炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
口腔粘膜水疱形成	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
舌乾燥	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
舌異形成	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
舌潰瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
上部消化管出血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血液およびリンパ系障害	4 (22.2)	9 (47.4)	21 (26.3)	26 (31.7)	25 (25.5)	35 (34.7)
好中球減少症	1 (5.6)	5 (26.3)	13 (16.3)	18 (22.0)	14 (14.3)	23 (22.8)
血小板減少症	0 (0.0)	3 (15.8)	12 (15.0)	8 (9.8)	12 (12.2)	11 (10.9)
貧血	0 (0.0)	3 (15.8)	6 (7.5)	4 (4.9)	6 (6.1)	7 (6.9)
発熱性好中球減少症	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.7)	0 (0.0)	3 (3.0)
内出血発生の増加傾向	3 (16.7)	0 (0.0)	2 (2.5)	3 (3.7)	5 (5.1)	3 (3.0)
出血性素因	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
特発性血腫	0 (0.0)	1 (5.3)	1 (1.3)	0 (0.0)	1 (1.0)	1 (1.0)
溶血性貧血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
出血性障害	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
白血球減少症	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
リンパ球減少症	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
感染症および寄生虫症	10 (55.6)	5 (26.3)	29 (36.3)	28 (34.1)	39 (39.8)	33 (32.7)
上気道感染	2 (11.1)	1 (5.3)	14 (17.5)	7 (8.5)	16 (16.3)	8 (7.9)
下気道感染	2 (11.1)	0 (0.0)	4 (5.0)	7 (8.5)	6 (6.1)	7 (6.9)
尿路感染	1 (5.6)	1 (5.3)	5 (6.3)	5 (6.1)	6 (6.1)	6 (5.9)
インフルエンザ	0 (0.0)	1 (5.3)	0 (0.0)	3 (3.7)	0 (0.0)	4 (4.0)
帯状疱疹	0 (0.0)	0 (0.0)	2 (2.5)	3 (3.7)	2 (2.0)	3 (3.0)
蜂巣炎	2 (11.1)	0 (0.0)	2 (2.5)	2 (2.4)	4 (4.1)	2 (2.0)
皮膚真菌感染	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
限局性感染	1 (5.6)	0 (0.0)	3 (3.8)	2 (2.4)	4 (4.1)	2 (2.0)
肺炎	3 (16.7)	0 (0.0)	7 (8.8)	2 (2.4)	10 (10.2)	2 (2.0)
鼻炎	0 (0.0)	0 (0.0)	3 (3.8)	2 (2.4)	3 (3.1)	2 (2.0)
副鼻腔炎	2 (11.1)	0 (0.0)	2 (2.5)	2 (2.4)	4 (4.1)	2 (2.0)
細菌尿	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
耳感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
細菌性眼感染	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
陰部ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
歯肉膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
膿痂疹	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
好中球減少性敗血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
口腔ヘルペス	1 (5.6)	0 (0.0)	2 (2.5)	1 (1.2)	3 (3.1)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
肺結核	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
気道感染	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
皮膚感染	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
真菌性舌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
歯感染	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
肛門カンジダ症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
肛門感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
角膜膿瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
毛包炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
せつ	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
歯肉炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
帯状疱疹再燃	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
喉頭炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
爪感染	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
上咽頭炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
神経クリプトコッカス症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
食道カンジダ症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
爪真菌症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
パラインフルエンザウイルス感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
爪囲炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼窩周囲蜂巣炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
膿疱性皮疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ライノウイルス感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
敗血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
レンサ球菌性菌血症	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
レンサ球菌性敗血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
皮下組織膿瘍	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
水痘帯状疱疹ウイルス感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ウイルス感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
創傷感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ブドウ球菌性創感染	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚および皮下組織障害	8 (44.4)	4 (21.1)	26 (32.5)	24 (29.3)	34 (34.7)	28 (27.7)
発疹	4 (22.2)	2 (10.5)	8 (10.0)	8 (9.8)	12 (12.2)	10 (9.9)
点状出血	2 (11.1)	2 (10.5)	3 (3.8)	3 (3.7)	5 (5.1)	5 (5.0)
斑状丘疹状皮疹	0 (0.0)	0 (0.0)	1 (1.3)	4 (4.9)	1 (1.0)	4 (4.0)
そう痒症	0 (0.0)	2 (10.5)	3 (3.8)	1 (1.2)	3 (3.1)	3 (3.0)
紫斑	1 (5.6)	0 (0.0)	3 (3.8)	3 (3.7)	4 (4.1)	3 (3.0)
皮膚潰瘍	0 (0.0)	1 (5.3)	1 (1.3)	1 (1.2)	1 (1.0)	2 (2.0)
光線角化症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
脱毛症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
皮膚乾燥	2 (11.1)	1 (5.3)	1 (1.3)	0 (0.0)	3 (3.1)	1 (1.0)
斑状出血	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
湿疹	1 (5.6)	1 (5.3)	1 (1.3)	0 (0.0)	2 (2.0)	1 (1.0)
紅斑	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
苔癬様角化症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
紅斑性皮疹	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
皮膚亀裂	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
皮膚出血	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
皮膚毒性	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.2)	3 (3.1)	1 (1.0)
うっ滞性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
血性水疱	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
ざ瘡様皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
アレルギー性皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
薬疹	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
爪の障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
爪破損	2 (11.1)	0 (0.0)	4 (5.0)	0 (0.0)	6 (6.1)	0 (0.0)
陰茎潰瘍形成	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
老人性紫斑	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
丘疹性皮疹	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
そう痒性皮疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
酒さ	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
皮膚障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
皮膚病変	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
一般・全身障害および投与部位の状態	4 (22.2)	6 (31.6)	16 (20.0)	18 (22.0)	20 (20.4)	24 (23.8)
疲労	4 (22.2)	3 (15.8)	7 (8.8)	9 (11.0)	11 (11.2)	12 (11.9)
薬剤離脱症候群	0 (0.0)	1 (5.3)	2 (2.5)	4 (4.9)	2 (2.0)	5 (5.0)
発熱	0 (0.0)	1 (5.3)	1 (1.3)	3 (3.7)	1 (1.0)	4 (4.0)
無力症	0 (0.0)	0 (0.0)	2 (2.5)	2 (2.4)	2 (2.0)	2 (2.0)
末梢性浮腫	0 (0.0)	2 (10.5)	2 (2.5)	0 (0.0)	2 (2.0)	2 (2.0)
治癒不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
倦怠感	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
疼痛	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
末梢腫脹	1 (5.6)	1 (5.3)	2 (2.5)	0 (0.0)	3 (3.1)	1 (1.0)
注入部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血管穿刺部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
傷害、中毒および処置合併症	5 (27.8)	6 (31.6)	23 (28.8)	13 (15.9)	28 (28.6)	19 (18.8)
挫傷	4 (22.2)	6 (31.6)	20 (25.0)	8 (9.8)	24 (24.5)	14 (13.9)
眼窩周囲出血	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
処置後出血	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.4)	1 (1.0)	2 (2.0)
皮膚創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
硬膜下血腫	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
四肢損傷	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
口腔挫傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
処置後血腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
ストーマ部出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	7 (38.9)	5 (26.3)	21 (26.3)	12 (14.6)	28 (28.6)	17 (16.8)
鼻出血	4 (22.2)	3 (15.8)	12 (15.0)	7 (8.5)	16 (16.3)	10 (9.9)
咳嗽	1 (5.6)	1 (5.3)	3 (3.8)	4 (4.9)	4 (4.1)	5 (5.0)
湿性咳嗽	0 (0.0)	1 (5.3)	0 (0.0)	1 (1.2)	0 (0.0)	2 (2.0)
喘鳴	1 (5.6)	1 (5.3)	0 (0.0)	1 (1.2)	1 (1.0)	2 (2.0)
急性呼吸不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
慢性閉塞性肺疾患	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
発声障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
呼吸困難	2 (11.1)	0 (0.0)	0 (0.0)	1 (1.2)	2 (2.0)	1 (1.0)
血胸	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
肺陰影	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
鼻閉	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
鼻部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
口腔咽頭痛	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)
鼻漏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
上気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
咽喉乾燥	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
労作性呼吸困難	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
喀血	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
間質性肺疾患	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肺浸潤	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
鼻乾燥	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
咽頭潰瘍	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
胸水	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
肺臓炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
逆流性喉頭炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
筋骨格系および結合組織障害	6 (33.3)	5 (26.3)	17 (21.3)	10 (12.2)	23 (23.5)	15 (14.9)
関節痛	2 (11.1)	2 (10.5)	7 (8.8)	5 (6.1)	9 (9.2)	7 (6.9)
筋痙縮	5 (27.8)	3 (15.8)	10 (12.5)	3 (3.7)	15 (15.3)	6 (5.9)
筋肉痛	0 (0.0)	2 (10.5)	0 (0.0)	1 (1.2)	0 (0.0)	3 (3.0)
四肢痛	1 (5.6)	1 (5.3)	1 (1.3)	2 (2.4)	2 (2.0)	3 (3.0)
側腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
関節腫脹	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
関節炎	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
背部痛	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
筋攣縮	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
腱痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血管障害	4 (22.2)	5 (26.3)	18 (22.5)	10 (12.2)	22 (22.4)	15 (14.9)
高血圧	3 (16.7)	3 (15.8)	14 (17.5)	7 (8.5)	17 (17.3)	10 (9.9)
血腫	0 (0.0)	0 (0.0)	5 (6.3)	3 (3.7)	5 (5.1)	3 (3.0)
出血性静脈瘤	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
末梢冷感	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
末梢静脈疾患	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
出血	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
起立性低血圧	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
神経系障害	5 (27.8)	3 (15.8)	14 (17.5)	10 (12.2)	19 (19.4)	13 (12.9)
浮動性めまい	1 (5.6)	2 (10.5)	1 (1.3)	5 (6.1)	2 (2.0)	7 (6.9)
頭痛	2 (11.1)	1 (5.3)	5 (6.3)	4 (4.9)	7 (7.1)	5 (5.0)
末梢性感覚ニューロパチー	0 (0.0)	1 (5.3)	3 (3.8)	1 (1.2)	3 (3.1)	2 (2.0)
脱髄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
注意力障害	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
錯感覚	1 (5.6)	0 (0.0)	2 (2.5)	1 (1.2)	3 (3.1)	1 (1.0)
下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
神経痛	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
ヘルペス後神経痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
失神寸前の状態	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
失神	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	3 (3.1)	0 (0.0)
味覚障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心臓障害	7 (38.9)	2 (10.5)	19 (23.8)	10 (12.2)	26 (26.5)	12 (11.9)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
心房細動	5 (27.8)	1 (5.3)	14 (17.5)	2 (2.4)	19 (19.4)	3 (3.0)
動悸	2 (11.1)	1 (5.3)	2 (2.5)	1 (1.2)	4 (4.1)	2 (2.0)
上室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (2.0)
急性左室不全	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
急性心筋梗塞	1 (5.6)	1 (5.3)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.0)
狭心症	2 (11.1)	1 (5.3)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.0)
第二度房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心タンポナーデ	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心拡大	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
頻脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
心房粗動	0 (0.0)	0 (0.0)	4 (5.0)	0 (0.0)	4 (4.1)	0 (0.0)
徐脈	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
心不全	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
心粗動	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
心嚢内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
上室性頻脈	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心室性不整脈	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
心室性期外収縮	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
臨床検査	2 (11.1)	1 (5.3)	7 (8.8)	10 (12.2)	9 (9.2)	11 (10.9)
好中球数減少	2 (11.1)	0 (0.0)	0 (0.0)	7 (8.5)	2 (2.0)	7 (6.9)
血中ビリルビン増加	0 (0.0)	0 (0.0)	2 (2.5)	1 (1.2)	2 (2.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
血中鉄減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
γーグルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
インターフェロンγ応答測定陽性	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
体重減少	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
アラニンアミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血中アルカリホスファターゼ増加	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
血圧上昇	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼圧上昇	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
血小板数減少	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
腎および尿路障害	5 (27.8)	4 (21.1)	7 (8.8)	5 (6.1)	12 (12.2)	9 (8.9)
血尿	4 (22.2)	2 (10.5)	6 (7.5)	4 (4.9)	10 (10.2)	6 (5.9)
慢性腎臓病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
蛋白尿	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
腎臓痛	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
尿閉	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
急性腎障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
排尿困難	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
代謝および栄養障害	1 (5.6)	1 (5.3)	6 (7.5)	6 (7.3)	7 (7.1)	7 (6.9)
食欲減退	1 (5.6)	0 (0.0)	2 (2.5)	2 (2.4)	3 (3.1)	2 (2.0)
高尿酸血症	0 (0.0)	0 (0.0)	3 (3.8)	2 (2.4)	3 (3.1)	2 (2.0)
脱水	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
高カリウム血症	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
低ナトリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
鉄欠乏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
低マグネシウム血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼障害	5 (27.8)	2 (10.5)	7 (8.8)	4 (4.9)	12 (12.2)	6 (5.9)
結膜出血	1 (5.6)	1 (5.3)	3 (3.8)	1 (1.2)	4 (4.1)	2 (2.0)
ドライアイ	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
眼出血	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
眼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼瞼発疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
眼の障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
眼刺激	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
眼充血	2 (11.1)	0 (0.0)	1 (1.3)	0 (0.0)	3 (3.1)	0 (0.0)
眼窩嚢胞	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
網膜出血	1 (5.6)	0 (0.0)	1 (1.3)	0 (0.0)	2 (2.0)	0 (0.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	1 (1.3)	3 (3.7)	1 (1.0)	3 (3.0)
基底細胞癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
遠隔転移を伴う悪性黒色腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
骨髄異形成症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
皮膚有棘細胞癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
皮膚血管腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
精神障害	1 (5.6)	1 (5.3)	2 (2.5)	1 (1.2)	3 (3.1)	2 (2.0)
譫妄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
神経過敏	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)
不安	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

System Organ Class Preferred Term	Treatment Naive		Relapsed/Refractory		Overall	
	Ibrutinib (N = 18) n (%)	Zanubrutinib (N = 19) n (%)	Ibrutinib (N = 80) n (%)	Zanubrutinib (N = 82) n (%)	Ibrutinib (N = 98) n (%)	Zanubrutinib (N = 101) n (%)
不眠症	1 (5.6)	0 (0.0)	2 (2.5)	0 (0.0)	3 (3.1)	0 (0.0)
耳および迷路障害	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
耳痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.0)
耳鳴	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肝胆道系障害	1 (5.6)	0 (0.0)	2 (2.5)	1 (1.2)	3 (3.1)	1 (1.0)
薬物性肝障害	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.2)	1 (1.0)	1 (1.0)
肝硬変	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
肝炎	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)
生殖系および乳房障害	1 (5.6)	0 (0.0)	1 (1.3)	1 (1.2)	2 (2.0)	1 (1.0)
血精液症	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.0)	1 (1.0)
生殖器病変	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
免疫系障害	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	2 (2.0)	0 (0.0)
造影剤反応	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)
免疫再構築炎症反応症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.0)	0 (0.0)

Source: Table 14.3.1.2.5.1 in BGB-3111-302 clinical study report (final database lock date: [redacted] 20[redacted]). Data cutoff: 21JUN2022; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE
Abbreviation(s): TEAE, treatment-emergent adverse event.
Cohort 1 includes patients with activating mutations in MYD88.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
Treatment-related is defined as related or with missing relationship.
MedDRA Version: 24.0

表 36： 投与と関連のある TEAE：器官別大分類別及び基本語別（ザヌブルチニブを投与した被験者全例）（BGB-3111-302 試験、安全性解析対象集団）

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
Patients with at least 1 Treatment-Related TEAE	83 (82.2)	23 (82.1)	106 (82.2)
胃腸障害	36 (35.6)	8 (28.6)	44 (34.1)
下痢	11 (10.9)	5 (17.9)	16 (12.4)
悪心	8 (7.9)	0 (0.0)	8 (6.2)
便秘	7 (6.9)	0 (0.0)	7 (5.4)
腹痛	2 (2.0)	1 (3.6)	3 (2.3)
消化不良	0 (0.0)	3 (10.7)	3 (2.3)
胃食道逆流性疾患	3 (3.0)	0 (0.0)	3 (2.3)
口腔血性水疱	3 (3.0)	0 (0.0)	3 (2.3)
口内炎	3 (3.0)	0 (0.0)	3 (2.3)
嘔吐	3 (3.0)	0 (0.0)	3 (2.3)
口内乾燥	2 (2.0)	0 (0.0)	2 (1.6)
歯肉出血	2 (2.0)	0 (0.0)	2 (1.6)
歯肉痛	2 (2.0)	0 (0.0)	2 (1.6)
口腔内出血	2 (2.0)	0 (0.0)	2 (1.6)
腹部膨満	1 (1.0)	0 (0.0)	1 (0.8)
肛門の炎症	1 (1.0)	0 (0.0)	1 (0.8)
十二指腸潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
鼓腸	1 (1.0)	0 (0.0)	1 (0.8)
胃出血	1 (1.0)	0 (0.0)	1 (0.8)
出血性胃潰瘍	0 (0.0)	1 (3.6)	1 (0.8)
痔出血	1 (1.0)	0 (0.0)	1 (0.8)
口腔内潰瘍形成	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
耳下腺腫大	1 (1.0)	0 (0.0)	1 (0.8)
直腸出血	1 (1.0)	0 (0.0)	1 (0.8)
感染症および寄生虫症	33 (32.7)	11 (39.3)	44 (34.1)
上気道感染	8 (7.9)	1 (3.6)	9 (7.0)
下気道感染	7 (6.9)	0 (0.0)	7 (5.4)
帯状疱疹	3 (3.0)	3 (10.7)	6 (4.7)
尿路感染	6 (5.9)	0 (0.0)	6 (4.7)
インフルエンザ	4 (4.0)	0 (0.0)	4 (3.1)
肺炎	2 (2.0)	2 (7.1)	4 (3.1)
限局性感染	2 (2.0)	1 (3.6)	3 (2.3)
蜂巣炎	2 (2.0)	0 (0.0)	2 (1.6)
皮膚真菌感染	2 (2.0)	0 (0.0)	2 (1.6)
気道感染	1 (1.0)	1 (3.6)	2 (1.6)
鼻炎	2 (2.0)	0 (0.0)	2 (1.6)
副鼻腔炎	2 (2.0)	0 (0.0)	2 (1.6)
細菌尿	1 (1.0)	0 (0.0)	1 (0.8)
体部白癬	0 (0.0)	1 (3.6)	1 (0.8)
気管支炎	0 (0.0)	1 (3.6)	1 (0.8)
結膜炎	0 (0.0)	1 (3.6)	1 (0.8)
耳感染	1 (1.0)	0 (0.0)	1 (0.8)
大腸菌感染	0 (0.0)	1 (3.6)	1 (0.8)
眼感染	0 (0.0)	1 (3.6)	1 (0.8)
細菌性眼感染	1 (1.0)	0 (0.0)	1 (0.8)
ウイルス性胃腸炎	0 (0.0)	1 (3.6)	1 (0.8)
陰部ヘルペス	1 (1.0)	0 (0.0)	1 (0.8)
歯肉膿瘍	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
B 型肝炎	0 (0.0)	1 (3.6)	1 (0.8)
膿痂疹	1 (1.0)	0 (0.0)	1 (0.8)
喉頭炎	0 (0.0)	1 (3.6)	1 (0.8)
好中球減少性敗血症	1 (1.0)	0 (0.0)	1 (0.8)
口腔ヘルペス	1 (1.0)	0 (0.0)	1 (0.8)
肺結核	1 (1.0)	0 (0.0)	1 (0.8)
皮膚感染	1 (1.0)	0 (0.0)	1 (0.8)
真菌性舌感染	1 (1.0)	0 (0.0)	1 (0.8)
歯感染	1 (1.0)	0 (0.0)	1 (0.8)
ウイルス性上気道感染	1 (1.0)	0 (0.0)	1 (0.8)
血液およびリンパ系障害	35 (34.7)	6 (21.4)	41 (31.8)
好中球減少症	23 (22.8)	3 (10.7)	26 (20.2)
血小板減少症	11 (10.9)	2 (7.1)	13 (10.1)
貧血	7 (6.9)	0 (0.0)	7 (5.4)
内出血発生の増加傾向	3 (3.0)	2 (7.1)	5 (3.9)
発熱性好中球減少症	3 (3.0)	0 (0.0)	3 (2.3)
出血性素因	1 (1.0)	0 (0.0)	1 (0.8)
特発性血腫	1 (1.0)	0 (0.0)	1 (0.8)
皮膚および皮下組織障害	28 (27.7)	7 (25.0)	35 (27.1)
発疹	10 (9.9)	2 (7.1)	12 (9.3)
点状出血	5 (5.0)	0 (0.0)	5 (3.9)
そう痒症	3 (3.0)	1 (3.6)	4 (3.1)
斑状丘疹状皮疹	4 (4.0)	0 (0.0)	4 (3.1)
紫斑	3 (3.0)	0 (0.0)	3 (2.3)
皮膚炎	0 (0.0)	2 (7.1)	2 (1.6)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
斑状出血	1 (1.0)	1 (3.6)	2 (1.6)
皮膚潰瘍	2 (2.0)	0 (0.0)	2 (1.6)
光線角化症	1 (1.0)	0 (0.0)	1 (0.8)
脱毛症	1 (1.0)	0 (0.0)	1 (0.8)
アトピー性皮膚炎	1 (1.0)	0 (0.0)	1 (0.8)
皮膚乾燥	1 (1.0)	0 (0.0)	1 (0.8)
湿疹	1 (1.0)	0 (0.0)	1 (0.8)
紅斑	1 (1.0)	0 (0.0)	1 (0.8)
多汗症	1 (1.0)	0 (0.0)	1 (0.8)
苔癬様角化症	1 (1.0)	0 (0.0)	1 (0.8)
光線過敏性反応	0 (0.0)	1 (3.6)	1 (0.8)
紅斑性皮疹	1 (1.0)	0 (0.0)	1 (0.8)
斑状皮疹	0 (0.0)	1 (3.6)	1 (0.8)
皮膚亀裂	1 (1.0)	0 (0.0)	1 (0.8)
皮膚出血	1 (1.0)	0 (0.0)	1 (0.8)
皮膚腫瘤	0 (0.0)	1 (3.6)	1 (0.8)
皮膚毒性	1 (1.0)	0 (0.0)	1 (0.8)
うっ滞性皮膚炎	1 (1.0)	0 (0.0)	1 (0.8)
一般・全身障害および投与部位の状態	24 (23.8)	6 (21.4)	30 (23.3)
疲労	12 (11.9)	2 (7.1)	14 (10.9)
発熱	4 (4.0)	3 (10.7)	7 (5.4)
薬剤離脱症候群	5 (5.0)	1 (3.6)	6 (4.7)
末梢性浮腫	2 (2.0)	1 (3.6)	3 (2.3)
無力症	2 (2.0)	0 (0.0)	2 (1.6)
治癒不良	1 (1.0)	0 (0.0)	1 (0.8)
倦怠感	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
疼痛	1 (1.0)	0 (0.0)	1 (0.8)
末梢腫脹	1 (1.0)	0 (0.0)	1 (0.8)
傷害、中毒および処置合併症	19 (18.8)	5 (17.9)	24 (18.6)
挫傷	14 (13.9)	4 (14.3)	18 (14.0)
眼窩周囲出血	2 (2.0)	0 (0.0)	2 (1.6)
処置後出血	2 (2.0)	0 (0.0)	2 (1.6)
皮膚創傷	1 (1.0)	0 (0.0)	1 (0.8)
硬膜下血腫	1 (1.0)	0 (0.0)	1 (0.8)
硬膜下出血	0 (0.0)	1 (3.6)	1 (0.8)
呼吸器、胸郭および縦隔障害	17 (16.8)	2 (7.1)	19 (14.7)
鼻出血	10 (9.9)	1 (3.6)	11 (8.5)
咳嗽	5 (5.0)	0 (0.0)	5 (3.9)
湿性咳嗽	2 (2.0)	0 (0.0)	2 (1.6)
喘鳴	2 (2.0)	0 (0.0)	2 (1.6)
急性呼吸不全	1 (1.0)	0 (0.0)	1 (0.8)
慢性閉塞性肺疾患	1 (1.0)	0 (0.0)	1 (0.8)
発声障害	1 (1.0)	0 (0.0)	1 (0.8)
呼吸困難	1 (1.0)	0 (0.0)	1 (0.8)
血胸	1 (1.0)	0 (0.0)	1 (0.8)
肺陰影	1 (1.0)	0 (0.0)	1 (0.8)
鼻閉	1 (1.0)	0 (0.0)	1 (0.8)
鼻部不快感	1 (1.0)	0 (0.0)	1 (0.8)
口腔咽頭痛	1 (1.0)	0 (0.0)	1 (0.8)
肺臓炎	0 (0.0)	1 (3.6)	1 (0.8)
鼻漏	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
上気道うっ血	1 (1.0)	0 (0.0)	1 (0.8)
筋骨格系および結合組織障害	15 (14.9)	3 (10.7)	18 (14.0)
関節痛	7 (6.9)	1 (3.6)	8 (6.2)
筋痙縮	6 (5.9)	2 (7.1)	8 (6.2)
筋肉痛	3 (3.0)	0 (0.0)	3 (2.3)
四肢痛	3 (3.0)	0 (0.0)	3 (2.3)
側腹部痛	1 (1.0)	0 (0.0)	1 (0.8)
関節腫脹	1 (1.0)	0 (0.0)	1 (0.8)
腱鞘炎	0 (0.0)	1 (3.6)	1 (0.8)
血管障害	15 (14.9)	3 (10.7)	18 (14.0)
高血圧	10 (9.9)	2 (7.1)	12 (9.3)
血腫	3 (3.0)	1 (3.6)	4 (3.1)
出血性静脈瘤	1 (1.0)	0 (0.0)	1 (0.8)
末梢冷感	1 (1.0)	0 (0.0)	1 (0.8)
末梢静脈疾患	1 (1.0)	0 (0.0)	1 (0.8)
心臓障害	12 (11.9)	4 (14.3)	16 (12.4)
動悸	2 (2.0)	2 (7.1)	4 (3.1)
心房細動	3 (3.0)	0 (0.0)	3 (2.3)
上室性期外収縮	2 (2.0)	0 (0.0)	2 (1.6)
頻脈	1 (1.0)	1 (3.6)	2 (1.6)
急性左室不全	1 (1.0)	0 (0.0)	1 (0.8)
急性心筋梗塞	1 (1.0)	0 (0.0)	1 (0.8)
狭心症	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
第二度房室ブロック	1 (1.0)	0 (0.0)	1 (0.8)
心タンポナーデ	1 (1.0)	0 (0.0)	1 (0.8)
心拡大	1 (1.0)	0 (0.0)	1 (0.8)
期外収縮	1 (1.0)	0 (0.0)	1 (0.8)
心筋虚血	1 (1.0)	0 (0.0)	1 (0.8)
洞性徐脈	1 (1.0)	0 (0.0)	1 (0.8)
心室性期外収縮	0 (0.0)	1 (3.6)	1 (0.8)
神経系障害	13 (12.9)	1 (3.6)	14 (10.9)
浮動性めまい	7 (6.9)	0 (0.0)	7 (5.4)
頭痛	5 (5.0)	0 (0.0)	5 (3.9)
末梢性感覚ニューロパチー	2 (2.0)	0 (0.0)	2 (1.6)
灼熱感	0 (0.0)	1 (3.6)	1 (0.8)
脱髄	1 (1.0)	0 (0.0)	1 (0.8)
注意力障害	1 (1.0)	0 (0.0)	1 (0.8)
錯感覚	1 (1.0)	0 (0.0)	1 (0.8)
下肢静止不能症候群	1 (1.0)	0 (0.0)	1 (0.8)
臨床検査	11 (10.9)	2 (7.1)	13 (10.1)
好中球数減少	7 (6.9)	1 (3.6)	8 (6.2)
血中アルカリホスファターゼ増加	0 (0.0)	1 (3.6)	1 (0.8)
血中ビリルビン増加	1 (1.0)	0 (0.0)	1 (0.8)
血中鉄減少	1 (1.0)	0 (0.0)	1 (0.8)
γ－グルタミルトランスフェラーゼ増加	1 (1.0)	0 (0.0)	1 (0.8)
インターフェロンγ応答測定陽性	1 (1.0)	0 (0.0)	1 (0.8)
体重減少	1 (1.0)	0 (0.0)	1 (0.8)
腎および尿路障害	9 (8.9)	1 (3.6)	10 (7.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
血尿	6 (5.9)	1 (3.6)	7 (5.4)
慢性腎臓病	1 (1.0)	0 (0.0)	1 (0.8)
夜間頻尿	1 (1.0)	0 (0.0)	1 (0.8)
蛋白尿	1 (1.0)	0 (0.0)	1 (0.8)
腎臓痛	1 (1.0)	0 (0.0)	1 (0.8)
尿閉	1 (1.0)	0 (0.0)	1 (0.8)
代謝および栄養障害	7 (6.9)	2 (7.1)	9 (7.0)
食欲減退	2 (2.0)	1 (3.6)	3 (2.3)
高尿酸血症	2 (2.0)	0 (0.0)	2 (1.6)
脱水	1 (1.0)	0 (0.0)	1 (0.8)
高カリウム血症	1 (1.0)	0 (0.0)	1 (0.8)
低ナトリウム血症	1 (1.0)	0 (0.0)	1 (0.8)
低蛋白血症	0 (0.0)	1 (3.6)	1 (0.8)
鉄欠乏	1 (1.0)	0 (0.0)	1 (0.8)
眼障害	6 (5.9)	0 (0.0)	6 (4.7)
結膜出血	2 (2.0)	0 (0.0)	2 (1.6)
ドライアイ	1 (1.0)	0 (0.0)	1 (0.8)
眼出血	1 (1.0)	0 (0.0)	1 (0.8)
眼痛	1 (1.0)	0 (0.0)	1 (0.8)
眼瞼発疹	1 (1.0)	0 (0.0)	1 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3 (3.0)	2 (7.1)	5 (3.9)
基底細胞癌	1 (1.0)	1 (3.6)	2 (1.6)
リンパ腫の転化	0 (0.0)	1 (3.6)	1 (0.8)
遠隔転移を伴う悪性黒色腫	1 (1.0)	0 (0.0)	1 (0.8)

System Organ Class Preferred Term	Cohort 1 (N = 101) n (%)	Cohort 2 (N = 28) n (%)	Total (N = 129) n (%)
骨髄異形成症候群	1 (1.0)	0 (0.0)	1 (0.8)
皮膚有棘細胞癌	1 (1.0)	0 (0.0)	1 (0.8)
耳および迷路障害	1 (1.0)	1 (3.6)	2 (1.6)
難聴	0 (0.0)	1 (3.6)	1 (0.8)
耳痛	1 (1.0)	0 (0.0)	1 (0.8)
肝胆道系障害	1 (1.0)	1 (3.6)	2 (1.6)
胆汁うっ滞	0 (0.0)	1 (3.6)	1 (0.8)
薬物性肝障害	1 (1.0)	0 (0.0)	1 (0.8)
精神障害	2 (2.0)	0 (0.0)	2 (1.6)
譫妄	1 (1.0)	0 (0.0)	1 (0.8)
神経過敏	1 (1.0)	0 (0.0)	1 (0.8)
生殖系および乳房障害	1 (1.0)	1 (3.6)	2 (1.6)
血精液症	1 (1.0)	0 (0.0)	1 (0.8)
陰茎不快感	0 (0.0)	1 (3.6)	1 (0.8)

Source: Table 14.3.1.2.5.2 in BGB-3111-302 clinical study report (final database lock date: [redacted] 20[redacted]). Data cutoff: 21JUN2022; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE.
Abbreviation(s): TEAE, treatment-emergent adverse event.
Cohort 1 includes patients with activating mutations in MYD88; Cohort 2 includes patients with wild type and unknown MYD88.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
Treatment-related is defined as related or with missing relationship.
MedDRA Version: 24.0.

表 37： 重篤な有害事象の一覧（コホート 1 及びコホート 2）（BGB-3111-302 試験、安全性解析対象集団）

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (255)\ Ongoing\ -	TRAUMATIC L2 VERTEBRAL COMPRESSION FRACTURE\ 脊椎圧迫骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
6\Yes	20[redacted] (459)\ 20[redacted] (508)\ 50	CRYPTOCOCCAL FUNGEMIA\ クリプトコッカス性真菌血症\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
10\Yes	20[redacted] (528)\ 20[redacted] (548)\ 21	CRYPTOCOCCAL FUNGEMIA RELAPSED\ クリプトコッカス性真菌血症\ 感染症および寄生虫症	3\ NOT RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
7\Yes	20[redacted] (378)\ 20[redacted] (378)\ 1	DEATH OF UNKNOWN ORIGIN\ 死亡\ 一般・全身障害および投与部位の状態	5\ NOT RELATED	DRUG WITHDRAWN\ NONE\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
10\Yes	20[redacted] (266)\ 20[redacted] (267)\ 2	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	2\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
26\Yes	20[redacted] (852)\ 20[redacted] (873)\ 22	PERIPHERAL VASCULAR DISEASE R LEG\ 末梢血管障害\ 血管障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
28\Yes	20[redacted] (283)\ 20[redacted] (285)\ 3	WORSENING OF SPINAL STENOSIS\ 脊柱管狭窄症\ 筋骨格系および結合組織障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
36\Yes	20[redacted] (420)\ 20[redacted] (428)\ 9	RIGHT OCCIPITAL SUBARACHNOID HAEMORRHAGE\ くも膜下出血\ 神経系障害	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
37\Yes	20[redacted] (420)\ 20[redacted] (420)\ 1	UNEXPLAINED LOSS OF CONSCIOUSNESS\ 意識消失\ 神経系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
46\Yes	20[redacted] (571)\ 20[redacted] (589)\ 19	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ RELATED	DRUG WITHDRAWN\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
35\Yes	20[redacted] (868)\ 20[redacted] (872)\ 5	CELLULITIS - LEFT HAND\ 蜂巣炎\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
6\Yes	20[redacted] (31)\ Ongoing\ -	ACUTE KIDNEY INJURY\ 急性腎障害\ 腎および尿路障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (521)\ Ongoing\ -	THROMBOCYTOPENIA (WORSENED)\ 血小板減少症\ 血液およびリンパ系障害	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
15\Yes	20[redacted] (521)\ Ongoing\ -	WORSENING ANAEMIA\ 貧血\ 血液およびリンパ系障害	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
6\Yes	20[redacted] (197)\ Ongoing\ -	BLEEDING ADENOCARCINOMA\ 腫瘍出血\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\Yes	20[redacted] (51)\ 20[redacted] (63)\ 13	ATRIAL FLUTTER\ 心房粗動\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
13\Yes	20[redacted] (476)\ 20[redacted] (478)\ 3	PERIPHERAL OEDEMA\ 末梢性浮腫\ 一般・全身障害および投与部位の状態	2\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
21\Yes	20[redacted] (521)\ 20[redacted] (525)\ 5	PYREXIA OF UNKNOWN ORIGIN - TEMP 38.3 C\ 発熱\ 一般・全身障害および投与部位の状態	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
25\Yes	20[redacted] (565)\ 20[redacted] (570)\ 6	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
26\Yes	20[redacted] (586)\ 20[redacted] (586)\ 1	DEATH OF UNKNOWN CAUSE\ 死亡\ 一般・全身障害および投与部位の状態	5\ NOT RELATED	NOT APPLICABLE\ NONE\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
23\Yes	20[redacted] (844)\ 20[redacted] (845)\ 2	HAEMATURIA\ 血尿\ 腎および尿路障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
17\Yes	20[redacted] (336)\ 20[redacted] (338)\ 3	BLEEDING FROM BMAT SITE (RECURRENT)\ 処置後出血\ 傷害、中毒および処置合併症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
17\Yes	20[redacted] (991)\ 20[redacted] (1009)\ 19	RIGHT FACIAL WOUND ABCESS POST OPERATIVE\ 術後膿瘍\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
10\Yes	20[redacted] (197)\ 20[redacted] (203)\ 7	AEROCOCCUS SANGUINICOLA URINARY TRACT INFECTION\ 細菌性尿路感染\ 感染症および寄生虫症	3\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED
14\Yes	20[redacted] (258)\ 20[redacted] (260)\ 3	VAGINAL PROLAPSE\ 膣脱\ 生殖系および乳房障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
25\Yes	20[redacted] (713)\ 20[redacted] (720)\ 8	LEFT PARONYCHIA\ 爪囲炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
26\Yes	20[redacted] (713)\ 20[redacted] (720)\ 8	SOFT TISSUE INFECTION\ 軟部組織感染\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
12\Yes	20[redacted] (199)\ 20[redacted] (208)\ 10	COMMUNITY ACQUIRED PNEUMONIA (RHINOVIRUS/ENTEROVIRUS DETECTED)\ ウイルス性肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
10\Yes	20[redacted] (68)\ Ongoing\ -	L2 INSUFFICIENCY FRACTURE\ ストレス骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ NOT RECOVERED/NOT RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
13\Yes	20[redacted]\ 20[redacted] (123)\ 44	NEGATIVE GRAM SEPTICAEMIA\ 細菌性敗血症\ 感染症および寄生虫症	5\ NOT RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ -\ FATAL
17\Yes	20[redacted] (90)\ Ongoing\ -	HOSPITAL ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
19\Yes	20[redacted] (92)\ Ongoing\ -	SEPTIC SHOCK\ 敗血症性ショック\ 感染症および寄生虫症	4\ NOT RELATED	DRUG INTERRUPTED\ -\ NOT RECOVERED/NOT RESOLVED
20\Yes	20[redacted] (98)\ 20[redacted] (123)\ 26	RESPIRATORY COMPROMISE\ 呼吸障害\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\No	20[redacted] (-21)\ 20[redacted] (29)\ 50	ANAEMIA\ 貧血\ 血液およびリンパ系障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\No	20[redacted] (-15)\ 20[redacted] (-10)\ 6	SYMPTOMATIC HYPERVISCOSITY CAUSING DYSPNOEA\ 過粘稠度症候群\ 血液およびリンパ系障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
9\Yes	20[redacted] (350)\ 20[redacted] (354)\ 5	PYREXIA\ 発熱\ 一般・全身障害および投与部位の状態	1\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
22\Yes	20[redacted] (811)\ 20[redacted] (818)\ 8	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
32\Yes	20[redacted] (1096)\ 20[redacted] (1100)\ 5	ACUTE PULMONARY OEDEMA\ 急性肺水腫\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
25\Yes	20[redacted] (955)\ 20[redacted] (959)\ 5	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
28\Yes	20[redacted] (1249)\ 20[redacted] (1287)\ 39	NEUROCRYPTOCOCCOSUS\ 神経クリプトコッカス症\ 感染症および寄生虫症	3\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ OTHER: PATIENT IS DISCHARGED FROM WARD AND INTO REHAB\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
3\Yes	20[redacted] (21)\ 20[redacted] (22)\ 2	RAPID AF\ 心房細動\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
7\Yes	20[redacted] (34)\ 20[redacted] (40)\ 7	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
4\Yes	20[redacted] (88)\ 20[redacted] (89)\ 2	CARDIOMEGALY\ 心拡大\ 心臓障害	5\ RELATED	DRUG WITHDRAWN\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ FATAL

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (209)\ 20[redacted] (213)\ 5	SHINGLES\ 帯状疱疹\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (22)\ Ongoing\ -	AV WENCKEBACH\ 第二度房室ブロック\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERING/RESOLVING
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
26\Yes	20[redacted] (500)\ 20[redacted] (557)\ 58	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
21\Yes	20[redacted] (512)\ 20[redacted] (530)\ 19	WORSENING OF MITRAL VALVE REGURGITATION\ 僧帽弁閉鎖不全症\ 心臓障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
5\Yes	20[redacted] (180)\ 20[redacted] (181)\ 2	WORSENING ANXIETY\ 不安\ 精神障害	2\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
6\Yes	20[redacted] (180)\ 20[redacted] (181)\ 2	WORSENING PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
7\Yes	20[redacted] (184)\ 20[redacted] (187)\ 4	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
10\Yes	20[redacted] (202)\ 20[redacted] (204)\ 3	WORSENING ANXIETY\ 不安\ 精神障害	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
11\Yes	20[redacted] (209)\ 20[redacted] (215)\ 7	WORSENING ANXIETY\ 不安\ 精神障害	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
20\Yes	20[redacted] (891)\ 20[redacted] (896)\ 6	ATRIAL FLUTTER\ 心房粗動\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED WITH SEQUELAE
22\Yes	20[redacted] (925)\ 20[redacted] (929)\ 5	ATRIAL FLUTTER\ 心房粗動\ 心臓障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
3\Yes	20[redacted] (61)\ 20[redacted] (198)\ 138	MALUNION LEFT FEMORAL NECK FRACTURE\ 大腿骨頚部骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
4\Yes	20[redacted] (152)\ 20[redacted] (160)\ 9	FEVER OF UNKNOWN ORIGIN\ 発熱\ 一般・全身障害および投与部位の状態	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
11\Yes	20[redacted] (482)\ 20[redacted] (491)\ 10	BASALIOMA EAR-HELIX RIGHT DORSAL\ 基底細胞癌\	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）		OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
9\Yes	20[redacted] (427)\ 20[redacted] (446)\ 20	PNEUMONIAE (AESI) WORSENING CONDITIONS\ 肺炎\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
21\Yes	20[redacted] (1273)\ 20[redacted] (1291)\ 19	INTERSTITIAL PNEUMONIA\ 間質性肺疾患\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
14\Yes	20[redacted] (789)\ 20[redacted] (808)\ 20	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
15\Yes	20[redacted] (789)\ 20[redacted] (808)\ 20	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
16\Yes	20[redacted] (794)\ 20[redacted] (808)\ 15	PERICARDITIS\ 心膜炎\ 心臓障害	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
20\Yes	20[redacted] (831)\ 20[redacted] (846)\ 16	HAEMOPERICARDIUM\ 心嚢内出血\ 心臓障害	3\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\No	20[redacted] (-6)\ 20[redacted] (-1)\ 6	WORSENING OF ASTHENIA\ 無力症\ 一般・全身障害および投与部位の状態	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
3\Yes	20[redacted] (9)\ Ongoing\ -	AMYLOIDOSIS\ アミロイドーシス\ 免疫系障害	3\ NOT RELATED	DRUG WITHDRAWN\ -\ NOT RECOVERED/NOT RESOLVED
4\Yes	20[redacted] (10)\ 20[redacted] (15)\ 6	ACUTE CARDIAC FAILURE\ 急性心不全\ 心臓障害	5\ NOT RELATED	DRUG INTERRUPTED\ -\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (62)\ 20[redacted] (69)\ 8	DIPLOPIA (DOUBLE VISION)\ 複視\ 眼障害	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
17\Yes	20[redacted] (243)\ 20[redacted] (260)\ 18	ACUTE HEMORRHAGE FROM CHRONIC SUBDURAL HEMATOMA\ 硬膜下出血\ 傷害、中毒および処置合併症	4\ NOT RELATED	DRUG WITHDRAWN\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
24\Yes	20[redacted] (685)\ 20[redacted] (687)\ 3	POSITIVE QUANTIFERON TEST\ インターフェロンγ応答測定陽性\ 臨床検査	2\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
31\Yes	20[redacted] (1532)\ 20[redacted] (1558)\ 27	COVID-19 INFECTION\ COVID-19\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
21\Yes	20[redacted] (1283)\ 20[redacted] (1309)\ 27	MODERATE/SEVERE DYSPASTIC PANCREATIC LESION (ETIOLOGY UNKNOWN)\ 膵臓障害\ 胃腸障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
29\Yes	20[redacted]\ 20[redacted] (1422)\ 61	SEPSIS\ 敗血症\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
30\Yes	20[redacted] (1390)\ 20[redacted] (1471)\ 82	MALNUTRITION\ 栄養障害\ 代謝および栄養障害	3\ NOT RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ OTHER: HOSPITALIZATION\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
10\Yes	20[redacted] (1307)\ 20[redacted] (1335)\ 29	PNEUMONIA COVID-19 RELATED\ COVID-19 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (1250)\ 20[redacted] (1254)\ 5	MALLEOLAR BONE FRACTURE\ 足関節部骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
3\Yes	20[redacted] (1315)\ 20[redacted] (1321)\ 7	ACUTE MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
3\Yes	20[redacted] (183)\ 20[redacted] (193)\ 11	CHRONIC SUBDURAL HEMATOMA\	4\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		硬膜下血腫\ 傷害、中毒および処置合併症		OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\No	20[redacted] (-14)\ 20[redacted] (-2)\ 13	HEART DECOMPENSATION\ 心不全\ 心臓障害	3\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED
2\Yes	20[redacted] (37)\ 20[redacted] (41)\ 5	NEUTROPENIA\ 好中球減少症\ 血液およびリンパ系障害	4\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ -\ RECOVERED/RESOLVED
3\Yes	20[redacted] (37)\ 20[redacted] (40)\ 4	PLATELETS DECREASED (THROMBOCITOPENIA)\ 血小板減少症\ 血液およびリンパ系障害	2\ RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
27\Yes	20[redacted] (1018)\ 20[redacted] (1020)\ 3	CONGESTIVE HEART FAILURE\ うっ血性心不全\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
28\Yes	20[redacted] (1018)\ 20[redacted] (1020)\ 3	WORSERING CHRONIC KIDNEY DISEASE\ 慢性腎臓病\ 腎および尿路障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
29\Yes	20[redacted] (1025)\ 20[redacted] (1101)\ 77	WORSERING OF CHRONIC KIDNEY DISEASE\ 慢性腎臓病\ 腎および尿路障害	4\ NOT RELATED	DRUG WITHDRAWN\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERING/RESOLVING

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\Yes	20[redacted] (3)\ 20[redacted] (4)\ 2	HEMATURIA\ 血尿\ 腎および尿路障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
51\Yes	20[redacted] (955)\ 20[redacted] (996)\ 42	COVID 19 RESPIRATORY INFECTION\ COVID-19\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
76\Yes	20[redacted]\ 20[redacted] (1441)\ 28	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
77\Yes	20[redacted]\ 20[redacted] (1441)\ 28	URINARY BLADDER HAEMORORRHAGE\ 膀胱出血\ 腎および尿路障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
78\Yes	20[redacted] (1445)\ 20[redacted] (1451)\ 7	URINARY BLADDER HAEMORRHAGE\ 膀胱出血\ 腎および尿路障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (53)\ 20[redacted] (56)\ 4	ROTAVIRUS DIARRHEA\ ロタウイルス胃腸炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (759)\ 20[redacted] (768)\ 10	ACUTE PRERENAL RENAL FAILURE\ 急性腎障害\ 腎および尿路障害	2\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
5\Yes	20[redacted] (759)\ 20[redacted] (768)\ 10	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\Yes	20[redacted] (171)\ 20[redacted] (180)\ 10	BILATERAL PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
2\Yes	20[redacted] (171)\ 20[redacted] (180)\ 10	STREPTOCOCCUS SEPSIS\ レンサ球菌性敗血症\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
3\Yes	20[redacted] (213)\ 20[redacted] (218)\ 6	RIGHT-SIDED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
4\Yes	20[redacted] (585)\ 20[redacted] (606)\ 22	ANEMIA (HEMOLYTIC)\ 溶血性貧血\ 血液およびリンパ系障害	3\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ -\ RECOVERING/RESOLVING
5\Yes	20[redacted] (585)\ 20[redacted] (632)\ 48	UPPER RESPIRATORY TRACT INFECTION\ 上気道感染\ 感染症および寄生虫症	2\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
13\Yes	20[redacted] (1563)\ 20[redacted] (1570)\ 8	PNEUMONIA IN THE COURSE COVID-19 INFECTION\ COVID-19 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
14\Yes	20[redacted] (1570)\ 20[redacted] (1580)\ 11	STROKE\ 脳血管発作\ 神経系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
6\Yes	20[redacted] (741)\ 20[redacted] (744)\ 4	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ RELATED	DOSE REDUCED\ OTHER: ELECTRICAL CARDIOVERSION\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
8\Yes	20[redacted] (62)\ 20[redacted] (85)\ 24	CLOSTRIDIUM DIFFICILE INFECTION\ クロストリジウム・ディフィシレ感染\ 感染症および寄生虫症	3\ NOT RELATED	UNKNOWN\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
7\Yes	20[redacted] (298)\ 20[redacted] (316)\ 19	PNEUMONIA ON THE RIGHT\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
6\Yes	20[redacted] (289)\ 20[redacted] (337)\ 49	ANEMIA HB 7,9 G/DL\ 貧血\ 血液およびリンパ系障害	3\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
10\Yes	20[redacted] (663)\ 20[redacted] (701)\ 39	ANEMIA\ 貧血\ 血液およびリンパ系障害	2\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
15\Yes	20[redacted] (842)\ 20[redacted] (876)\ 35	NODULAR MELANOMA\ 結節性黒色腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
17\Yes	20[redacted] (1189)\ 20[redacted] (1291)\ 103	METASTATIC MELANOMA\ 遠隔転移を伴う悪性黒色腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5\ RELATED	DRUG WITHDRAWN\ -\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
8\Yes	20[redacted] (103)\ 20[redacted] (111)\ 9	RESPIRATORY INFECTION BY INFLUENZA B\ インフルエンザ\ 感染症および寄生虫症	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
29\Yes	20[redacted] (1063)\ Ongoing\ -	MDS\ 骨髄異形成症候群\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED; DOSE REDUCED\ NONE\ NOT RECOVERED/NOT RESOLVED
33\Yes	20[redacted] (1083)\ 20[redacted] (1089)\ 7	SUBDURAL HEMATOMA\ 硬膜下血腫\ 傷害、中毒および処置合併症	5\ RELATED	NOT APPLICABLE\ -\ FATAL
34\Yes	20[redacted] (1083)\ 20[redacted] (1083)\ 1	SYNCOPE\ 失神\ 神経系障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
				OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
4\Yes	20[redacted] (279)\ 20[redacted] (284)\ 6	PROSTATITIS\ 前立腺炎\ 生殖系および乳房障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
6\Yes	20[redacted] (117)\ 20[redacted] (130)\ 14	GASTROINTESTINAL FOCUS INFECTION\ 消化管感染\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
15\Yes	20[redacted] (161)\ 20[redacted] (175)\ 15	ACUTE PERICARDITIS\ 心膜炎\ 心臓障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
50\Yes	20[redacted] (1094)\ 20[redacted] (1123)\ 30	PNEUMONIA BY COVID-19\ COVID-19 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
56\Yes	20[redacted] (1637)\ 20[redacted] (1656)\ 20	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	5\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (372)\ 20[redacted] (379)\ 8	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	2\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
18\Yes	20[redacted] (550)\ 20[redacted] (644)\ 95	ENDOMETRIAL ADENOCARCINOMA (STAGE I B)\ 子宮内膜腺癌\	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）		
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
8\Yes	20[redacted] (69)\ 20[redacted] (71)\ 3	L4-L5 ACUTE FRACTURE\ 腰椎骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
32\Yes	20[redacted] (942)\ 20[redacted] \ 86	VERTEBRAL FRACTURE ON L2\ 腰椎骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
34\Yes	20[redacted] \ 20[redacted] (1017)\ 21	LOWER AIRWAYS RESPIRATORY INFECTION (COVID-19 +)\ COVID-19\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ OTHER: FROTIS TEST PERFOMED (COVID-19 POSITIVE RESULT)\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
51\No	20[redacted] (1297)\ 20[redacted] (1302)\ 6	HERPES SIMPLEX 1\ 単純ヘルペス\ 感染症および寄生虫症	3\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
7\Yes	20[redacted] (535)\ 20[redacted] (591)\ 57	WORSENING LUMBAR HERPES ZOSTER\ 帯状疱疹\ 感染症および寄生虫症	3\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\Yes	20[redacted] (648)\ 20[redacted] (662)\ 15	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
3\Yes	20[redacted] (1001)\ 20[redacted] (1004)\ 4	STROKE\ 脳血管発作\ 神経系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (453)\ 20[redacted] (467)\ 15	COMPLETE ATRIOVENTRICULAR BLOCK\ 完全房室ブロック\ 心臓障害	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (235)\ 20[redacted] (242)\ 8	WORSENING HEADACHE\ 頭痛\ 神経系障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
18\Yes	20[redacted] (290)\ 20[redacted] (292)\ 3	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
31\Yes	20[redacted] (1089)\ 20[redacted] (1241)\ 153	LYMPHOMA TRANSFORMATION\ リンパ腫の転化\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
32\No	20[redacted] (1123)\ 20[redacted] (1129)\ 7	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (1008)\ 20[redacted] (1010)\ 3	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ RELATED	DOSE NOT CHANGED\ OTHER: ECHOCARDIOGRAM\ RECOVERED/RESOLVED
15\Yes	20[redacted] (1008)\ 20[redacted] (1010)\ 3	HEART FAILURE\ 心不全\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
12\Yes	20[redacted] (334)\ 20[redacted] (335)\ 2	PERICARDIAL TAMPONADE\ 心タンポナーデ\ 心臓障害	4\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
13\Yes	20[redacted] (335)\ 20[redacted] (345)\ 11	PLEURAL HEMORRHAGE\ 血胸\ 呼吸器、胸郭および縦隔障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
21\Yes	20[redacted] (975)\ Ongoing\ -	BREAST CANCER\ 乳癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	DRUG WITHDRAWN\ -\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
1\No	20[redacted] (-28)\ 20[redacted] (-17)\ 12	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
30\Yes	20[redacted] (641)\ 20[redacted] (643)\ 3	SYNCOPE\ 失神\ 神経系障害	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
44\Yes	20[redacted] (1440)\ 20[redacted] (1442)\ 3	VIRUS INFECTION UNSPECIFIED\ ウイルス感染\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (73)\ 20[redacted] (87)\ 15	E COLI SEPSIS\ 大腸菌性敗血症\ 感染症および寄生虫症	4\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
7\Yes	20[redacted] (143)\ 20[redacted] (148)\ 6	SEPSIS OF UNKNOWN ORIGIN\ 敗血症\ 感染症および寄生虫症	4\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
10\Yes	20[redacted] (300)\ 20[redacted] (303)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
13\Yes	20[redacted] (466)\ 20[redacted] (472)\ 7	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
17\Yes	20[redacted] (623)\ 20[redacted] (627)\ 5	LUNG INFECTION\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
18\Yes	20[redacted] (639)\ 20[redacted] (650)\ 12	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
18\Yes	20[redacted] (151)\ 20[redacted] (198)\ 48	INFLUENZA B VIRAL INFECTION\ インフルエンザ\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
36\Yes	20[redacted] (225)\ 20[redacted] (226)\ 2	NEUTROPAENIA\ 好中球減少症\ 血液およびリンパ系障害	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
37\Yes	20[redacted] (225)\ 20[redacted] (233)\ 9	WORSENED PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
41\Yes	20[redacted] (230)\ 20[redacted] (236)\ 7	NEUTROPENIC SEPSIS\ 好中球減少性敗血症\ 感染症および寄生虫症	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
52\Yes	20[redacted] (255)\ 20[redacted] (266)\ 12	WORSENING PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
62\Yes	20[redacted] (294)\ 20[redacted] (306)\ 13	WORSENING PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
64\Yes	20[redacted] (355)\ 20[redacted] (379)\ 25	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
66\Yes	20[redacted] (355)\ 20[redacted] (361)\ 7	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
68\Yes	20[redacted] (355)\ 20[redacted] (366)\ 12	WORSENED LEFT PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
70\Yes	20[redacted] (356)\ 20[redacted] (356)\ 1	HYPOKALEMIA\ 低カリウム血症\ 代謝および栄養障害	4\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
73\Yes	20[redacted] (362)\ 20[redacted] (369)\ 8	NEUTROPAENIA\ 好中球減少症\ 血液およびリンパ系障害	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
85\Yes	20[redacted] (411)\ 20[redacted] (437)\ 27	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
87\Yes	20[redacted] (411)\ 20[redacted] (443)\ 33	WORSENING PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
39\Yes	20[redacted] (1150)\ 20[redacted] (1160)\ 11	HAEMATURIA\ 血尿\ 腎および尿路障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
18\Yes	20[redacted] (832)\ 20[redacted] (874)\ 43	DRUG INDUCED LIVER INJURY\ 薬物性肝障害\ 肝胆道系障害	4\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ MULTIPLE: PERIPHERAL BLOODS, VIRAL HEPATITIS SCREENING, LIVER ULTRASOUND, LIVER BIOPSY\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
17\Yes	20[redacted] (75)\ 20[redacted] (77)\ 3	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
27\Yes	20[redacted] (418)\ 20[redacted] (428)\ 11	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ -\ RECOVERED/RESOLVED
28\Yes	20[redacted] (418)\ 20[redacted] (434)\ 17	PERI-ANAL INFLAMMATION\ 肛門の炎症\ 胃腸障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
12\Yes	20[redacted] (269)\ 20[redacted] (276)\ 8	LEFT KNEE OSTEOARTHRITIS\ 変形性関節症\ 筋骨格系および結合組織障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
13\Yes	20[redacted] (271)\ 20[redacted] (276)\ 6	ASPIRATION PNEUMONIA\ 誤嚥性肺炎\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
10\Yes	20[redacted] (699)\ 20[redacted] (712)\ 14	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
19\Yes	20[redacted] (469)\ 20[redacted] (470)\ 2	ACUTE PERICARDITIS\ 心膜炎\ 心臓障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
2\Yes	20[redacted] (57)\ 20[redacted] (106)\ 50	DRUG INDUCED HEPATOTOXICITY\ 薬物性肝障害\ 肝胆道系障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
4\Yes	20[redacted] (100)\ 20[redacted] (105)\ 6	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
10\Yes	20[redacted] (267)\ 20[redacted] (272)\ 6	BRUTONS TYROSINE KINASE INHIBITOR WITHDRAWAL SYMTOMS-FEVER, RIGORS, LEG PAIN\ 薬剤離脱症候群\ 一般・全身障害および投与部位の状態	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (1520)\ 20[redacted] (1521)\ 2	DIZZINESS\ 浮動性めまい\ 神経系障害	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
11\Yes	20[redacted] (928)\ 20[redacted] (931)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	5\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ MULTIPLE: ADMISSION TO LOCAL HOSPITAL\ FATAL

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
12\Yes	20[redacted] (835)\ 20[redacted] (836)\ 2	SYNCOPE\ 失神\ 神経系障害	3\ NOT RELATED	DRUG INTERRUPTED\ OTHER: DOSE REDUCTION OF LOSARTAN (CONMED PRESCRIBED FOR HYPERTENSION)\ RECOVERED/RESOLVED
15\Yes	20[redacted] (1008)\ 20[redacted] (1009)\ 2	WORSENING AORTIC VALVE STENOSIS\ 大動脈弁狭窄\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
3\Yes	20[redacted] (210)\ 20[redacted] (215)\ 6	LARYNGEAL OEDEMA\ 喉頭浮腫\ 呼吸器、胸郭および縦隔障害	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
5\Yes	20[redacted] (625)\ 20[redacted] (633)\ 9	PYELONEPHRITIS\ 腎盂腎炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
6\Yes	20[redacted] (631)\ 20[redacted] (730)\ 100	BRAIN ABSCESS\ 脳膿瘍\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ OTHER: CT SCAN AND MRI SCAN, LUMBAR PUNCTION\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
2\Yes	20[redacted] (176)\ 20[redacted] (193)\ 18	INTERMITENT UNCONSCIOUSNESS\ 意識消失\ 神経系障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
12\Yes	20[redacted] (331)\ 20[redacted] (340)\ 10	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
3\No	20[redacted] (483)\ Ongoing\ -	RECTUM CANCER\ 直腸癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (688)\ 20[redacted] (707)\ 20	ACUTE ONSET DYSPHAGIA\ 嚥下障害\ 胃腸障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
7\Yes	20[redacted] (178)\ Ongoing\ -	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	4\ NOT RELATED	DRUG INTERRUPTED\ -\ NOT RECOVERED/NOT RESOLVED
8\Yes	20[redacted] (178)\ 20[redacted] (183)\ 6	SEPSIS\ 敗血症\ 感染症および寄生虫症	5\ NOT RELATED	DRUG WITHDRAWN\ -\ FATAL
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (58)\ 20[redacted] (141)\ 84	OSTEOMYELITIS DISTAL LEFT SHOULDER\ 骨髄炎\ 感染症および寄生虫症	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
4\Yes	20[redacted] (58)\ 20[redacted] (141)\ 84	SEPTIC ARTHRITIS DISTAL LEFT CLAVICLE\ 細菌性関節炎\ 感染症および寄生虫症	4\ NOT RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
7\Yes	20[redacted] (59)\ 20[redacted] (141)\ 83	GROUP B STREP BLOODSTREAM INFECTION\ レンサ球菌性敗血症\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Ibrutinib				
21\Yes	20[redacted] (637)\ 20[redacted] (641)\ 5	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
23\Yes	20[redacted] (637)\ 20[redacted] (647)\ 11	UPPER RESPIRATORY INFECTION\ 上気道感染\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
18\Yes	20[redacted] (638)\ 20[redacted] (643)\ 6	SPINAL FRACTURE (T8)\ 胸椎骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (48)\ 20[redacted] (57)\ 10	INFLUENZA A INFECTION\ インフルエンザ\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
11\Yes	20[redacted] (285)\ 20[redacted] (288)\ 4	ADVERSE REACTION TO ZOLEDRONIC ACID\ 医薬品副作用\ 一般・全身障害および投与部位の状態	1\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (35)\ 20[redacted] (54)\ 20	PULMONARY TUBERCULOSIS REACTIVATED\ 肺結核\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERING/RESOLVING
3\Yes	20[redacted] (193)\ Ongoing\ -	RESPIRATORY FAILURE\ 呼吸不全\ 呼吸器、胸郭および縦隔障害	4\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
				OR PROCEDURE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
5\Yes	20[redacted] (42)\ 20[redacted] (64)\ 23	GASTROINTESTINAL BLEED (MELENA)\ メレナ\ 胃腸障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
32\Yes	20[redacted] (889)\ 20[redacted] (892)\ 4	CELLULITIS R HAND\ 蜂巣炎\ 感染症および寄生虫症	3\ RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
35\Yes	20[redacted] (1075)\ 20[redacted] (1083)\ 9	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED - OTHER, SPECIFY: UROTHELIAL CARCINOMA - BLADDER\ 膀胱移行上皮癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
37\Yes	20[redacted] (1098)\ 20[redacted] (1107)\ 10	SKIN INFECTION - CELLULITIS LEFT FOOT\ 蜂巣炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
39\Yes	20[redacted] (1121)\ 20[redacted] (1131)\ 11	SKIN INFECTION - CELLULITIS LEFT FOOT\ 蜂巣炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
45\Yes	20[redacted] (1277)\ 20[redacted] (1282)\ 6	UPPER GI BLEED\ 上部消化管出血\ 胃腸障害	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
47\Yes	20[redacted] (1297)\ Ongoing\ -	LETHARGY\ 嗜眠\ 神経系障害	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
23\Yes	20[redacted] (1123)\ 20[redacted] (1125)\ 3	FEBRILE\ 発熱\ 一般・全身障害および投与部位の状態	1\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
42\Yes	20[redacted] (1512)\ 20[redacted] (1522)\ 11	MECHANICAL FALL\ 転倒\ 傷害、中毒および処置合併症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED WITH SEQUELAE
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
13\Yes	20[redacted] (598)\ 20[redacted] (601)\ 4	WORSENED SIGNIFICANT OBSTRUCTIVE CORONARY ARTERY DISEASE\ 冠動脈疾患\ 心臓障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
20\Yes	20[redacted] (845)\ 20[redacted] (850)\ 6	SYNCOPE\ 失神\ 神経系障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
23\Yes	20[redacted] (999)\ 20[redacted] (1004)\ 6	COLITIS\ 大腸炎\ 胃腸障害	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
2\Yes	20[redacted] (11)\ 20[redacted] (11)\ 1	VASOVAGAL SYNCOPE\ 失神\ 神経系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
7\Yes	20[redacted] (121)\ 20[redacted] (128)\ 8	CHOLECYSTITIS\ 胆嚢炎\ 肝胆道系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
12\Yes	20[redacted] (328)\ 20[redacted] (361)\ 34	COMMUNITY ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
13\Yes	20[redacted] (328)\ 20[redacted] (361)\ 34	TYPE 2 MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
17\Yes	20[redacted] (340)\ 20[redacted] (361)\ 22	STREP BACTERAEMIA\ レンサ球菌性菌血症\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
15\Yes	20[redacted] (406)\ 20[redacted] (412)\ 7	WORSENING DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED WITH SEQUELAE
18\Yes	20[redacted] (413)\ 20[redacted] (420)\ 8	WORSENING DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
19\Yes	20[redacted] (428)\ 20[redacted] (432)\ 5	DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
22\Yes	20[redacted] (447)\ 20[redacted] (453)\ 7	DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
32\Yes	20[redacted] (816)\ 20[redacted] (818)\ 3	DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
35\Yes	20[redacted] (823)\ 20[redacted] (826)\ 4	WORSENING DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
40\Yes	20[redacted] (1082)\ 20[redacted] (1086)\ 5	ANTIBIOTIC SIDE EFFECTS (VOMITING)\ 嘔吐\ 胃腸障害	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
4\Yes	20[redacted] (34)\ 20[redacted] (37)\ 4	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED
5\Yes	20[redacted] (34)\ 20[redacted] (37)\ 4	STEMI\ 急性心筋梗塞\ 心臓障害	3\ NOT RELATED	DRUG WITHDRAWN\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
11\Yes	20[redacted] (537)\ 20[redacted] (558)\ 22	FALL\ 転倒\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
12\Yes	20[redacted] (537)\ 20[redacted] (558)\ 22	HEMATOMA RIGHT PERIORBITAL\ 眼窩周囲血腫\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
14\Yes	20[redacted] (559)\ 20[redacted] (560)\ 2	FALL\ 転倒\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
20\Yes	20[redacted] (756)\ 20[redacted] (787)\ 32	INTRACRANIAL HAEMORRHAGE (TRAUMATIC)\ 外傷性頭蓋内出血\ 傷害、中毒および処置合併症	4\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
9\Yes	20[redacted] (194)\ 20[redacted] (243)\ 50	STAPHYLOCOCCUS EPIDERMIDIS PROSTHETIC INFECTION\ 医療機器関連感染\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
14\Yes	20[redacted] (523)\ 20[redacted] (527)\ 5	INFLUENZA A\ インフルエンザ\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
19\Yes	20[redacted] (1035)\ 20[redacted] (1095)\ 61	NON-INVASIVE PAPILLARY UROTHELIAL CARCINOMA OF BLADDER\ 膀胱移行上皮癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
11\Yes	20[redacted] (258)\ 20[redacted] (309)\ 52	MRSA INFECTION IN THE L) THUMB WOUND\ ブドウ球菌性創感染\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
12\Yes	20[redacted] (258)\ 20[redacted] (309)\ 52	PROLONGED BLEEDING OF L) THUMB POST LACERATION\ 出血性障害\ 血液およびリンパ系障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
16\Yes	20[redacted] (377)\ 20[redacted] (512)\ 136	R) INDEX FINGER PARONYCHIA\ 爪囲炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
19\Yes	20[redacted] (533)\ 20[redacted] (589)\ 57	PARONYCHIA L) GREAT TOE\ 爪囲炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
20\Yes	20[redacted] (553)\ 20[redacted] (589)\ 37	R) INDEX FINGER PARONYCHIA\ 爪囲炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (120)\ 20[redacted] (121)\ 2	L5 LUMBAR VETERBRAL FRACTURE\ 腰椎骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
5\Yes	20[redacted] (240)\ 20[redacted] (254)\ 15	STREP BOVIS ENDOCARDITIS\ レンサ球菌性心内膜炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
9\Yes	20[redacted] (282)\ 20[redacted] (294)\ 13	NEUTROPENIA\ 好中球減少症\ 血液およびリンパ系障害	4\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
13\Yes	20[redacted] (688)\ 20[redacted] (694)\ 7	WORSENING AORTIC REGURGITATION\ 大動脈弁閉鎖不全症\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
2\Yes	20[redacted] (80)\ 20[redacted] (84)\ 5	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
3\Yes	20[redacted] (175)\ 20[redacted] (178)\ 4	CHOLECYSTITIS\ 胆嚢炎\ 肝胆道系障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
8\Yes	20[redacted] (512)\ 20[redacted] (531)\ 20	POST OPERATIVE SEPSIS\ 処置後敗血症\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
10\Yes	20[redacted] (653)\ 20[redacted] (661)\ 9	UROSEPSIS\ 尿路性敗血症\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
11\Yes	20[redacted] (762)\ 20[redacted] (763)\ 2	BLADDER NEOPLASMS (LOW GRADE NON-INVASIVE PAPILLARY CARCINOMA)\ 膀胱移行上皮癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
13\Yes	20[redacted] (959)\ 20[redacted] (997)\ 39	FEMUR FRACTURE\ 大腿骨骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
14\Yes	20[redacted] (959)\ 20[redacted] (997)\ 39	UROSEPSIS\ 尿路性敗血症\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
9\Yes	20[redacted] (118)\ 20[redacted] (119)\ 2	HEAD INJURY\ 頭部損傷\ 傷害、中毒および処置合併症	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
12\Yes	20[redacted] (558)\ 20[redacted] (569)\ 12	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (40)\ 20[redacted] (54)\ 15	SYNCOPAL EPISODE\ 失神\ 神経系障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
6\Yes	20[redacted] (171)\ 20[redacted] (182)\ 12	GASTRIC HEMORRHAGE\ 胃出血\ 胃腸障害	4\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
10\Yes	20[redacted] (282)\ 20[redacted] (312)\ 31	HEMORRAGE AT RIGHT EYE\ 眼出血\ 眼障害	2\ RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
9\Yes	20[redacted] (1172)\ 20[redacted] (1193)\ 22	INTERSTITIAL PNEUMONIA IN THE COURSE OF SARS-COV-2\	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED WITH SEQUELAE

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		COVID-19 肺炎\ 感染症および寄生虫症		
12\Yes	20[redacted] (1212)\ 20[redacted] (1222)\ 11	DYSPNEA AS THE SEQUEL SARS-COV-2\ 急性 COVID-19 後症候群\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
20\Yes	20[redacted] (1318)\ 20[redacted] (1320)\ 3	INTERSTITIAL LUNG DISEASE\ 間質性肺疾患\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
37\Yes	20[redacted] (942)\ 20[redacted] (954)\ 13	FRACTURE RIGHT FEMUR\ 大腿骨骨折\ 傷害、中毒および処置合併症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
22\Yes	20[redacted] (362)\ 20[redacted] (363)\ 2	CARDIAC CHEST PAIN\ 狭心症\ 心臓障害	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
25\Yes	20[redacted] (417)\ 20[redacted] (420)\ 4	COMMUNITY ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
71\Yes	20[redacted] (1353)\ 20[redacted] (1359)\ 7	FALL\ 転倒\ 傷害、中毒および処置合併症	3\ NOT RELATED	DRUG INTERRUPTED\ NONE\ RECOVERED/RESOLVED
72\Yes	20[redacted] (1356)\ 20[redacted] (1359)\ 4	NSTEMI MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	2\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
75\Yes	20[redacted] (1381)\ 20[redacted] (1395)\ 15	BRUISING RIGHT SIDE OF FACE\ 挫傷\ 傷害、中毒および処置合併症	1\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
76\Yes	20[redacted] (1381)\ 20[redacted] (1395)\ 15	INTRAORAL BLOOD BLISTER BLEED ON RIGHT SIDE OF FACE\ 口腔血性水疱\ 胃腸障害	2\ NOT RELATED	DOSE NOT CHANGED\ OTHER: RIVAROXABAN STOPPED\ RECOVERED/RESOLVED
77\Yes	20[redacted] (1381)\ Ongoing\ -	STAGE 3B CHRONIC KIDNEY DISEASE\ 慢性腎臓病\ 腎および尿路障害	2\ NOT RELATED	DOSE NOT CHANGED\ NONE\ NOT RECOVERED/NOT RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (232)\ 20[redacted] (235)\ 4	SICK SINUS SYNDROME\ 洞結節機能不全\ 心臓障害	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
3\Yes	20[redacted] (254)\ 20[redacted] (292)\ 39	ENDOCARDITIS - BACTERIAL(E.COLI)\ 細菌性心内膜炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
20\Yes	20[redacted] (1058)\ 20[redacted] (1063)\ 6	HYPONATREMIA\ 低ナトリウム血症\ 代謝および栄養障害	4\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
21\Yes	20[redacted] (1058)\ 20[redacted] (1063)\ 6	LEG WEAKNESS (SECONDARY TO FEMOROFEMORAL ARTERIAL BYPASS SURGERY)\ 処置後合併症\ 傷害、中毒および処置合併症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERING/RESOLVING
32\Yes	20[redacted] (1413)\ Ongoing\ -	ACUTE DIASTOLIC CONGESTIVE HEART FAILURE\ 急性左室不全\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ -\ NOT RECOVERED/NOT RESOLVED
35\Yes	20[redacted] (1413)\ 20[redacted] (1415)\ 3	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
38\Yes	20[redacted] (1414)\ 20[redacted] (1415)\ 2	NSTEMI\ 急性心筋梗塞\ 心臓障害	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
40\Yes	20[redacted] (1424)\ 20[redacted] (1426)\ 3	ACUTE HYPOXIC, HYPERCAPNIC RESPIRATORY FAILURE\ 急性呼吸不全\ 呼吸器、胸郭および縦隔障害	4\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
47\Yes	20[redacted] (1425)\ 20[redacted] (1438)\ 14	NON-ST ELEVATED MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	4\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
58\No	20[redacted] (1482)\ 20[redacted] (1501)\ 20	ANEMIA\ 貧血\ 血液およびリンパ系障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
59\No	20[redacted] (1482)\ 20[redacted] (1493)\ 12	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Ibrutinib				
5\Yes	20[redacted] (15)\ 20[redacted] (18)\ 4	HYPERVISCOSITY SYNDROME\ 過粘稠度症候群\ 血液およびリンパ系障害	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 1 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (85)\ 20[redacted] (121)\ 37	BASAL CELL CARCINOMA\ 基底細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
10\Yes	20[redacted] (540)\ 20[redacted] (543)\ 4	NECK PAIN\ 頚部痛\ 筋骨格系および結合組織障害	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (19)\ 20[redacted] (22)\ 4	NOROVIRUS DIARRHOEA\ ノロウイルス性胃腸炎\ 感染症および寄生虫症	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
3\Yes	20[redacted] (56)\ 20[redacted] (85)\ 30	CELLULITIS OF LOWER LIMBS\ 蜂巣炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
16\Yes	20[redacted] (666)\ 20[redacted] (678)\ 13	TRANSFORMED LYMPHOMA\ リンパ腫の転化\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ -\ FATAL
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
14\Yes	20[redacted] (193)\ 20[redacted] (195)\ 3	LEFT PERIORBITAL HAEMATOMA\ 眼窩周囲血腫\ 傷害、中毒および処置合併症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
23\Yes	20[redacted] (197)\ 20[redacted] (209)\ 13	SUBDURAL HAEMATOMA\ 硬膜下血腫\ 傷害、中毒および処置合併症	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED WITH SEQUELAE
40\Yes	20[redacted] (216)\ 20[redacted] (250)\ 35	ACUTE ON SUBACUTE LEFT CONVEXITY SUBDURAL HAEMORRHAGE\ 硬膜下出血\ 傷害、中毒および処置合併症	4\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ OTHER: BLOOD THINNERS CEASED, CLEXANE WITHHELD, ZANUBRUTINIB WITHELD. NOT FOR SURGERY. DULOXETINE CEASED DUE TO HYPONATRAEMIA SECONDARY TO SIADH, NEUROSURGERY TO FOLLOW UP AS OUTPATIENT. TARGIN CEASED\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
6\Yes	20[redacted] (96)\ 20[redacted] (117)\ 22	ZANUBRUTINIB WITHDRAWAL SYNDROME-FEVER\ 薬剤離脱症候群\	3\ RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		一般・全身障害および投与部位の状態		
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
11\Yes	20[redacted] (1371)\ 20[redacted] (1391)\ 21	COVID-19 INFECTION\ COVID-19\ 感染症および寄生虫症	5\ NOT RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ NONE\ FATAL
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
4\Yes	20[redacted] (129)\ 20[redacted] (139)\ 11	LOWER RESPIRATORY INFECTION\ 下気道感染\ 感染症および寄生虫症	2\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
8\Yes	20[redacted] (173)\ 20[redacted] (180)\ 8	CELLULITIS LOWER EXTREMITIES\ 蜂巣炎\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
9\Yes	20[redacted] (173)\ 20[redacted] (181)\ 9	EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE\ 慢性閉塞性肺疾患\ 呼吸器、胸郭および縦隔障害	2\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
13\Yes	20[redacted] (274)\ 20[redacted] (288)\ 15	RESPIRATORY INFECTION\ 気道感染\ 感染症および寄生虫症	4\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
21\Yes	20[redacted] (488)\ 20[redacted] (496)\ 9	RESPIRATORY INFECTION\ 気道感染\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
25\Yes	20[redacted] (547)\ 20[redacted] (553)\ 7	RESPIRATORY INFECTION\ 気道感染\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
26\Yes	20[redacted] (576)\ 20[redacted] (582)\ 7	RESPIRATORY INSUFFICIENCY\ 呼吸不全\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
9\Yes	20[redacted] (43)\ 20[redacted] (60)\ 18	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	1\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (55)\ 20[redacted] (64)\ 10	BILATERAL PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
5\Yes	20[redacted] (237)\ 20[redacted] (250)\ 14	COMMUNITY ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	NOT APPLICABLE\ -\ RECOVERED/RESOLVED
6\Yes	20[redacted] (257)\ 20[redacted] (260)\ 4	ORGANIZING PNEUMONIA\ 器質化肺炎\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	NOT APPLICABLE\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
25\Yes	20[redacted] (815)\ 20[redacted] (825)\ 11	LOWER EXTREMITIES OEDEMA\ 末梢性浮腫\ 一般・全身障害および投与部位の状態	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED WITH SEQUELAE

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
27\Yes	20[redacted] (883)\ 20[redacted] (889)\ 7	RECURRENCE OF ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
28\Yes	20[redacted] (883)\ 20[redacted] (889)\ 7	WORSENING OF LOWER EXTREMITIES OEDEMA\ 末梢性浮腫\ 一般・全身障害および投与部位の状態	3\ NOT RELATED	DOSE NOT CHANGED\ NONE\ RECOVERED/RESOLVED
29\Yes	20[redacted] (889)\ 20[redacted] (889)\ 1	CARDIAC ARREST\ 心停止\ 心臓障害	5\ NOT RELATED	DRUG WITHDRAWN\ NONE\ FATAL
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
5\Yes	20[redacted] (402)\ Ongoing\ -	VIRAL HEPATITIS B\ B 型肝炎\ 感染症および寄生虫症	3\ RELATED	MULTIPLE: DRUG WITHDRAWN; DRUG INTERRUPTED\ -\ NOT RECOVERED/NOT RESOLVED
Cohort: 2 Treatment Type: RR Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (1484)\ 20[redacted] (1492)\ 9	COVID-19 INFECTION\ COVID-19\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
1\Yes	20[redacted] (3)\ 20[redacted] (6)\ 4	WORSENING OF DUODENAL ULCER\ 十二指腸潰瘍\ 胃腸障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
2\Yes	20[redacted] (64)\ 20[redacted] (66)\ 3	VIRAL GASTROENTERITIS\ ウイルス性胃腸炎\ 感染症および寄生虫症	2\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
10\Yes	20[redacted] (339)\ 20[redacted] (340)\ 2	HYPONATRAEMIA\ 低ナトリウム血症\ 代謝および栄養障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
21\Yes	20[redacted] (484)\ 20[redacted] (536)\ 53	RESPIRATORY INFECTION\ 気道感染\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
22\Yes	20[redacted] (503)\ 20[redacted] (536)\ 34	EXACERBATION OF ASTHMA\ 喘息\ 呼吸器、胸郭および縦隔障害	3\ NOT RELATED	DOSE NOT CHANGED\ -\ RECOVERED/RESOLVED
27\Yes	20[redacted] (702)\ 20[redacted] (743)\ 42	UROSEPSIS\ 尿路性敗血症\ 感染症および寄生虫症	3\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
38\Yes	20[redacted] (1524)\ 20[redacted] (1530)\ 7	COVID-19 INFECTION\ COVID-19\ 感染症および寄生虫症	2\ NOT RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
3\Yes	20[redacted] (57)\ 20[redacted] (59)\ 3	HYPERVISCOSITY\ 過粘稠度症候群\ 血液およびリンパ系障害	3\ NOT RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
2\Yes	20[redacted] (105)\ 20[redacted] (114)\ 10	PNEUMONITIS\ 肺臓炎\ 呼吸器、胸郭および縦隔障害	3\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
4\Yes	20[redacted] (132)\ 20[redacted] (141)\ 10	PNEUMONITIS\ 肺臓炎\ 呼吸器、胸郭および縦隔障害	2\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
8\Yes	20[redacted] (316)\ 20[redacted] (322)\ 7	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ RELATED	MULTIPLE: DRUG INTERRUPTED; DOSE REDUCED\ NON-MEDICATION CONCOMITANT THERAPY

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
				OR PROCEDURE\ RECOVERED/RESOLVED
Cohort: 2 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
20\Yes	20[redacted] (354)\ 20[redacted]\ 40	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
22\Yes	20[redacted] (355)\ 20[redacted]\ 39	PSEUDOMEMBRANOUS CONJUNCTIVITIS\ 結膜炎\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
25\Yes	20[redacted] (357)\ 20[redacted] (359)\ 3	GASTRIC ULCER HAEMORRHAGE\ 出血性胃潰瘍\ 胃腸障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
35\No	20[redacted] (383)\ 20[redacted] (415)\ 33	DECOMPENSATED HEART FAILURE WITH PRESERVED EJECTION FRACTION\ 心不全\ 心臓障害	5\ NOT RELATED	DRUG INTERRUPTED\ -\ FATAL
36\No	20[redacted] (386)\ 20[redacted] (409)\ 24	HOSPITAL ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ NOT RELATED	DOSE NOT CHANGED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED

AE No\ Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Cohort: 2 Treatment Type: TN Patient ID: [redacted] Treatment: Zanubrutinib				
32\Yes	20[redacted] (940)\ 20[redacted] (942)\ 3	TENOSYNOVITIS\ 腱鞘炎\ 筋骨格系および結合組織障害	3\ RELATED	DRUG INTERRUPTED\ NON-MEDICATION CONCOMITANT THERAPY OR PROCEDURE\ RECOVERED/RESOLVED
33\Yes	20[redacted] (964)\ 20[redacted] (1433)\ 470	GRAM NEGATIVE BACILLI BACTERIAL INFECTION ON RIGHT HAND\ 限局性感染\ 感染症および寄生虫症	3\ RELATED	DRUG INTERRUPTED\ -\ RECOVERED/RESOLVED WITH SEQUELAE

Source: Listing 16.2.7.2 in BGB-3111-302 clinical study report (final database lock date: [redacted] 20[redacted]). Data cutoff: 21JUN2022; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE.
Abbreviation(s): RR, relapsed/refractory; TN, treatment naive.
Cohort 1 includes patients with activating mutations in MYD88; Cohort 2 includes patients with wild type and unknown MYD88.
MedDRA Version: 24.0.
Adverse event grades are evaluated based on NCI-CTCAE (Version 4.03).

表 38： 治療下で発現した有害事象：器官別大分類別及び基本語別（BGB-3111-AU-003 試験、統合したパート 1 及びパート 2 の安全性解析対象集団、診断名別）

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
Patients with at least 1 TEAE	125 (100.0)	13 (100.0)	78 (100.0)	56 (98.2)	32 (97.0)	20 (100.0)	43 (95.6)	11 (91.7)	380 (98.7)
感染症および寄生虫症	106 (84.8)	9 (69.2)	72 (92.3)	43 (75.4)	21 (63.6)	15 (75.0)	23 (51.1)	8 (66.7)	299 (77.7)
上気道感染	60 (48.0)	4 (30.8)	43 (55.1)	20 (35.1)	9 (27.3)	6 (30.0)	9 (20.0)	6 (50.0)	158 (41.0)
尿路感染	28 (22.4)	1 (7.7)	15 (19.2)	11 (19.3)	8 (24.2)	2 (10.0)	3 (6.7)	0 (0.0)	68 (17.7)
肺炎	24 (19.2)	1 (7.7)	7 (9.0)	6 (10.5)	3 (9.1)	3 (15.0)	6 (13.3)	1 (8.3)	52 (13.5)
副鼻腔炎	24 (19.2)	1 (7.7)	8 (10.3)	4 (7.0)	1 (3.0)	4 (20.0)	1 (2.2)	0 (0.0)	43 (11.2)
蜂巣炎	13 (10.4)	1 (7.7)	10 (12.8)	5 (8.8)	3 (9.1)	1 (5.0)	1 (2.2)	1 (8.3)	35 (9.1)
下気道感染	21 (16.8)	0 (0.0)	8 (10.3)	5 (8.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	35 (9.1)
上咽頭炎	9 (7.2)	0 (0.0)	6 (7.7)	5 (8.8)	0 (0.0)	5 (25.0)	2 (4.4)	1 (8.3)	29 (7.5)
限局性感染	5 (4.0)	0 (0.0)	8 (10.3)	7 (12.3)	0 (0.0)	2 (10.0)	0 (0.0)	1 (8.3)	23 (6.0)
口腔ヘルペス	9 (7.2)	0 (0.0)	3 (3.8)	2 (3.5)	2 (6.1)	2 (10.0)	2 (4.4)	1 (8.3)	22 (5.7)
結膜炎	9 (7.2)	0 (0.0)	4 (5.1)	3 (5.3)	1 (3.0)	2 (10.0)	1 (2.2)	0 (0.0)	20 (5.2)
皮膚感染	10 (8.0)	1 (7.7)	5 (6.4)	1 (1.8)	0 (0.0)	2 (10.0)	1 (2.2)	0 (0.0)	20 (5.2)
帯状疱疹	9 (7.2)	0 (0.0)	2 (2.6)	2 (3.5)	1 (3.0)	2 (10.0)	2 (4.4)	1 (8.3)	19 (4.9)
気管支炎	7 (5.6)	1 (7.7)	4 (5.1)	1 (1.8)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	16 (4.2)
インフルエンザ	5 (4.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	1 (5.0)	4 (8.9)	0 (0.0)	12 (3.1)
耳感染	6 (4.8)	1 (7.7)	2 (2.6)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	11 (2.9)
胃腸炎	6 (4.8)	0 (0.0)	2 (2.6)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	10 (2.6)
ウイルス性上気道感染	3 (2.4)	0 (0.0)	5 (6.4)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	10 (2.6)
毛包炎	3 (2.4)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	9 (2.3)
中耳炎	5 (4.0)	0 (0.0)	0 (0.0)	1 (1.8)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
膀胱炎	0 (0.0)	1 (7.7)	0 (0.0)	1 (1.8)	1 (3.0)	2 (10.0)	1 (2.2)	0 (0.0)	6 (1.6)
憩室炎	2 (1.6)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
爪感染	2 (1.6)	1 (7.7)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
気道感染	2 (1.6)	1 (7.7)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	6 (1.6)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
敗血症	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
外陰部腟カンジダ症	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
創傷感染	2 (1.6)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
大腸菌性尿路感染	0 (0.0)	1 (7.7)	0 (0.0)	1 (1.8)	0 (0.0)	3 (15.0)	0 (0.0)	0 (0.0)	5 (1.3)
爪真菌症	1 (0.8)	0 (0.0)	3 (3.8)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
爪囲炎	3 (2.4)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
歯膿瘍	3 (2.4)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
歯感染	4 (3.2)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
気管支肺アスペルギルス症	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	4 (1.0)
眼感染	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	4 (1.0)
皮膚真菌感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	1 (8.3)	4 (1.0)
ウイルス性下気道感染	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
口腔カンジダ症	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
歯周炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	4 (1.0)
処置後感染	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
ウイルス感染	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
異型肺炎	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
菌血症	1 (0.8)	1 (7.7)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
COVID-19	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
歯肉炎	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
ヘモフィルス感染	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
B 型肝炎再活性化	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
単純ヘルペス	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
感染性皮膚嚢腫	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
喉頭炎	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
クリプトコッカス性髄膜炎	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
鼻ヘルペス	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
外耳炎	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
パラインフルエンザウイルス感染	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
腎盂腎炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (10.0)	0 (0.0)	0 (0.0)	3 (0.8)
敗血症性ショック	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
ブドウ球菌皮膚感染	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
扁桃炎	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
外陰腟真菌感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
細菌性関節炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
細気管支炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
カンピロバクター胃腸炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
クロストリジウム・ディフィシレ大腸炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
大腸菌性敗血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
せつ	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
ノロウイルス性胃腸炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
ウイルス性胃腸炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
単純ヘルペス再燃	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
播種性帯状疱疹	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
麦粒腫	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
咬傷感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
クリプトコッカス性肺炎	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
真菌性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
術後創感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
膿疱性皮疹	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
ライノウイルス感染	1 (0.8)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
陰嚢感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
軟部組織感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
足部白癬	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)

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腸球菌性尿路感染	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
膣感染	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腹部敗血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
アデノウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
歯槽骨炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
真菌性肛門感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
無症候性 COVID-19	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性疾患キャリアー	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性膣症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
体部白癬	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘモフィルス性気管支炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染性滑液包炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
よう	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
ネコ引っかき病	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
男性外性器蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脳アスペルギルス症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
胸壁膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性副鼻腔炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
合併症を伴う虫垂炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性結膜炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性結膜炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪の皮膚糸状菌症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
糖尿病性足感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
赤痢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
真菌性耳感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
真菌性脳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染性腸炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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精巣上体炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
エプスタイン・バーウイルス血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
大腸菌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性眼感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
赤痢菌性胃腸炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
H1N1 インフルエンザ	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘモフィルス性敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘリコバクター感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性肝炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
単純ヘルペスウイルス血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
帯状疱疹性髄膜脳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳帯状疱疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膿痂疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染性嚢腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染性皮膚潰瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染による気管支拡張症の増悪	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染性強膜炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口唇感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リステリア性敗血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リンパ節感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
乳様突起炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
レンサ球菌性髄膜炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
マイコバクテリウム・ウルセランス感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪床感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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鼻膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
食道カンジダ症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
食道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼帯状疱疹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精巣炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
真菌性外耳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
副鼻腔膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼窩周囲蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
百日咳	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
咽頭扁桃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
肺炎球菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
インフルエンザ性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
マイコプラズマ性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ブドウ球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
レンサ球菌性肺炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス感染後疲労症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
シュードモナス性敗血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
膿疱	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
RS ウイルス感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性気道感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
スケドスポリウム感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
唾液腺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚カンジダ	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
植皮感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
ブドウ球菌性膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
レンサ球菌性菌血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮下組織膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
全身性ウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
白癬感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
結核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
前庭神経炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性食道炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
外陰部炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胃腸障害	92 (73.6)	4 (30.8)	53 (67.9)	39 (68.4)	16 (48.5)	14 (70.0)	26 (57.8)	5 (41.7)	251 (65.2)
下痢	44 (35.2)	2 (15.4)	18 (23.1)	24 (42.1)	4 (12.1)	7 (35.0)	6 (13.3)	1 (8.3)	107 (27.8)
便秘	30 (24.0)	1 (7.7)	14 (17.9)	16 (28.1)	4 (12.1)	3 (15.0)	10 (22.2)	0 (0.0)	78 (20.3)
悪心	27 (21.6)	2 (15.4)	11 (14.1)	8 (14.0)	8 (24.2)	4 (20.0)	9 (20.0)	0 (0.0)	69 (17.9)
嘔吐	14 (11.2)	0 (0.0)	8 (10.3)	5 (8.8)	4 (12.1)	1 (5.0)	4 (8.9)	1 (8.3)	38 (9.9)
胃食道逆流性疾患	13 (10.4)	1 (7.7)	13 (16.7)	5 (8.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	34 (8.8)
腹痛	11 (8.8)	1 (7.7)	6 (7.7)	5 (8.8)	2 (6.1)	1 (5.0)	6 (13.3)	0 (0.0)	32 (8.3)
口内炎	3 (2.4)	0 (0.0)	1 (1.3)	3 (5.3)	1 (3.0)	2 (10.0)	4 (8.9)	0 (0.0)	14 (3.6)
上腹部痛	4 (3.2)	0 (0.0)	3 (3.8)	3 (5.3)	0 (0.0)	3 (15.0)	0 (0.0)	0 (0.0)	13 (3.4)
口腔内潰瘍形成	7 (5.6)	0 (0.0)	3 (3.8)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	13 (3.4)
消化不良	1 (0.8)	0 (0.0)	3 (3.8)	6 (10.5)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	11 (2.9)
腹部膨満	1 (0.8)	0 (0.0)	4 (5.1)	3 (5.3)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	10 (2.6)
口内乾燥	6 (4.8)	0 (0.0)	0 (0.0)	3 (5.3)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	10 (2.6)
歯痛	3 (2.4)	0 (0.0)	2 (2.6)	0 (0.0)	2 (6.1)	1 (5.0)	0 (0.0)	2 (16.7)	10 (2.6)
痔核	4 (3.2)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	8 (2.1)
下腹部痛	2 (1.6)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
嚥下障害	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
鼓腸	1 (0.8)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)

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鼡径ヘルニア	3 (2.4)	1 (7.7)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
直腸出血	0 (0.0)	0 (0.0)	3 (3.8)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
腹部不快感	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	4 (1.0)
歯肉出血	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	4 (1.0)
痔出血	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)
口腔内痛	1 (0.8)	0 (0.0)	0 (0.0)	2 (3.5)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
肛門そう痒症	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
齲歯	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
裂孔ヘルニア	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
大腸ポリープ	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
口腔内出血	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
膵嚢胞	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
舌潰瘍	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
歯の障害	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
大腸炎	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腸膀胱瘻	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
食中毒	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
胃炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
消化器痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
過敏性腸症候群	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
消化性潰瘍	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
逆流性胃炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
レッチング	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
小腸閉塞	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
上部消化管出血	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
腹部硬直	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
裂肛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肛門出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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肛門直腸不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腹水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
便習慣変化	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性胃炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
虚血性大腸炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血性下痢	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腸憩室	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
小腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
変色便	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
排便回数増加	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胃ポリープ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
胃軸捻転	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胃腸出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
消化管運動低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
歯肉痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口の感覚鈍麻	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
イレウス	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
絞扼性臍径ヘルニア	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口唇痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
メレナ	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
非感染性歯肉炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
嚥下痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
食道炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口腔粘膜水疱形成	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口腔粘膜紅斑	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口腔内紫斑	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口蓋潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腹膜障害	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腸壁気腫症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
後腹膜腫瘤	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
舌腫脹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
舌不快感	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
地図状舌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
臍ヘルニア	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚および皮下組織障害	79 (63.2)	8 (61.5)	48 (61.5)	34 (59.6)	18 (54.5)	12 (60.0)	17 (37.8)	6 (50.0)	223 (57.9)
発疹	29 (23.2)	2 (15.4)	13 (16.7)	17 (29.8)	3 (9.1)	7 (35.0)	4 (8.9)	3 (25.0)	78 (20.3)
そう痒症	9 (7.2)	1 (7.7)	12 (15.4)	7 (12.3)	3 (9.1)	2 (10.0)	5 (11.1)	0 (0.0)	39 (10.1)
点状出血	10 (8.0)	1 (7.7)	10 (12.8)	4 (7.0)	5 (15.2)	1 (5.0)	1 (2.2)	1 (8.3)	33 (8.6)
皮膚病変	10 (8.0)	1 (7.7)	7 (9.0)	4 (7.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	24 (6.2)
皮膚乾燥	3 (2.4)	1 (7.7)	2 (2.6)	6 (10.5)	2 (6.1)	0 (0.0)	2 (4.4)	0 (0.0)	16 (4.2)
紫斑	9 (7.2)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	13 (3.4)
光線角化症	7 (5.6)	0 (0.0)	3 (3.8)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (3.1)
紅斑	4 (3.2)	0 (0.0)	3 (3.8)	3 (5.3)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	12 (3.1)
多汗症	6 (4.8)	0 (0.0)	1 (1.3)	3 (5.3)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	12 (3.1)
寝汗	3 (2.4)	1 (7.7)	4 (5.1)	2 (3.5)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	12 (3.1)
斑状丘疹状皮疹	7 (5.6)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	12 (3.1)
丘疹性皮疹	5 (4.0)	0 (0.0)	3 (3.8)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (2.6)
斑状皮疹	3 (2.4)	3 (23.1)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
そう痒性皮疹	2 (1.6)	0 (0.0)	2 (2.6)	2 (3.5)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	8 (2.1)
脱毛症	3 (2.4)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	7 (1.8)
斑状出血	1 (0.8)	0 (0.0)	2 (2.6)	3 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	7 (1.8)
皮膚潰瘍	3 (2.4)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
血性水疱	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)
湿疹	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)

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嵌入爪	1 (0.8)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
紅斑性皮疹	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)
皮膚変色	1 (0.8)	1 (7.7)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
水疱	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
接触皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	3 (0.8)
皮膚疼痛	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
光線過敏性反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
酒さ	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
皮膚腫瘤	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
蕁麻疹	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
褥瘡性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
皮膚炎	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
アレルギー性皮膚炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
糖尿病性足病変	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
薬疹	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
過角化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
苔癬様角化症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
爪破損	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
光線性皮膚症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
前癌性皮膚病変	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
乾癬	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚剥脱	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
ざ瘡	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
冷汗	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚嚢腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ざ瘡様皮膚炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
多形紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
剥脱性発疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
手皮膚炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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過敏性血管炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
ケロイド瘢痕	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
さじ状爪	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
網状皮斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
斑	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
機械性蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
粘液様嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪変色	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪ジストロフィー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
好中球性皮膚症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
丘疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脂漏性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚亀裂	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚色素過剰	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
日光皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
日光黒子	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
うっ滞性皮膚炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
蕁麻疹様血管炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
尋常性白斑	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
呼吸器、胸郭および縦隔障害	75 (60.0)	4 (30.8)	44 (56.4)	34 (59.6)	14 (42.4)	7 (35.0)	24 (53.3)	2 (16.7)	206 (53.5)
咳嗽	43 (34.4)	4 (30.8)	20 (25.6)	12 (21.1)	8 (24.2)	4 (20.0)	11 (24.4)	0 (0.0)	104 (27.0)
呼吸困難	10 (8.0)	0 (0.0)	4 (5.1)	12 (21.1)	3 (9.1)	1 (5.0)	8 (17.8)	0 (0.0)	38 (9.9)
鼻出血	10 (8.0)	0 (0.0)	10 (12.8)	6 (10.5)	4 (12.1)	2 (10.0)	3 (6.7)	2 (16.7)	37 (9.6)
口腔咽頭痛	9 (7.2)	0 (0.0)	10 (12.8)	4 (7.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	26 (6.8)
湿性咳嗽	6 (4.8)	0 (0.0)	2 (2.6)	6 (10.5)	1 (3.0)	2 (10.0)	3 (6.7)	0 (0.0)	21 (5.5)
鼻閉	10 (8.0)	0 (0.0)	2 (2.6)	3 (5.3)	2 (6.1)	1 (5.0)	0 (0.0)	0 (0.0)	18 (4.7)
胸水	3 (2.4)	1 (7.7)	2 (2.6)	6 (10.5)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	15 (3.9)

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鼻漏	6 (4.8)	0 (0.0)	3 (3.8)	2 (3.5)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	13 (3.4)
労作性呼吸困難	3 (2.4)	0 (0.0)	0 (0.0)	6 (10.5)	1 (3.0)	0 (0.0)	0 (0.0)	1 (8.3)	12 (3.1)
アレルギー性鼻炎	5 (4.0)	0 (0.0)	2 (2.6)	1 (1.8)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	10 (2.6)
上気道咳症候群	8 (6.4)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (2.6)
喀血	4 (3.2)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	2 (10.0)	1 (2.2)	0 (0.0)	8 (2.1)
副鼻腔痛	2 (1.6)	0 (0.0)	3 (3.8)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	7 (1.8)
喘息	2 (1.6)	0 (0.0)	2 (2.6)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
発声障害	0 (0.0)	0 (0.0)	1 (1.3)	3 (5.3)	0 (0.0)	2 (10.0)	0 (0.0)	0 (0.0)	6 (1.6)
喘鳴	1 (0.8)	0 (0.0)	1 (1.3)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
低酸素症	1 (0.8)	0 (0.0)	0 (0.0)	2 (3.5)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
胸膜痛	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
急性肺水腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
気管支拡張症	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
しゃっくり	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
口腔咽頭不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
肺臓炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
肺腫瘤	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
呼吸不全	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
咽喉刺激感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
上気道の炎症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
アレルギー性咳嗽	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性閉塞性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
横隔膜痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
横隔膜障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
安静時呼吸困難	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血胸	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
間質性肺疾患	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
鼻腔腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
鼻部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
鼻の炎症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
夜間呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
閉塞性気道障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
器質化肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
副鼻腔分泌過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
咽頭出血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
咽頭の炎症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
咽頭嚢	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胸膜肥厚	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
誤嚥性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
気胸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
肺塞栓症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺肉芽腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺高血圧症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺水腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ラ音	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
鼻痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
副鼻腔うっ血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
副鼻腔障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
睡眠時無呼吸症候群	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
くしゃみ	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
扁桃肥大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
傷害、中毒および処置合併症	87 (69.6)	2 (15.4)	44 (56.4)	33 (57.9)	12 (36.4)	10 (50.0)	11 (24.4)	3 (25.0)	202 (52.5)
挫傷	64 (51.2)	2 (15.4)	26 (33.3)	26 (45.6)	8 (24.2)	7 (35.0)	5 (11.1)	2 (16.7)	140 (36.4)
転倒	15 (12.0)	1 (7.7)	9 (11.5)	9 (15.8)	3 (9.1)	1 (5.0)	1 (2.2)	0 (0.0)	39 (10.1)
皮膚裂傷	4 (3.2)	1 (7.7)	7 (9.0)	4 (7.0)	2 (6.1)	2 (10.0)	2 (4.4)	0 (0.0)	22 (5.7)
処置による疼痛	7 (5.6)	0 (0.0)	2 (2.6)	3 (5.3)	2 (6.1)	1 (5.0)	2 (4.4)	0 (0.0)	17 (4.4)

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四肢損傷	7 (5.6)	0 (0.0)	4 (5.1)	3 (5.3)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	16 (4.2)
皮膚擦過傷	1 (0.8)	0 (0.0)	2 (2.6)	5 (8.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	9 (2.3)
処置後挫傷	5 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	7 (1.8)
足骨折	2 (1.6)	1 (7.7)	2 (2.6)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
肉離れ	3 (2.4)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
処置後出血	2 (1.6)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
節足動物咬傷	3 (2.4)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
関節損傷	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
熱傷	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
歯牙破折	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	4 (1.0)
靱帯断裂	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
靱帯捻挫	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
外傷後疼痛	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
橈骨骨折	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
腱断裂	0 (0.0)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
創傷	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
胸部損傷	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
眼瞼損傷	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
大腿骨頚部骨折	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腓骨骨折	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
上腕骨骨折	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
半月板損傷	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
肋骨骨折	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
瘢痕	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
漿液腫	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚創傷	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
サンバーン	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
外傷性出血	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
動物咬傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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背部損傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
骨挫傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頚椎骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
凍瘡	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
鎖骨骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼挫傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
大腿骨骨折	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
股関節部骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
関節脱臼	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
靱帯損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
下肢骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腰椎骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
骨盤骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
陰茎損傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後合併症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後発熱	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後血腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
処置後腫脹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
術後創合併症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置による悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
放射線皮膚損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
反復性挫傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
網膜損傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
引っかき傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
軟部組織損傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脊椎圧迫骨折	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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スポーツ損傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮下血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
滑膜断裂	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脛骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
輸血反応	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
尺骨骨折	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
上肢骨折	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ワクチン接種合併症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
創離開	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
創傷出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
手首関節骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
筋骨格系および結合組織障害	74 (59.2)	7 (53.8)	44 (56.4)	31 (54.4)	12 (36.4)	10 (50.0)	21 (46.7)	3 (25.0)	202 (52.5)
背部痛	24 (19.2)	1 (7.7)	13 (16.7)	10 (17.5)	4 (12.1)	2 (10.0)	7 (15.6)	0 (0.0)	61 (15.8)
関節痛	27 (21.6)	1 (7.7)	10 (12.8)	7 (12.3)	4 (12.1)	1 (5.0)	4 (8.9)	0 (0.0)	54 (14.0)
筋痙縮	17 (13.6)	0 (0.0)	3 (3.8)	7 (12.3)	4 (12.1)	2 (10.0)	2 (4.4)	2 (16.7)	37 (9.6)
四肢痛	7 (5.6)	2 (15.4)	6 (7.7)	7 (12.3)	1 (3.0)	0 (0.0)	5 (11.1)	1 (8.3)	29 (7.5)
筋肉痛	11 (8.8)	1 (7.7)	5 (6.4)	5 (8.8)	2 (6.1)	0 (0.0)	2 (4.4)	0 (0.0)	26 (6.8)
筋骨格痛	5 (4.0)	1 (7.7)	4 (5.1)	5 (8.8)	0 (0.0)	4 (20.0)	2 (4.4)	0 (0.0)	21 (5.5)
頚部痛	9 (7.2)	1 (7.7)	3 (3.8)	2 (3.5)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	16 (4.2)
筋骨格系胸痛	4 (3.2)	0 (0.0)	4 (5.1)	3 (5.3)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	13 (3.4)
関節腫脹	5 (4.0)	0 (0.0)	3 (3.8)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	11 (2.9)
筋力低下	5 (4.0)	2 (15.4)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	10 (2.6)
関節炎	3 (2.4)	1 (7.7)	2 (2.6)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	1 (8.3)	9 (2.3)
滑液包炎	5 (4.0)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (2.3)
変形性関節症	6 (4.8)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (2.3)
側腹部痛	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
鼡径部痛	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
滑液嚢腫	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
骨痛	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
椎間板突出	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	3 (0.8)
関節滲出液	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
筋骨格硬直	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
骨粗鬆症	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
肩回旋筋腱板症候群	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
腱炎	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
弾発指	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
肋軟骨炎	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
痛風性関節炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
関節可動域低下	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
筋肉疲労	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
頚部腫瘤	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
骨減少症	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
脊柱管狭窄症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腱痛	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
斜頚	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
骨病変	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胸壁嚢胞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
デュプイトラン拘縮	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
外骨腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
線維筋痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
出血性関節症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
四肢不快感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
四肢腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腰部脊柱管狭窄症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
筋緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
筋骨格不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
関節周囲炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
足底腱膜線維腫症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
仙腸骨炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
側弯症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
軟部組織壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
変形性脊椎症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脊椎痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脊椎炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脊椎すべり症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腱不快感	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
椎間孔狭窄	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
一般・全身障害および投与部位の状態	67 (53.6)	7 (53.8)	34 (43.6)	39 (68.4)	13 (39.4)	11 (55.0)	24 (53.3)	2 (16.7)	198 (51.4)
疲労	28 (22.4)	1 (7.7)	15 (19.2)	17 (29.8)	7 (21.2)	4 (20.0)	8 (17.8)	1 (8.3)	81 (21.0)
発熱	10 (8.0)	3 (23.1)	7 (9.0)	6 (10.5)	4 (12.1)	5 (25.0)	12 (26.7)	2 (16.7)	50 (13.0)
末梢性浮腫	12 (9.6)	1 (7.7)	5 (6.4)	14 (24.6)	2 (6.1)	3 (15.0)	3 (6.7)	0 (0.0)	40 (10.4)
インフルエンザ様疾患	9 (7.2)	0 (0.0)	6 (7.7)	6 (10.5)	2 (6.1)	1 (5.0)	1 (2.2)	0 (0.0)	26 (6.8)
末梢腫脹	8 (6.4)	1 (7.7)	3 (3.8)	5 (8.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (4.4)
疼痛	8 (6.4)	0 (0.0)	3 (3.8)	2 (3.5)	1 (3.0)	1 (5.0)	1 (2.2)	0 (0.0)	16 (4.2)
無力症	2 (1.6)	1 (7.7)	1 (1.3)	0 (0.0)	0 (0.0)	2 (10.0)	6 (13.3)	0 (0.0)	13 (3.4)
胸痛	5 (4.0)	0 (0.0)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	11 (2.9)
悪寒	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	2 (6.1)	2 (10.0)	2 (4.4)	0 (0.0)	9 (2.3)
多臓器機能不全症候群	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	4 (1.0)
非心臓性胸痛	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)
腋窩痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
倦怠感	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)

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胸部不快感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
嚢胞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
顔面浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
歩行障害	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
カテーテル留置部位出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
死亡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
顔面痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
全身健康状態悪化	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘルニア	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
不明確な障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
炎症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
注入部位損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
注射部位出血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
限局性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
小結節	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
浮腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
分泌物分泌	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
異物感	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
恥骨上痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
ワクチン接種部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血管穿刺部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
神経系障害	65 (52.0)	1 (7.7)	35 (44.9)	30 (52.6)	10 (30.3)	9 (45.0)	18 (40.0)	0 (0.0)	168 (43.6)
頭痛	33 (26.4)	0 (0.0)	16 (20.5)	10 (17.5)	4 (12.1)	3 (15.0)	3 (6.7)	0 (0.0)	69 (17.9)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
浮動性めまい	16 (12.8)	0 (0.0)	8 (10.3)	10 (17.5)	0 (0.0)	3 (15.0)	2 (4.4)	0 (0.0)	39 (10.1)
末梢性感覚ニューロパチー	7 (5.6)	0 (0.0)	4 (5.1)	3 (5.3)	2 (6.1)	1 (5.0)	5 (11.1)	0 (0.0)	22 (5.7)
錯感覚	4 (3.2)	0 (0.0)	7 (9.0)	3 (5.3)	1 (3.0)	3 (15.0)	2 (4.4)	0 (0.0)	20 (5.2)
嗜眠	4 (3.2)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	2 (10.0)	1 (2.2)	0 (0.0)	10 (2.6)
感覚鈍麻	4 (3.2)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	9 (2.3)
ヘルペス後神経痛	4 (3.2)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.8)
失神	3 (2.4)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.8)
健忘	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
体位性めまい	2 (1.6)	0 (0.0)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
記憶障害	4 (3.2)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
平衡障害	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
認知障害	1 (0.8)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
味覚不全	0 (0.0)	0 (0.0)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
末梢性ニューロパチー	1 (0.8)	1 (7.7)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	5 (1.3)
坐骨神経痛	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
灼熱感	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
失神寸前の状態	0 (0.0)	0 (0.0)	1 (1.3)	3 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
片頭痛	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
一過性脳虚血発作	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
運動失調	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
脳症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
神経痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腓骨神経麻痺	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
傾眠	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
振戦	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
味覚消失	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
無嗅覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
中枢神経系病変	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
脳梗塞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脳コロイド嚢胞	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
意識レベルの低下	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
塞栓性脳卒中	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
顔面麻痺	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頭蓋内出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頭部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
舌下神経麻痺	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
意識消失	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感覚異常性大腿神経痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
モートン神経痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
神経系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
パーキンソン病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
進行性核上性麻痺	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
会話障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
声帯麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血液およびリンパ系障害	35 (28.0)	5 (38.5)	30 (38.5)	20 (35.1)	12 (36.4)	6 (30.0)	14 (31.1)	6 (50.0)	129 (33.5)
好中球減少症	21 (16.8)	2 (15.4)	12 (15.4)	4 (7.0)	4 (12.1)	5 (25.0)	3 (6.7)	4 (33.3)	56 (14.5)
貧血	14 (11.2)	3 (23.1)	16 (20.5)	8 (14.0)	5 (15.2)	3 (15.0)	5 (11.1)	1 (8.3)	55 (14.3)
血小板減少症	10 (8.0)	2 (15.4)	7 (9.0)	4 (7.0)	1 (3.0)	1 (5.0)	2 (4.4)	3 (25.0)	30 (7.8)
内出血発生の増加傾向	5 (4.0)	0 (0.0)	2 (2.6)	4 (7.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	13 (3.4)
発熱性好中球減少症	2 (1.6)	0 (0.0)	3 (3.8)	2 (3.5)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	9 (2.3)
鉄欠乏性貧血	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
自己免疫性溶血性貧血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
溶血性貧血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
出血性素因	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
白血球増加症	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
リンパ節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
リンパ節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
リンパ球増加症	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
脾腫	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
特発性出血	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
凝血異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血球減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肉芽腫性リンパ節炎	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
過粘稠度症候群	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
白血球減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
汎血球減少症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
代謝および栄養障害	39 (31.2)	1 (7.7)	18 (23.1)	20 (35.1)	6 (18.2)	4 (20.0)	20 (44.4)	2 (16.7)	111 (28.8)
食欲減退	6 (4.8)	0 (0.0)	3 (3.8)	5 (8.8)	2 (6.1)	2 (10.0)	10 (22.2)	1 (8.3)	29 (7.5)
低カリウム血症	7 (5.6)	1 (7.7)	2 (2.6)	6 (10.5)	2 (6.1)	1 (5.0)	1 (2.2)	0 (0.0)	20 (5.2)
低マグネシウム血症	3 (2.4)	1 (7.7)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	10 (2.6)
低リン酸血症	1 (0.8)	1 (7.7)	1 (1.3)	3 (5.3)	1 (3.0)	0 (0.0)	3 (6.7)	0 (0.0)	10 (2.6)
高血糖	4 (3.2)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	9 (2.3)
痛風	5 (4.0)	1 (7.7)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
低ナトリウム血症	4 (3.2)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	8 (2.1)
高カルシウム血症	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	7 (1.8)
高マグネシウム血症	3 (2.4)	0 (0.0)	1 (1.3)	2 (3.5)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.8)
鉄欠乏	3 (2.4)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	6 (1.6)
脱水	2 (1.6)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
糖尿病	1 (0.8)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
高カリウム血症	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
低カルシウム血症	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
ビタミン D 欠乏	2 (1.6)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
水分過負荷	2 (1.6)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
高コレステロール血症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
高脂血症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
高尿酸血症	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
低アルブミン血症	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
腫瘍崩壊症候群	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
体液貯留	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
コントロール不良の糖尿病	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
糖尿病性ケトアシドーシス	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
高フェリチン血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
高リン酸塩血症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
低血糖	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
2 型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ビタミン B12 欠乏	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
臨床検査	38 (30.4)	3 (23.1)	18 (23.1)	15 (26.3)	11 (33.3)	5 (25.0)	16 (35.6)	1 (8.3)	108 (28.1)
好中球数減少	6 (4.8)	0 (0.0)	3 (3.8)	2 (3.5)	2 (6.1)	1 (5.0)	5 (11.1)	1 (8.3)	21 (5.5)
血小板数減少	4 (3.2)	2 (15.4)	1 (1.3)	5 (8.8)	2 (6.1)	2 (10.0)	5 (11.1)	0 (0.0)	21 (5.5)
アラニンアミノトランスフェラーゼ増加	7 (5.6)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	1 (5.0)	2 (4.4)	0 (0.0)	14 (3.6)
血中クレアチニン増加	4 (3.2)	1 (7.7)	1 (1.3)	3 (5.3)	2 (6.1)	0 (0.0)	3 (6.7)	0 (0.0)	14 (3.6)
アスパラギン酸アミノトランスフェラーゼ増加	4 (3.2)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	7 (1.8)
血中アルカリホスファターゼ増加	1 (0.8)	0 (0.0)	2 (2.6)	1 (1.8)	2 (6.1)	1 (5.0)	0 (0.0)	0 (0.0)	7 (1.8)
体重減少	3 (2.4)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
血中マグネシウム減少	1 (0.8)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
体重増加	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
活性化部分トロンボプラスチン時間延長	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
血中ビリルビン増加	1 (0.8)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
血中尿酸増加	1 (0.8)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
心雑音	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
A 型インフルエンザウイルス検査陽性	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
リンパ球数減少	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
血清フェリチン減少	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
血中コレステロール増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
血中クレアチン増加	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
血中ブドウ糖増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	2 (0.5)
血中鉄減少	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
呼吸音異常	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
γーグルタミルトランスフェラーゼ増加	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
抱合ビリルビン増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中リン減少	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中カリウム減少	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中カリウム増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中尿素増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
尿中血陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
体温上昇	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胸部コンピュータ断層撮影異常	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
尿中クレアチニン増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心電図 QT 延長	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
心電図 T 波振幅減少	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
大腸菌検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
γ－グルタミルトランスフェラーゼ減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
尿中ブドウ糖陽性	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヘリコバクター検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヒト乳頭腫ウイルス検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ヒトライノウイルス検査陽性	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
インフルエンザウイルス検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
国際標準比増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リパーゼ増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肝機能検査異常	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リンパ球数増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
便潜血陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
酸素飽和度低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
前立腺特異性抗原増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血沈亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
トランスアミナーゼ上昇	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
トランスフェリン減少	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
トロポニン T 増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
尿量減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
水痘ウイルス検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	39 (31.2)	3 (23.1)	28 (35.9)	17 (29.8)	4 (12.1)	4 (20.0)	5 (11.1)	2 (16.7)	102 (26.5)
基底細胞癌	11 (8.8)	1 (7.7)	11 (14.1)	7 (12.3)	0 (0.0)	0 (0.0)	2 (4.4)	2 (16.7)	34 (8.8)
皮膚有棘細胞癌	8 (6.4)	1 (7.7)	7 (9.0)	3 (5.3)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	22 (5.7)
前立腺癌	3 (2.4)	1 (7.7)	3 (3.8)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	8 (2.1)
悪性黒色腫	4 (3.2)	1 (7.7)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	7 (1.8)

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脂漏性角化症	4 (3.2)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
ボーエン病	2 (1.6)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
メラノサイト性母斑	1 (0.8)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
皮膚癌	2 (1.6)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
皮膚良性新生物	1 (0.8)	1 (7.7)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
B 細胞性リンパ腫	1 (0.8)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
大腸腺腫	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
結腸癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
外耳の悪性新生物	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
浸潤性乳管癌	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
悪性黒子	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
腎細胞癌	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚乳頭腫	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
扁平上皮癌	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
耳下腺扁平上皮癌	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
急性骨髄性白血病	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胃腺癌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
未分化大細胞型リンパ腫、T 細胞およびヌル細胞型	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管筋脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
乳房の良性新生物	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳の良性新生物	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
陰嚢の良性新生物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膀胱癌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
乳癌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性骨髄性白血病	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚 T 細胞性リンパ腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼瞼脂漏性角化症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
顆粒細胞腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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感染性新生物	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膵管内乳頭粘液性腫瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脂肪腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
乳房脂肪腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺の悪性新生物	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
表皮内悪性黒色腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
悪性黒色腫第 2 期	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
悪性胸水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
中枢神経系転移	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
骨髄異形成症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
悪性新生物	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
前立腺新生物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
遠隔転移を伴う神経内分泌癌	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼表面扁平上皮腫瘍	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
多形型悪性線維性組織球腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リクター症候群	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺肉腫様癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
シュワン細胞腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚新生物出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
再発皮膚有棘細胞癌	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
小細胞肺癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
軟部組織新生物	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頭頚部扁平上皮癌	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腫瘍疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管障害	34 (27.2)	3 (23.1)	26 (33.3)	17 (29.8)	5 (15.2)	3 (15.0)	10 (22.2)	1 (8.3)	99 (25.7)
高血圧	23 (18.4)	1 (7.7)	15 (19.2)	4 (7.0)	3 (9.1)	1 (5.0)	5 (11.1)	1 (8.3)	53 (13.8)
低血圧	4 (3.2)	0 (0.0)	3 (3.8)	3 (5.3)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	12 (3.1)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
血腫	0 (0.0)	1 (7.7)	3 (3.8)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	7 (1.8)
ほてり	1 (0.8)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
リンパ浮腫	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
起立性低血圧	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
表在性血栓性静脈炎	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
深部静脈血栓症	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
末梢静脈疾患	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
血栓性静脈炎	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
大動脈拡張	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
大動脈壁内血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
動脈壁内血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
蒼白	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
末梢冷感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
レイノー現象	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
静脈破裂	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
四肢静脈血栓症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
白衣性高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎および尿路障害	38 (30.4)	2 (15.4)	20 (25.6)	17 (29.8)	9 (27.3)	4 (20.0)	7 (15.6)	1 (8.3)	98 (25.5)
血尿	21 (16.8)	0 (0.0)	8 (10.3)	9 (15.8)	4 (12.1)	1 (5.0)	4 (8.9)	0 (0.0)	47 (12.2)
頻尿	7 (5.6)	0 (0.0)	3 (3.8)	2 (3.5)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (3.4)
急性腎障害	2 (1.6)	0 (0.0)	2 (2.6)	5 (8.8)	2 (6.1)	1 (5.0)	0 (0.0)	0 (0.0)	12 (3.1)
排尿困難	2 (1.6)	1 (7.7)	3 (3.8)	0 (0.0)	2 (6.1)	0 (0.0)	1 (2.2)	0 (0.0)	9 (2.3)
腎結石症	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
夜間頻尿	2 (1.6)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	5 (1.3)

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水腎症	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
尿意切迫	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
蛋白尿	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
尿失禁	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
尿閉	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
着色尿	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腎仙痛	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腎臓痛	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
排尿躊躇	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
尿路閉塞	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
尿臭異常	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
無尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
膀胱壁肥厚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
膀胱脱	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膀胱痙縮	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膀胱結石	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
出血性膀胱炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
非感染性膀胱炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
糞尿	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
水尿管症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
ケトン尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎動脈血栓症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
腎機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
腹圧性尿失禁	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎被膜下血腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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尿管結石症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
切迫性尿失禁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
尿流量減少	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心臓障害	21 (16.8)	1 (7.7)	16 (20.5)	13 (22.8)	5 (15.2)	3 (15.0)	4 (8.9)	1 (8.3)	64 (16.6)
心房細動	5 (4.0)	0 (0.0)	7 (9.0)	4 (7.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	18 (4.7)
動悸	5 (4.0)	0 (0.0)	3 (3.8)	2 (3.5)	1 (3.0)	1 (5.0)	0 (0.0)	1 (8.3)	13 (3.4)
狭心症	3 (2.4)	0 (0.0)	1 (1.3)	2 (3.5)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	8 (2.1)
徐脈	1 (0.8)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	6 (1.6)
心嚢液貯留	1 (0.8)	0 (0.0)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
うっ血性心不全	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
頻脈	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
急性心筋梗塞	1 (0.8)	1 (7.7)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
心房粗動	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
急性冠動脈症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
第一度房室ブロック	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
心不全	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
心筋虚血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
心膜炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
洞性徐脈	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
心室性期外収縮	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
上室性不整脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
完全房室ブロック	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
右脚ブロック	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
急性心不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性心不全	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心原性ショック	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
伝導障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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冠動脈狭窄	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
期外収縮	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
右室不全	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
洞性頻脈	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ストレス心筋症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
上室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
上室性頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心室性不整脈	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精神障害	24 (19.2)	1 (7.7)	10 (12.8)	7 (12.3)	6 (18.2)	6 (30.0)	5 (11.1)	1 (8.3)	60 (15.6)
不眠症	8 (6.4)	0 (0.0)	5 (6.4)	1 (1.8)	2 (6.1)	4 (20.0)	4 (8.9)	0 (0.0)	24 (6.2)
不安	1 (0.8)	0 (0.0)	2 (2.6)	1 (1.8)	1 (3.0)	1 (5.0)	1 (2.2)	0 (0.0)	7 (1.8)
うつ病	3 (2.4)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	7 (1.8)
譫妄	2 (1.6)	1 (7.7)	1 (1.3)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
激越	1 (0.8)	0 (0.0)	0 (0.0)	2 (3.5)	1 (3.0)	0 (0.0)	0 (0.0)	1 (8.3)	5 (1.3)
錯乱状態	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	5 (1.3)
幻覚	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
抑うつ気分	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
易刺激性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
睡眠障害	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
双極性障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性特発性疼痛症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
振戦譫妄	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
妄想性障害、詳細不明	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
情動障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
幻視	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
気分変化	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼障害	13 (10.4)	0 (0.0)	15 (19.2)	13 (22.8)	3 (9.1)	4 (20.0)	2 (4.4)	2 (16.7)	52 (13.5)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
白内障	4 (3.2)	0 (0.0)	3 (3.8)	3 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (2.6)
霧視	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.3)	2 (6.1)	1 (5.0)	0 (0.0)	1 (8.3)	7 (1.8)
ドライアイ	1 (0.8)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
結膜出血	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	5 (1.3)
流涙増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	2 (10.0)	1 (2.2)	0 (0.0)	5 (1.3)
眼瞼炎	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
眼出血	0 (0.0)	0 (0.0)	1 (1.3)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
眼そう痒症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
眼窩周囲浮腫	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
網膜出血	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
視力障害	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
眼精疲労	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼瞼痙攣	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
霰粒腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
結膜嚢胞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
結膜充血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
後天性涙道狭窄	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
複視	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
異常 3 色覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
眼の炎症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼刺激	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
角膜炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
黄斑変性	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
変視症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼充血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼痛さ	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
視神経症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼窩周囲腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
羞明	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
網膜血管瘤	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
網膜静脈閉塞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
睫毛乱生	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
硝子体浮遊物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳および迷路障害	17 (13.6)	1 (7.7)	15 (19.2)	6 (10.5)	2 (6.1)	3 (15.0)	4 (8.9)	0 (0.0)	48 (12.5)
回転性めまい	8 (6.4)	0 (0.0)	5 (6.4)	1 (1.8)	1 (3.0)	0 (0.0)	2 (4.4)	0 (0.0)	17 (4.4)
耳痛	1 (0.8)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	2 (10.0)	1 (2.2)	0 (0.0)	8 (2.1)
耳鳴	3 (2.4)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
耳不快感	1 (0.8)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
聴力低下	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
鼓膜穿孔	0 (0.0)	1 (7.7)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
難聴	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
耳出血	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
頭位性回転性めまい	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
耳垢栓塞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳部腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳管機能障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳管開放	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳漏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
生殖系および乳房障害	12 (9.6)	0 (0.0)	6 (7.7)	2 (3.5)	5 (15.2)	2 (10.0)	5 (11.1)	0 (0.0)	32 (8.3)
良性前立腺肥大症	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	5 (1.3)
勃起不全	3 (2.4)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
腟出血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
性器錯感覚	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.5)
骨盤痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
前立腺閉塞	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
前立腺腫大	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)

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精巣痛	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
子宮脱	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
萎縮性外陰腟炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
乳房腫脹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
乳房圧痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精巣上体嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
子宮留水症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
陰茎痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
陰茎腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
前立腺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
陰嚢腫脹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精巣腫脹	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
子宮出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
腟分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
免疫系障害	9 (7.2)	0 (0.0)	5 (6.4)	3 (5.3)	3 (9.1)	2 (10.0)	2 (4.4)	1 (8.3)	26 (6.8)
低γグロブリン血症	5 (4.0)	0 (0.0)	2 (2.6)	0 (0.0)	3 (9.1)	1 (5.0)	0 (0.0)	0 (0.0)	11 (2.9)
季節性アレルギー	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	5 (1.3)
造影剤アレルギー	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	3 (0.8)
薬物過敏症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
節足動物咬傷アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
縫合糸アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
抗好中球細胞質抗体陽性血管炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
造影剤反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
免疫再構築炎症反応症候群	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
ダニアレルギー	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肝胆道系障害	6 (4.8)	0 (0.0)	2 (2.6)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (3.1)
急性胆嚢炎	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
脂肪肝	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
胆管結石	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胆嚢炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胆石症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胆嚢腫大	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胆嚢閉塞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血性胆汁	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肝硬変	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肝不全	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
高ビリルビン血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
内分泌障害	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
甲状腺機能低下症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
悪性腫瘍に伴う高カルシウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
原発性精巣機能不全	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
甲状腺腫瘤	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
製品の問題	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
医療機器沈着物の問題	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
医療機器位置異常	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
医療機器閉塞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

Source: Table 14.3.1.2.2.1.3 in BGB-3111-AU-003 clinical study report. Data cutoff: 31MAR2021; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE.
Abbreviations: CLL/SLL, chronic lymphocytic leukemia/small lymphocytic lymphoma; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HCL, hairy cell leukemia; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; RT, Richter's transformation; TEAE, treatment-emergent adverse event; WM, Waldenström's macroglobulinemia.

Notes: 1 patient with B lineage lymphoma and 1 patient with indolent lymphoma were included in the Overall column.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
Events are sorted by decreasing frequency of System Organ Class and Preferred Term in the last column.
MedDRA Version 23.0.

表 39： 投与と関連のある TEAE：器官別大分類別及び基本語別（BGB-3111-AU-003 試験、統合したパート 1 及びパート 2 の安全性解析対象集団、診断名別）

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
Patients with at least 1 Treatment-Related TEAE	105 (84.0)	6 (46.2)	61 (78.2)	47 (82.5)	26 (78.8)	14 (70.0)	23 (51.1)	7 (58.3)	291 (75.6)
傷害、中毒および処置合併症	50 (40.0)	2 (15.4)	21 (26.9)	16 (28.1)	5 (15.2)	6 (30.0)	1 (2.2)	2 (16.7)	103 (26.8)
挫傷	48 (38.4)	2 (15.4)	19 (24.4)	16 (28.1)	5 (15.2)	5 (25.0)	1 (2.2)	2 (16.7)	98 (25.5)
処置後挫傷	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
処置後出血	1 (0.8)	1 (7.7)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
処置による疼痛	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚裂傷	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
眼挫傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
処置後血腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
放射線皮膚損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮下血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
熱傷	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚および皮下組織障害	34 (27.2)	2 (15.4)	19 (24.4)	18 (31.6)	11 (33.3)	5 (25.0)	6 (13.3)	3 (25.0)	98 (25.5)
発疹	13 (10.4)	1 (7.7)	6 (7.7)	7 (12.3)	3 (9.1)	4 (20.0)	2 (4.4)	1 (8.3)	37 (9.6)
点状出血	8 (6.4)	0 (0.0)	7 (9.0)	4 (7.0)	3 (9.1)	1 (5.0)	1 (2.2)	1 (8.3)	25 (6.5)
そう痒症	3 (2.4)	0 (0.0)	1 (1.3)	3 (5.3)	1 (3.0)	1 (5.0)	1 (2.2)	0 (0.0)	10 (2.6)
紫斑	4 (3.2)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	8 (2.1)
皮膚乾燥	2 (1.6)	1 (7.7)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	6 (1.6)
斑状出血	0 (0.0)	0 (0.0)	2 (2.6)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	5 (1.3)
丘疹性皮疹	1 (0.8)	0 (0.0)	3 (3.8)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
多汗症	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
光線過敏性反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
紅斑性皮疹	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
斑状丘疹状皮疹	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
皮膚病変	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
脱毛症	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
紅斑	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
斑状皮疹	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
そう痒性皮疹	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚変色	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
光線角化症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血性水疱	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚嚢腫	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
接触皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
多形紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
過敏性血管炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
機械性蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
爪変色	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
蕁麻疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
蕁麻疹様血管炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染症および寄生虫症	46 (36.8)	4 (30.8)	15 (19.2)	8 (14.0)	8 (24.2)	4 (20.0)	5 (11.1)	2 (16.7)	92 (23.9)
肺炎	15 (12.0)	1 (7.7)	3 (3.8)	1 (1.8)	2 (6.1)	0 (0.0)	2 (4.4)	1 (8.3)	25 (6.5)
上気道感染	10 (8.0)	1 (7.7)	5 (6.4)	3 (5.3)	4 (12.1)	0 (0.0)	0 (0.0)	0 (0.0)	23 (6.0)
帯状疱疹	5 (4.0)	0 (0.0)	2 (2.6)	0 (0.0)	1 (3.0)	1 (5.0)	0 (0.0)	1 (8.3)	10 (2.6)
尿路感染	2 (1.6)	0 (0.0)	1 (1.3)	2 (3.5)	2 (6.1)	0 (0.0)	1 (2.2)	0 (0.0)	8 (2.1)
副鼻腔炎	3 (2.4)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	2 (10.0)	0 (0.0)	0 (0.0)	7 (1.8)
下気道感染	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)
口腔ヘルペス	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	5 (1.3)
蜂巣炎	3 (2.4)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
皮膚感染	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
気管支炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
胃腸炎	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	3 (0.8)
B 型肝炎再活性化	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
憩室炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
耳感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
ヘモフィルス感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
クリプトコッカス性髄膜炎	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
クリプトコッカス性肺炎	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
ブドウ球菌皮膚感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
創傷感染	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
菌血症	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性疾患キャリアー	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
細気管支炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
気管支肺アスペルギルス症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
男性外性器蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
脳アスペルギルス症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (0.3)
真菌性耳感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
真菌性脳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
毛包炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮膚真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性肝炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
単純ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
播種性帯状疱疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
帯状疱疹性髄膜脳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳帯状疱疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
感染による気管支拡張症の増悪	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
喉頭炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
限局性感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
マイコバクテリウム・ウルセランス感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪真菌症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口腔カンジダ症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
外耳炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
爪囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
細菌性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
インフルエンザ性肺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
膿疱性皮疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
RS ウイルス感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
気道感染	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ウイルス性気道感染	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
軟部組織感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
ブドウ球菌性膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
皮下組織膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
歯膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
歯感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胃腸障害	30 (24.0)	2 (15.4)	14 (17.9)	21 (36.8)	6 (18.2)	5 (25.0)	5 (11.1)	1 (8.3)	85 (22.1)
下痢	16 (12.8)	1 (7.7)	5 (6.4)	10 (17.5)	0 (0.0)	3 (15.0)	2 (4.4)	1 (8.3)	39 (10.1)
悪心	7 (5.6)	0 (0.0)	4 (5.1)	4 (7.0)	5 (15.2)	2 (10.0)	0 (0.0)	0 (0.0)	22 (5.7)
胃食道逆流性疾患	4 (3.2)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
便秘	0 (0.0)	0 (0.0)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	6 (1.6)
口内炎	2 (1.6)	0 (0.0)	0 (0.0)	2 (3.5)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	6 (1.6)
腹痛	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
消化不良	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
口内乾燥	2 (1.6)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
口腔内出血	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
嘔吐	2 (1.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
上腹部痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
大腸炎	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
鼓腸	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
歯肉出血	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
口腔内潰瘍形成	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
腹部膨満	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
変色便	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
排便回数増加	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
食道炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
口腔内紫斑	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
逆流性胃炎	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
上部消化管出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (0.3)
血液およびリンパ系障害	19 (15.2)	1 (7.7)	16 (20.5)	10 (17.5)	4 (12.1)	3 (15.0)	6 (13.3)	4 (33.3)	64 (16.6)
好中球減少症	14 (11.2)	0 (0.0)	9 (11.5)	2 (3.5)	2 (6.1)	3 (15.0)	3 (6.7)	3 (25.0)	37 (9.6)
血小板減少症	4 (3.2)	1 (7.7)	3 (3.8)	1 (1.8)	1 (3.0)	1 (5.0)	0 (0.0)	2 (16.7)	13 (3.4)
内出血発生の増加傾向	4 (3.2)	0 (0.0)	1 (1.3)	4 (7.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	10 (2.6)
貧血	0 (0.0)	1 (7.7)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
発熱性好中球減少症	1 (0.8)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
出血性素因	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
血球減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
白血球増加症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リンパ節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
リンパ球増加症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
特発性出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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呼吸器、胸郭および縦隔障害	21 (16.8)	1 (7.7)	13 (16.7)	8 (14.0)	7 (21.2)	1 (5.0)	5 (11.1)	2 (16.7)	59 (15.3)
鼻出血	7 (5.6)	0 (0.0)	6 (7.7)	3 (5.3)	4 (12.1)	1 (5.0)	1 (2.2)	2 (16.7)	24 (6.2)
咳嗽	6 (4.8)	1 (7.7)	3 (3.8)	0 (0.0)	3 (9.1)	0 (0.0)	2 (4.4)	0 (0.0)	16 (4.2)
鼻漏	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	5 (1.3)
湿性咳嗽	2 (1.6)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
口腔咽頭痛	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
胸水	1 (0.8)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
鼻閉	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
肺臓炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (0.5)
肺腫瘤	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
発声障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
喀血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血胸	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
間質性肺疾患	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
肺高血圧症	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
ラ音	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
一般・全身障害および投与部位の状態	21 (16.8)	1 (7.7)	8 (10.3)	12 (21.1)	3 (9.1)	1 (5.0)	3 (6.7)	1 (8.3)	50 (13.0)
疲労	13 (10.4)	0 (0.0)	7 (9.0)	6 (10.5)	3 (9.1)	1 (5.0)	0 (0.0)	1 (8.3)	31 (8.1)
末梢性浮腫	1 (0.8)	1 (7.7)	0 (0.0)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.6)
疼痛	3 (2.4)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
末梢腫脹	2 (1.6)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)
発熱	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	3 (0.8)
胸痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
カテーテル留置部位出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

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悪寒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
インフルエンザ様疾患	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
限局性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管穿刺部位内出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
神経系障害	7 (5.6)	1 (7.7)	7 (9.0)	11 (19.3)	4 (12.1)	3 (15.0)	5 (11.1)	0 (0.0)	38 (9.9)
頭痛	1 (0.8)	0 (0.0)	4 (5.1)	5 (8.8)	2 (6.1)	2 (10.0)	0 (0.0)	0 (0.0)	14 (3.6)
末梢性感覚ニューロパチー	2 (1.6)	0 (0.0)	0 (0.0)	3 (5.3)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	7 (1.8)
浮動性めまい	1 (0.8)	0 (0.0)	0 (0.0)	2 (3.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	4 (1.0)
味覚不全	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.3)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
ヘルペス後神経痛	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.2)	0 (0.0)	2 (0.5)
味覚消失	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
健忘	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
無嗅覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
塞栓性脳卒中	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頭蓋内出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
記憶障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
神経痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
末梢性ニューロパチー	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
失神	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
臨床検査	11 (8.8)	2 (15.4)	6 (7.7)	7 (12.3)	2 (6.1)	2 (10.0)	7 (15.6)	0 (0.0)	37 (9.6)
好中球数減少	4 (3.2)	0 (0.0)	3 (3.8)	1 (1.8)	1 (3.0)	1 (5.0)	3 (6.7)	0 (0.0)	13 (3.4)
血小板数減少	2 (1.6)	1 (7.7)	0 (0.0)	4 (7.0)	1 (3.0)	1 (5.0)	4 (8.9)	0 (0.0)	13 (3.4)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
血中クレアチニン増加	1 (0.8)	1 (7.7)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	4 (1.0)
アラニンアミノトランスフェラーゼ増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	2 (0.5)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中ビリルビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中コレステロール増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血中クレアチン増加	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中マグネシウム減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血中尿素増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血中尿酸増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
尿中血陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
胸部コンピュータ断層撮影異常	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心電図 T 波振幅減少	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リンパ球数減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
トランスアミナーゼ上昇	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
水痘ウイルス検査陽性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
体重増加	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
筋骨格系および結合組織障害	15 (12.0)	1 (7.7)	4 (5.1)	7 (12.3)	3 (9.1)	1 (5.0)	0 (0.0)	0 (0.0)	31 (8.1)
筋痙縮	5 (4.0)	0 (0.0)	1 (1.3)	4 (7.0)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	12 (3.1)
関節痛	5 (4.0)	0 (0.0)	2 (2.6)	2 (3.5)	1 (3.0)	1 (5.0)	0 (0.0)	0 (0.0)	11 (2.9)
筋肉痛	4 (3.2)	0 (0.0)	0 (0.0)	3 (5.3)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
筋力低下	1 (0.8)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
背部痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
骨痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
滑液包炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
側腹部痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
出血性関節症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
筋骨格痛	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頚部痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
仙腸骨炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管障害	9 (7.2)	1 (7.7)	11 (14.1)	1 (1.8)	2 (6.1)	0 (0.0)	2 (4.4)	0 (0.0)	26 (6.8)
高血圧	9 (7.2)	0 (0.0)	8 (10.3)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (4.7)
低血圧	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
深部静脈血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
血腫	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
リンパ浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
末梢静脈疾患	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
血管炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (0.3)
腎および尿路障害	8 (6.4)	0 (0.0)	5 (6.4)	2 (3.5)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	17 (4.4)
血尿	8 (6.4)	0 (0.0)	5 (6.4)	2 (3.5)	1 (3.0)	0 (0.0)	1 (2.2)	0 (0.0)	17 (4.4)
排尿困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頻尿	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
腎仙痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心臓障害	5 (4.0)	0 (0.0)	7 (9.0)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (4.2)
心房細動	2 (1.6)	0 (0.0)	5 (6.4)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (2.3)
動悸	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
心嚢液貯留	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
急性心筋梗塞	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
第一度房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心不全	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
慢性心不全	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
伝導障害	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
期外収縮	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
心膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
頻脈	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
代謝および栄養障害	2 (1.6)	0 (0.0)	1 (1.3)	3 (5.3)	2 (6.1)	0 (0.0)	1 (2.2)	1 (8.3)	10 (2.6)
食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.5)	2 (6.1)	0 (0.0)	1 (2.2)	1 (8.3)	6 (1.6)
痛風	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
高カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
低カリウム血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
鉄欠乏	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼障害	1 (0.8)	0 (0.0)	2 (2.6)	3 (5.3)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	8 (2.1)
結膜出血	1 (0.8)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	1 (8.3)	4 (1.0)
結膜充血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
流涙増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼窩周囲浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼窩周囲腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
網膜出血	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
免疫系障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
低γグロブリン血症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
生殖系および乳房障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	CLL/SLL (N = 125) n (%)	RT (N = 13) n (%)	WM (N = 78) n (%)	MCL (N = 57) n (%)	FL (N = 33) n (%)	MZL (N = 20) n (%)	DLBCL (N = 45) n (%)	HCL (N = 12) n (%)	Overall (N = 385) n (%)
前立腺炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳および迷路障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
耳出血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
基底細胞癌	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精神障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
譫妄	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

Source: Table 14.3.1.2.2.2.3 in BGB-3111-AU-003 clinical study report. Data cutoff: 31MAR2021; Data extraction: [redacted] 20[redacted]; Data Source: ADSL, ADAE.
Abbreviations: CLL/SLL, chronic lymphocytic leukemia/small lymphocytic lymphoma; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HCL, hairy cell leukemia; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; RT, Richter's transformation; TEAE, treatment-emergent adverse event; WM, Waldenström's macroglobulinemia.
Note: 1 patient with B lineage lymphoma and 1 patient with indolent lymphoma were included in the Overall column.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
Events are sorted by decreasing frequency of System Organ Class and Preferred Term in the last column.
Treatment-related is defined as related or with missing relationship.
MedDRA Version 23.0.

表 40： 重篤な有害事象の一覧（BGB-3111-AU-003 試験、安全性解析対象集団）

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Disease type: CLL						
[redacted]	TN	Yes	20[redacted] (84)\ 20[redacted] (117)\ 34	RENAL COLIC\ 腎仙痛\ 腎および尿路障害	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (402)\ 20[redacted] (485)\ 84	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (1500)\ 20[redacted] (1508)\ 9	OTITIS EXTERNA\ 外耳炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (1504)\ 20[redacted] (1555)\ 52	HERPES ZOSTER OTICUS\ 耳帯状疱疹\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae
[redacted]	TN	Yes	20[redacted] (717)\ 20[redacted] (719)\ 3	FEVER (UNKNOWN ORIGIN)\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (976)\ 20[redacted] (986)\ 11	LEFT TEMPORAL ABSCESS - SUBCUTANEOUS\ 皮下組織膿瘍\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (308)\ 20[redacted] (326)\ 19	POST-BRONCHOSCOPY NON NEUTROPENIC FEVER\ 処置後発熱\ 傷害、中毒および処置合併症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (424)\ 20[redacted] (429)\ 6	SCROTAL INFECTION\ 陰嚢感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (700)\ 20[redacted] (701)\ 2	CENTRAL CHEST PAIN - UNKNOWN ETIOLOGY\ 胸痛\ 一般・全身障害および投与部位の状態	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (89)\ 20[redacted] (203)\ 115	HEPATITIS VIRAL\ ウイルス性肝炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (139)\ 20[redacted] (162)\ 24	MUSCLE WEAKNESS\ 筋力低下\ 筋骨格系および結合組織障害	3\ Related	Drug Withdrawn\ -\ Recovered/Resolved
[redacted]	TN	No	20[redacted] (-9)\ 2016-09-22 (9)\ 18	HYDRONEPHROSIS\ 水腎症\ 腎および尿路障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (463)\ 20[redacted] (533)\ 71	WOUND INFECTION MOUTH\ 創傷感染\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (723)\ 20[redacted] (900)\ 178	NEOPLASM-MALIGNANT-RECURRENT SCC RIGHT PERI AURICULAR AREA\ 再発皮膚有棘細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (767)\ 20[redacted] (771)\ 5	WOUND INFECTION RIGHT PERIAURICULAR AREA\ 創傷感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (901)\ 20[redacted] (901)\ 1	NEOPLASM-MALIGNANT-RECURRENT SCC RIGHT PERIAURICULAR AREA\ 再発皮膚有棘細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	TN	Yes	20[redacted] (371)\ 20[redacted] (372)\ 2	DEPRESSED LEVEL OF CONSCIOUSNESS\ 意識レベルの低下\ 神経系障害	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (138)\ 20[redacted] (143)\ 6	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		No	20[redacted] (1074)\ 20[redacted] (1127)\ 54	FEBRILE NEUTROPENIA SECONDARY TO RESPIRATORY SYNCYTIAL VIRUS (RSV)\ RS ウイルス感染\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (24)\ 20[redacted] (190)\ 167	CORONARY ARTERY STENOSIS\ 冠動脈狭窄\ 心臓障害	2\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (601)\ 20[redacted] (648)\ 48	RIGHT LOWER LOBE PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (612)\ 20[redacted] (615)\ 4	NEUTROPENIA\ 好中球減少症\ 血液およびリンパ系障害	4\ Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1239)\ Ongoing\ -	CRYPTOCOCCAL PNEUMONIA\ クリプトコッカス性肺炎\ 感染症および寄生虫症	4\ Related	Drug Withdrawn, Dose Reduced\ -\ Recovering/Resolving
		Yes	20[redacted] (1241)\ 20[redacted] (1332)\ 92	PULMONARY CRYPTOCOCCOSIS\ クリプトコッカス性肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovering/Resolving
		Yes	20[redacted] (1247)\ 20[redacted] (1332)\ 86	CRYPTOCOCCAL MENINGITIS\ クリプトコッカス性髄膜炎\ 感染症および寄生虫症	4\ Related	Dose Reduced\ -\ Recovering/Resolving
		Yes	20[redacted] (1307)\ 20[redacted] (1332)\ 26	CRYPTOCOCCAL ENCEPHALITIS\ 真菌性脳炎\ 感染症および寄生虫症	4\ Related	Drug Interrupted\ -\ Recovering/Resolving
		Yes	20[redacted] (1307)\ 20[redacted] (1332)\ 26	DIABETIC KETOACIDOSIS\ 糖尿病性ケトアシドーシス\ 代謝および栄養障害	4\ Not Related	Dose Not Changed\ -\ Recovered/Resolved With Sequelae
		No	20[redacted] (1452)\ 20[redacted] (1458)\ 7	NSTEMI\ 急性心筋梗塞\ 心臓障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
		No	20[redacted] (1489)\ 20[redacted] (1492)\ 4	FEVER, UNKNOWN CAUSE\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (429)\ 20[redacted] (435)\ 7	ZOSTER MENINGOENCEPHALITIS\ 帯状疱疹性髄膜脳炎\ 感染症および寄生虫症	2\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (436)\ 20[redacted] (449)\ 14	DISSEMINATED ZOSTER & ZOSTER MENINGOENCEPHALITIS\ 帯状疱疹性髄膜脳炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (1488)\ 20[redacted] (1492)\ 5	L3, 4 DISC HERNIATION AND NERVE COMPRESSION\ 椎間板突出\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (749)\ 20[redacted] (750)\ 2	RSV RESPIRATORY TRACT INFECTION\ RS ウイルス感染\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (197)\ 20[redacted] (203)\ 7	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ Related	Drug Interrupted, Dose Reduced\ -\ Recovered/Resolved
		Yes	20[redacted] (285)\ 20[redacted] (288)\ 4	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	4\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (23)\ 20[redacted] (32)\ 10	CHEST INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (474)\ 20[redacted] (479)\ 6	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (612)\ 20[redacted] (617)\ 6	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (719)\ 20[redacted] (722)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (800)\ 20[redacted] (802)\ 3	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1099)\ 20[redacted] (1100)\ 2	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1321)\ 20[redacted] (1323)\ 3	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1392)\ 20[redacted] (1395)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1647)\ 20[redacted] (1651)\ 5	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (2169)\ 20[redacted] (2174)\ 6	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1951)\ 20[redacted] (1954)\ 4	INFECTIVE EXACERBATION OF BRONCHIECTASIS\ 感染による気管支拡張症の増悪\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (744)\ 20[redacted] (745)\ 2	PAIN (LEFT HIP)\ 関節痛\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (358)\ 20[redacted] (378)\ 21	BIPOLAR DISORDER\ 双極性障害\ 精神障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (834)\ 20[redacted] (836)\ 3	ACUTE CHOLECYSTITIS\ 急性胆嚢炎\ 肝胆道系障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (328)\ 20[redacted] (388)\ 61	INVASIVE DUCTAL CARCINOMA OF THE BREAST\ 浸潤性乳管癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy / Procedure, Other(Drug Interrupted, Concomitant Medication), Concomitant Medication\ Recovered/Resolved
		Yes	20[redacted] (1336)\ 20[redacted] (1345)\ 10	SHINGLES\ 帯状疱疹\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1174)\ 20[redacted] (1176)\ 3	CONSTIPATION\ 便秘\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (62)\ 20[redacted] (109)\ 48	HEART FAILURE\ 心不全\ 心臓障害	2\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (72)\ 20[redacted] (74)\ 3	SPLENOMEGALY\ 脾腫\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (499)\ 20[redacted] (507)\ 9	LEFT SIDE OF NECK SQUAMOUS CELL CARCINOMA\ 頭頚部扁平上皮癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (499)\ 20[redacted] (507)\ 9	SQUAMOUS CELL CARCINOMA LEFT CHEEK\ 皮膚有棘細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (499)\ 20[redacted] (507)\ 9	SQUAMOUS CELL CARCINOMA LEFT PAROTID\ 耳下腺扁平上皮癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (499)\ 20[redacted] (507)\ 9	SQUAMOUS CELL CARCINOMA LEFT PINNA\ 外耳の悪性新生物\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (499)\ 20[redacted] (507)\ 9	SQUAMOUS CELL CARCINOMA LEFT TEMPORAL BONE\ 外耳の悪性新生物\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (519)\ 20[redacted] (538)\ 20	POST OPERATIVE WOUND PSEUDOMONAS INFECTION ON FACE\ 術後創感染\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (925)\ 20[redacted] (929)\ 5	RIGHT LEG LYMPHOEDEMA\ リンパ浮腫\ 血管障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (928)\ Ongoing\ -	HIGH GRADE CARCINOMA FROM POSSIBLE GYNECOLOGICAL ORIGIN\ 悪性新生物\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ -\ Not Recovered/Not Resolved
[redacted]	RR	Yes	20[redacted] (1495)\ 20[redacted] (1518)\ 24	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (10)\ 20[redacted] (19)\ 10	LEFT LOW LEG CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (57)\ 20[redacted] (85)\ 29	HEMARTHROSIS ON LEGS\ 出血性関節症\ 筋骨格系および結合組織障害	3\ Related	Dose Not Changed\ Other\ Recovered/Resolved
		Yes	20[redacted] (74)\ 20[redacted] (80)\ 7	CELLULITIS LEFT FOOT\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (74)\ 20[redacted] (80)\ 7	CELLULITIS ON RIGHT KNEE\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (723)\ 20[redacted] (751)\ 29	URINARY TRACT INFECTION (WORSENED)\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (358)\ 20[redacted] (369)\ 12	ATYPICAL PNEUMONIA\ 異型肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (358)\ 20[redacted] (369)\ 12	CONGESTIVE HEART FAILURE\ うっ血性心不全\ 心臓障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (501)\ 20[redacted] (506)\ 6	SMALL BOWEL OBSTRUCTION\ 小腸閉塞\ 胃腸障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (513)\ 20[redacted] (518)\ 6	POST OPERATIVE WOUND INFECTION\ 術後創感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (798)\ 20[redacted] (1070)\ 273	SINUSITIS\ 副鼻腔炎\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (22)\ 20[redacted] (24)\ 3	VIRAL ILLNESS\ ウイルス感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-15)\ 20[redacted] (1)\ 16	CLL INFILTRATES IN LIVER\ 白血病肝浸潤\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Not Applicable\ Other\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (6)\ 20[redacted] (8)\ 3	CELLULITIS RIGHT LEG\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (59)\ 20[redacted] (64)\ 6	SCIATICA (LEFT SIDED)\ 坐骨神経痛\ 神経系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (988)\ 20[redacted] (1017)\ 30	DELUSIONAL DISORDER\ 妄想性障害、詳細不明\ 精神障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (224)\ Ongoing\ -	CHEST INFECTION\ 下気道感染\ 感染症および寄生虫症	4\ Related	Dose Not Changed\ Other\ Not Recovered/Not Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (538)\ 20[redacted] (558)\ 21	COVID-19 INFECTON\ COVID-19\ 感染症および寄生虫症	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (219)\ 20[redacted] (235)\ 17	STAPHYLOCOCCUS AUREUS ABSCESS\ ブドウ球菌性膿瘍\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-1)\ 20[redacted] (11)\ 12	CELLULITIS LEFT UPPER EXTREMITY\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (88)\ 20[redacted] (89)\ 2	RIGHT HIP PAIN\ 関節痛\ 筋骨格系および結合組織障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (88)\ 20[redacted] (89)\ 2	RIGHT KNEE PAIN\ 関節痛\ 筋骨格系および結合組織障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (254)\ 20[redacted] (256)\ 3	DYSPHAGIA\ 嚥下障害\ 胃腸障害	2\ Not Related	Not Applicable\ -\ Recovered/Resolved
		No	20[redacted] (262)\ 20[redacted] (284)\ 23	OBSTRUCTIVE JAUNDICE\ 胆汁うっ滞性黄疸\ 肝胆道系障害	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1219)\ Ongoing\ -	THROMBOEMBOLIC EVENT, PULMONARY EMOBOLUS\ 肺塞栓症\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovering/Resolving
[redacted]	RR	Yes	20[redacted] (241)\ 20[redacted] (246)\ 6	WIDE COMPLEX TACHYCARDIA\ 頻脈\ 心臓障害	3\ Related	Drug Withdrawn\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (39)\ 20[redacted] (50)\ 12	KIDNEY INFECTION\ 腎感染\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (700)\ 20[redacted] (727)\ 28	ANEMIA\ 貧血\ 血液およびリンパ系障害	3\ Not Related	Drug Withdrawn\ Non-Medication Concomitant Therapy / Procedure, Other(Hospitalization), Concomitant Medication\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (711)\ 20[redacted] (747)\ 37	ACUTE HYPOXEMIC DISTRESS/VENTILATORY DEPENDENT RESPIRATORY FAILURE\ 呼吸不全\ 呼吸器、胸郭および縦隔障害	4\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (410)\ 20[redacted] (414)\ 5	STRANGULATED INGUINAL HERNIA\ 絞扼性単径ヘルニア\ 胃腸障害	4\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (268)\ 20[redacted] (273)\ 6	ISCHEMIC COLITIS\ 虚血性大腸炎\ 胃腸障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (528)\ 20[redacted] (532)\ 5	GASTROENTERITIS\ 胃腸炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (874)\ 20[redacted] (885)\ 12	LUNG INFECTION\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (874)\ 20[redacted] (886)\ 13	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1191)\ 20[redacted] (1223)\ 33	INFECTIONS/INFESTATIONS-COVID-19\ COVID-19\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1193)\ 20[redacted] (1196)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1223)\ 20[redacted] (1233)\ 11	INFECTIONS INFESTATIONS-COVID 19\ COVID-19\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	No	20[redacted] (-21)\ 20[redacted] (-5)\ 17	NEUTROPHIL COUNT DECREASED\ 好中球数減少\ 臨床検査	4\ Not Related	Not Applicable\ -\ Recovered/Resolved
		No	20[redacted] (-15)\ 20[redacted] (-5)\ 11	ASPIRATION PNEUMONIA\ 誤嚥性肺炎\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		No	20[redacted] (-14)\ 20[redacted] (-5)\ 10	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
		Yes	20[redacted] (926)\ 20[redacted] (956)\ 31	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED - OTHERS, BASAL CELL CARCINOMA ON NOSE\ 基底細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (114)\ 20[redacted] (119)\ 6	INFECTIONS AND INFESTATIONS - OTHER, BACTEREMIA\ 菌血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (114)\ 20[redacted] (119)\ 6	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (140)\ 20[redacted] (146)\ 7	NEUTROPHIL COUNT DECREAED\ 好中球数減少\ 臨床検査	4\ Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (147)\ 20[redacted] (154)\ 8	NEUTROPHIL COUNT DECREASE\ 好中球数減少\ 臨床検査	3\ Related	Drug Interrupted\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (113)\ 20[redacted] (125)\ 13	NEUTROPHIL COUNT DECREASE\ 好中球数減少\ 臨床検査	4\ Related	Drug Interrupted, Dose Reduced\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (26)\ 20[redacted] (199)\ 174	GASTROINTESTINAL DISORDERS, OTHERS - PNEUMATOSIS COLI\ 腸壁気腫症\ 胃腸障害	1\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (185)\ 20[redacted] (187)\ 3	LEFT HYDRONEPHROSIS\ 水腎症\ 腎および尿路障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (2)\ 20[redacted] (39)\ 38	WORSENING OF HEMATURIA\ 血尿\ 腎および尿路障害	3\ Related	Drug Withdrawn, Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (238)\ 20[redacted] (298)\ 61	MELANOMA RIGHT EARLOBE (LENTIGO MALIGNA)\ 悪性黒子\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (822)\ 20[redacted] (840)\ 19	12TH NERVE PALSY\ 舌下神経麻痺\ 神経系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (530)\ 20[redacted] (592)\ 63	OTOMASTOIDITIS\ 乳様突起炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (530)\ 20[redacted] (593)\ 64	ORGANIZING CRYPTOGENIC PNEUMONIA\ 器質化肺炎\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Drug Withdrawn, Drug Interrupted\ -\ Recovered/Resolved
		No	20[redacted] (608)\ 20[redacted] (621)\ 14	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (7)\ 20[redacted] (12)\ 6	SEPSIS\ 敗血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1010)\ 20[redacted] (1012)\ 3	LOWER RESPIRATORY TRACT INFECTION RHINOVIRUS\ ウイルス性下気道感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1061)\ 20[redacted] (1078)\ 18	WORSENING PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (33)\ 20[redacted] (38)\ 6	DISSEMENATED VARICELLA ZOSTER VIRUS AGGRAVATION\ 播種性帯状疱疹\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (110)\ 20[redacted] (116)\ 7	EXACERBATION OF GOUT\ 痛風\ 代謝および栄養障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (602)\ 20[redacted] (604)\ 3	CELLULITIS LEFT LEG\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (641)\ 20[redacted] (642)\ 2	NSTEMI\ 急性心筋梗塞\ 心臓障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (988)\ 20[redacted] (1114)\ 127	HAEMOPHILUS INFLUENZA\ ヘモフィルス感染\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1100)\ 20[redacted] (1114)\ 15	UPPER RESPIRATORY TRACT INFECTION RHINOVIRUS POSITIVE\ ウイルス性上気道感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (280)\ 20[redacted] (304)\ 25	FALL\ 転倒\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (9)\ 20[redacted] (18)\ 10	PREMATURE VENTRICULAR CONTRACTIONS\ 心室性期外収縮\ 心臓障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (634)\ 20[redacted] (648)\ 15	COMPLETE HEART BLOCK\ 完全房室ブロック\ 心臓障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (702)\ 20[redacted] (708)\ 7	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (747)\ 20[redacted] (749)\ 3	PALPITATIONS\ 動悸\ 心臓障害	2\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved
		Yes	20[redacted] (1450)\ Ongoing\ -	SECOND MALIGNANCY- CML\ 慢性骨髄性白血病\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
[redacted]	RR	Yes	20[redacted] (37)\ 20[redacted] (44)\ 8	LISTERIA SEPSIS\ リステリア性敗血症\ 感染症および寄生虫症	4\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (182)\ 20[redacted] (200)\ 19	DIARROHEA\ 下痢\ 胃腸障害	2\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
		Yes	20[redacted] (439)\ 20[redacted] (480)\ 42	DELIRIUM\ 譫妄\ 精神障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (9)\ 20[redacted] (27)\ 19	PURPURA(RIGHT FLANK)\ 紫斑\ 皮膚および皮下組織障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (49)\ 20[redacted] (65)\ 17	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	2\ Related	Drug Withdrawn\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (764)\ 20[redacted] (768)\ 5	ALCOHOL WITHDRAWAL DELIRIUM\ 振戦譫妄\ 精神障害	4\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (920)\ 20[redacted] (957)\ 38	DIARROHEA\ 下痢\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (986)\ 20[redacted] (991)\ 6	LUNG INFECTION(INFLUENZA A)\ インフルエンザ性肺炎\ 感染症および寄生虫症	5\ Related	Drug Interrupted\ -\ Fatal
		Yes	20[redacted] (986)\ 20[redacted] (991)\ 6	MULTI ORGAN FAILURE\ 多臓器機能不全症候群\ 一般・全身障害および投与部位の状態	5\ Not Related	Drug Withdrawn, Drug Interrupted\ None\ Fatal
[redacted]	RR	Yes	20[redacted] (774)\ 20[redacted] (779)\ 6	INFLUENZA\ インフルエンザ\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (337)\ 20[redacted] (340)\ 4	WORSENING OF HAEMORRHOIDS\ 痔核\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1452)\ 20[redacted] (1460)\ 9	LUNG INFECTION\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1467)\ 20[redacted] (1484)\ 18	DYSPNEA\ 呼吸困難\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (522)\ 20[redacted] (526)\ 5	UTI\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (883)\ 20[redacted] (888)\ 6	NEUTROPAENIA\ 好中球減少症\ 血液およびリンパ系障害	4\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (549)\ 20[redacted] (550)\ 2	WORSENING OF CONSTIPATION\ 便秘\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (962)\ 20[redacted] (974)\ 13	INTRADUCTAL PAPILLARY MUCINOUS NEOPLASM\ 膵管内乳頭粘液性腫瘍\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (975)\ 20[redacted] (982)\ 8	SEPSIS PSEUDMONAS\ シュードモナス性敗血症\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1001)\ 20[redacted] (1005)\ 5	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1017)\ 20[redacted] (1025)\ 9	UTI\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1442)\ 20[redacted] (1445)\ 4	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (396)\ 20[redacted] (397)\ 2	CELLULITS RIGHT ARM\ 蜂巣炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (490)\ 20[redacted] (491)\ 2	CELLULITIS LEFT ARM\ 蜂巣炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (1247)\ 20[redacted] (1248)\ 2	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (641)\ 20[redacted] (651)\ 11	FRACTURED RIGHT NECK OF FEMUR\ 大腿骨頚部骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy / Procedure, Other(Rehabilitation), Concomitant Medication\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (1422)\ 20[redacted] (1429)\ 8	FALL\ 転倒\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (21)\ 20[redacted] (24)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (840)\ 20[redacted] (845)\ 6	INFLUENZA A (DETAILS UNKNOWN)\ インフルエンザ\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (189)\ 20[redacted] (192)\ 4	VIRAL INFECTION\ ウイルス感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (500)\ 20[redacted] (505)\ 6	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (678)\ 20[redacted] (689)\ 12	VIRAL INFECTION\ ウイルス感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (820)\ 20[redacted] (821)\ 2	CHEST WALL PAIN\ 筋骨格系胸痛\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (828)\ 20[redacted] (829)\ 2	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ Related	Dose Not Changed\ None\ Recovered/Resolved
		Yes	20[redacted] (976)\ 20[redacted] (980)\ 5	PERICARDIAL EFFUSION\ 心嚢液貯留\ 心臓障害	3\ Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (982)\ 20[redacted] (991)\ 10	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1274)\ 20[redacted] (1313)\ 40	FRACTURED LEFT FEMUR\ 大腿骨骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy / Procedure\ Recovered/Resolved
		Yes	20[redacted] (1274)\ 20[redacted] (1313)\ 40	FRACTURED LEFT RADIUS\ 橈骨骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy / Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (111)\ 20[redacted] (141)\ 31	CRYPTOCOCCAL MENINGITIS\ クリプトコッカス性髄膜炎\ 感染症および寄生虫症	4\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (382)\ 20[redacted] (384)\ 3	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (7)\ 20[redacted] (10)\ 4	RIGHT BASAL PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (247)\ 20[redacted] (251)\ 5	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (45)\ 20[redacted] (52)\ 8	MYALGIA\ 筋肉痛\ 筋骨格系および結合組織障害	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
Disease type: SLL						
[redacted]	TN	Yes	20[redacted] (845)\ 20[redacted] (870)\ 26	LEFT ARM FRACTURE\ 上肢骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (1000)\ 20[redacted] (1021)\ 22	VERTIGO\ 回転性めまい\ 耳および迷路障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (788)\ 20[redacted] (805)\ 18	ACUTE CHOLECYSTITIS\ 急性胆嚢炎\ 肝胆道系障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
Disease type: WM						
[redacted]	TN	Yes	20[redacted] (12)\ 20[redacted] (23)\ 12	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (12)\ 20[redacted] (23)\ 12	SEPTIC SHOCK\ 敗血症性ショック\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (12)\ 20[redacted] (23)\ 12	STREPTOCOCCAL MENINGITIS\ レンサ球菌性髄膜炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (12)\ 20[redacted] (23)\ 12	STREPTOCOCCAL PNEUMONIA\ レンサ球菌性肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (14)\ Ongoing\ -	HEARING LOSS\ 難聴\ 耳および迷路障害	3\ Not Related	Drug Interrupted\ None\ Not Recovered/Not Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (78)\ Ongoing\ -	METASTATIC ADENOCARCINOMA IN LIVER WITH NEUROENDOCRINE DIFFERENTIATION\ 遠隔転移を伴う神経内分泌癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4\ Not Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
[redacted]	TN	Yes	20[redacted] (85)\ Ongoing\ -	LEFT PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	2\ Related	Dose Not Changed\ None\ Recovering/Resolving
		Yes	20[redacted] (116)\ 20[redacted] (147)\ 32	HAEMOTHORAX\ 血胸\ 呼吸器、胸郭および縦隔障害	3\ Related	Drug Interrupted\ Other\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (199)\ 20[redacted] (200)\ 2	ANAEMIA\ 貧血\ 血液およびリンパ系障害	2\ Related	Dose Not Changed, Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (1419)\ 20[redacted] (1432)\ 14	COVID19 INFECTION\ COVID-19\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn, Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Fatal
[redacted]	TN	Yes	20[redacted] (22)\ 20[redacted] (27)\ 6	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (22)\ 20[redacted] (27)\ 6	FLU-LIKE SYMPTOMS\ インフルエンザ様疾患\ 一般・全身障害および投与部位の状態	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (72)\ 20[redacted] (75)\ 4	DIARRHOEA\ 下痢\ 胃腸障害	3\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	TN	Yes	20[redacted] (447)\ 20[redacted] (529)\ 83	NEOPLASMS MALIGNANT BREAST CANCER\ 乳癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Withdrawn\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (181)\ 20[redacted] (182)\ 2	MULTIPLE BLADDER CALCULI\ 膀胱結石\ 腎および尿路障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1455)\ 20[redacted] (1458)\ 4	NOROVIRUS (GASTROENTERITIS)\ ノロウイルス性胃腸炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1691)\ 20[redacted] (1694)\ 4	TYPE II MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1691)\ 20[redacted] (1694)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (36)\ 20[redacted] (37)\ 2	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	2\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (887)\ 20[redacted] (891)\ 5	FATAL-SEPTIC RIGHT SHOULDER\ 細菌性関節炎\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ -\ Fatal

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (94)\ 20[redacted] (94)\ 1	SQUAMOUS CELL CARCINOMA (LEFT ANTERIOR SCALP, RIGHT FOREHEAD, POSTERIOR VERTEX OF SCALP)\ 皮膚有棘細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (196)\ 20[redacted] (199)\ 4	STREPTOCOCCUS A PYOGENES BACTERAEMIA\ レンサ球菌性菌血症\ 感染症および寄生虫症	3\ Not Related	Dose Reduced\ -\ Recovered/Resolved
		Yes	20[redacted] (458)\ 20[redacted] (562)\ 105	ILEAL OBSTRUCTION\ 小腸閉塞\ 胃腸障害	4\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (925)\ 20[redacted] (938)\ 14	EMBOLIC STROKE\ 塞栓性脳卒中\ 神経系障害	4\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1658)\ Ongoing\ -	CERVICAL FRACTURE WITH FLEXION INJURY\ 頚椎骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
		Yes	20[redacted] (1658)\ 20[redacted] (1658)\ 1	POSTURAL SYNCOPE\ 失神\ 神経系障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1658)\ 20[redacted] (1662)\ 5	E. COLI SEPSIS\ 大腸菌性敗血症\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ -\ Fatal
		Yes	20[redacted] (1660)\ Ongoing\ -	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (1134)\ 20[redacted] (1163)\ 30	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (121)\ 20[redacted] (135)\ 15	WORSENING OF BRONCHIECTASIS\ 気管支拡張症\ 呼吸器、胸郭および縦隔障害	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (911)\ 20[redacted] (921)\ 11	SEPTICEMIA\ 敗血症\ 感染症および寄生虫症	4\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (961)\ 20[redacted] (969)\ 9	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (797)\ 20[redacted] (893)\ 97	LEFT FRACTURED (NON PATHOLOGIC) FIBULA\ 腓骨骨折\ 傷害、中毒および処置合併症	1\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (698)\ 20[redacted] (994)\ 297	THERAPY ASSOCIATED AML\ 急性骨髄性白血病\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5\ Not Related	Drug Withdrawn\ None\ Fatal
[redacted]	RR	Yes	20[redacted] (254)\ 20[redacted] (268)\ 15	VESTIBULAR NEURONITIS\ 前庭神経炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (929)\ 20[redacted] (938)\ 10	URTI NON NEUTROPAENIC FEVER\ 上気道感染\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1244)\ 20[redacted] (1245)\ 2	VIRAL INFECTION-RESPIRATORY TRACT\ ウイルス性気道感染\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1462)\ 20[redacted] (1464)\ 3	CLOSTRIDIUM DIFFICILE DIARRHEA\ クロストリジウム・ディフィシレ大腸炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1573)\ 20[redacted] (1574)\ 2	VIRAL UPPER RESPIRATORY TRACT INFECTION\ ウイルス性上気道感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (21)\ 20[redacted] (24)\ 4	INFLUENZA WITH POSITIVE H1N1\ H1N1 インフルエンザ\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (21)\ 20[redacted] (24)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (21)\ 20[redacted] (24)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (963)\ 20[redacted] (965)\ 3	TRANSFUSION REACTION\ 輸血反応\ 傷害、中毒および処置合併症	2\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (481)\ 20[redacted] (500)\ 20	COLITIS OF UNKNOWN AETIOLOGY\ 大腸炎\ 胃腸障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (282)\ 20[redacted] (287)\ 6	ULCERTAED SUPERIFICAL MULTIFOCAL BASAL CELL CELL CARCINOMAS\ 基底細胞癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (162)\ 20[redacted] (197)\ 36	CRYPTOCOCCAL MENINGITIS\ クリプトコッカス性髄膜炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (213)\ 20[redacted] (216)\ 4	VOMITING\ 嘔吐\ 胃腸障害	3\ Not Related	Dose Reduced\ Other\ Recovered/Resolved
		Yes	20[redacted] (228)\ 20[redacted] (235)\ 8	ATYPICAL LUNG INFECTION (TYPE UNKNOWN)\ 異型肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (402)\ 20[redacted] (412)\ 11	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1732)\ 20[redacted] (1756)\ 25	OBSTRUCTION GASTRIC - GASTRIC VOLVULUS\ 胃軸捻転\ 胃腸障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (720)\ 20[redacted] (723)\ 4	TRANSIENT ISCHEMIC ATTACK\ 一過性脳虚血発作\ 神経系障害	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (925)\ 20[redacted] (973)\ 49	HEMATURIA\ 血尿\ 腎および尿路障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (925)\ 20[redacted] (973)\ 49	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (862)\ 20[redacted] (866)\ 5	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (862)\ 20[redacted] (873)\ 12	BRONCHIOLITIS\ 細気管支炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (705)\ 20[redacted] (725)\ 21	SEVERE HEADACHE\ 頭痛\ 神経系障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (737)\ 20[redacted] (756)\ 20	MILD HEADACHE\ 頭痛\ 神経系障害	1\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (737)\ 20[redacted] (756)\ 20	SHORTNESS OF BREATH\ 呼吸困難\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
		Yes	20[redacted] (1235)\ Ongoing\ -	GANGRENOUS APPENDICITIS\ 合併症を伴う虫垂炎\ 感染症および寄生虫症	4\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Not Recovered/Not Resolved
		Yes	20[redacted] (1242)\ 20[redacted] (1303)\ 62	ABDOMINAL CRE SEPSIS\ 腹部敗血症\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ -\ Fatal
		No	20[redacted] (1289)\ 20[redacted] (1303)\ 15	RENAL FAILURE\ 腎不全\ 腎および尿路障害	5\ Not Related	Dose Not Changed\ None\ Fatal

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (467)\ 20[redacted] (484)\ 18	LEFT RENAL ARTERY THROMBOSIS\ 腎動脈血栓症\ 腎および尿路障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (146)\ 20[redacted] (275)\ 130	INFECTED FOOT ULCER (DIABETIC)\ 糖尿病性足感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (260)\ 20[redacted] (273)\ 14	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (416)\ 20[redacted] (422)\ 7	EXACERBATION OF POLYARTICULAR PAIN/GOUT\ 痛風\ 代謝および栄養障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (539)\ 20[redacted] (541)\ 3	RIGHT WRIST DISTAL RADIUS FRACTURE\ 橈骨骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1759)\ 20[redacted] (1759)\ 1	FALL\ 転倒\ 傷害、中毒および処置合併症	4\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1759)\ 20[redacted] (1759)\ 1	NECK HAEMATOMA\ 血腫\ 血管障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1759)\ 20[redacted] (1760)\ 2	PROXIMAL RIGHT ULNA FRACTURE\ 尺骨骨折\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1759)\ 20[redacted] (1760)\ 2	RIGHT DISTAL HUMERUS FRACTURE\ 上腕骨骨折\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1759)\ 20[redacted] (1871)\ 113	PELVIC FRACTURE\ 骨盤骨折\ 傷害、中毒および処置合併症	2\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (759)\ 20[redacted] (869)\ 111	DIABETIC FOOT ULCER\ 糖尿病性足病変\ 皮膚および皮下組織障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (797)\ 20[redacted] (821)\ 25	CELLULITIS INDEX FINGER\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1152)\ 20[redacted] (1160)\ 9	WOUND INFECTION RIGHT HAND\ 創傷感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1258)\ 20[redacted] (1260)\ 3	LEFT FINGER INFECTION\ 限局性感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (1409)\ 20[redacted] (1412)\ 4	RIGHT DIGITAL CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (1449)\ 20[redacted] (1501)\ 53	SCIATICA\ 坐骨神経痛\ 神経系障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1451)\ 20[redacted] (1456)\ 6	RAPID ATRIAL FLUTTER\ 心房粗動\ 心臓障害	3\ Not Related	Dose Reduced\ -\ Recovered/Resolved
		Yes	20[redacted] (1504)\ 20[redacted] (1509)\ 6	BRADYCARDIA\ 徐脈\ 心臓障害	4\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (51)\ 20[redacted] (53)\ 3	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (4)\ 20[redacted] (15)\ 12	HAEMATURIA\ 血尿\ 腎および尿路障害	3\ Related	Drug Interrupted, Dose Reduced\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (322)\ 20[redacted] (326)\ 5	INJURY- FALL FROM TREE\ 転倒\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-4)\ 20[redacted] (30)\ 34	HAEMOLYTIC ANAEMIA\ 溶血性貧血\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (128)\ 20[redacted] (135)\ 8	PARAINFLUENZA VIRUS INFECTION\ パラインフルエンザウイルス感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (448)\ Ongoing\ -	PROSTATE ADENOCARCINOMA\ 前立腺癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Withdrawn, Drug Interrupted\ -\ Not Recovered/Not Resolved
[redacted]	RR	Yes	20[redacted] (89)\ 20[redacted] (90)\ 2	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (526)\ 20[redacted] (594)\ 69	ADENOCARCINOMA OF PYLORI\ 胃腺癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (492)\ 20[redacted] (494)\ 3	TRANSIENT ISCHEMIC ATTACK\ 一過性脳虚血発作\ 神経系障害	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1359)\ 20[redacted] (1380)\ 22	WORSENING OF ANXIETY\ 不安\ 精神障害	4\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (341)\ 20[redacted] (373)\ 33	NEOPLASM MALIGNANT (SQUAMOUS CELL CARCINOMA)RIGHT EAR PINNA\ 外耳の悪性新生物\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (355)\ 20[redacted] (368)\ 14	INFECTION (RIGHT PINNA OF EAR)\ 外耳炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (374)\ 20[redacted] (396)\ 23	NEOPLASM MALIGNANT (SQUAMOUS CELL CARCINOMA)RIGHT EAR PINNA\ 外耳の悪性新生物\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (615)\ Ongoing\ -	BACK PAIN\ 背部痛\ 筋骨格系および結合組織障害	2\ Not Related	Dose Not Changed\ -\ Recovering/Resolving
		Yes	20[redacted] (746)\ 20[redacted] (751)\ 6	HIP FRACTURE\ 股関節部骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (273)\ 20[redacted] (274)\ 2	VERTIGO\ 回転性めまい\ 耳および迷路障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (2)\ 20[redacted] (8)\ 7	ABDOMINAL PAIN\ 腹痛\ 胃腸障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (62)\ 20[redacted] (190)\ 129	DISSEMINATED SCEDOSPORIUM INFECTION AND INFECTIOUS OTHER\ スケドスポリウム感染\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ -\ Fatal
		Yes	20[redacted] (126)\ 20[redacted] (129)\ 4	ACUTE KIDNEY INJURY\ 急性腎障害\ 腎および尿路障害	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (126)\ 20[redacted] (130)\ 5	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (131)\ 20[redacted] (141)\ 11	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (200)\ 20[redacted] (216)\ 17	RIGHT KNEE INJURY\ 関節損傷\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (478)\ 20[redacted] (489)\ 12	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (953)\ 20[redacted] (976)\ 24	LOCALISED PROSTATE CANCER\ 前立腺癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (235)\ 20[redacted] (252)\ 18	CYSTITIS HEMORRHAGIC\ 出血性膀胱炎\ 腎および尿路障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (5)\ 20[redacted] (8)\ 4	HYPERVISCOSITY SYNDROME\ 過粘稠度症候群\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (238)\ 20[redacted] (241)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
Disease type: MCL						
[redacted]	TN	Yes	20[redacted] (341)\ 20[redacted] (349)\ 9	HYPOXIA\ 低酸素症\ 呼吸器、胸郭および縦隔障害	2\ Not Related	Not Applicable\ -\ Recovered/Resolved
		Yes	20[redacted] (353)\ 20[redacted] (356)\ 4	SEPTIC SHOCK\ 敗血症性ショック\ 感染症および寄生虫症	5\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Fatal
[redacted]	TN	Yes	20[redacted] (150)\ 20[redacted] (153)\ 4	ACUTE KIDNEY INJURY\ 急性腎障害\ 腎および尿路障害	5\ Not Related	Not Applicable\ -\ Fatal
		Yes	20[redacted] (150)\ 20[redacted] (153)\ 4	TUMOR LYSIS\ 腫瘍崩壊症候群\ 代謝および栄養障害	5\ Not Related	Not Applicable\ -\ Fatal
[redacted]	TN	Yes	20[redacted] (112)\ 20[redacted] (125)\ 14	ACUTE KIDNEY INSUFFICIENCY\ 急性腎障害\ 腎および尿路障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (112)\ 20[redacted] (125)\ 14	FATIGUE\ 疲労\ 一般・全身障害および投与部位の状態	3\ Not Related	Not Applicable\ None\ Recovered/Resolved
		Yes	20[redacted] (112)\ 20[redacted] (125)\ 14	SHORTNESS OF BREATH\ 呼吸困難\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Not Applicable\ None\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (331)\ 20[redacted] (332)\ 2	SYNCOPE\ 失神\ 神経系障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	TN	No	20[redacted] (840)\ 20[redacted] (840)\ 1	DEATH NATURAL CAUSES\ 死亡\ 一般・全身障害および投与部位の状態	5\ Not Related	Not Applicable\ None\ Fatal
[redacted]	TN	Yes	20[redacted] (78)\ 20[redacted] (82)\ 5	HYPERCALCEMIA\ 高カルシウム血症\ 代謝および栄養障害	2\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (32)\ Ongoing\ -	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ None\ Not Recovered/Not Resolved
		Yes	20[redacted] (33)\ 20[redacted] (49)\ 17	SEPSIS (NOT SECONDARY TO PROGRESSION)\ 敗血症\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ Other\ Fatal
[redacted]	TN	Yes	20[redacted] (27)\ 20[redacted] (30)\ 4	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (35)\ 20[redacted] (46)\ 12	EXACERBATION OF CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (113)\ 20[redacted] (126)\ 14	WORSENING OF PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (792)\ 20[redacted] (799)\ 8	FRACTURED NECK OF FEMUR\ 大腿骨頚部骨折\ 傷害、中毒および処置合併症	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (799)\ 20[redacted] (801)\ 3	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (245)\ 20[redacted] (246)\ 2	MUSCULOSKELETAL CHEST PAIN\ 筋骨格系胸痛\ 筋骨格系および結合組織障害	3\ Not Related	Unknown\ -\ Recovered/Resolved
		Yes	20[redacted] (262)\ 20[redacted] (273)\ 12	COMMON BILE DUCT STONES\ 胆管結石\ 肝胆道系障害	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (262)\ 20[redacted] (273)\ 12	PERICARDIAL EFFUSION\ 心嚢液貯留\ 心臓障害	2\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved
		Yes	20[redacted] (882)\ Ongoing\ -	LYMPHOCYTOSIS\ リンパ球増加症\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ -\ Not Recovered/Not Resolved
[redacted]	TN	Yes	20[redacted] (9)\ 20[redacted] (35)\ 27	INTRACRANIAL HEMORRHAGE\ 頭蓋内出血\ 神経系障害	3\ Related	Drug Withdrawn\ -\ Recovered/Resolved
[redacted]	TN	Yes	20[redacted] (81)\ 20[redacted] (84)\ 4	ABDOMINAL PAIN\ 腹痛\ 胃腸障害	2\ Not Related	Dose Not Changed\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (81)\ 20[redacted] (84)\ 4	DIARRHOEA\ 下痢\ 胃腸障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-1)\ 20[redacted] (2)\ 3	RENAL IMPAIRMENT\ 腎機能障害\ 腎および尿路障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (8)\ 20[redacted] (18)\ 11	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (23)\ 20[redacted] (35)\ 13	GI BLEEDING\ 胃腸出血\ 胃腸障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (165)\ 20[redacted] (171)\ 7	HAEMOLYTIC ANAEMIA\ 溶血性貧血\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (193)\ 20[redacted] (206)\ 14	EPSTEIN-BARR VIRUS VIREMIA\ エプスタイン・バーウイルス血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (193)\ 20[redacted] (206)\ 14	HSV-1 VIREMIA\ 単純ヘルペスウイルス血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (208)\ 20[redacted] (212)\ 5	SYSTEMIC VIRAL INFECTION\ 全身性ウイルス感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (364)\ 20[redacted] (408)\ 45	DIARRHOEA\ 下痢\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (412)\ 20[redacted] (416)\ 5	TUMOUR LYSIS SYNDROME\ 腫瘍崩壊症候群\ 代謝および栄養障害	3\ Not Related	Not Applicable\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (118)\ 20[redacted] (127)\ 10	CELLULITUS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (622)\ 20[redacted] (625)\ 4	ATRIAL FLUTTER\ 心房粗動\ 心臓障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (636)\ 20[redacted] (641)\ 6	LEFT MIDDLE CEREBRAL ARTERY INFARCT\ 脳梗塞\ 神経系障害	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (142)\ 20[redacted] (147)\ 6	ACUTE KIDNEY INJURY\ 急性腎障害\ 腎および尿路障害	3\ Not Related	Drug Withdrawn\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (142)\ 20[redacted] (161)\ 20	ANCA VASCULITIS\ 抗好中球細胞質抗体陽性血管炎\ 免疫系障害	3\ Not Related	Drug Withdrawn\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1249)\ 20[redacted] (1253)\ 5	WORSENING PERICARDIAL EFFUSION\ 心嚢液貯留\ 心臓障害	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1262)\ 20[redacted] (1268)\ 7	SHORTNESS OF BREATH DUE TO PERICARDIAL EFFUSION\ 呼吸困難\ 呼吸器、胸郭および縦隔障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (1285)\ 20[redacted] (1358)\ 74	S.O.B DUE PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ Related	Drug Withdrawn, Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1285)\ 20[redacted] (1358)\ 74	SHORTNESS OF BREATH DUE TO PERICARDIAL EFFUSION\ 心嚢液貯留\ 心臓障害	3\ Related	Drug Withdrawn, Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (1285)\ 20[redacted] (1358)\ 74	WORSENING OF PERICARDIAL EFFUSION\ 心嚢液貯留\ 心臓障害	3\ Related	Drug Withdrawn, Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae
[redacted]	RR	Yes	20[redacted] (562)\ 20[redacted] (570)\ 9	PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (216)\ 20[redacted] (217)\ 2	LEFT NOSTRIL POST-PROCEDURAL BLEEDING FROM NASOPHARYNGEAL LESION (EXTRANODAL MANTLE CELL LYMPHOMA IN NASOPHARANGEL MUCOSA)\ 処置後出血\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-13)\ 20[redacted] (-6)\ 8	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (470)\ 20[redacted] (471)\ 2	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (480)\ 20[redacted] (499)\ 20	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (5)\ 20[redacted] (6)\ 2	HIATUS HERNIA\ 裂孔ヘルニア\ 胃腸障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
		Yes	20[redacted] (11)\ 20[redacted] (14)\ 4	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Withdrawn\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (11)\ 20[redacted] (25)\ 15	FLUID OVERLOAD\ 水分過負荷\ 代謝および栄養障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (22)\ 20[redacted] (53)\ 32	BACK PAIN\ 背部痛\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
		Yes	20[redacted] (57)\ 20[redacted] (59)\ 3	JOINT EFFUSION\ 関節滲出液\ 筋骨格系および結合組織障害	3\ Not Related	Not Applicable\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (840)\ 20[redacted] (844)\ 5	DIVERTICULITIS\ 憩室炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (851)\ 20[redacted] (861)\ 11	SPLENOMEGALY\ 脾腫\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (383)\ 20[redacted] (394)\ 12	CHRONIC IDIOPATHIC PAIN SYNDROME\ 慢性特発性疼痛症候群\ 精神障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (57)\ 20[redacted] (58)\ 2	LEUKOCYTOSIS\ 白血球増加症\ 血液およびリンパ系障害	3\ Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (59)\ 20[redacted] (64)\ 6	ANEMIA\ 貧血\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (64)\ 20[redacted] (71)\ 8	LEUKOCYTOSIS\ 白血球増加症\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (944)\ 20[redacted] (946)\ 3	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1374)\ 20[redacted] (1376)\ 3	ATRIAL FIBRILLATION\ 心房細動\ 心臓障害	3\ Related	Drug Interrupted, Dose Reduced\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (125)\ 20[redacted] (149)\ 25	MELANOMA\ 悪性黒色腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (55)\ 20[redacted] (73)\ 19	PAIN(MUSCULOSKELETAL)\ 筋骨格痛\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (209)\ 20[redacted] (234)\ 26	LUNG INFECTION(ATYPICAL CHEST INFECTION)\ 下気道感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (241)\ 20[redacted] (262)\ 22	LUNG INFECTION ((ASPERGILLUS))\ 気管支肺アスペルギルス症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (268)\ 20[redacted] (295)\ 28	LUNG INFECTION(BRONCHO-PNEUMONIA)\ 肺炎\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn, Drug Interrupted\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (3)\ 20[redacted] (6)\ 4	SYMPTOMATIC ANEMIA\ 貧血\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (45)\ 20[redacted] (59)\ 15	WORSENING OF CONGESTIVE CARDIAC FAILURE\ うっ血性心不全\ 心臓障害	5\ Not Related	Drug Withdrawn, Drug Interrupted\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (40)\ 20[redacted] (42)\ 3	ACUTE CORONARY SYNDROME\ 急性冠動脈症候群\ 心臓障害	3\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (1)\ 20[redacted] (4)\ 4	BRONCHITIS\ 気管支炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (465)\ 20[redacted] (467)\ 3	LETHARGY\ 嗜眠\ 神経系障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (262)\ 20[redacted] (285)\ 24	LEFT RENAL SUBCAPSULAR HAEMATOMA WITH RETROPERITONEAL EXTRAVASATION\ 腎被膜下血腫\ 腎および尿路障害	3\ Not Related	Drug Withdrawn\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
Disease type: MZL						
[redacted]	RR	Yes	20[redacted] (1)\ 20[redacted] (4)\ 4	HYPERTENSION\ 高血圧\ 血管障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (166)\ 20[redacted] (167)\ 2	DIARRHOEA\ 下痢\ 胃腸障害	3\ Related	Drug Withdrawn, Drug Interrupted, Dose Reduced\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (800)\ 20[redacted] (802)\ 3	GASTROENTERITIS\ 胃腸炎\ 感染症および寄生虫症	4\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (742)\ 20[redacted] (975)\ 234	INFILTRATING DUCTAL CARCINOMA RIGHT BREAST\ 浸潤性乳管癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (958)\ 20[redacted] (1078)\ 121	WORSENING OF RIGHT BREAST BRUISING AFTER RE-STARTING IP\ 挫傷\ 傷害、中毒および処置合併症	2\ Related	Drug Interrupted\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (1100)\ 20[redacted] (1119)\ 20	WORSENING OF RIGHT BREAST BRUISING AFTER RE-STARTING IP\ 挫傷\ 傷害、中毒および処置合併症	2\ Related	Dose Reduced\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (253)\ 20[redacted] (260)\ 8	CARBUNCLES SKIN OF BACK AND LEFT UPPER ARM (MSSA)\ よう\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ Other\ Recovered/Resolved
		Yes	20[redacted] (261)\ 20[redacted] (270)\ 10	FEBRILE ILLNESS CAUSED BY FLUCLOXACILLIN\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (480)\ 20[redacted] (484)\ 5	PYELONEPHRITIS\ 腎盂腎炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (957)\ 20[redacted] (960)\ 4	COMMUNITY ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (77)\ 20[redacted] (83)\ 7	GENERAL ACHE\ 疼痛\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (141)\ 20[redacted] (163)\ 23	GENERAL ACHE\ 疼痛\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (31)\ 20[redacted] (88)\ 58	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (33)\ 20[redacted] (88)\ 56	INFLUENZA VIRUS INFECTION\ インフルエンザ\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (73)\ 20[redacted] (81)\ 9	C. DIFFICILE DIARRHEA\ クロストリジウム・ディフィシレ大腸炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (585)\ 20[redacted] (605)\ 21	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (62)\ 20[redacted] (62)\ 1	FEVER OF UNKNOWN ORIGIN\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (147)\ 2018-06-02 (149)\ 3	DIARRHEA\ 下痢\ 胃腸障害	2\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (147)\ 20[redacted] (149)\ 3	VOMITING\ 嘔吐\ 胃腸障害	2\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (147)\ 20[redacted] (162)\ 16	CUTANEOUS INFECTION\ 皮膚感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (289)\ 20[redacted] (306)\ 18	SEPSIS (E.COLI)\ 大腸菌性敗血症\ 感染症および寄生虫症	4\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (376)\ 20[redacted] (377)\ 2	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (445)\ 20[redacted] (445)\ 1	ACUTE PULMUNARY EDEMA\ 急性肺水腫\ 呼吸器、胸郭および縦隔障害	4\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (978)\ 20[redacted] (1008)\ 31	FEVER (INTENSE SUFFERING)\ 発熱\ 一般・全身障害および投与部位の状態	2\ Not Related	Drug Withdrawn, Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (43)\ 20[redacted] (46)\ 4	ANAEMIA\ 貧血\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (39)\ 20[redacted] (51)\ 13	CHEST PAIN (NON CARDIAC)\ 非心臓性胸痛\ 一般・全身障害および投与部位の状態	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (162)\ 20[redacted] (167)\ 6	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
Disease type: FL						
[redacted]	RR	Yes	20[redacted] (174)\ 20[redacted] (191)\ 18	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (261)\ Ongoing\ -	LUNG CANCER (SPINDLE CELL CARCINOMA RIGHT LUNG)\ 肺肉腫様癌\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved With Sequelae

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (276)\ 20[redacted] (279)\ 4	NON NEUTROPENIC FEVER\ 発熱\ 一般・全身障害および投与部位の状態	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (458)\ Ongoing\ -	BRAIN METASTASES\ 中枢神経系転移\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Withdrawn, Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Not Recovered/Not Resolved
		Yes	20[redacted] (498)\ 20[redacted] (504)\ 7	ASPIRATION PNEUMONIA\ 誤嚥性肺炎\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (50)\ 20[redacted] (72)\ 23	WORSENING OF ISCHEMIC HEART DISEASE\ 心筋虚血\ 心臓障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (29)\ Ongoing\ -	NAUSEA\ 悪心\ 胃腸障害	3\ Related	Drug Interrupted\ -\ Not Recovered/Not Resolved
[redacted]	RR	Yes	20[redacted] (67)\ 20[redacted] (79)\ 13	BILATERAL PNEUMONIA\ 肺炎\ 感染症および寄生虫症	5\ Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (255)\ 20[redacted] (258)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (721)\ 20[redacted] (726)\ 6	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (11)\ 20[redacted] (15)\ 5	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (30)\ 20[redacted] (32)\ 3	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (119)\ 20[redacted] (121)\ 3	COPD WITH ACUTE EXACERBATION\ 慢性閉塞性肺疾患\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (829)\ 20[redacted] (830)\ 2	SEPSIS\ 敗血症\ 感染症および寄生虫症	4\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (829)\ 20[redacted] (832)\ 4	LUNG INFECTION\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (829)\ 20[redacted] (832)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (54)\ 20[redacted] (56)\ 3	URINARY TRACT OBSTRUCTION\ 尿路閉塞\ 腎および尿路障害	3\ Not Related	Dose Not Changed, Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (11)\ 20[redacted] (13)\ 3	BACTREMIA\ 菌血症\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (117)\ 20[redacted] (123)\ 7	ACUTE KIDNEY INJURY\ 急性腎障害\ 腎および尿路障害	2\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (1028)\ 20[redacted] (1071)\ 44	BRONCHIAL ASTHMA\ 喘息\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (3)\ 20[redacted] (10)\ 8	HEMATURIA\ 血尿\ 腎および尿路障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (35)\ Ongoing\ -	WORSENING OF HYDRONEPHROSIS\ 水腎症\ 腎および尿路障害	3\ Not Related	Dose Not Changed\ -\ Unknown
[redacted]	RR	Yes	20[redacted] (6)\ 20[redacted] (29)\ 24	CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (85)\ 20[redacted] (113)\ 29	RIGHT LEG CELLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (107)\ 20[redacted] (112)\ 6	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (137)\ 20[redacted] (141)\ 5	VIRAL GASTROENTERITIS\ ウイルス性胃腸炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (443)\ 20[redacted] (445)\ 3	EXACERBATION OF ANXIETY\ 不安\ 精神障害	4\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (130)\ 20[redacted] (133)\ 4	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (221)\ 20[redacted] (250)\ 30	ABDOMINAL PAIN DUE TO PROGRESSIVE LYMPHOMA\ 腫瘍疼痛\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (1)\ 20[redacted] (5)\ 5	SCROTAL INFECTION\ 陰嚢感染\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
Disease type: DLBCL						
[redacted]	RR	Yes	20[redacted] (4)\ 20[redacted] (15)\ 12	POSTURAL HYPOTENSION\ 起立性低血圧\ 血管障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (882)\ 20[redacted] (902)\ 21	INTRACEREBRAL MASS LESION\ 中枢神経系病変\ 神経系障害	5\ Not Related	Drug Withdrawn\ Other\ Fatal
[redacted]	RR	No	20[redacted] (-14)\ 20[redacted] (11)\ 25	LOWER RESPIRATORY TRACT INFECTION\ 下気道感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy / Procedure, Other(Hospitalization), Concomitant Medication\ Recovered/Resolved
		Yes	20[redacted] (9)\ 20[redacted] (31)\ 23	MULTIPLE ORGAN FAILURE\ 多臓器機能不全症候群\ 一般・全身障害および投与部位の状態	5\ Not Related	Drug Withdrawn\ None\ Fatal
		Yes	20[redacted] (15)\ 20[redacted] (31)\ 17	RIGHT PLEURAL EFFUSION\ 胸水\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (310)\ 20[redacted] (311)\ 2	WORSENING HYPERTENSION\ 高血圧\ 血管障害	2\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (38)\ 20[redacted] (44)\ 7	HYPERCALCEMIA\ 高カルシウム血症\ 代謝および栄養障害	4\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (216)\ 20[redacted] (221)\ 6	FATIGUE\ 疲労\ 一般・全身障害および投与部位の状態	3\ Not Related	Not Applicable\ None\ Recovered/Resolved
		Yes	20[redacted] (221)\ 20[redacted] (221)\ 1	UNEXPLAINED DEATH\ 死亡\ 一般・全身障害および投与部位の状態	5\ Not Related	Dose Not Changed\ None\ Fatal
[redacted]	RR	Yes	20[redacted] (4)\ 20[redacted] (6)\ 3	STAPHYLOCOCCUS AUREUS PNEUMONIA\ ブドウ球菌性肺炎\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ Non-Medication Concomitant Therapy Or Procedure\ Fatal
[redacted]	RR	Yes	20[redacted] (58)\ Ongoing\ -	FATIGUE\ 疲労\ 一般・全身障害および投与部位の状態	3\ Not Related	Dose Not Changed\ -\ Not Recovered/Not Resolved
		Yes	20[redacted] (61)\ Ongoing\ -	DYSPNEA\ 呼吸困難\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Not Applicable\ None\ Not Recovered/Not Resolved
[redacted]	RR	No	20[redacted] (56)\ 20[redacted] (56)\ 1	UNKNOWN CAUSE OF DEATH\ 死亡\ 一般・全身障害および投与部位の状態	5\ Not Related	Not Applicable\ None\ Fatal

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (46)\ 20[redacted] (58)\ 13	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	1\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (15)\ 20[redacted] (78)\ 64	MALIGNANT PLEURAL EFFUSION\ 悪性胸水\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	-\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (83)\ 20[redacted] (104)\ 22	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (100)\ 20[redacted] (125)\ 26	HEMOLYTIC ANEMIA\ 溶血性貧血\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (57)\ 20[redacted] (58)\ 2	ANEMIA\ 貧血\ 血液およびリンパ系障害	4\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (57)\ 20[redacted] (58)\ 2	HYPERKALEMIA\ 高カリウム血症\ 代謝および栄養障害	3\ Not Related	Drug Withdrawn, Drug Interrupted\ None\ Recovered/Resolved
		Yes	20[redacted] (58)\ 20[redacted] (62)\ 5	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (37)\ 20[redacted] (46)\ 10	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (38)\ Ongoing\ -	VASCULITIS\ 血管炎\ 血管障害	2\ Related	Drug Withdrawn, Drug Interrupted\ -\ Not Recovered/Not Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (7)\ 20[redacted] (25)\ 19	SORE THROAT PAIN\ 口腔咽頭痛\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-6)\ 20[redacted] (7)\ 13	MELENA\ メレナ\ 胃腸障害	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (156)\ 20[redacted] (176)\ 21	NAUSEA\ 悪心\ 胃腸障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (43)\ 20[redacted] (60)\ 18	NECK SOFT TISSUE NECROSIS\ 軟部組織壊死\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (46)\ 20[redacted] (91)\ 46	VESICOCOLIC FISTULA\ 腸膀胱瘻\ 胃腸障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (32)\ 20[redacted] (86)\ 55	LEFT LOWER LEG CELLLULITIS\ 蜂巣炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (88)\ 20[redacted] (121)\ 34	PNEUMONITIS\ 肺臓炎\ 呼吸器、胸郭および縦隔障害	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (122)\ 20[redacted] (169)\ 48	PNEUMONITIS\ 肺臓炎\ 呼吸器、胸郭および縦隔障害	1\ Related	Dose Reduced\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-9)\ 20[redacted] (1)\ 10	ELEVATED LIVER ENZYME(ALANINE AMINOTRANSFERASE)\ アラニンアミノトランスフェラーゼ増加\ 臨床検査	4\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		No	20[redacted] (-9)\ 20[redacted] (1)\ 10	ELEVATED LIVER ENZYME(ASPARTATE AMINOTRANSFERASE)\ アスパラギン酸アミノトランスフェラーゼ増加\ 臨床検査	4\ Not Related	Not Applicable\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (8)\ 20[redacted] (48)\ 41	WORSENING OF ABDOMINAL PAIN\ 腹痛\ 胃腸障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (416)\ 20[redacted] (418)\ 3	NEUTROPHIL COUNT DECREASED\ 好中球数減少\ 臨床検査	4\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (421)\ Ongoing\ -	INCREASED PELVIC PAIN\ 骨盤痛\ 生殖系および乳房障害	2\ Not Related	Dose Not Changed\ -\ Not Recovered/Not Resolved
[redacted]	RR	Yes	20[redacted] (322)\ Ongoing\ -	FEVER\ 発熱\ 一般・全身障害および投与部位の状態	2\ Not Related	Not Applicable\ Other\ Not Recovered/Not Resolved
		Yes	20[redacted] (335)\ 20[redacted] (336)\ 2	MULTI ORGAN FAILURE\ 多臓器機能不全症候群\ 一般・全身障害および投与部位の状態	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	No	20[redacted] (-12)\ 20[redacted] (32)\ 44	BRONCHIECTASIS, INFECTIVE EXACERBATION\ 感染による気管支拡張症の増悪\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (2)\ 20[redacted] (168)\ 167	PELVIC PAIN\ 骨盤痛\ 生殖系および乳房障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (36)\ Ongoing\ -	SEPTIC ARTHRITIS\ 細菌性関節炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Not Recovered/Not Resolved
		Yes	20[redacted] (40)\ 20[redacted] (51)\ 12	LUNG SEPSIS\ 肺敗血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (161)\ 20[redacted] (168)\ 8	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	5\ Not Related	Dose Not Changed\ Other\ Fatal
		Yes	20[redacted] (161)\ 20[redacted] (168)\ 8	SEPTIC SHOCK\ 敗血症性ショック\ 感染症および寄生虫症	5\ Not Related	Drug Withdrawn\ None\ Fatal
[redacted]	RR	Yes	20[redacted] (184)\ 20[redacted] (189)\ 6	HYPERCALCAEMIA (SECONDARY TO PROGRESSIVE DISEASE)\ 悪性腫瘍に伴う高カルシウム血症\ 内分泌障害	3\ Not Related	Dose Not Changed\ None\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (428)\ 20[redacted] (453)\ 26	MELANOMA ON SHOULDER (UNKNOWN ANATOMICAL BODY SITE)\ 悪性黒色腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (104)\ 20[redacted] (117)\ 14	COMMUNITY ACQUIRED PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (78)\ 20[redacted] (138)\ 61	RESPIRATORY OBSTRUCTION (DUE TO LOCAL RECURRENCE OF DIFFUSE LARGE B CELL LYMPHOMA)\ 閉塞性気道障害\ 呼吸器、胸郭および縦隔障害	3\ Not Related	Drug Withdrawn\ -\ Recovered/Resolved With Sequelae
		Yes	20[redacted] (86)\ 20[redacted] (90)\ 5	FEBRILE NEUTROPENIA\ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (28)\ Ongoing\ -	PLEURITIC CHEST PAIN\ 胸膜痛\ 呼吸器、胸郭および縦隔障害	2\ Not Related	Drug Withdrawn\ None\ Unknown
Disease type: RT						
[redacted]	RR	No	20[redacted] (-13)\ 20[redacted] (-6)\ 8	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
		Yes	20[redacted] (160)\ Ongoing\ -	ABDOMINAL PAIN ETIOLOGY-LEFT RETROPERITONEAL MASS\ 後腹膜腫瘤\ 胃腸障害	2\ Not Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
		Yes	20[redacted] (160)\ Ongoing\ -	LEFT RETRO PERITONEAL MASS (ETIOLOGY UNKNOWN)\ 後腹膜腫瘤\ 胃腸障害	3\ Not Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
[redacted]	RR	No	20[redacted] (-25)\ 20[redacted] (-22)\ 4	VIRAL GASTROENTERITIS\ ウイルス性胃腸炎\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved
		No	20[redacted] (-18)\ 20[redacted] (-6)\ 13	URINARY TRACT INFECTION\ 尿路感染\ 感染症および寄生虫症	3\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (16)\ 20[redacted] (17)\ 2	NON ST ELEVATION MYOCARDIAL INFARCTION\ 急性心筋梗塞\ 心臓障害	5\ Not Related	Drug Withdrawn\ -\ Fatal
[redacted]	RR	Yes	20[redacted] (105)\ 20[redacted] (128)\ 24	BACTEREMIA\ 菌血症\ 感染症および寄生虫症	5\ Related	Drug Withdrawn\ Non-Medication Concomitant Therapy / Procedure, Other(Patient Was Discharged To Hospice), Concomitant Medication\ Fatal
[redacted]	RR	Yes	20[redacted] (21)\ 20[redacted] (37)\ 17	MULTIFOCAL PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	Yes	20[redacted] (567)\ 20[redacted] (578)\ 12	COUGH\ 咳嗽\ 呼吸器、胸郭および縦隔障害	2\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (644)\ 20[redacted] (681)\ 38	COLOVESCICAL FISTULA\ 腸膀胱瘻\ 胃腸障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (645)\ 20[redacted] (675)\ 31	ASYMPTOMATIC COVID-19 INFECTION\ 無症候性 COVID-19\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (-16)\ 20[redacted] (-14)\ 3	WORSENING OF IDIOPATHIC THROMBOCYTOPENIC PURPURA\ 免疫性血小板減少症\ 血液およびリンパ系障害	3\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (617)\ 20[redacted] (716)\ 100	MELANOMA ON BACK\ 悪性黒色腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		Yes	20[redacted] (699)\ 20[redacted] (704)\ 6	RHINOVIRUS VIRAL RESPIRATORY TRACT INFECTION\ ライノウイルス感染\ 感染症および寄生虫症	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (717)\ 20[redacted] (720)\ 4	BLEEDING POST MELANOMA REMOVAL\ 処置後出血\ 傷害、中毒および処置合併症	3\ Not Related	Dose Not Changed\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (841)\ 20[redacted] (845)\ 5	OBSTRUCTED LEFT KIDNEY\ 尿路閉塞\ 腎および尿路障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
		Yes	20[redacted] (855)\ 20[redacted] (882)\ 28	ANAEMIA\ 貧血\ 血液およびリンパ系障害	3\ Not Related	Drug Interrupted\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (162)\ 20[redacted] (175)\ 14	HEADACHE\ 頭痛\ 神経系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		No	20[redacted] (162)\ 20[redacted] (175)\ 14	VOMITING\ 嘔吐\ 胃腸障害	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
Disease type: HCL						
[redacted]	RR	Yes	20[redacted] (89)\ 20[redacted] (98)\ 10	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Related	Drug Interrupted\ -\ Recovered/Resolved
[redacted]	RR	No	20[redacted] (745)\ 20[redacted] (758)\ 14	CYTOKINE RELEASE SYNDROME (CRS)\ サイトカイン放出症候群\ 免疫系障害	3\ Not Related	Not Applicable\ -\ Recovered/Resolved

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	RR	Yes	20[redacted] (16)\ 20[redacted] (20)\ 5	NEUTROPAENIA\ 好中球減少症\ 血液およびリンパ系障害	3\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (106)\ 20[redacted] (108)\ 3	FEBRILE\ 発熱\ 一般・全身障害および投与部位の状態	1\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (132)\ Ongoing\ -	BRAIN ASPERGILLUS INFECTION\ 脳アスペルギルス症\ 感染症および寄生虫症	3\ Related	Drug Withdrawn\ -\ Not Recovered/Not Resolved
Disease type: OTHER						
[redacted]	RR	Yes	20[redacted] (27)\ 20[redacted] (46)\ 20	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (321)\ 20[redacted] (333)\ 13	PNEUMONIA\ 肺炎\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (605)\ 20[redacted] (614)\ 10	PNEUMONIA (RHINOVIRUS INFECTION)\ ウイルス性肺炎\ 感染症および寄生虫症	2\ Not Related	Dose Not Changed\ -\ Recovered/Resolved
		Yes	20[redacted] (665)\ 20[redacted] (691)\ 27	SEPSIS (HAEMOPHYLUS INFLUENZAE)\ ヘモフィルス性敗血症\ 感染症および寄生虫症	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved
		Yes	20[redacted] (673)\ 20[redacted] (691)\ 19	ENTERITIS\ 小腸炎\ 胃腸障害	3\ Not Related	Drug Interrupted\ -\ Recovered/Resolved

Source: Listing 16.2.7.3 in BGB-3111-AU-003 clinical study report. Data cutoff: 31MAR2021; Data extraction: [redacted]20[redacted]; Data Source: ADAE, ADSL.

Patient ID	TN \RR	Treatment Emergent?	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome

Abbreviations: AE, adverse event; CLL, chronic lymphocytic leukemia; SLL, small lymphocytic lymphoma; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HCL, hairy cell leukemia; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; RT, Richter's transformation; TEAE, treatment-emergent adverse event; WM, Waldenström's macroglobulinemia.
Adverse event grades are evaluated based on NCI-CTCAE (Version 4.03). MedDRA Version 23.0.

表 41： 治療下で発現した有害事象：器官別大分類別、基本語別、及び最も重症度の高いグレード別（BGB-3111-210 試験、安全性解析対象集団）

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Patients with at least one TEAE	2 (4.5)	8 (18.2)	25 (56.8)	7 (15.9)	2 (4.5)	44 (100.0)
臨床検査	10 (22.7)	10 (22.7)	12 (27.3)	6 (13.6)	0 (0.0)	38 (86.4)
好中球数減少	5 (11.4)	7 (15.9)	10 (22.7)	4 (9.1)	0 (0.0)	26 (59.1)
白血球数減少	2 (4.5)	7 (15.9)	5 (11.4)	0 (0.0)	0 (0.0)	14 (31.8)
血小板数減少	3 (6.8)	1 (2.3)	7 (15.9)	2 (4.5)	0 (0.0)	13 (29.5)
体重増加	4 (9.1)	5 (11.4)	1 (2.3)	0 (0.0)	0 (0.0)	10 (22.7)
アラニンアミノトランスフェラーゼ増加	3 (6.8)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
アスパラギン酸アミノトランスフェラーゼ増加	4 (9.1)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
リンパ球数減少	2 (4.5)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	4 (9.1)
γ－グルタミルトランスフェラーゼ増加	1 (2.3)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
体重減少	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
尿中白血球陽性	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
抱合ビリルビン増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中アルカリホスファターゼ増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中ビリルビン増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中クレアチニン増加	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中免疫グロブリン M 増加	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (4.5)
二酸化炭素増加	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
心電図 QT 延長	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中非抱合ビリルビン増加	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血中リン減少	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
拡張期血圧低下	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血圧上昇	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血中尿酸増加	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
尿中血陽性	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心電図 PR 短縮	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心電図 ST-T 変化	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
グロブリン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
ヘモグロビン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
リポ蛋白（a）増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%) Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
リンパ球数増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
好中球数増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
尿中亜硝酸塩陽性	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
尿中ビリルビン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
尿量減少	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
白血球数増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
感染症および寄生虫症	2 (4.5)	13 (29.5)	19 (43.2)	0 (0.0)	1 (2.3)	35 (79.5)
肺炎	0 (0.0)	4 (9.1)	9 (20.5)	0 (0.0)	0 (0.0)	13 (29.5)
上気道感染	1 (2.3)	9 (20.5)	3 (6.8)	0 (0.0)	0 (0.0)	13 (29.5)
尿路感染	3 (6.8)	4 (9.1)	1 (2.3)	0 (0.0)	0 (0.0)	8 (18.2)
上咽頭炎	5 (11.4)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)
帯状疱疹	0 (0.0)	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
気管支炎	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (4.5)
結膜炎	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
歯周炎	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
咽頭炎	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
副鼻腔炎	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
皮膚感染	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (4.5)
扁桃炎	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
四肢膿瘍	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
急性 B 型肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)
無症候性細菌尿	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
感染性下痢	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
精巣上体炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
歯肉炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
B 型肝炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
単純ヘルペス	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
インフルエンザ	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
限局性感染	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
鼓膜炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
爪囲炎	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
肺真菌症	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
気道感染	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
軟部組織感染	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
気管炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
尿道炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%) Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
ウイルス性発疹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
胃腸障害	13 (29.5)	13 (29.5)	2 (4.5)	0 (0.0)	0 (0.0)	28 (63.6)
下痢	7 (15.9)	4 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	11 (25.0)
上腹部痛	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
歯痛	1 (2.3)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
嘔吐	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
便秘	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
鼓腸	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
胃炎	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
歯肉出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
歯肉痛	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
腹部膨満	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
細菌叢異常	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
消化不良	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
排便回数増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
歯肉腫脹	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
弛緩歯	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔内出血	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔内潰瘍形成	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
耳下腺腫大	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口内炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
上部消化管出血	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
代謝および栄養障害	12 (27.3)	11 (25.0)	2 (4.5)	0 (0.0)	0 (0.0)	25 (56.8)
食欲減退	5 (11.4)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	7 (15.9)
低アルブミン血症	1 (2.3)	5 (11.4)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)
低カリウム血症	2 (4.5)	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	6 (13.6)
高血糖	1 (2.3)	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	5 (11.4)
高尿酸血症	4 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
耐糖能障害	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
低カルシウム血症	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
高カリウム血症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
高リン酸塩血症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
栄養障害	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
皮膚および皮下組織障害	11 (25.0)	11 (25.0)	1 (2.3)	0 (0.0)	0 (0.0)	23 (52.3)
紫斑	3 (6.8)	5 (11.4)	0 (0.0)	0 (0.0)	0 (0.0)	8 (18.2)

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
発疹	5 (11.4)	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	8 (18.2)
斑状出血	3 (6.8)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	4 (9.1)
皮下出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
神経皮膚炎	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
点状出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
皮膚出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
水疱	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
皮膚炎	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
接触皮膚炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
薬疹	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
そう痒症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
乾癬	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
紅斑性皮疹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
日光皮膚炎	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
丘疹状蕁麻疹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
呼吸器、胸郭および縦隔障害	10 (22.7)	8 (18.2)	1 (2.3)	0 (0.0)	0 (0.0)	19 (43.2)
咳嗽	4 (9.1)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)
鼻出血	4 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
口腔咽頭痛	4 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
湿性咳嗽	0 (0.0)	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
間質性肺疾患	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
胸水	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
肺腫瘤	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
無気肺	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
呼吸困難	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
肺陰影	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
鼻閉	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔咽頭不快感	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
肺臓炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
気胸	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
アレルギー性鼻炎	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
扁桃肥大	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
一般・全身障害および投与部位の状態	7 (15.9)	6 (13.6)	1 (2.3)	0 (0.0)	2 (4.5)	16 (36.4)
発熱	4 (9.1)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)
胸部不快感	2 (4.5)	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	5 (11.4)
末梢性浮腫	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
疲労	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
胸痛	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
無力症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
死亡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)
倦怠感	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
多臓器機能不全症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)
末梢腫脹	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
筋骨格系および結合組織障害	5 (11.4)	7 (15.9)	3 (6.8)	0 (0.0)	0 (0.0)	15 (34.1)
関節痛	6 (13.6)	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	9 (20.5)
背部痛	2 (4.5)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
筋膜炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
関節腫脹	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
筋痙縮	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
筋肉痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
骨粗鬆症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
四肢痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
仙腸骨炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
脊椎すべり症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
滑液嚢腫	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
腱鞘炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
神経系障害	7 (15.9)	2 (4.5)	4 (9.1)	0 (0.0)	0 (0.0)	13 (29.5)
浮動性めまい	2 (4.5)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
頭痛	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
失神	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (4.5)
感覚鈍麻	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
低酸素性虚血性脳症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
頭蓋内腫瘤	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
末梢性感覚ニューロパチー	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
ヘルペス後神経痛	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
感覚障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
眼障害	6 (13.6)	3 (6.8)	3 (6.8)	0 (0.0)	0 (0.0)	12 (27.3)
白内障	3 (6.8)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	4 (9.1)
網膜出血	1 (2.3)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
結膜出血	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
眼部不快感	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%) Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
網脈絡膜症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
結膜充血	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
眼の障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
眼痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
黄斑変性	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
屈折障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
網膜色素上皮症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
網膜裂孔	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血液およびリンパ系障害	2 (4.5)	4 (9.1)	5 (11.4)	0 (0.0)	0 (0.0)	11 (25.0)
貧血	2 (4.5)	3 (6.8)	3 (6.8)	0 (0.0)	0 (0.0)	8 (18.2)
白血球減少症	0 (0.0)	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
好中球減少症	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
鉄欠乏性貧血	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
白血球増加症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
好中球増加症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血小板減少症	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
血管障害	1 (2.3)	4 (9.1)	5 (11.4)	0 (0.0)	0 (0.0)	10 (22.7)
高血圧	1 (2.3)	2 (4.5)	5 (11.4)	0 (0.0)	0 (0.0)	8 (18.2)
動脈硬化症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
深部静脈血栓症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
末梢動脈閉塞性疾患	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
四肢静脈血栓症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心臓障害	8 (18.2)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	9 (20.5)
狭心症	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
冠動脈硬化症	1 (2.3)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
右脚ブロック	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
冠動脈疾患	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
左室肥大	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心筋虚血	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
動悸	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
上室性期外収縮	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
頻脈	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
傷害、中毒および処置合併症	1 (2.3)	6 (13.6)	2 (4.5)	0 (0.0)	0 (0.0)	9 (20.5)
骨折	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
四肢損傷	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
挫傷	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
転倒	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
切開部位痛	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
橈骨骨折	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
軟部組織損傷	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
脊椎圧迫骨折	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
手首関節骨折	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
腎および尿路障害	4 (9.1)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
血尿	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
慢性腎臓病	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
蛋白尿	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
腎機能障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (2.3)	0 (0.0)	2 (4.5)	1 (2.3)	0 (0.0)	4 (9.1)
肝臓血管腫	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
喉頭癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.3)
肺の悪性新生物	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
ワルデンストローム・マクログロブリン血症 [a]	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
生殖系および乳房障害	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
後天性陰嚢水瘤	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
良性前立腺肥大症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
女性化乳房	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
骨盤液貯留	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
前立腺炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
耳および迷路障害	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
耳部腫脹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
聴力低下	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
精神障害	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
不眠症	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)

Source: Table 14.3.1.2.2 in BGB-3111-210 clinical study report. Data cutoff: 11JAN2021; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE.

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Total**

Abbreviations: NCI-CTCAE, National Cancer Institute-Common Terminology Criteria for Adverse Events; TEAE, treatment-emergent adverse event.
[a] This patient ([redacted]) discontinued study treatment and subsequently died due to "progression of Waldenstrom's macroglobulinemia" that was reported as an adverse event.
Adverse event grades are evaluated based on NCI-CTCAE (Version 4.03).
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once at the worst severity for each Preferred Term and System Organ Class, respectively.
MedDRA Version: 23.0.

表 42： 投与と関連のある TEAE：器官別大分類別、基本語別、及び最も重症度の高いグレード別（BGB-3111-210 試験、安全性解析対象集団）

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Total**
Patients with at least one Treatment-related TEAE	5 (11.4)	9 (20.5)	21 (47.7)	5 (11.4)	1 (2.3)	41 (93.2)
臨床検査	4 (9.1)	9 (20.5)	12 (27.3)	5 (11.4)	0 (0.0)	30 (68.2)
好中球数減少	4 (9.1)	8 (18.2)	9 (20.5)	4 (9.1)	0 (0.0)	25 (56.8)
白血球数減少	3 (6.8)	5 (11.4)	5 (11.4)	0 (0.0)	0 (0.0)	13 (29.5)
血小板数減少	2 (4.5)	1 (2.3)	7 (15.9)	2 (4.5)	0 (0.0)	12 (27.3)
体重増加	3 (6.8)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
アラニンアミノトランスフェラーゼ増加	2 (4.5)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
アスパラギン酸アミノトランスフェラーゼ増加	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
リンパ球数減少	2 (4.5)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
抱合ビリルビン増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中ビリルビン増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
二酸化炭素増加	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
心電図 QT 延長	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
γ－グルタミルトランスフェラーゼ増加	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
血中アルカリホスファターゼ増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血中非抱合ビリルビン増加	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血中クレアチニン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
拡張期血圧低下	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血中尿酸増加	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心電図 PR 短縮	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
心電図 ST-T 変化	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
ヘモグロビン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
リポ蛋白（a）増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
尿中ビリルビン増加	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
皮膚および皮下組織障害	12 (27.3)	7 (15.9)	1 (2.3)	0 (0.0)	0 (0.0)	20 (45.5)
紫斑	3 (6.8)	5 (11.4)	0 (0.0)	0 (0.0)	0 (0.0)	8 (18.2)
発疹	4 (9.1)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)
斑状出血	2 (4.5)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
皮下出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)

	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
System Organ Class Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
点状出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
皮膚出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
そう痒症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
紅斑性皮疹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
丘疹状蕁麻疹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
感染症および寄生虫症	3 (6.8)	6 (13.6)	8 (18.2)	0 (0.0)	1 (2.3)	18 (40.9)
肺炎	0 (0.0)	2 (4.5)	3 (6.8)	0 (0.0)	0 (0.0)	5 (11.4)
帯状疱疹	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
上気道感染	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
尿路感染	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
急性 B 型肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)
無症候性細菌尿	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
結膜炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
歯肉炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
B 型肝炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
鼓膜炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
上咽頭炎	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
咽頭炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
肺真菌症	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
気道感染	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
軟部組織感染	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
扁桃炎	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
代謝および栄養障害	9 (20.5)	4 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	13 (29.5)
食欲減退	4 (9.1)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
高尿酸血症	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
耐糖能障害	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
高血糖	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
高リン酸塩血症	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
低アルブミン血症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
胃腸障害	5 (11.4)	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	8 (18.2)
下痢	2 (4.5)	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)
歯肉出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
消化不良	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔内出血	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔内潰瘍形成	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
上部消化管出血	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
血液およびリンパ系障害	0 (0.0)	5 (11.4)	2 (4.5)	0 (0.0)	0 (0.0)	7 (15.9)
貧血	1 (2.3)	3 (6.8)	1 (2.3)	0 (0.0)	0 (0.0)	5 (11.4)
白血球減少症	0 (0.0)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	2 (4.5)
好中球減少症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血小板減少症	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (2.3)
一般・全身障害および投与部位の状態	4 (9.1)	2 (4.5)	0 (0.0)	0 (0.0)	1 (2.3)	7 (15.9)
疲労	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
末梢性浮腫	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
無力症	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
多臓器機能不全症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)
末梢腫脹	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
発熱	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
筋骨格系および結合組織障害	5 (11.4)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	7 (15.9)
関節痛	4 (9.1)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	6 (13.6)
背部痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
関節腫脹	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
筋肉痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
眼障害	3 (6.8)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	5 (11.4)
網膜出血	1 (2.3)	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	3 (6.8)
眼痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
眼部不快感	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
呼吸器、胸郭および縦隔障害	2 (4.5)	3 (6.8)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)
鼻出血	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
間質性肺疾患	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
口腔咽頭痛	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
胸水	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
肺臓炎	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血管障害	0 (0.0)	1 (2.3)	3 (6.8)	0 (0.0)	0 (0.0)	4 (9.1)
高血圧	0 (0.0)	1 (2.3)	3 (6.8)	0 (0.0)	0 (0.0)	4 (9.1)
神経系障害	2 (4.5)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)
浮動性めまい	1 (2.3)	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)

System Organ Class Preferred Term	Zanubrutinib (N = 44) n (%)					
	Worst Grade					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
感覚障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
精神障害	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
不眠症	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)
心臓障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
上室性期外収縮	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
腎および尿路障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
血尿	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
生殖系および乳房障害	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
女性化乳房	1 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)

Source: Table 14.3.1.2.3 in BGB-3111-210 clinical study report. Data cutoff: 11JAN2021; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE.
Abbreviations: TEAE, treatment-emergent adverse event.
Adverse event grades are evaluated based on NCI-CTCAE (Version 4.03).
Treatment-related AEs include those events considered by the investigator to be related, possibly related, probably related to study drug, or with missing assessment of the causal relationship.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once at the worst severity for each Preferred Term and System Organ Class, respectively.
MedDRA Version: 23.0

表 43： 重篤な有害事象の一覧（BGB-3111-210 試験、安全性解析対象集団）

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	血液およびリンパ系障害/ 貧血/ [ANEMIA(WORSEN)] (43)	20[redacted] (672)/ 20[redacted] (672) [1]	Grade 3: Severe or medically significant	Dose Not Changed	Possibly Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	心臓障害/ 冠動脈硬化症/ [CORONARY ARTERIOSCLEROTIC CARDIOPATHY] (10)	20[redacted] (65)/ 20[redacted] (71) [7]	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (19)	20[redacted] (263)/ 20[redacted] (282) [20]	Grade 3: Severe or medically significant	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2
	心臓障害/ 冠動脈疾患/ [CORONARY HEART DISEASE WORSENING] (24)	20[redacted] (435)/ 20[redacted] (437) [3]	Grade 3: Severe or medically significant	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	眼障害/ 白内障/ [CATARACT (RIGHT EYE)] (3)	20[redacted] (124)/ 20[redacted] (124) [1]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (11)	20[redacted] (98)/ 20[redacted] (119) [22]	Grade 3: Severe or medically significant	Drug Interrupted	Possibly Related	Recovered/ Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (7)	20[redacted] (114)/ ONGOING	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 四肢膿瘍/ [LEFT HAND ABSCESS] (14)	20[redacted] (432)/ 20[redacted] (439) [8]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY TRACT INFECTION] (3)	20[redacted] (18)/ 20[redacted] (26) [9]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
	眼障害/ 黄斑変性/ [BINOCULAR MACULAR DEGENERATION] (15)	20[redacted] (151)/ ONGOING	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Not recovered/ Not resolved		2
	神経系障害/ 失神/ [SYNCOPE] (30)	20[redacted] (418)/ 20[redacted] (418) [1]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		3
	感染症および寄生虫症/ 肺炎/ [COMMUNITY ACQUIRED PNEUMONIA] (32)	20[redacted] (422)/ ONGOING	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ ワルデンストローム・マクログロブリン血症 c/ [PROGRESSION OF WALDENSTROM MACROGLOBULINEMIA] (15)	20[redacted] (113)/ 20[redacted] (161) [49]	Grade 3: Severe or medically significant	Drug Withdrawn	Not Related	Not recovered/ Not resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ ワルデンストローム・マクログロブリン血症 [c] [d]/ [PROGRESSION OF WALDENSTROM MACROGLOBULINEMIA] (17)	20[redacted] (161)/ 20[redacted] (161) [1]	Grade 5: Death related to AE	Not Applicable	Not Related	Fatal		4
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (13)	20[redacted] (10)/ 20[redacted] (24) [15]	Grade 3: Severe or medically significant	Drug Interrupted	Not Related	Recovering/ Resolving		2
	胃腸障害/ 上部消化管出血/ [UPPERGASTROINTESTINAL BLEEDING] (16)	20[redacted] (68)/ ONGOING	Grade 3: Severe or medically significant	Drug Interrupted	Probably Related	Not recovered/ Not resolved		2
	一般・全身障害および投与部位の状態/ 死亡/ [DEATH WITH UNKNOW REASON] (17)	20[redacted] (98)/ 20[redacted] (98) [1]	Grade 5: Death related to AE	Not Applicable	Unlikely Related	Fatal		4
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	呼吸器、胸郭および縦隔障害/ 胸水/ [PLEURAL EFFUSION] (8)	20[redacted] (582)/ ONGOING	Grade 3: Severe or medically significant	Not Applicable	Not Related	Recovering/ Resolving		2
	神経系障害/ ヘルペス後神経痛/ [POSTHERPETIC NEURALGIA] (9)	20[redacted] (582)/ 20[redacted] (599) [18]	Grade 3: Severe or medically significant	Not Applicable	Not Related	Recovered/ Resolved with sequelae		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (19)	20[redacted] (301)/ 20[redacted] (306) [6]	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (24)	20[redacted] (473)/ 20[redacted] (481) [9]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (27)	20[redacted] (544)/ 20[redacted] (558) [15]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 精巣上体炎/ [EPIDIDYMITIS] (33)	20[redacted] (727)/ 20[redacted] (738) [12]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovering/ Resolving		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	傷害、中毒および処置合併症/ 骨折/ [BONE FRACTURE] (11)	20[redacted] (572)/ 20[redacted] (585) [14]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovering/ Resolving		2
	傷害、中毒および処置合併症/ 骨折/ [BONE FRACTURE] (16)	20[redacted] (615)/ 20[redacted] (626) [12]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovering/ Resolving		2
	傷害、中毒および処置合併症/ 骨折/ [BONE FRACTURE] (20)	20[redacted] (646)/ 20[redacted] (663) [18]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovering/ Resolving		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	血管障害/ 高血圧/ [HYPERTENSION] (25)	20[redacted] (695)/ 20[redacted] (701) [7]	Grade 3: Severe or medically significant	Dose Not Changed	Possibly Related	Recovering/ Resolving		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted]/ 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 喉頭癌/ [LARYNGOCARCINOMA] (5)	20[redacted] (78)/ ONGOING	Grade 4: Life-threatening or disabling	Drug Withdrawn	Not Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 上気道感染/ [ACUTE UPPER RESPIRATORY INFECTION(AESI)] (24)	20[redacted] (989)/ 20[redacted] (1000) [12]	Grade 3: Severe or medically significant	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺真菌症/ [PULMONARY FUNGAL INFECTION] (2)	20[redacted] (285)/ 20[redacted] (308) [24]	Grade 1: Mild	Dose Not Changed	Not Related	Not recovered/ Not resolved		2
	感染症および寄生虫症/ 肺真菌症/ [PULMONARY FUNGAL INFECTION] (3)	20[redacted] (308)/ ONGOING	Grade 3: Severe or medically significant	Not Applicable	Possibly Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted]/ 160 mg BID	筋骨格系および結合組織障害/ 滑液嚢腫/ [GANGLION CYST] (5)	20[redacted] (71)/ 20[redacted] (74) [4]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 急性 B 型肝炎/ [ACUTE HEPATITIS B] (8)	20[redacted] (300)/ 20[redacted] (302) [3]	Grade 5: Death related to AE	Drug Withdrawn	Related	Fatal		2, 4
	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ [MULTIPLE ORGAN FAILURE] (9)	20[redacted] (300)/ 20[redacted] (302) [3]	Grade 5: Death related to AE	Drug Withdrawn	Related	Fatal		2, 4

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (2)	20[redacted] (8)/ 20[redacted] (11) [4]	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 皮膚感染/ [HEAD SKIN INFECTION] (2)	20[redacted] (51)/ 20[redacted] (103) [53]	Grade 3: Severe or medically significant	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2
	神経系障害/ 頭蓋内腫瘤/ [INTRACRANIAL MASS(ETIOLOGY UNKNOWN)] (3)	20[redacted] (74)/ ONGOING	Grade 3: Severe or medically significant	Drug Withdrawn	Unlikely Related	Recovering/ Resolving		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (4)	20[redacted] (16)/ 20[redacted] (43) [28]	Grade 3: Severe or medically significant	Drug Interrupted	Probably Related	Recovering/ Resolving		2
	傷害、中毒および処置合併症/ 脊椎圧迫骨折/ [COMPRESSION FRACTURE OF THORACOLUMBAR VERTEBRAL BODY(NEW AND OLD)] (7)	20[redacted] (17)/ 20[redacted] (43) [27]	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovering/ Resolving		2
	胃腸障害/ 細菌叢異常/ [ALTERATION OF INTESTINAL FLORA] (10)	20[redacted] (23)/ 20[redacted] (31) [9]	Grade 3: Severe or medically significant	Not Applicable	Not Related	Recovered/ Resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (12)	20[redacted] (67)/ 20[redacted] (143) [77]	Grade 2: Moderate	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺の悪性新生物/ [LEFT LOWER LUNG CANCER] (22)	20[redacted] (424)/ 20[redacted] (427) [4]	Grade 3: Severe or medically significant	Drug Interrupted	Unlikely Related	Recovered/ Resolved		2
	呼吸器、胸郭および縦隔障害/ 胸水/ [PLEURAL EFFUSION (LEFT, PLEURAL EFFUSION BESIDE PNEUMONIA)] (40)	20[redacted] (810)/ ONGOING	Grade 2: Moderate	Dose Not Changed	Possibly Related	Recovering/ Resolving		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION (AESI)] (4)	20[redacted] (5)/ 20[redacted] (13) [9]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
	臨床検査/ 血小板数減少/ [PLATELET COUNT DECREASED] (17)	20[redacted] (26)/ 20[redacted] (28) [3]	Grade 4: Life-threatening or disabling	Drug Interrupted	Related	Recovering/ Resolving		2
	感染症および寄生虫症/ 皮膚感染/ [SKIN INFECTION] (26)	20[redacted] (51)/ 20[redacted] (60) [10]	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (39)	20[redacted] (147)/ ONGOING	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Not recovered/ Not resolved		2
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (1)	20[redacted] (-11)/ 20[redacted] (1) [12]	Grade 3: Severe or medically significant	Not Applicable	Not Related	Recovered/ Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Patient: [redacted]								
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (14)	20[redacted] (88)/ 20[redacted] (99) [12]	Grade 3: Severe or medically significant	Drug Interrupted	Possibly Related	Recovered/ Resolved		2
	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (24)	20[redacted] (171)/ 20[redacted] (195) [25]	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovering/ Resolving		2

Source: Listing 16.2.7.2 in BGB-3111-210 clinical study report. Data cutoff: 11JAN2021; Data extraction: [redacted] 20[redacted]; Data Source: ADAE, EC.
Abbreviations: AE, adverse event; AESI, adverse event of special interest; BID, twice a day; NCI-CTCAE, National Cancer Institute-Common Terminology Criteria for Adverse Events.
[a] AE Association: 1 - Persistent or significant disability or incapacity, 2 - Congenital anomaly or birth defect.
[b] AE Resulted In: 1- Important medical event, 2 - Hospitalization, 3 - Life Threatening, 4 - Death.
[c] This patient ([redacted] discontinued study treatment and subsequently died due to "progression of Waldenstrom's Macroglobulinemia" that was reported as an adverse event.
[d] indicates the AE occurred > 30 days after the last dose of study drug or after initiation of new anticancer therapy, whichever came first, for discontinued patients.
Adverse event grades are evaluated based on NCI-CTCAE (Version 4.03). MedDRA Version: 23.0.

表 44： 重篤な有害事象の一覧（BGB-3111-1002 試験、安全性解析対象集団）

Patient ID	Diag-nosis	AE No\ Treatment Emergent	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
Treatment: Zanubrutinib 160 mg BID (Part I)						
[redacted]	NHL	21\Yes	[redacted]20[redacted] (45)\ [redacted]20[redacted] (140)\ 96	TOXIC EPIDERMAL NECROLYSIS \ 中毒性表皮壊死融解症\ 皮膚および皮下組織障害	5\ Possibly Related	Drug Withdrawn\ Hospitalization Or Prolonged Hospitalization\ Fatal
[redacted]	CLL/SLL	19\Yes	[redacted]20[redacted] (737)\ [redacted]20[redacted] (780)\ 44	RIGHT MIDDLE EAR CHOLESTEROL GRANULOMA \ 中耳のコレステリン肉芽腫\ 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3\ Unlikely Related	Drug Interrupted\ Multiple\ Recovered/Resolved
Treatment: Zanubrutinib 320 mg QD (Part I)						
[redacted]	CLL/SLL	12\Yes	[redacted]20[redacted] (170)\ [redacted]20[redacted] (170)\ 1	NEUTROPHIL COUNT DECREASED \ 好中球数減少\ 臨床検査	4\ Possibly Related	Drug Interrupted\ Hospitalization Or Prolonged Hospitalization\ Recovering/Resolving
		14\Yes	[redacted]20[redacted] (170)\ [redacted]20[redacted] (171)\ 2	NEUTROPHIL COUNT DECREASED \ 好中球数減少\ 臨床検査	3\ Possibly Related	Dose Not Changed\ -\ Recovering/Resolving
		16\Yes	[redacted]20[redacted] (171)\ [redacted]20[redacted] (175)\ 5	NEUTROPHIL COUNT DECREASED \ 好中球数減少\ 臨床検査	2\ Possibly Related	Dose Not Changed\ -\ Recovered/Resolved
[redacted]	NHL	20\Yes	[redacted]20[redacted] (215)\ [redacted]20[redacted] (222)\ 8	FEBRILE NEUTROPENIA \ 発熱性好中球減少症\ 血液およびリンパ系障害	3\ Related	Drug Interrupted\ Hospitalization Or Prolonged Hospitalization\ Recovered/Resolved

Patient ID	Diag-nosis	AE No\ Treatment Emergent	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		21\Yes	[redacted]20[redacted] (216)\ [redacted]20[redacted] (218)\ 3	PLATELET COUNT DECREASED \ 血小板数減少\ 臨床検査	3\ Possibly Related	Dose Not Changed\ Hospitalization Or Prolonged Hospitalization\ Not Recovered/Not Resolved
		22\Yes	[redacted]20[redacted] (218)\ [redacted]20[redacted] (219)\ 2	PLATELET COUNT DECREASED \ 血小板数減少\ 臨床検査	4\ Possibly Related	Dose Not Changed\ Hospitalization Or Prolonged Hospitalization\ Recovering/Resolving
		23\Yes	[redacted]20[redacted] (219)\ [redacted]20[redacted] (222)\ 4	PLATELET COUNT DECREASED \ 血小板数減少\ 臨床検査	3\ Possibly Related	Dose Not Changed\ Hospitalization Or Prolonged Hospitalization\ Recovering/Resolving
		26\Yes	[redacted]20[redacted] (222)\ [redacted]20[redacted] (225)\ 4	PLATELET COUNT DECREASED \ 血小板数減少\ 臨床検査	2\ Possibly Related	Dose Not Changed\ -\ Recovered/Resolved
Treatment: Zanubrutinib 160 mg BID (Part II)						
[redacted]	FL	7\Yes	[redacted]20[redacted] (225)\ [redacted]20[redacted] (225)\ 1	INDUCED ABORTION \ 人工流産\ 外科および内科処置	-\ Unlikely Related	Drug Withdrawn\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	FL	8\Yes	[redacted]20[redacted] (257)\ [redacted]20[redacted] (272)\ 16	LUMBAR DISC HERNIATION(PAIN GRADE 3) \ 椎間板突出\ 筋骨格系および結合組織障害	3\ Not Related	Dose Not Changed\ Other\ Recovered/Resolved
		18\Yes	[redacted]20[redacted] (451)\ [redacted]20[redacted] (505)\ 55	HYPERGLYCEMIA \ 高血糖\ 代謝および栄養障害	2\ Possibly Related	Dose Not Changed\ -\ Recovered/Resolved

Patient ID	Diag-nosis	AE No\ Treatment Emergent	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
[redacted]	MZL	4\Yes	[redacted]20[redacted] (43)\ [redacted]20[redacted] (65)\ 23	ANEMIA \ 貧血\ 血液およびリンパ系障害	3\ Possibly Related	Drug Interrupted\ Multiple\ Recovering/Resolving
		6\Yes	[redacted]20[redacted] (62)\ Ongoing\ -	FATIGUE \ 疲労\ 一般・全身障害および投与部位の状態	3\ Unlikely Related	Not Applicable\ Hospitalization Or Prolonged Hospitalization\ Recovering/Resolving
[redacted]	FL	3\Yes	[redacted]20[redacted] (264)\ [redacted]20[redacted] (264)\ 1	CERVICAL LYMPH GLAND SWOLLEN \ リンパ節症\ 血液およびリンパ系障害	-\ Not Related	Not Applicable\ Non-Medication Concomitant Therapy Or Procedure\ Recovered/Resolved
[redacted]	FL	28\No	[redacted]20[redacted] (378)\ Ongoing\ -	RETINOPATHY(RIGHT EYE) \ 網膜症\ 眼障害	4\ Possibly Related	Not Applicable\ None\ Not Recovered/Not Resolved
[redacted]	FL	14\Yes	[redacted]20[redacted] (9)\ [redacted]20[redacted] (36)\ 28	ASCITES \ 腹水\ 胃腸障害	2\ Unlikely Related	Dose Not Changed\ Multiple\ Recovering/Resolving
		15\Yes	[redacted]20[redacted] (9)\ Ongoing\ -	PLEURAL EFFUSION \ 胸水\ 呼吸器、胸郭および縦隔障害	2\ Unlikely Related	Dose Not Changed\ Multiple\ Not Recovered/Not Resolved
		16\Yes	[redacted]20[redacted] (9)\ [redacted]20[redacted] (29)\ 21	PLEURAL INFECTION \ 胸膜感染\ 感染症および寄生虫症	3\ Unlikely Related	Dose Not Changed\ Hospitalization Or Prolonged Hospitalization\ Recovered/Resolved

Patient ID	Diag-nosis	AE No\ Treatment Emergent	AE Start Date (Study Day)\ AE End Date (Study Day)\ Duration (Days)	AE Term\ Preferred Term\ System Organ Class	AE Tox Grade\ AE Relationship	Action with Study Treatment\ Other Action\ AE Outcome
		22\Yes	[redacted]20[redacted] (12)\ Ongoing\ -	LUNG INFECTION (BACTERIAL FUNGAL MIXED INFECTION) \ 肺炎\ 感染症および寄生虫症	3\ Unlikely Related	Dose Not Changed\ Hospitalization Or Prolonged Hospitalization\ Not Recovered/Not Resolved
		25\No	[redacted]20[redacted] (36)\ Ongoing\ -	ASCITES \ 腹水\ 胃腸障害	1\ Unlikely Related	Not Applicable\ -\ Not Recovered/Not Resolved

Source: Listing 16.2.7.1.2 in BGB-3111-1002 clinical study report. Data cutoff: [redacted]20[redacted]; Data extraction: 15OCT2020; Data Source: ADAE

表 45： 重篤な有害事象の一覧（BGB-3111-206 試験、安全性解析対象集団）

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In[b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
傷害、中毒および処置合併症/ 交通事故/ [DEATH (CAR ACCIDENT)] (2)	20[redacted] (149)/ 20[redacted] (149) [1]	Yes	Grade 5: Death related to AE	Drug Withdrawn/ None	Not Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 尿路感染/ [URINARY TRACT INFECTION WITH ACUTE ATTACK] (6)	20[redacted] (29)/ 20[redacted] (40) [12]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Possibly Related	Recovering/ Resolving		2
感染症および寄生虫症/ 感染/ [INFECTION (NOS)] (9)	20[redacted] (53)/ ONGOING	Yes	Grade 4: Life-threatening or disabling	Drug Withdrawn/ None	Possibly Related	Not Recovered/ Not Resolved		3
一般・全身障害および投与部位の状態/ 死亡/ [DEATH WITH UNKNOWN REASON] (10)	20[redacted] (56)/ 20[redacted] (56) [1]	Yes	Grade 5: Death related to AE	Not Applicable/ None	Possibly Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
傷害、中毒および処置合併症/ 上腕骨骨折/ [LEFT HUMERAL FRACTURE] (8)	20[redacted] (156)/ 20[redacted] (364) [209]	Yes	Grade 3: Severe or medically significant	Dose Not Changed/ Non-Medication Concomitant Therapy Or Procedure	Not Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
呼吸器、胸郭および縦隔障害/ 間質性肺疾患/ [RESPIRATORY SYSTEM, CHEST, AND MEDIASTINAL DISEASE - INTERSTITIAL PNEUMONIA] (7)	20[redacted] (164)/ 20[redacted] (184) [21]	Yes	Grade 3: Severe or medically significant	Drug Withdrawn	Possibly Related	Recovering/ Resolving		2

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
感染症および寄生虫症/ 真菌性肺炎/ [FUNGAL PNEUMONIA] (10)	20[redacted] (198)/ 20[redacted] (227) [30]	Yes	Grade 3: Severe or medically significant	Not Applicable	Unlikely Related	Not Recovered/ Not Resolved		2
感染症および寄生虫症/ 真菌性肺炎/ [FUNGAL PNEUMONIA] (11)	20[redacted] (227)/ 20[redacted] (236) [10]	No	Grade 4: Life-threatening or disabling	Not Applicable/ Other: NONINVASIVE VENTILATOR/ BLOOD TRANSFUSION /NUTRITIONAL SUPPORT	Unlikely Related	Not Recovered/ Not Resolved		3
感染症および寄生虫症/ 真菌性肺炎/ [FUNGAL PNEUMONIA] (12)	20[redacted] (236)/ 20[redacted] (236) [1]	Yes	Grade 5: Death related to AE	Not Applicable/ None	Unlikely Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
神経系障害/ 脳虚血/ [CEREBRAL ISCHEMIA] (6)	20[redacted] (159)/ 20[redacted] (166) [8]	Yes	Grade 4: Life-threatening or disabling	Drug Interrupted	Unlikely Related	Recovering/ Resolving		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
神経系障害/ 一過性脳虚血発作/ [TRANSIENT ISCHEMIC ATTACKS] (19)	20[redacted] (458)/ 20[redacted] (464) [7]	Yes	Grade 1: Mild	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 気管支炎/ [ACUTE BRONCHITIS] (6)	20[redacted] (948)/ 20[redacted] (952) [5]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
感染症および寄生虫症/ 上気道感染/ [ACUTE UPPER RESPIRATORY INFECTION] (7)	20[redacted] (948)/ 20[redacted] (952) [5]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In[b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
胃腸障害/ 上部消化管出血/ [UPPER GASTROINTESTINAL HEMORRHAGE] (17)	20[redacted] (430)/ 20[redacted] (438) [9]	Yes	Grade 2: Moderate	Drug Interrupted	Not Related	Recovered/ Resolved With Sequelae		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (6)	20[redacted] (25)/ ONGOING	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Unknown		2
一般・全身障害および投与部位の状態/ 死亡/ [DEATH (THE CAUSE OF THE DEATH IS UNKNOWN)] (8)	20[redacted] (53)/ 20[redacted] (53) [1]	No	Grade 5: Death related to AE	Not Applicable/ None	Not Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION(NO FURTHER INFO)] (22)	20[redacted] (145)/ 20[redacted] (257) [113]	Yes	Grade 3: Severe or medically significant	Drug Interrupted	Possibly Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
神経系障害/ 脳出血/ [CEREBRAL HEMORRHAGE] (1)	20[redacted] (7)/ 20[redacted] (8) [2]	Yes	Grade 4: Life-threatening or disabling	Drug Interrupted/ Non-Medication Concomitant Therapy Or Procedure	Possibly Related	Not Recovered/ Not Resolved		3
神経系障害/ 脳出血/ [CEREBRAL HEMORRHAGE] (2)	20[redacted] (8)/ 20[redacted] (8) [1]	Yes	Grade 5: Death related to AE	Drug Withdrawn/ None	Possibly Related	Fatal		4

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (16)	20[redacted] (86)/ 20[redacted] (111) [26]	Yes	Grade 4: Life-threatening or disabling	Dose Not Changed/ None	Possibly Related	Not Recovered/ Not Resolved		2
感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (19)	20[redacted] (111)/ 20[redacted] (111) [1]	Yes	Grade 5: Death related to AE	Not Applicable/ None	Possibly Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
臨床検査/ 血小板数減少/ [PLATELET COUNT DECREASED] (5)	20[redacted] (280)/ ONGOING	Yes	Grade 4: Life-threatening or disabling	Drug Interrupted/ Non-Medication Concomitant Therapy Or Procedure	Possibly Related	Not Recovered/ Not Resolved		2
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (6)	20[redacted] (283)/ ONGOING	Yes	Grade 2: Moderate	Not Applicable	Probably Related	Not Recovered/ Not Resolved		2
一般・全身障害および投与部位の状態/ 死亡/ [DEATH WITH UNKNOWN REASON] (13)	20[redacted] (300)/ 20[redacted] (300) [1]	Yes	Grade 5: Death related to AE	Drug Withdrawn/ None	Possibly Related	Fatal		4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (11)	20[redacted] (786)/ ONGOING	Yes	Grade 3: Severe or medically significant	Not Applicable	Possibly Related	Not Recovered/ Not Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
臨床検査/ 血小板数減少/ [PLATELET COUNT DECREASED] (6)	20[redacted] (300)/ ONGOING	Yes	Grade 3: Severe or medically significant	Drug Interrupted/ Drug Withdrawn	Possibly Related	Unknown		2

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (25)	20[redacted] (5)/ ONGOING	Yes	Grade 3: Severe or medically significant	Drug Interrupted/ Drug Withdrawn	Possibly Related	Unknown		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
血液およびリンパ系障害/ 骨髄壊死/ [BONE MARROW NECROSIS] (11)	20[redacted] (575)/ 20[redacted] (594) [20]	Yes	Grade 5: Death related to AE	Not Applicable	Unlikely Related	Fatal		2, 4
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION (FUNGAL INFECTION POSSIBILITY)(AESI)] (16)	20[redacted] (256)/ 20[redacted] (281) [26]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (27)	20[redacted] (499)/ 20[redacted] (562) [64]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (38)	20[redacted] (840)/ 20[redacted] (869) [30]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
血液およびリンパ系障害/ 貧血/ [ANEMIA] (9)	20[redacted] (20)/ 20[redacted] (24) [5]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [LUNG INFECTION (FUNGAL INFECTION POSSIBILITY)(AESI)] (10)	20[redacted] (258)/ 20[redacted] (283) [26]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
感染症および寄生虫症/ クレブシエラ菌性肺炎/ [LUNG INFECTION (KLEBSIELLA PNEUMONIA)] (20)	20[redacted] (693)/ 20[redacted] (731) [39]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (10)	20[redacted] (505)/ 20[redacted] (581) [77]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Not Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
腎および尿路障害/ 尿管結石症/ [URETERAL CALCULI] (22)	20[redacted] (773)/ 20[redacted] (806) [34]	Yes	Grade 3: Severe or medically significant	Dose Not Changed/ Non-Medication Concomitant Therapy Or Procedure	Unlikely Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
臨床検査/ 好中球数減少/ [NEUTROPHIL COUNT DECREASED] (10)	20[redacted] (281)/ 20[redacted] (293) [13]	Yes	Grade 3: Severe or medically significant	Dose Not Changed	Possibly Related	Recovered/ Resolved		2

System Organ Class/ AE Preferred Term/ [AE Term] (AE Sequence Number)	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	TEAE?	AE Toxicity Grade	Action Taken	AE Relationship	AE Outcome	AE Assoc. [a]	AE Resulted In [b]
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
胃腸障害/ 上部消化管出血/ [UPPER GASTROINTESTINAL HEMORRHAGE] (24)	20[redacted]-[redacted]-[redacted] (495)/ 20[redacted]-[redacted]-[redacted] (499) [5]	Yes	Grade 2: Moderate	Dose Not Changed	Unlikely Related	Recovered/ Resolved		2
胃腸障害/ 胃腸出血/ [GASTROINTESTINAL BLEEDING] (27)	20[redacted]-[redacted]-[redacted] (526)/ 20[redacted]-[redacted]-[redacted] (530) [5]	Yes	Grade 2: Moderate	Dose Not Changed	Possibly Related	Recovered/ Resolved		2
Subject: [redacted] (Treatment Start Date: [redacted] 20[redacted]; Prescribed Dose: 160 mg BID)								
感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION (SEVERE PULOMNARY INFECTION)] (6)	20[redacted]-[redacted]-[redacted] (9)/ ONGOING	Yes	Grade 3: Severe or medically significant	Drug Interrupted/ Drug Withdrawn	Unlikely Related	Recovering/ Resolving		2

Source: Listing 16.2.7.4 in BGB-3111-206 clinical study report. Data cutoff: 08SEP2020; Data extraction: [redacted] 20[redacted]; Data Source: ADAE, AE
[a] AE Association: 1 - Persistent or significant disability or incapacity, 2 - Congenital anomaly or birth defect
[b] AE Resulted In: 1 - Important medical event, 2 - Hospitalization, 3 - Life Threatening, 4 - Death

表 46： 重篤な有害事象の一覧（BGB-3111-214 試験、安全性解析対象集団）

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/6[redacted]/M	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	[redacted]20[redacted] (468)/ 20[redacted] (488)	Y/5/ Not Related	Multiple (Drug Withdrawn, Drug Interrupted)/ Fatal	2	Y	Y
[redacted]/7[redacted]/M	感染症および寄生虫症/ インフルエンザ/ INFLUENZA A INFECTION	[redacted]20[redacted] (189)/ 20[redacted] (193)	Y/3/ Not Related	Not Applicable/ Recovered/Resolved	2	Y	N
[redacted]/8[redacted]/M	感染症および寄生虫症/ 肺炎/ PNEUMONIA	[redacted]20[redacted] (655)/ 20[redacted] (661)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
[redacted]/5[redacted]/M	血液およびリンパ系障害/ 貧血/ ANEMIA	[redacted]20[redacted] (100)/ 20[redacted] (106)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	1,2	Y	N
	神経系障害/ 坐骨神経痛/ SCIATICA	[redacted]20[redacted] (294)/ 20[redacted] (321)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
	血液およびリンパ系障害/ 汎血球減少症/ FEBRILE TRICYTOPENIA	[redacted]20[redacted] (429)/ 20[redacted] (471)	Y/3/ Related	Drug Interrupted/ Not Recovered/Not Resolved	1,2	N	N
	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	[redacted]20[redacted] (448)/ 20[redacted] (471)	Y/5/ Not Related	Drug Withdrawn/ Fatal	2,3	Y	Y
[redacted]/8[redacted]/M	胃腸障害/ 糞塊/ FECAL IMPACTION	[redacted]20[redacted] (858)/ 20[redacted] (866)	Y/4/ Not Related	Not Applicable/ Recovered/Resolved		N	N
[redacted]/7[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ FEVER	[redacted]20[redacted] (80)/ 20[redacted] (91)	Y/1/ Related	Dose Not Changed/ Recovered/Resolved	2,4	N	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	[redacted] (456)/ [redacted] (509)	Y/4/ Not Related	Drug Interrupted/ Recovered/Resolved	2	N	N
[redacted]/5[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 甲状腺乳頭癌/ PAPILLARY THYROID CANCER	[redacted] (108)/ [redacted] (125)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	3	Y	N
[redacted]/6[redacted]/F	感染症および寄生虫症/ COVID-19肺炎/ BILATERAL INTERSTITIAL PNEUMONIA DUE TO COVID-19 (CORONAVIRUS)	[redacted] (130)/ [redacted] (157)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	Y	Y
[redacted]/5[redacted]/F	感染症および寄生虫症/ 気管支炎/ BRONCHITIS	[redacted] (57)/ [redacted] (71)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	Y	N
	感染症および寄生虫症/ 副鼻腔炎/ SINUSITIS	[redacted] (57)/ [redacted] (71)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
[redacted]/7[redacted]/M	感染症および寄生虫症/ COVID-19肺炎/ COVID 19 PNEUMONIA	[redacted] (729)/ [redacted] (754)	Y/4/ Not Related	Drug Interrupted/ Recovered/Resolved with Sequelae	3	Y	Y
[redacted]/8[redacted]/M	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	[redacted] (40)/ [redacted] (41)	Y/2/ Not Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
	神経系障害/ 失神/ SYNCOPE	[redacted] (40)/ [redacted] (41)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved		N	N
	心臓障害/ 狭心症/ CARDIAC CHEST PAIN	[redacted] (440)/ [redacted] (441)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved		N	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
	心臓障害/ 狭心症/ CARDIAC CHEST PAIN	[redacted]20[redacted] (451)/ 20[redacted] (458)	Y/3/ Not Related	Not Applicable/ Recovered/Resolved	2	N	N
	一般・全身障害および投与部位の状態/ 無力症/ FRAILTY	[redacted]20[redacted] (470)/ Ongoing	Y/3/ Not Related	Not Applicable/ Not Recovered/Not Resolved		N	N
[redacted]/5[redacted]/M	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	[redacted]20[redacted] (91)/ 20[redacted] (103)	Y/3/ Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 急性骨髄性白血病/ ACUTE MYELOID LEUKEMIA	[redacted]20[redacted] (503)/ 20[redacted] (503)	Y/5/ Not Related	Dose Not Changed/ Fatal	1,2	Y	N
[redacted]/7[redacted]/M	代謝および栄養障害/ 高カリウム血症/ HYPERKALEMIA WORSENING	[redacted]20[redacted] (15)/ 20[redacted] (16)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
	感染症および寄生虫症/ 扁桃炎/ TONSILLITIS	[redacted]20[redacted] (42)/ 20[redacted] (48)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
	代謝および栄養障害/ 高カリウム血症/ HYPERKALAEMIA WORSENING	[redacted]20[redacted] (113)/ 20[redacted] (113)	Y/4/ Not Related	Drug Interrupted/ Recovered/Resolved	2	N	N
	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	[redacted]20[redacted] (599)/ 20[redacted] (607)	Y/2/ Not Related	Dose Not Changed/ Recovered/Resolved	2,4	Y	N
	胃腸障害/ 大腸閉塞/ COLONIC OBSTRUCTION	[redacted]20[redacted] (925)/ 20[redacted] (928)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	3	N	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/7[redacted]/M	腎および尿路障害/ 急性腎障害/ ACUTE KIDNEY INJURY	[redacted]20[redacted] (15)/ 20[redacted] (16)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved with Sequelae		N	N
	呼吸器、胸郭および縦隔障害/ 器質化肺炎/ EXACERBATION OF CRYPTOGENIC ORGANISING PNEUMONIA	[redacted]20[redacted] (15)/ 20[redacted] (29)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	N	N
	腎および尿路障害/ 急性腎障害/ ACUTE KIDNEY INJURY	[redacted]20[redacted] (43)/ 20[redacted] (46)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	N	N
	感染症および寄生虫症/ RSウイルス感染/ RSV LUNG INFECTION	[redacted]20[redacted] (53)/ 20[redacted] (59)	Y/3/ Not Related	Not Applicable/ Recovered/Resolved with Sequelae	2	Y	N
[redacted]/7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 再発膀胱癌/ RECURRENT BLADDER CANCER	[redacted]20[redacted] (199)/ 20[redacted] (757)	Y/3/ Not Related	Dose Not Changed/ Not Recovered/Not Resolved	3	Y	N
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATE CANCER	[redacted]20[redacted] (610)/ 20[redacted] (610)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	3	Y	N
[redacted]/7[redacted]/M	感染症および寄生虫症/ 下気道感染/ CHEST INFECTION	[redacted]20[redacted] (711)/ 20[redacted] (718)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	Y	N
	感染症および寄生虫症/ 敗血症性脳症/ SEPSIS ASSOCIATED ENCEPHALOPATHY	[redacted]20[redacted] (724)/ 20[redacted] (757)	Y/5/ Not Related	Drug Withdrawn/ Fatal	2	Y	N
[redacted]/6[redacted]/M	心臓障害/ 心房細動/ RAPID ATRIAL FIBRILLATION	[redacted]20[redacted] (358)/ 20[redacted] (359)	Y/3/ Not Related	Not Applicable/ Recovered/Resolved	2	Y	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/5[redacted]/F	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ BILATERAL PULMONARY EMBOLISM	[redacted]20[redacted] (847)/ 20[redacted] (850)	Y/3/ Not Related	Dose Not Changed/ Recovering/Resolving	2,3	N	N
	胃腸障害/ 胃腸出血/ GASTROINTESTINAL BLEEDING	[redacted]20[redacted] (862)/ 20[redacted] (867)	Y/3/ Related	Dose Not Changed/ Recovered/Resolved	1,2,3	Y	N
	感染症および寄生虫症/ 腎盂腎炎/ PYELONEPHRITIS	[redacted]20[redacted] (862)/ 20[redacted] (867)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	Y	N
	感染症および寄生虫症/ 蜂巣炎/ RIGHT LOWER LIMB CELLULITIS	[redacted]20[redacted] (884)/ 20[redacted] (895)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2,3	Y	N
[redacted]/5[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ NON-NEUTROPENIC FEVER	[redacted]20[redacted] (91)/ 20[redacted] (93)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
	一般・全身障害および投与部位の状態/ 発熱/ NON NEUTROPENIC FEVER	[redacted]20[redacted] (105)/ 20[redacted] (112)	Y/3/ Not Related	Drug Withdrawn/ Recovered/Resolved		N	N
	一般・全身障害および投与部位の状態/ 発熱/ NON- NEUTROPENIC FEVER ATTRIBUTED TO TRANSFORMATION OF MARGINAL ZONE LYMPHOMA AND CONCURRENT DIAGNOSIS OF HODGKINS LYMPHOMA	[redacted]20[redacted] (133)/ 20[redacted] (162)	Y/3/ Not Related	Drug Withdrawn/ Recovered/Resolved with Sequelae		N	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/7[redacted]/F	胃腸障害/ 小腸閉塞/ SMALL BOWEL OBSTRUCTION	[redacted]20[redacted] (9)/ [redacted]20[redacted] (13)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	N	N
	一般・全身障害および投与部位の状態/ 発熱/ NON-NEUTROPENIC FEVER	[redacted]20[redacted] (114)/ [redacted]20[redacted] (132)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
[redacted]/7[redacted]/F	胃腸障害/ 上腹部痛/ R UPPER QUADRANT PAIN	[redacted]20[redacted] (2)/ [redacted]20[redacted] (3)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2	N	N
	肝胆道系障害/ 胆管結石/ CHOLEDOCHOLITHIASIS	[redacted]20[redacted] (370)/ [redacted]20[redacted] (386)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2,3	N	N
	心臓障害/ 冠動脈狭窄/ RIGHT CORONARY ARTERY STENOSIS	[redacted]20[redacted] (375)/ [redacted]20[redacted] (386)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	N	N
[redacted]/8[redacted]/M	傷害、中毒および処置合併症/ 転倒/ FALL	[redacted]20[redacted] (275)/ [redacted]20[redacted] (275)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved with Sequelae	3	N	N
	胃腸障害/ 嚥下障害/ DYSPHAGIA	[redacted]20[redacted] (523)/ [redacted]20[redacted] (526)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	N	N
	神経系障害/ 失神/ SYNCOPE	[redacted]20[redacted] (523)/ [redacted]20[redacted] (548)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved	2,3	N	N
[redacted]/7[redacted]/M	胃腸障害/ 胃食道逆流性疾患/ WORSENING OF GORD	[redacted]20[redacted] (385)/ [redacted]20[redacted] (386)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2,3	N	N
	神経系障害/ 小脳梗塞/ ACUTE CEREBELLAR INFARCTION	[redacted]20[redacted] (734)/ [redacted]20[redacted] (771)	Y/3/ Not Related	Drug Interrupted/ Recovered/Resolved with Sequelae	2,4	N	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/8[redacted]/M	傷害、中毒および処置合併症/ 寛骨臼骨折/ RIGHT ACETABULAR COLUMN FRACTURE	[redacted] 20[redacted] (35)/ 20[redacted] (39)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
	傷害、中毒および処置合併症/ 骨盤骨折/ RIGHT INFERIOR PUBIS RAMUS FRACTURE	[redacted] 20[redacted] (35)/ 20[redacted] (39)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
[redacted]/6[redacted]/F	心臓障害/ 心房粗動/ ATRIAL FLUTTER	[redacted] 20[redacted] (238)/ 20[redacted] (238)	Y/2/ Related	Dose Not Changed/ Recovered/Resolved	2,3	Y	N
	一般・全身障害および投与部位の状態/ 胸痛/ ATYPICAL CHEST PAIN UNKNOWN ETIOLOGY	[redacted] 20[redacted] (266)/ 20[redacted] (267)	Y/2/ Not Related	Dose Not Changed/ Recovered/Resolved	3	N	N
[redacted]/7[redacted]/F	傷害、中毒および処置合併症/ 転倒/ FALL	[redacted] 20[redacted] (47)/ 20[redacted] (47)	Y/2/ Not Related	Dose Not Changed/ Recovered/Resolved with Sequelae		N	N
	傷害、中毒および処置合併症/ 上腕骨骨折/ HUMERAL FRACTURE	[redacted] 20[redacted] (47)/ 20[redacted] (85)	Y/2/ Not Related	Dose Not Changed/ Not Recovered/Not Resolved	2,3	N	N
	胃腸障害/ 大腸炎/ FLARE OF COLITIS	[redacted] 20[redacted] (56)/ 20[redacted] (85)	Y/4/ Not Related	Dose Not Changed/ Not Recovered/Not Resolved	2	N	N
	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ MULTI ORGAN FAILURE	[redacted] 20[redacted] (85)/ 20[redacted] (85)	N/5/ Not Related	Not Applicable/ Fatal		N	N
[redacted]/6[redacted]/F	感染症および寄生虫症/ 結核/ TUBERCULOSIS	[redacted] 20[redacted] (26)/ Ongoing	Y/2/ Not Related	Dose Not Changed/ Not Recovered/Not Resolved	2	Y	N

Patient ID/ Age (years)/ Sex	SOC/PT/ VT	AE Start Date/ (Study Day)/ AE Stop Date/ (Study Day) [a]	TEAE/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Outcome	Other Action Taken [b]	AESI	COVID-19 Related
[redacted]/6[redacted]/F	感染症および寄生虫症/ 気管支炎/ BRONCHITIS	[redacted]20[redacted] (-15)/ 20[redacted] (-1)	N/2/ Not Related	Not Applicable/ Recovering/Resolving	2	Y	N
	神経系障害/ 椎骨脳底動脈不全/ POSTERIOR CIRCULATION ISCHEMIA	[redacted]20[redacted] (337)/ 20[redacted] (350)	Y/2/ Related	Dose Not Changed/ Recovered/Resolved	2	N	N
[redacted]/6[redacted]/M	神経系障害/ 虚血性脳卒中/ CEREBRAL ISCHEMIC STROKE	[redacted]20[redacted] (269)/ 20[redacted] (280)	Y/3/ Not Related	Dose Not Changed/ Recovered/Resolved with Sequelae		N	N
[redacted]/5[redacted]/M	肝胆道系障害/ 胆嚢炎/ CHOLECYSTITIS	[redacted]20[redacted] (268)/ 20[redacted] (274)	Y/2/ Not Related	Dose Not Changed/ Recovered/Resolved	2	N	N
[redacted]/7[redacted]/M	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	[redacted]20[redacted] (105)/ 20[redacted] (109)	Y/3/ Related	Dose Not Changed/ Not Recovered/Not Resolved		Y	N
	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	[redacted]20[redacted] (109)/ 20[redacted] (109)	Y/5/ Not Related	Drug Withdrawn/ Fatal	2	N	N

Source: Listing 16.2.7.2 in BGB-3111-214 clinical study report. Data cutoff: 04MAY2022. Data extraction: [redacted]20[redacted].
Abbreviations: AESI, adverse event of special interest; CTCAE, Common Terminology Criteria for Adverse Events; PT, Preferred Term; SOC, System Organ Class; TEAE, treatment emergent adverse event; VT, verbatim term.
Notes: Age is age at Informed Consent.
Adverse event grades are evaluated based on NCI-CTCAE Version 4.03.
[a] If AE stop date is missing and the ongoing variable in adverse events dataset is yes, please put “Ongoing” after adverse events start date and day.
[b] Other action taken: 1 = blood products transfusion, 2 = concomitant medication, 3 = concomitant procedure or surgery, 4 = Other.

表 47： 治療下で発現した有害事象、及び治療下で発現した有害事象＋治験薬投与期間終了後に発現した有害事象：器官別大分類別及び基本語別、コホート 1 及びコホート 2（BGB-3111-304 試験、安全性解析対象集団）

	Cohort 1				Cohort 2	
	BR (N = 227)		Zanubrutinib (N = 240)		Zanubrutinib (N = 111)	
System Organ Class Preferred Term	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
Patients With at Least One AE	214 (94.3)	221 (97.4)	227 (94.6)	227 (94.6)	109 (98.2)	109 (98.2)
感染症および寄生虫症	97 (42.7)	142 (62.6)	174 (72.5)	175 (72.9)	89 (80.2)	89 (80.2)
COVID-19	0 (0.0)	19 (8.4)	60 (25.0)	61 (25.4)	24 (21.6)	24 (21.6)
上気道感染	17 (7.5)	29 (12.8)	41 (17.1)	42 (17.5)	27 (24.3)	27 (24.3)
尿路感染	14 (6.2)	21 (9.3)	24 (10.0)	24 (10.0)	12 (10.8)	12 (10.8)
肺炎	13 (5.7)	23 (10.1)	19 (7.9)	20 (8.3)	14 (12.6)	14 (12.6)
上咽頭炎	10 (4.4)	14 (6.2)	19 (7.9)	19 (7.9)	10 (9.0)	11 (9.9)
COVID-19 肺炎	0 (0.0)	3 (1.3)	16 (6.7)	16 (6.7)	6 (5.4)	6 (5.4)
副鼻腔炎	4 (1.8)	11 (4.8)	16 (6.7)	16 (6.7)	6 (5.4)	6 (5.4)
蜂巣炎	0 (0.0)	2 (0.9)	14 (5.8)	14 (5.8)	3 (2.7)	3 (2.7)
下気道感染	2 (0.9)	5 (2.2)	12 (5.0)	12 (5.0)	9 (8.1)	9 (8.1)
気管支炎	10 (4.4)	18 (7.9)	10 (4.2)	10 (4.2)	4 (3.6)	4 (3.6)
気道感染	7 (3.1)	9 (4.0)	9 (3.8)	9 (3.8)	6 (5.4)	6 (5.4)
鼻炎	2 (0.9)	5 (2.2)	6 (2.5)	6 (2.5)	1 (0.9)	1 (0.9)
皮膚感染	1 (0.4)	1 (0.4)	6 (2.5)	6 (2.5)	3 (2.7)	3 (2.7)
結膜炎	4 (1.8)	8 (3.5)	5 (2.1)	5 (2.1)	5 (4.5)	5 (4.5)
帯状疱疹	2 (0.9)	11 (4.8)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)
限局性感染	1 (0.4)	1 (0.4)	5 (2.1)	5 (2.1)	4 (3.6)	4 (3.6)
胃腸炎	1 (0.4)	2 (0.9)	4 (1.7)	4 (1.7)	3 (2.7)	3 (2.7)
麦粒腫	0 (0.0)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
口腔ヘルペス	6 (2.6)	8 (3.5)	4 (1.7)	4 (1.7)	3 (2.7)	3 (2.7)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
爪囲炎	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
慢性副鼻腔炎	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
膀胱炎	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
インフルエンザ	2 (0.9)	2 (0.9)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
口腔カンジダ症	1 (0.4)	2 (0.9)	3 (1.3)	3 (1.3)	3 (2.7)	3 (2.7)
外耳炎	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
急性 COVID-19 後症候群	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
ウイルス性気道感染	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
敗血症性ショック	0 (0.0)	0 (0.0)	2 (0.8)	3 (1.3)	0 (0.0)	0 (0.0)
憩室炎	2 (0.9)	3 (1.3)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
耳感染	0 (0.0)	4 (1.8)	2 (0.8)	2 (0.8)	5 (4.5)	5 (4.5)
精巣上体炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
丹毒	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
眼感染	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
皮膚真菌感染	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
ウイルス性胃腸炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
B 型肝炎再活性化	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
単純ヘルペス	0 (0.0)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
歯周炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
敗血症	6 (2.6)	6 (2.6)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
軟部組織感染	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
歯感染	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
尿路性敗血症	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
創傷感染	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
唾液腺膿瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
口腔膿瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
急性副鼻腔炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
虫垂炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
菌血症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ブラストシスティス感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
感染性水疱	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ボレリア感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
気管支肺アスペルギルス症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
涙嚢炎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
感染性湿疹	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心内膜炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
遊走性紅斑	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
大腸菌性敗血症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
大腸菌性尿路感染	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
毛包炎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
サルモネラ菌性胃腸炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
赤痢菌性胃腸炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
歯肉炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
H3N2 インフルエンザ	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ヘルペスウイルス感染	0 (0.0)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
咬傷感染	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
感染	5 (2.2)	7 (3.1)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
感染による気管支拡張症の増悪	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
注入部位感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
迷路炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
細菌性下気道感染	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
真菌性下気道感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ライム病	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
モルガネラ感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
爪床感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
爪感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鼻ヘルペス	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
神経ボレリア症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
中咽頭カンジダ症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
中耳炎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
急性中耳炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
パラインフルエンザウイルス気管支炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
咽頭炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	4 (3.6)	4 (3.6)
ニューモシスチス・イロベチイ肺炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ウイルス性肺炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
術後創感染	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
唾液腺炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
細菌性副鼻腔炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
真菌性副鼻腔炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
糞線虫症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ダニ媒介熱	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
白癬感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
足部白癬	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
癜風	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
トキソプラズマ症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
気管炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腟感染	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ウイルス性心膜炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
爪真菌症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (1.8)	2 (1.8)
ブドウ球菌性菌血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
腹部敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
真菌性肛門感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
穿孔性虫垂炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
異型肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
細菌尿	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
細気管支炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
細菌性気管支炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ウイルス性気管支炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
カンピロバクター胃腸炎	2 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
カテーテル留置部位感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
感染性胆嚢炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
クロストリジウム・ディフィシレ大腸炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
クロストリジウム・ディフィシレ感染	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ウイルス性結膜炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
感染性皮膚炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
医療機器関連感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
播種性水痘帯状疱疹ウイルス感染	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
真菌性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
蟯虫症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
熱性感染症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
せつ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
陰部ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
陰部単純ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
真菌性性器感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肛径部膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ヘモフィルス感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ヘリコバクター性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ヘリコバクター感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
B 型肝炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
E 型肝炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ヘルペス眼感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
膿痂疹	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
感染性皮膚潰瘍	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
椎間板炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
大腸感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
喉頭炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ウイルス性喉頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ウイルス性下気道感染	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
クリプトコッカス性髄膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
好中球減少性敗血症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
パラインフルエンザウイルス感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
陰茎感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
軟骨膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
レンサ球菌性咽頭炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
クラミジア性肺炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
シュードモナス性菌血症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
シュードモナス性敗血症	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
RS ウイルス感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
真菌性気道感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚カンジダ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ブドウ球菌皮膚感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
全身性カンジダ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
股部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
扁桃炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
歯膿瘍	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ブドウ球菌性尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ウイルス感染	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ウイルス性咽頭炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
外陰腟真菌感染	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
胃腸障害	119 (52.4)	133 (58.6)	131 (54.6)	131 (54.6)	71 (64.0)	71 (64.0)
下痢	26 (11.5)	31 (13.7)	41 (17.1)	41 (17.1)	22 (19.8)	22 (19.8)
悪心	74 (32.6)	74 (32.6)	31 (12.9)	31 (12.9)	20 (18.0)	20 (18.0)
嘔吐	31 (13.7)	34 (15.0)	28 (11.7)	28 (11.7)	12 (10.8)	12 (10.8)
便秘	40 (17.6)	44 (19.4)	27 (11.3)	27 (11.3)	20 (18.0)	20 (18.0)
腹痛	9 (4.0)	15 (6.6)	13 (5.4)	13 (5.4)	11 (9.9)	11 (9.9)
上腹部痛	0 (0.0)	0 (0.0)	11 (4.6)	11 (4.6)	5 (4.5)	5 (4.5)
消化不良	8 (3.5)	8 (3.5)	11 (4.6)	11 (4.6)	10 (9.0)	10 (9.0)
胃食道逆流性疾患	3 (1.3)	5 (2.2)	10 (4.2)	10 (4.2)	3 (2.7)	3 (2.7)
鼓腸	0 (0.0)	0 (0.0)	7 (2.9)	7 (2.9)	1 (0.9)	1 (0.9)
胃炎	3 (1.3)	5 (2.2)	7 (2.9)	7 (2.9)	2 (1.8)	2 (1.8)
口腔内潰瘍形成	3 (1.3)	3 (1.3)	6 (2.5)	6 (2.5)	2 (1.8)	2 (1.8)
口内炎	8 (3.5)	9 (4.0)	5 (2.1)	5 (2.1)	2 (1.8)	2 (1.8)
腹部膨満	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	3 (2.7)	3 (2.7)
口内乾燥	9 (4.0)	12 (5.3)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
痔核	5 (2.2)	7 (3.1)	4 (1.7)	4 (1.7)	2 (1.8)	2 (1.8)
口腔内出血	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
直腸出血	2 (0.9)	2 (0.9)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
齲歯	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	4 (3.6)	4 (3.6)
腸憩室	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
胃腸障害	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
鼡径ヘルニア	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
大腸ポリープ	1 (0.4)	2 (0.9)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
口腔内痛	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
歯痛	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
下腹部痛	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
慢性胃炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
歯肉出血	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
痔出血	1 (0.4)	3 (1.3)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
裂孔ヘルニア	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
食道静脈瘤	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
腹部不快感	2 (0.9)	2 (0.9)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
腹部腫瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腹壁血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腹水	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
憩室	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
嚥下障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
心窩部不快感	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
びらん性食道炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
変色便	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
軟便	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
食中毒	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
排便回数増加	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
出血性胃潰瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
びらん性胃炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
出血性胃炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
消化管浮腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
消化管壁肥厚	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
歯肉浮腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
歯肉痛	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
舌炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血便排泄	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
弛緩歯	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
メレナ	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
閉塞性膵炎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
嚥下痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
食道瘻	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
食道食物嵌入	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
食道潰瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
食道炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膵炎	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
急性膵炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
慢性膵炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肛門周囲痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
直腸異形成	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
直腸ポリープ	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
レッチング	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
後腹膜血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
流涎過多	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
舌障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
歯の障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
上部消化管出血	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
裂肛	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肛門失禁	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
アフタ性潰瘍	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
バレット食道	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
大腸炎	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ダンピング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
十二指腸ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
出血性十二指腸潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腸炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
糞塊	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
胃ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃潰瘍	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸出血	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
歯肉潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
潰瘍性歯肉炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃酸過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
口の感覚鈍麻	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
イレウス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
腸閉塞	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腸管ポリープ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腹腔内血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
過敏性腸症候群	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
大腸出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
口腔白斑症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
口唇水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
巨大結腸	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
口腔血性水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
口蓋障害	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
膵嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
膵臓障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
膵不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
耳下腺腫大	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
歯周病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
直腸しぶり	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
小腸閉塞	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
脂肪便	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
毛舌症	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	79 (34.8)	96 (42.3)	115 (47.9)	116 (48.3)	64 (57.7)	64 (57.7)
発疹	44 (19.4)	45 (19.8)	29 (12.1)	29 (12.1)	18 (16.2)	18 (16.2)
そう痒症	15 (6.6)	16 (7.0)	21 (8.8)	22 (9.2)	11 (9.9)	11 (9.9)
点状出血	0 (0.0)	0 (0.0)	19 (7.9)	19 (7.9)	5 (4.5)	5 (4.5)
斑状丘疹状皮疹	11 (4.8)	11 (4.8)	10 (4.2)	10 (4.2)	4 (3.6)	4 (3.6)
皮膚病変	1 (0.4)	3 (1.3)	10 (4.2)	10 (4.2)	5 (4.5)	5 (4.5)
紅斑	8 (3.5)	10 (4.4)	9 (3.8)	9 (3.8)	3 (2.7)	3 (2.7)
斑状出血	1 (0.4)	1 (0.4)	7 (2.9)	7 (2.9)	6 (5.4)	6 (5.4)
皮膚乾燥	5 (2.2)	7 (3.1)	6 (2.5)	6 (2.5)	3 (2.7)	3 (2.7)
皮膚変色	1 (0.4)	1 (0.4)	6 (2.5)	6 (2.5)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
皮膚潰瘍	0 (0.0)	1 (0.4)	6 (2.5)	6 (2.5)	3 (2.7)	3 (2.7)
湿疹	0 (0.0)	0 (0.0)	5 (2.1)	5 (2.1)	2 (1.8)	2 (1.8)
多汗症	2 (0.9)	4 (1.8)	5 (2.1)	5 (2.1)	0 (0.0)	0 (0.0)
紫斑	0 (0.0)	0 (0.0)	5 (2.1)	5 (2.1)	4 (3.6)	4 (3.6)
水疱	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
皮膚炎	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	3 (2.7)	3 (2.7)
蕁麻疹	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
光線角化症	0 (0.0)	6 (2.6)	3 (1.3)	3 (1.3)	4 (3.6)	4 (3.6)
脱毛症	1 (0.4)	2 (0.9)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
ざ瘡様皮膚炎	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
アレルギー性皮膚炎	2 (0.9)	3 (1.3)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
皮膚出血	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
うっ滞性皮膚炎	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
薬疹	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
手皮膚炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
過角化	1 (0.4)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
寝汗	5 (2.2)	6 (2.6)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
爪破損	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
前癌性皮膚病変	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
紅斑性皮疹	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
酒さ	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
皮膚障害	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
ざ瘡	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
皮膚血管炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
褥瘡性潰瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
皮膚嚢腫	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
虚血性皮膚潰瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
苔癬様角化症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
斑	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
爪床出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
爪変色	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
神経皮膚炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
爪甲脱落症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
手掌紅斑	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
光線過敏性反応	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
乾癬	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
斑状皮疹	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
丘疹性皮疹	2 (0.9)	2 (0.9)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
脂漏性皮膚炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
皮膚剥脱	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
皮膚亀裂	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
皮膚毒性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
毛細血管拡張症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
臍血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
水疱性皮膚炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮脂欠乏性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
好酸球性蜂巣炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
剥脱性発疹	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
環状肉芽腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚肉芽腫	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
網状皮斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
皮膚粘膜出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
好中球性皮膚症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
脂肪織炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
丘疹	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
光線性皮膚症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
足底紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
痒疹	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
そう痒性皮疹	2 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
鼻瘤	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚刺激	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
皮膚腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
皮膚腫脹	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
日光皮膚炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
日光黒子	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
中毒性皮疹	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
一過性棘融解性皮膚症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
筋骨格系および結合組織障害	49 (21.6)	70 (30.8)	113 (47.1)	113 (47.1)	60 (54.1)	61 (55.0)
関節痛	16 (7.0)	23 (10.1)	37 (15.4)	37 (15.4)	26 (23.4)	26 (23.4)
四肢痛	10 (4.4)	14 (6.2)	25 (10.4)	25 (10.4)	12 (10.8)	12 (10.8)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
背部痛	10 (4.4)	18 (7.9)	24 (10.0)	24 (10.0)	19 (17.1)	19 (17.1)
筋痙縮	3 (1.3)	5 (2.2)	12 (5.0)	12 (5.0)	8 (7.2)	8 (7.2)
関節炎	1 (0.4)	2 (0.9)	10 (4.2)	10 (4.2)	4 (3.6)	4 (3.6)
筋肉痛	3 (1.3)	4 (1.8)	9 (3.8)	9 (3.8)	7 (6.3)	8 (7.2)
変形性関節症	3 (1.3)	6 (2.6)	9 (3.8)	9 (3.8)	2 (1.8)	2 (1.8)
筋骨格系胸痛	0 (0.0)	1 (0.4)	8 (3.3)	8 (3.3)	7 (6.3)	7 (6.3)
頚部痛	1 (0.4)	1 (0.4)	5 (2.1)	5 (2.1)	7 (6.3)	7 (6.3)
骨粗鬆症	1 (0.4)	2 (0.9)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)
脊椎痛	1 (0.4)	1 (0.4)	5 (2.1)	5 (2.1)	0 (0.0)	0 (0.0)
腱炎	1 (0.4)	1 (0.4)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)
骨減少症	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
側腹部痛	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
関節腫脹	2 (0.9)	2 (0.9)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
滑液包炎	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
椎間板障害	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
筋力低下	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
筋骨格不快感	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
顎痛	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
変形性脊椎症	1 (0.4)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	1 (0.9)
腋窩腫瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
骨痛	9 (4.0)	9 (4.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
肋軟骨炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
変性骨疾患	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
デュプイトラン拘縮	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
外骨腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
痛風性関節炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
尺径部痛	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
四肢腫瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
筋拘縮	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
筋攣縮	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
筋骨格痛	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
筋炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肩回旋筋腱板症候群	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
側弯症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
軟部組織出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ピロリン酸カルシウム結晶性軟骨石灰化症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
線維筋痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
足変形	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
骨折の変形治癒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
高クレアチン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
棘突起間関節形成症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
椎間板変性症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
椎間板突出	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
関節滲出液	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
関節可動域低下	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
四肢の変形	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
下顎腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
筋萎縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
結節性変形性関節症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
骨端症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
顎関節症候群	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腱障害	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	122 (53.7)	130 (57.3)	104 (43.3)	104 (43.3)	41 (36.9)	41 (36.9)
疲労	34 (15.0)	39 (17.2)	40 (16.7)	40 (16.7)	14 (12.6)	14 (12.6)
末梢性浮腫	17 (7.5)	19 (8.4)	23 (9.6)	23 (9.6)	9 (8.1)	9 (8.1)
発熱	60 (26.4)	61 (26.9)	23 (9.6)	23 (9.6)	11 (9.9)	11 (9.9)
末梢腫脹	4 (1.8)	6 (2.6)	12 (5.0)	12 (5.0)	4 (3.6)	4 (3.6)
無力症	16 (7.0)	20 (8.8)	8 (3.3)	8 (3.3)	4 (3.6)	4 (3.6)
胸痛	1 (0.4)	3 (1.3)	8 (3.3)	8 (3.3)	2 (1.8)	2 (1.8)
インフルエンザ様疾患	2 (0.9)	3 (1.3)	5 (2.1)	5 (2.1)	2 (1.8)	2 (1.8)
胸部不快感	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
悪寒	20 (8.8)	21 (9.3)	4 (1.7)	4 (1.7)	5 (4.5)	5 (4.5)
疼痛	3 (1.3)	3 (1.3)	4 (1.7)	4 (1.7)	2 (1.8)	2 (1.8)
顔面浮腫	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
冷感	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
熱感	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
全身健康状態悪化	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
非心臓性胸痛	3 (1.3)	5 (2.2)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
血管穿刺部位内出血	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
ヘルニア	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
疾患	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
埋込み部位びらん	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
注射部位内出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
注射部位血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
注射部位疼痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
倦怠感	4 (1.8)	4 (1.8)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
全身性炎症反応症候群	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血管穿刺部位出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
医薬品副作用	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
有害食物反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腋窩痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
カテーテル留置部位疼痛	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
カテーテル留置部位そう痒感	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
医療機器関連合併症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
不快感	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
溢出	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
びくびく感	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
歩行障害	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
異常高熱	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
埋込み部位血腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
注入部位血管外漏出	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
注射部位発疹	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
注射部位反応	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
ポリープ	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
偽ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
温度変化不耐症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
乾燥症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
呼吸器、胸郭および縦隔障害	56 (24.7)	74 (32.6)	101 (42.1)	101 (42.1)	43 (38.7)	43 (38.7)
咳嗽	21 (9.3)	24 (10.6)	35 (14.6)	35 (14.6)	17 (15.3)	17 (15.3)
呼吸困難	9 (4.0)	12 (5.3)	16 (6.7)	16 (6.7)	11 (9.9)	11 (9.9)
鼻出血	1 (0.4)	1 (0.4)	13 (5.4)	13 (5.4)	8 (7.2)	8 (7.2)
口腔咽頭痛	4 (1.8)	8 (3.5)	10 (4.2)	10 (4.2)	4 (3.6)	4 (3.6)
湿性咳嗽	1 (0.4)	3 (1.3)	10 (4.2)	10 (4.2)	7 (6.3)	7 (6.3)
鼻閉	0 (0.0)	2 (0.9)	5 (2.1)	5 (2.1)	4 (3.6)	4 (3.6)
胸水	2 (0.9)	2 (0.9)	5 (2.1)	5 (2.1)	4 (3.6)	4 (3.6)
肺臓炎	1 (0.4)	2 (0.9)	5 (2.1)	5 (2.1)	2 (1.8)	2 (1.8)
鼻漏	2 (0.9)	2 (0.9)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)
労作性呼吸困難	1 (0.4)	4 (1.8)	4 (1.7)	4 (1.7)	4 (3.6)	4 (3.6)
慢性閉塞性肺疾患	1 (0.4)	1 (0.4)	3 (1.3)	4 (1.7)	1 (0.9)	1 (0.9)
間質性肺疾患	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
肺線維症	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
肺塞栓症	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
呼吸不全	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
睡眠時無呼吸症候群	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
急性呼吸不全	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
喘息	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

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咽喉乾燥	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
発声障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
喀血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	4 (3.6)	4 (3.6)
低酸素症	3 (1.3)	3 (1.3)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
喉頭肉芽腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
喉頭の炎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肺浸潤	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肺陰影	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鼻部不快感	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鼻粘膜潰瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
副鼻腔嚢胞	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
副鼻腔分泌過多	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
気胸	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
肺高血圧症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ラ音	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
気道の炎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
アレルギー性鼻炎	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
副鼻腔うっ血	2 (0.9)	2 (0.9)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
副鼻腔痛	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
くしゃみ	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
咽喉刺激感	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
扁桃の炎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
上気道うっ血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
上気道咳症候群	1 (0.4)	3 (1.3)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
高粘稠性上気道分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
無気肺	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
前屈呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
気管支拡張症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
気管支痙攣	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
しゃっくり	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
肺硬化	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肺障害	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
鼻嚢胞	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
鼻茸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
器質化肺炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
咽頭の炎症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
誤嚥性肺炎	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肺のエアリーク	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
肺腫瘤	3 (1.3)	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肺水腫	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
副鼻腔ポリープ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
上気道の炎症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
喘鳴	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	59 (26.0)	71 (31.3)	93 (38.8)	93 (38.8)	55 (49.5)	55 (49.5)
挫傷	5 (2.2)	8 (3.5)	49 (20.4)	49 (20.4)	23 (20.7)	23 (20.7)
転倒	6 (2.6)	8 (3.5)	15 (6.3)	16 (6.7)	13 (11.7)	13 (11.7)
皮膚裂傷	3 (1.3)	4 (1.8)	6 (2.5)	7 (2.9)	7 (6.3)	7 (6.3)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
節足動物咬傷	1 (0.4)	3 (1.3)	6 (2.5)	6 (2.5)	3 (2.7)	3 (2.7)
四肢損傷	0 (0.0)	0 (0.0)	6 (2.5)	6 (2.5)	5 (4.5)	5 (4.5)
皮膚擦過傷	1 (0.4)	1 (0.4)	5 (2.1)	5 (2.1)	2 (1.8)	2 (1.8)
肋骨骨折	0 (0.0)	1 (0.4)	4 (1.7)	4 (1.7)	4 (3.6)	4 (3.6)
皮下血腫	0 (0.0)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
足骨折	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
処置後血腫	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
処置後出血	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
処置による疼痛	2 (0.9)	2 (0.9)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
脊椎骨折	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
熱傷	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
動物咬傷	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
外傷後疼痛	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
橈骨骨折	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
引っかき傷	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
節足動物刺傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	3 (2.7)	3 (2.7)
骨挫傷	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
白内障手術合併症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
胸部損傷	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
眼挫傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
注入に伴う反応	43 (18.9)	43 (18.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
靭帯損傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
筋断裂	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
筋骨格系損傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
膝蓋骨骨折	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
眼窩周囲出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
処置後挫傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
処置後腫脹	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
放射線損傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
放射線性直腸炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
陰嚢血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
皮膚創傷	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
脊椎圧迫骨折	2 (0.9)	3 (1.3)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
ストーマ部ヘルニア	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
硬膜下出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
胸椎骨折	0 (0.0)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
脛骨骨折	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
歯牙破折	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
外傷性血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
上肢骨折	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
尿路系処置合併症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
アナフィラキシー性輸血反応	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
動物の攻撃	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
足関節部骨折	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
造影剤毒性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
大腿骨頚部骨折	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
大腿骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
歯肉損傷	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
関節脱臼	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腰椎骨折	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
肉離れ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
鼻部損傷	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
骨盤骨折	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
処置後血尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
処置による出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
処置による低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
交通事故	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
硬膜下血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
サンバーン	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腱損傷	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腱断裂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
神経系障害	47 (20.7)	65 (28.6)	78 (32.5)	79 (32.9)	37 (33.3)	37 (33.3)
頭痛	15 (6.6)	21 (9.3)	29 (12.1)	29 (12.1)	13 (11.7)	13 (11.7)
浮動性めまい	10 (4.4)	12 (5.3)	22 (9.2)	22 (9.2)	10 (9.0)	11 (9.9)
失神	2 (0.9)	4 (1.8)	6 (2.5)	7 (2.9)	2 (1.8)	2 (1.8)
錯感覚	0 (0.0)	3 (1.3)	6 (2.5)	6 (2.5)	4 (3.6)	4 (3.6)
振戦	4 (1.8)	4 (1.8)	5 (2.1)	5 (2.1)	3 (2.7)	3 (2.7)
感覚鈍麻	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	2 (1.8)	2 (1.8)
記憶障害	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)

	Cohort 1				Cohort 2	
	BR (N = 227)		Zanubrutinib (N = 240)		Zanubrutinib (N = 111)	
System Organ Class Preferred Term	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
末梢性感覚ニューロパチー	3 (1.3)	5 (2.2)	3 (1.3)	3 (1.3)	5 (4.5)	5 (4.5)
坐骨神経痛	2 (0.9)	4 (1.8)	3 (1.3)	3 (1.3)	4 (3.6)	4 (3.6)
健忘	1 (0.4)	2 (0.9)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
平衡障害	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
頚動脈狭窄	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
脳血管発作	1 (0.4)	3 (1.3)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
不全片麻痺	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
嗜眠	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
失神寸前の状態	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
痙攣発作	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
三叉神経痛	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
くも膜嚢胞	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
運動失調	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
頚動脈硬化症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
手根管症候群	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
脳梗塞	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
異常感覚	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
脳症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
卒中の出血性変化	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
過眠症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ラクナ梗塞	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
意識消失	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
片頭痛	2 (0.9)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
脊髄症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
神経痛	0 (0.0)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
末梢性ニューロパチー	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
パーキンソン病	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
末梢性感覚運動ニューロパチー	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
感覚障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
くも膜下出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
一過性全健忘	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
前庭性片頭痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ベル麻痺	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
橈骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
意識変容状態	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
断端痛	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
失語症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
脳虚血	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
認知障害	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
認知症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
注意力障害	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
味覚不全	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
顔面神経障害	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
顔面麻痺	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ファンブル	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
水頭症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
高血圧性脳症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
虚血性脳卒中	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
単麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
多発性硬化症再発	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
パーキンソニズム	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
末梢性運動ニューロパチー	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ヘルペス後神経痛	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経根痛	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経根障害	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
下肢静止不能症候群	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
味覚障害	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
緊張性頭痛	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一過性脳虚血発作	2 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	41 (18.1)	56 (24.7)	76 (31.7)	76 (31.7)	33 (29.7)	33 (29.7)
高血圧	10 (4.4)	28 (12.3)	37 (15.4)	37 (15.4)	13 (11.7)	13 (11.7)
血腫	1 (0.4)	1 (0.4)	15 (6.3)	15 (6.3)	11 (9.9)	11 (9.9)
低血圧	22 (9.7)	23 (10.1)	6 (2.5)	7 (2.9)	5 (4.5)	5 (4.5)
ほてり	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
高血圧クリーゼ	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
リンパ浮腫	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
末梢血管障害	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
静脈瘤	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
白衣性高血圧	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
深部静脈血栓症	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	0 (0.0)
大動脈瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
大動脈壁内血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
動脈硬化症	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
本態性高血圧症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
頚静脈血栓症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
起立性低血圧	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
末梢動脈血栓症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
末梢性虚血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
末梢静脈疾患	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
表在性静脈炎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
表在性血栓性静脈炎	2 (0.9)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血管破裂	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血管炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
四肢静脈血栓症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
大動脈解離	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
血圧変動	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
潮紅	5 (2.2)	5 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
蒼白	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
末梢動脈閉塞性疾患	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
末梢動脈狭窄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
末梢冷感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
静脈炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
血栓性静脈炎	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
血液およびリンパ系障害	137 (60.4)	145 (63.9)	64 (26.7)	65 (27.1)	32 (28.8)	32 (28.8)
好中球減少症	102 (44.9)	104 (45.8)	32 (13.3)	32 (13.3)	13 (11.7)	13 (11.7)
貧血	40 (17.6)	46 (20.3)	16 (6.7)	17 (7.1)	7 (6.3)	7 (6.3)
血小板減少症	29 (12.8)	31 (13.7)	12 (5.0)	12 (5.0)	4 (3.6)	4 (3.6)
内出血発生の増加傾向	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	3 (2.7)	3 (2.7)
リンパ節痛	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
リンパ節症	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
好酸球増加症	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
発熱性好中球減少症	17 (7.5)	17 (7.5)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
白血球増加症	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
失血性貧血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
溶血	3 (1.3)	3 (1.3)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
溶血性貧血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鉄欠乏性貧血	2 (0.9)	4 (1.8)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
白血球減少症	7 (3.1)	7 (3.1)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
リンパ節炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
リンパ球減少症	3 (1.3)	3 (1.3)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
汎血球減少症	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
顆粒球減少症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
出血性素因	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
免疫性血小板減少症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
小赤血球症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
好中球増加症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
悪性貧血	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	51 (22.5)	65 (28.6)	63 (26.3)	63 (26.3)	32 (28.8)	32 (28.8)
高血糖	2 (0.9)	3 (1.3)	8 (3.3)	8 (3.3)	4 (3.6)	4 (3.6)
鉄欠乏	1 (0.4)	2 (0.9)	8 (3.3)	8 (3.3)	1 (0.9)	1 (0.9)
食欲減退	18 (7.9)	18 (7.9)	7 (2.9)	7 (2.9)	4 (3.6)	4 (3.6)
高尿酸血症	9 (4.0)	10 (4.4)	7 (2.9)	7 (2.9)	2 (1.8)	2 (1.8)
低ナトリウム血症	3 (1.3)	3 (1.3)	6 (2.5)	6 (2.5)	3 (2.7)	3 (2.7)
糖尿病	1 (0.4)	3 (1.3)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)
低カリウム血症	9 (4.0)	13 (5.7)	5 (2.1)	5 (2.1)	4 (3.6)	4 (3.6)
痛風	3 (1.3)	5 (2.2)	4 (1.7)	4 (1.7)	8 (7.2)	8 (7.2)
低カルシウム血症	3 (1.3)	4 (1.8)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
低マグネシウム血症	1 (0.4)	2 (0.9)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
高コレステロール血症	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
高カリウム血症	2 (0.9)	3 (1.3)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
ビタミン B12 欠乏	0 (0.0)	2 (0.9)	3 (1.3)	3 (1.3)	3 (2.7)	3 (2.7)
低血糖	2 (0.9)	3 (1.3)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
脱水	8 (3.5)	9 (4.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
コントロール不良の糖尿病	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
耐糖能障害	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
高カルシウム血症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
高脂血症	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
血液量減少症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

	Cohort 1				Cohort 2	
	BR (N = 227)		Zanubrutinib (N = 240)		Zanubrutinib (N = 111)	
System Organ Class Preferred Term	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
空腹時血中ブドウ糖不良	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
偽高カリウム血症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
2 型糖尿病	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
ビタミン D 欠乏	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
ビタミン K 欠乏	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
成人 FTT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
悪液質	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
糖尿病性ケトアシドーシス	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
体液貯留	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
葉酸欠乏	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
高ナトリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
高リン血症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
高トリグリセリド血症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血液量増加症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
低アルブミン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
過小食	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
低リン血症	1 (0.4)	3 (1.3)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
低蛋白血症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
栄養障害	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肥満	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
リフィーディング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腫瘍崩壊症候群	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (3.1)	41 (18.1)	56 (23.3)	56 (23.3)	33 (29.7)	33 (29.7)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
基底細胞癌	0 (0.0)	7 (3.1)	19 (7.9)	19 (7.9)	15 (13.5)	15 (13.5)
皮膚有棘細胞癌	0 (0.0)	7 (3.1)	8 (3.3)	8 (3.3)	4 (3.6)	4 (3.6)
大腸腺腫	0 (0.0)	1 (0.4)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
肺腺癌	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	2 (1.8)	2 (1.8)
ボーエン病	1 (0.4)	4 (1.8)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
悪性黒色腫	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
前立腺癌	0 (0.0)	4 (1.8)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
直腸腺癌	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
腎癌	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
皮膚癌	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
皮膚乳頭腫	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
遠隔転移を伴う肛門癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肛門扁平上皮癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肺の良性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膀胱の良性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
甲状腺の良性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膀胱癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
乳癌	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
小脳腫瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
慢性骨髄性白血病	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腎明細胞癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
外耳の悪性新生物	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
消化管間質性腫瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
感染性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
ケラトアカントーマ	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
口唇扁平上皮癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
脂肪腫	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
遠隔転移を伴う肺癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肺の悪性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
再発肺扁平上皮癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
メラノサイト性母斑	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
中枢神経系転移	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
遠隔転移を伴う扁平上皮癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
骨髄増殖性新生物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
神経内分泌腫瘍	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
卵巣腺腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
卵巣癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
真性多血症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
直腸腺腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腎細胞癌	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
脂漏性角化症	1 (0.4)	4 (1.8)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
肺扁平上皮癌	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腫瘍フレア	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
子宮平滑筋腫	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
聴神経腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腺癌	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
乳房の良性新生物	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
膀胱移行上皮癌	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
慢性骨髄単球性白血病	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
乳腺線維腺腫	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
消化器癌	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝臓血管腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
皮膚血管腫	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
膵管内乳頭粘液性腫瘍	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
大腸の良性新生物	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
表皮内悪性黒色腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
悪性胸水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
髄膜腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
非小細胞肺癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
陰茎疣贅	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎脂肪腫	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸器乳頭腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
遠隔転移を伴う皮膚有棘細胞癌	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎盂および尿管移行上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
尿道移行上皮癌	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腫瘍疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
外陰部癌第 0 期	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	16 (7.0)	27 (11.9)	49 (20.4)	50 (20.8)	19 (17.1)	19 (17.1)
動悸	2 (0.9)	4 (1.8)	11 (4.6)	11 (4.6)	3 (2.7)	3 (2.7)
心房細動	5 (2.2)	6 (2.6)	10 (4.2)	10 (4.2)	7 (6.3)	7 (6.3)
狭心症	1 (0.4)	2 (0.9)	5 (2.1)	5 (2.1)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
心不全	1 (0.4)	2 (0.9)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
心筋虚血	1 (0.4)	2 (0.9)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
急性冠動脈症候群	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
急性心筋梗塞	1 (0.4)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
心筋梗塞	1 (0.4)	3 (1.3)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
心室性期外収縮	0 (0.0)	1 (0.4)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
徐脈	0 (0.0)	0 (0.0)	2 (0.8)	3 (1.3)	3 (2.7)	3 (2.7)
大動脈弁狭窄	0 (0.0)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
うっ血性心不全	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
心嚢液貯留	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
頻脈	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
心房粗動	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	0 (0.0)
大動脈弁疾患	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
第一度房室ブロック	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
左脚ブロック	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心停止	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
急性心不全	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心原性ショック	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
高血圧性心疾患	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心臓内血栓	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
左房拡大	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心筋炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
右室機能不全	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
洞性徐脈	2 (0.9)	3 (1.3)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
上室性頻脈	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心室性頻脈	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
不安定狭心症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
心筋症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心血管不全	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
冠動脈疾患	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
冠動脈狭窄	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
左室機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
左室肥大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
僧帽弁閉鎖不全症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
無脈性電気活動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ストレス心筋症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心室性不整脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
臨床検査	63 (27.8)	70 (30.8)	44 (18.3)	44 (18.3)	27 (24.3)	27 (24.3)
好中球数減少	28 (12.3)	28 (12.3)	7 (2.9)	7 (2.9)	8 (7.2)	8 (7.2)
アラニンアミノトランスフェラーゼ増加	12 (5.3)	13 (5.7)	6 (2.5)	6 (2.5)	0 (0.0)	0 (0.0)
血中クレアチニン増加	2 (0.9)	2 (0.9)	4 (1.7)	4 (1.7)	4 (3.6)	4 (3.6)
体重減少	6 (2.6)	7 (3.1)	4 (1.7)	4 (1.7)	3 (2.7)	3 (2.7)
アスパラギン酸アミノトランスフェラーゼ増加	11 (4.8)	11 (4.8)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
血中テストステロン減少	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
γ－グルタミルトランスフェラーゼ増加	4 (1.8)	5 (2.2)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
血小板数減少	11 (4.8)	12 (5.3)	3 (1.3)	3 (1.3)	5 (4.5)	5 (4.5)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
血中ビリルビン増加	3 (1.3)	3 (1.3)	2 (0.8)	2 (0.8)	3 (2.7)	3 (2.7)
血中コレステロール増加	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
血中葉酸減少	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
心雑音	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
糸球体濾過率減少	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
ヒトライノウイルス検査陽性	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
アミラーゼ増加	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
アスペルギルス検査陽性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
出血時間延長	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血中アルカリホスファターゼ増加	5 (2.2)	6 (2.6)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血中鉄減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血中乳酸脱水素酵素増加	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
血圧上昇	3 (1.3)	4 (1.8)	1 (0.4)	1 (0.4)	2 (1.8)	2 (1.8)
血中ナトリウム減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
駆出率減少	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
心電図異常 P 波	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
A 型インフルエンザウイルス検査陽性	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
リパーゼ増加	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
リンパ球数減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ニューモシスチス検査陽性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
尿中赤血球陽性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
甲状腺ホルモン減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
トロポニン増加	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
ビタミン B12 減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
血中フィブリノゲン減少	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血中免疫グロブリン G 減少	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血中リン減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
血中カリウム減少	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血圧低下	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
体温上昇	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
C-反応性蛋白増加	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
サイトメガロウイルス検査陽性	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
フィブリン D ダイマー増加	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ヘマトクリット増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ヘモグロビン減少	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心拍数増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
心拍数不整	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
肝酵素上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
B 型肝炎 DNA 測定陽性	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼圧上昇	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
リンパ球数増加	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
酸素飽和度低下	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
前立腺特異性抗原増加	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血清フェリチン減少	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
トランスアミナーゼ上昇	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
ビタミン D 減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
体重増加	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
白血球数減少	4 (1.8)	4 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	10 (4.4)	18 (7.9)	41 (17.1)	41 (17.1)	15 (13.5)	15 (13.5)
白内障	2 (0.9)	7 (3.1)	11 (4.6)	11 (4.6)	4 (3.6)	4 (3.6)
ドライアイ	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
緑内障	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
網膜静脈閉塞	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
霧視	2 (0.9)	2 (0.9)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
加齢黄斑変性	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
眼の障害	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
眼出血	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
高眼圧症	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
霰粒腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
結膜出血	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
結膜刺激	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
後天性涙道狭窄	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
糖尿病網膜症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
複視	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
眼窩障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
眼刺激	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
眼痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
眼そう痒症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
黄斑線維症	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
新生血管加齢黄斑変性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
開放隅角緑内障	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
視神経症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
視神経乳頭浮腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
後嚢部混濁	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
網膜剥離	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
網膜出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
網膜裂孔	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
網膜血管障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
視力障害	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
硝子体浮遊物	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
硝子体混濁	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
眼瞼炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
眼瞼皮膚弛緩症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
眼の炎症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
眼部腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
虹彩毛様体炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
角膜炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
流涙増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
マイボーム腺機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
眼酒さ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
強膜炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼瞼腫脹	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
睫毛乱生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
視力低下	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
硝子体剥離	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
硝子体炎	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	25 (11.0)	29 (12.8)	38 (15.8)	38 (15.8)	29 (26.1)	29 (26.1)
血尿	2 (0.9)	6 (2.6)	17 (7.1)	17 (7.1)	14 (12.6)	14 (12.6)
尿閉	2 (0.9)	2 (0.9)	7 (2.9)	7 (2.9)	2 (1.8)	2 (1.8)
頻尿	3 (1.3)	3 (1.3)	4 (1.7)	4 (1.7)	4 (3.6)	4 (3.6)
急性腎障害	7 (3.1)	9 (4.0)	3 (1.3)	3 (1.3)	4 (3.6)	4 (3.6)
腎不全	3 (1.3)	3 (1.3)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
尿失禁	2 (0.9)	2 (0.9)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
着色尿	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
尿意切迫	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
腎結石症	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
腎仙痛	2 (0.9)	2 (0.9)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
尿路閉塞	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
膀胱障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膀胱憩室	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
慢性腎臓病	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
非感染性膀胱炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
水腎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
下部尿路症状	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
排尿回数減少	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
夜間頻尿	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
蛋白尿	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
腎嚢胞	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
有痛性排尿困難	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
尿管結石症	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膀胱出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
膀胱狭窄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
膀胱結石	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腺性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
排尿困難	1 (0.4)	2 (0.9)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
多尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腎機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
腎腫瘤	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
尿管障害	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
尿管ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
尿道狭窄	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
膀胱ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	17 (7.5)	25 (11.0)	32 (13.3)	32 (13.3)	18 (16.2)	18 (16.2)
不眠症	13 (5.7)	16 (7.0)	16 (6.7)	16 (6.7)	4 (3.6)	4 (3.6)
不安	1 (0.4)	1 (0.4)	7 (2.9)	7 (2.9)	3 (2.7)	3 (2.7)
うつ病	0 (0.0)	2 (0.9)	6 (2.5)	6 (2.5)	6 (5.4)	6 (5.4)
抑うつ気分	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
適応障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
快感消失	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
錯乱状態	0 (0.0)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

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譫妄	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
易刺激性	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
中期不眠症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
気分変化	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
精神運動制止遅滞	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
自殺企図	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
激越	2 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
不安障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
白日夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
ディスフェミア	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
大うつ病	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
落ち着きのなさ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
睡眠時驚愕	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
生殖系および乳房障害	7 (3.1)	12 (5.3)	28 (11.7)	28 (11.7)	11 (9.9)	11 (9.9)
良性前立腺肥大症	2 (0.9)	2 (0.9)	4 (1.7)	4 (1.7)	5 (4.5)	5 (4.5)
勃起不全	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
前立腺炎	0 (0.0)	0 (0.0)	4 (1.7)	4 (1.7)	1 (0.9)	1 (0.9)
重度月経出血	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
陰嚢浮腫	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
後天性陰嚢水瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
後天性包茎	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
乳房血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
子宮内膜増殖症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
性器発疹	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
卵巣嚢胞	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
骨盤血腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
骨盤痛	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
ペイロニー病	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
前立腺腫大	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
直腸瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
陰嚢出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
陰嚢の炎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
精索出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
子宮脱	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
腟脱	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
外陰腟痛	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
外陰腟発疹	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
子宮付属器腫瘤	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
乳房圧痛	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精巣上体嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
陰茎痛	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
会陰痛	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精巣痛	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
子宮ポリープ	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
腟分泌物	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
女性外陰部潰瘍	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
耳および迷路障害	7 (3.1)	9 (4.0)	23 (9.6)	23 (9.6)	11 (9.9)	11 (9.9)
回転性めまい	2 (0.9)	3 (1.3)	10 (4.2)	10 (4.2)	4 (3.6)	4 (3.6)
耳痛	1 (0.4)	1 (0.4)	4 (1.7)	4 (1.7)	0 (0.0)	0 (0.0)
難聴	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
聴力低下	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	2 (1.8)	2 (1.8)
耳鳴	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.8)	4 (3.6)	4 (3.6)
両耳難聴	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
耳閉	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
耳出血	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
外耳の炎症	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
内耳の炎症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
メニエール病	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鼓膜穿孔	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
前庭障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
感音性難聴	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
耳不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
中耳滲出液	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
中耳の炎症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳漏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
突発性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
肝胆道系障害	2 (0.9)	11 (4.8)	13 (5.4)	13 (5.4)	3 (2.7)	3 (2.7)
胆石症	1 (0.4)	4 (1.8)	3 (1.3)	3 (1.3)	0 (0.0)	0 (0.0)
胆管炎	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
胆嚢炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肝嚢胞	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肝腫瘤	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肝腫大	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
水腫性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
肝障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
結節性再生性過形成	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
鉄沈着再生肝結節	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
胆道仙痛	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
急性胆嚢炎	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胆嚢破裂	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝硬変	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝細胞融解	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
脂肪肝	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
肝損傷	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
脂肪性肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
免疫系障害	16 (7.0)	26 (11.5)	13 (5.4)	13 (5.4)	8 (7.2)	8 (7.2)
免疫反応	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	3 (2.7)	3 (2.7)
季節性アレルギー	0 (0.0)	0 (0.0)	3 (1.3)	3 (1.3)	1 (0.9)	1 (0.9)
造影剤アレルギー	0 (0.0)	8 (3.5)	2 (0.8)	2 (0.8)	1 (0.9)	1 (0.9)
低γグロブリン血症	3 (1.3)	5 (2.2)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
節足動物刺傷アレルギー	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
ワクチンアレルギー	0 (0.0)	1 (0.4)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
造影剤反応	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.9)	1 (0.9)
薬物過敏症	9 (4.0)	9 (4.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
過敏症	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
節足動物咬傷アレルギー	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.8)
サイトカイン放出症候群	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
輸注関連過敏反応	2 (0.9)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
続発性免疫不全症	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
内分泌障害	1 (0.4)	2 (0.9)	3 (1.3)	3 (1.3)	2 (1.8)	2 (1.8)
甲状腺機能亢進症	0 (0.0)	1 (0.4)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
副腎機能不全	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
尿崩症	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
甲状腺腫	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
甲状腺機能低下症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
甲状腺腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)
先天性、家族性および遺伝性障害	1 (0.4)	2 (0.9)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
前房分離不全症候群	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)
先天性涙道狭窄	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
先天性黄斑部ジストロフィー	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
製品の問題	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
医療機器内血栓	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

System Organ Class Preferred Term	Cohort 1 BR (N = 227) Treatment-Emergent n (%)	Cohort 1 BR (N = 227) Treatment-Emergent and Post-treatment n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent n (%)	Cohort 1 Zanubrutinib (N = 240) Treatment-Emergent and Post-treatment n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent n (%)	Cohort 2 Zanubrutinib (N = 111) Treatment-Emergent and Post-treatment n (%)
Uncoded	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)
Uncoded	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	0 (0.0)

Source: Table 14.3.1.2.2.1.1 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
Abbreviations: AE, adverse event; B, Bendamustine; R, Rituximab; BR, Bendamustine and Rituximab; TEAE, treatment-emergent adverse event.
Notes: Adverse events were classified based on MedDRA Version 24.0
TEAE is defined as an AE that had an onset date or was worsening in severity from baseline (pretreatment) on or after the first dose of study drug up to 30 days after the last dose of zanubrutinib for zanubrutinib arm A and 90 days after the last dose of B or R (Arm B) following study drug discontinuation or the start of new anticancer therapy (including the zanubrutinib for Arm B patients crossed over), whichever comes first.
Post-treatment AEs include AEs that had an onset date or was worsening in severity during the post-treatment follow-up phase, defined as from the day after the last dose (either zanubrutinib in Arm A, or B or R in Arm B) to the date of progressive disease, except for the events after patients in Arm B crossover to zanubrutinib.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively. Events were sorted by descending order within System Organ Class, and by Preferred Term within System Organ Class in the Treatment-Emergent and Post-treatment Cohort 1 Zanubrutinib column.

表 48： 投与に関連のある TEAE：器官別大分類別及び基本語別、コホート 1（BGB-3111-304 試験、安全性解析対象集団）

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
Patients With at Least One Treatment-Related TEAE	202 (89.0)	178 (74.2)	380 (81.4)
血液およびリンパ系障害	124 (54.6)	39 (16.3)	163 (34.9)
好中球減少症	98 (43.2)	24 (10.0)	122 (26.1)
貧血	30 (13.2)	6 (2.5)	36 (7.7)
血小板減少症	27 (11.9)	7 (2.9)	34 (7.3)
発熱性好中球減少症	17 (7.5)	1 (0.4)	18 (3.9)
白血球減少症	7 (3.1)	1 (0.4)	8 (1.7)
内出血発生の増加傾向	0 (0.0)	3 (1.3)	3 (0.6)
リンパ球減少症	2 (0.9)	1 (0.4)	3 (0.6)
失血性貧血	0 (0.0)	1 (0.4)	1 (0.2)
好酸球増加症	0 (0.0)	1 (0.4)	1 (0.2)
顆粒球減少症	1 (0.4)	0 (0.0)	1 (0.2)
溶血	0 (0.0)	1 (0.4)	1 (0.2)
リンパ節症	0 (0.0)	1 (0.4)	1 (0.2)
汎血球減少症	0 (0.0)	1 (0.4)	1 (0.2)
胃腸障害	88 (38.8)	53 (22.1)	141 (30.2)
悪心	66 (29.1)	10 (4.2)	76 (16.3)
嘔吐	24 (10.6)	2 (0.8)	26 (5.6)
下痢	10 (4.4)	15 (6.3)	25 (5.4)
便秘	13 (5.7)	5 (2.1)	18 (3.9)
口内炎	5 (2.2)	3 (1.3)	8 (1.7)
消化不良	3 (1.3)	3 (1.3)	6 (1.3)
口腔内潰瘍形成	2 (0.9)	4 (1.7)	6 (1.3)
口内乾燥	3 (1.3)	1 (0.4)	4 (0.9)
口腔内出血	0 (0.0)	4 (1.7)	4 (0.9)
腹部膨満	0 (0.0)	3 (1.3)	3 (0.6)
腹痛	2 (0.9)	1 (0.4)	3 (0.6)
上腹部痛	0 (0.0)	3 (1.3)	3 (0.6)
鼓腸	0 (0.0)	3 (1.3)	3 (0.6)
軟便	1 (0.4)	1 (0.4)	2 (0.4)
胃食道逆流性疾患	1 (0.4)	1 (0.4)	2 (0.4)
歯肉出血	0 (0.0)	2 (0.8)	2 (0.4)
腹部不快感	1 (0.4)	0 (0.0)	1 (0.2)
腹壁血腫	0 (0.0)	1 (0.4)	1 (0.2)
アフタ性潰瘍	1 (0.4)	0 (0.0)	1 (0.2)
腸炎	1 (0.4)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
排便回数増加	0 (0.0)	1 (0.4)	1 (0.2)
胃潰瘍	1 (0.4)	0 (0.0)	1 (0.2)
出血性胃潰瘍	0 (0.0)	1 (0.4)	1 (0.2)
胃炎	0 (0.0)	1 (0.4)	1 (0.2)
歯肉浮腫	0 (0.0)	1 (0.4)	1 (0.2)
嚥下痛	0 (0.0)	1 (0.4)	1 (0.2)
舌障害	0 (0.0)	1 (0.4)	1 (0.2)
上部消化管出血	0 (0.0)	1 (0.4)	1 (0.2)
食道静脈瘤	0 (0.0)	1 (0.4)	1 (0.2)
一般・全身障害および投与部位の状態	86 (37.9)	32 (13.3)	118 (25.3)
疲労	26 (11.5)	20 (8.3)	46 (9.9)
発熱	40 (17.6)	3 (1.3)	43 (9.2)
無力症	13 (5.7)	3 (1.3)	16 (3.4)
悪寒	14 (6.2)	1 (0.4)	15 (3.2)
末梢性浮腫	3 (1.3)	5 (2.1)	8 (1.7)
顔面浮腫	1 (0.4)	2 (0.8)	3 (0.6)
熱感	1 (0.4)	1 (0.4)	2 (0.4)
倦怠感	2 (0.9)	0 (0.0)	2 (0.4)
末梢腫脹	1 (0.4)	1 (0.4)	2 (0.4)
医薬品副作用	1 (0.4)	0 (0.0)	1 (0.2)
胸部不快感	1 (0.4)	0 (0.0)	1 (0.2)
不快感	1 (0.4)	0 (0.0)	1 (0.2)
溢出	1 (0.4)	0 (0.0)	1 (0.2)
注入部位血管外漏出	1 (0.4)	0 (0.0)	1 (0.2)
注射部位反応	1 (0.4)	0 (0.0)	1 (0.2)
非心臓性胸痛	1 (0.4)	0 (0.0)	1 (0.2)
疼痛	1 (0.4)	0 (0.0)	1 (0.2)
血管穿刺部位内出血	0 (0.0)	1 (0.4)	1 (0.2)
皮膚および皮下組織障害	44 (19.4)	64 (26.7)	108 (23.1)
発疹	21 (9.3)	14 (5.8)	35 (7.5)
点状出血	0 (0.0)	18 (7.5)	18 (3.9)
そう痒症	6 (2.6)	6 (2.5)	12 (2.6)
紅斑	6 (2.6)	4 (1.7)	10 (2.1)
斑状丘疹状皮疹	5 (2.2)	5 (2.1)	10 (2.1)
皮膚乾燥	3 (1.3)	5 (2.1)	8 (1.7)
斑状出血	0 (0.0)	5 (2.1)	5 (1.1)
ざ瘡様皮膚炎	1 (0.4)	2 (0.8)	3 (0.6)
紫斑	0 (0.0)	3 (1.3)	3 (0.6)
蕁麻疹	0 (0.0)	3 (1.3)	3 (0.6)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
脱毛症	0 (0.0)	2 (0.8)	2 (0.4)
アレルギー性皮膚炎	2 (0.9)	0 (0.0)	2 (0.4)
寝汗	1 (0.4)	1 (0.4)	2 (0.4)
爪破損	0 (0.0)	2 (0.8)	2 (0.4)
紅斑性皮疹	2 (0.9)	0 (0.0)	2 (0.4)
丘疹性皮疹	1 (0.4)	1 (0.4)	2 (0.4)
皮膚変色	0 (0.0)	2 (0.8)	2 (0.4)
皮膚剥脱	1 (0.4)	1 (0.4)	2 (0.4)
皮膚出血	0 (0.0)	2 (0.8)	2 (0.4)
皮膚病変	0 (0.0)	2 (0.8)	2 (0.4)
水疱	0 (0.0)	1 (0.4)	1 (0.2)
皮膚炎	0 (0.0)	1 (0.4)	1 (0.2)
手皮膚炎	0 (0.0)	1 (0.4)	1 (0.2)
多汗症	1 (0.4)	0 (0.0)	1 (0.2)
虚血性皮膚潰瘍	0 (0.0)	1 (0.4)	1 (0.2)
斑	0 (0.0)	1 (0.4)	1 (0.2)
爪床出血	0 (0.0)	1 (0.4)	1 (0.2)
光線過敏性反応	0 (0.0)	1 (0.4)	1 (0.2)
そう痒性皮疹	1 (0.4)	0 (0.0)	1 (0.2)
酒さ	0 (0.0)	1 (0.4)	1 (0.2)
中毒性皮疹	1 (0.4)	0 (0.0)	1 (0.2)
感染症および寄生虫症	44 (19.4)	53 (22.1)	97 (20.8)
肺炎	7 (3.1)	9 (3.8)	16 (3.4)
上気道感染	4 (1.8)	10 (4.2)	14 (3.0)
尿路感染	6 (2.6)	7 (2.9)	13 (2.8)
気管支炎	5 (2.2)	3 (1.3)	8 (1.7)
COVID-19	0 (0.0)	5 (2.1)	5 (1.1)
蜂巣炎	0 (0.0)	5 (2.1)	5 (1.1)
下気道感染	1 (0.4)	4 (1.7)	5 (1.1)
口腔ヘルペス	3 (1.3)	2 (0.8)	5 (1.1)
気道感染	2 (0.9)	3 (1.3)	5 (1.1)
敗血症	4 (1.8)	1 (0.4)	5 (1.1)
B 型肝炎再活性化	2 (0.9)	2 (0.8)	4 (0.9)
帯状疱疹	2 (0.9)	2 (0.8)	4 (0.9)
感染	4 (1.8)	0 (0.0)	4 (0.9)
上咽頭炎	1 (0.4)	2 (0.8)	3 (0.6)
口腔カンジダ症	1 (0.4)	2 (0.8)	3 (0.6)
副鼻腔炎	1 (0.4)	2 (0.8)	3 (0.6)
皮膚感染	0 (0.0)	3 (1.3)	3 (0.6)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
結膜炎	2 (0.9)	0 (0.0)	2 (0.4)
シュードモナス性敗血症	2 (0.9)	0 (0.0)	2 (0.4)
急性副鼻腔炎	0 (0.0)	1 (0.4)	1 (0.2)
COVID-19 肺炎	0 (0.0)	1 (0.4)	1 (0.2)
カンピロバクター胃腸炎	1 (0.4)	0 (0.0)	1 (0.2)
ウイルス性結膜炎	1 (0.4)	0 (0.0)	1 (0.2)
大腸菌性尿路感染	1 (0.4)	0 (0.0)	1 (0.2)
皮膚真菌感染	0 (0.0)	1 (0.4)	1 (0.2)
赤痢菌性胃腸炎	0 (0.0)	1 (0.4)	1 (0.2)
歯肉炎	0 (0.0)	1 (0.4)	1 (0.2)
ヘモフィルス感染	1 (0.4)	0 (0.0)	1 (0.2)
ヘルペス眼感染	1 (0.4)	0 (0.0)	1 (0.2)
迷路炎	0 (0.0)	1 (0.4)	1 (0.2)
限局性感染	0 (0.0)	1 (0.4)	1 (0.2)
真菌性下気道感染	0 (0.0)	1 (0.4)	1 (0.2)
モルガネラ感染	0 (0.0)	1 (0.4)	1 (0.2)
鼻ヘルペス	0 (0.0)	1 (0.4)	1 (0.2)
好中球減少性敗血症	1 (0.4)	0 (0.0)	1 (0.2)
パラインフルエンザウイルス気管支炎	0 (0.0)	1 (0.4)	1 (0.2)
パラインフルエンザウイルス感染	1 (0.4)	0 (0.0)	1 (0.2)
爪囲炎	0 (0.0)	1 (0.4)	1 (0.2)
ニューモシスチス・イロベチイ肺炎	0 (0.0)	1 (0.4)	1 (0.2)
シュードモナス性菌血症	1 (0.4)	0 (0.0)	1 (0.2)
敗血症性ショック	0 (0.0)	1 (0.4)	1 (0.2)
真菌性副鼻腔炎	0 (0.0)	1 (0.4)	1 (0.2)
尿路性敗血症	0 (0.0)	1 (0.4)	1 (0.2)
創傷感染	1 (0.4)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	44 (19.4)	46 (19.2)	90 (19.3)
注入に伴う反応	43 (18.9)	0 (0.0)	43 (9.2)
挫傷	1 (0.4)	40 (16.7)	41 (8.8)
皮下血腫	0 (0.0)	4 (1.7)	4 (0.9)
処置後出血	0 (0.0)	3 (1.3)	3 (0.6)
転倒	0 (0.0)	1 (0.4)	1 (0.2)
処置による疼痛	1 (0.4)	0 (0.0)	1 (0.2)
陰嚢血腫	0 (0.0)	1 (0.4)	1 (0.2)
硬膜下出血	0 (0.0)	1 (0.4)	1 (0.2)
臨床検査	50 (22.0)	17 (7.1)	67 (14.3)
好中球数減少	27 (11.9)	7 (2.9)	34 (7.3)
アラニンアミノトランスフェラーゼ増加	8 (3.5)	5 (2.1)	13 (2.8)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
アスパラギン酸アミノトランスフェラーゼ増加	7 (3.1)	3 (1.3)	10 (2.1)
血小板数減少	8 (3.5)	0 (0.0)	8 (1.7)
血中ビリルビン増加	2 (0.9)	2 (0.8)	4 (0.9)
γーグルタミルトランスフェラーゼ増加	2 (0.9)	2 (0.8)	4 (0.9)
体重減少	3 (1.3)	1 (0.4)	4 (0.9)
白血球数減少	4 (1.8)	0 (0.0)	4 (0.9)
血中アルカリホスファターゼ増加	2 (0.9)	1 (0.4)	3 (0.6)
血中クレアチニン増加	1 (0.4)	1 (0.4)	2 (0.4)
血中乳酸脱水素酵素増加	1 (0.4)	1 (0.4)	2 (0.4)
C-反応性蛋白増加	2 (0.9)	0 (0.0)	2 (0.4)
フィブリン D ダイマー増加	2 (0.9)	0 (0.0)	2 (0.4)
出血時間延長	0 (0.0)	1 (0.4)	1 (0.2)
血中フィブリノゲン減少	1 (0.4)	0 (0.0)	1 (0.2)
血圧低下	1 (0.4)	0 (0.0)	1 (0.2)
体温上昇	1 (0.4)	0 (0.0)	1 (0.2)
糸球体濾過率減少	0 (0.0)	1 (0.4)	1 (0.2)
ヘモグロビン減少	1 (0.4)	0 (0.0)	1 (0.2)
ヒトライノウイルス検査陽性	0 (0.0)	1 (0.4)	1 (0.2)
A 型インフルエンザウイルス検査陽性	1 (0.4)	0 (0.0)	1 (0.2)
リンパ球数減少	0 (0.0)	1 (0.4)	1 (0.2)
酸素飽和度低下	1 (0.4)	0 (0.0)	1 (0.2)
トランスアミナーゼ上昇	1 (0.4)	0 (0.0)	1 (0.2)
トロポニン増加	0 (0.0)	1 (0.4)	1 (0.2)
血管障害	20 (8.8)	28 (11.7)	48 (10.3)
高血圧	2 (0.9)	15 (6.3)	17 (3.6)
血腫	0 (0.0)	11 (4.6)	11 (2.4)
低血圧	11 (4.8)	0 (0.0)	11 (2.4)
潮紅	4 (1.8)	0 (0.0)	4 (0.9)
高血圧クリーゼ	0 (0.0)	1 (0.4)	1 (0.2)
末梢静脈疾患	1 (0.4)	0 (0.0)	1 (0.2)
静脈炎	1 (0.4)	0 (0.0)	1 (0.2)
表在性静脈炎	1 (0.4)	0 (0.0)	1 (0.2)
血栓性静脈炎	1 (0.4)	0 (0.0)	1 (0.2)
血管破裂	0 (0.0)	1 (0.4)	1 (0.2)
白衣性高血圧	0 (0.0)	1 (0.4)	1 (0.2)
代謝および栄養障害	32 (14.1)	15 (6.3)	47 (10.1)
食欲減退	13 (5.7)	2 (0.8)	15 (3.2)
高尿酸血症	5 (2.2)	2 (0.8)	7 (1.5)
脱水	6 (2.6)	0 (0.0)	6 (1.3)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
痛風	2 (0.9)	2 (0.8)	4 (0.9)
低ナトリウム血症	1 (0.4)	3 (1.3)	4 (0.9)
低カルシウム血症	1 (0.4)	2 (0.8)	3 (0.6)
腫瘍崩壊症候群	3 (1.3)	0 (0.0)	3 (0.6)
低カリウム血症	2 (0.9)	0 (0.0)	2 (0.4)
コントロール不良の糖尿病	0 (0.0)	1 (0.4)	1 (0.2)
耐糖能障害	0 (0.0)	1 (0.4)	1 (0.2)
高コレステロール血症	0 (0.0)	1 (0.4)	1 (0.2)
高血糖	0 (0.0)	1 (0.4)	1 (0.2)
高脂血症	0 (0.0)	1 (0.4)	1 (0.2)
高リン血症	1 (0.4)	0 (0.0)	1 (0.2)
低蛋白血症	1 (0.4)	0 (0.0)	1 (0.2)
血液量減少症	0 (0.0)	1 (0.4)	1 (0.2)
神経系障害	20 (8.8)	20 (8.3)	40 (8.6)
頭痛	9 (4.0)	11 (4.6)	20 (4.3)
浮動性めまい	4 (1.8)	3 (1.3)	7 (1.5)
味覚不全	3 (1.3)	0 (0.0)	3 (0.6)
末梢性感覚ニューロパチー	1 (0.4)	1 (0.4)	2 (0.4)
振戦	1 (0.4)	1 (0.4)	2 (0.4)
認知障害	1 (0.4)	0 (0.0)	1 (0.2)
顔面神経障害	1 (0.4)	0 (0.0)	1 (0.2)
卒中の出血性変化	0 (0.0)	1 (0.4)	1 (0.2)
感覚鈍麻	0 (0.0)	1 (0.4)	1 (0.2)
ラクナ梗塞	0 (0.0)	1 (0.4)	1 (0.2)
嗜眠	0 (0.0)	1 (0.4)	1 (0.2)
末梢性運動ニューロパチー	1 (0.4)	0 (0.0)	1 (0.2)
末梢性感覚運動ニューロパチー	0 (0.0)	1 (0.4)	1 (0.2)
くも膜下出血	0 (0.0)	1 (0.4)	1 (0.2)
一過性脳虚血発作	1 (0.4)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害	15 (6.6)	24 (10.0)	39 (8.4)
鼻出血	0 (0.0)	10 (4.2)	10 (2.1)
咳嗽	3 (1.3)	4 (1.7)	7 (1.5)
呼吸困難	3 (1.3)	2 (0.8)	5 (1.1)
胸水	1 (0.4)	2 (0.8)	3 (0.6)
肺臓炎	1 (0.4)	2 (0.8)	3 (0.6)
口腔咽頭痛	1 (0.4)	1 (0.4)	2 (0.4)
上気道咳症候群	1 (0.4)	1 (0.4)	2 (0.4)
急性呼吸不全	0 (0.0)	1 (0.4)	1 (0.2)
咽喉乾燥	0 (0.0)	1 (0.4)	1 (0.2)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
労作性呼吸困難	0 (0.0)	1 (0.4)	1 (0.2)
しゃっくり	1 (0.4)	0 (0.0)	1 (0.2)
低酸素症	1 (0.4)	0 (0.0)	1 (0.2)
肺障害	1 (0.4)	0 (0.0)	1 (0.2)
肺浸潤	0 (0.0)	1 (0.4)	1 (0.2)
肺線維症	0 (0.0)	1 (0.4)	1 (0.2)
肺腫瘤	1 (0.4)	0 (0.0)	1 (0.2)
呼吸不全	0 (0.0)	1 (0.4)	1 (0.2)
咽喉刺激感	1 (0.4)	0 (0.0)	1 (0.2)
上気道の炎症	1 (0.4)	0 (0.0)	1 (0.2)
筋骨格系および結合組織障害	10 (4.4)	27 (11.3)	37 (7.9)
関節痛	3 (1.3)	12 (5.0)	15 (3.2)
筋痙縮	0 (0.0)	5 (2.1)	5 (1.1)
背部痛	4 (1.8)	0 (0.0)	4 (0.9)
四肢痛	1 (0.4)	3 (1.3)	4 (0.9)
関節炎	0 (0.0)	2 (0.8)	2 (0.4)
骨痛	1 (0.4)	1 (0.4)	2 (0.4)
関節腫脹	1 (0.4)	1 (0.4)	2 (0.4)
筋肉痛	0 (0.0)	2 (0.8)	2 (0.4)
筋力低下	0 (0.0)	1 (0.4)	1 (0.2)
筋骨格系胸痛	0 (0.0)	1 (0.4)	1 (0.2)
筋炎	0 (0.0)	1 (0.4)	1 (0.2)
軟部組織出血	0 (0.0)	1 (0.4)	1 (0.2)
心臓障害	3 (1.3)	24 (10.0)	27 (5.8)
心房細動	0 (0.0)	10 (4.2)	10 (2.1)
動悸	1 (0.4)	6 (2.5)	7 (1.5)
心筋梗塞	1 (0.4)	2 (0.8)	3 (0.6)
洞性徐脈	1 (0.4)	1 (0.4)	2 (0.4)
狭心症	0 (0.0)	1 (0.4)	1 (0.2)
心房粗動	0 (0.0)	1 (0.4)	1 (0.2)
徐脈	0 (0.0)	1 (0.4)	1 (0.2)
左脚ブロック	0 (0.0)	1 (0.4)	1 (0.2)
急性心不全	0 (0.0)	1 (0.4)	1 (0.2)
心筋炎	0 (0.0)	1 (0.4)	1 (0.2)
心嚢液貯留	0 (0.0)	1 (0.4)	1 (0.2)
頻脈	0 (0.0)	1 (0.4)	1 (0.2)
心室性期外収縮	0 (0.0)	1 (0.4)	1 (0.2)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
心室性頻脈	0 (0.0)	1 (0.4)	1 (0.2)
腎および尿路障害	9 (4.0)	12 (5.0)	21 (4.5)
血尿	0 (0.0)	9 (3.8)	9 (1.9)
急性腎障害	6 (2.6)	0 (0.0)	6 (1.3)
頻尿	2 (0.9)	0 (0.0)	2 (0.4)
慢性腎臓病	0 (0.0)	1 (0.4)	1 (0.2)
水腎症	0 (0.0)	1 (0.4)	1 (0.2)
尿意切迫	0 (0.0)	1 (0.4)	1 (0.2)
腎不全	1 (0.4)	0 (0.0)	1 (0.2)
尿失禁	0 (0.0)	1 (0.4)	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3 (1.3)	7 (2.9)	10 (2.1)
基底細胞癌	0 (0.0)	3 (1.3)	3 (0.6)
肛門扁平上皮癌	0 (0.0)	1 (0.4)	1 (0.2)
ボーエン病	1 (0.4)	0 (0.0)	1 (0.2)
乳腺線維腺腫	1 (0.4)	0 (0.0)	1 (0.2)
遠隔転移を伴う扁平上皮癌	0 (0.0)	1 (0.4)	1 (0.2)
皮膚癌	0 (0.0)	1 (0.4)	1 (0.2)
遠隔転移を伴う皮膚有棘細胞癌	1 (0.4)	0 (0.0)	1 (0.2)
肺扁平上皮癌	0 (0.0)	1 (0.4)	1 (0.2)
免疫系障害	8 (3.5)	1 (0.4)	9 (1.9)
薬物過敏症	4 (1.8)	0 (0.0)	4 (0.9)
低γグロブリン血症	1 (0.4)	1 (0.4)	2 (0.4)
輸注関連過敏反応	2 (0.9)	0 (0.0)	2 (0.4)
サイトカイン放出症候群	1 (0.4)	0 (0.0)	1 (0.2)
耳および迷路障害	2 (0.9)	6 (2.5)	8 (1.7)
回転性めまい	1 (0.4)	2 (0.8)	3 (0.6)
難聴	0 (0.0)	1 (0.4)	1 (0.2)
耳出血	0 (0.0)	1 (0.4)	1 (0.2)
耳痛	0 (0.0)	1 (0.4)	1 (0.2)
耳鳴	1 (0.4)	0 (0.0)	1 (0.2)
前庭障害	0 (0.0)	1 (0.4)	1 (0.2)
眼障害	1 (0.4)	5 (2.1)	6 (1.3)
ドライアイ	0 (0.0)	3 (1.3)	3 (0.6)
眼出血	0 (0.0)	1 (0.4)	1 (0.2)
眼そう痒症	0 (0.0)	1 (0.4)	1 (0.2)
網膜出血	0 (0.0)	1 (0.4)	1 (0.2)

System Organ Class Preferred Term	BR (N = 227) n (%)	Zanubrutinib (N = 240) n (%)	Total (Cohort 1) (N = 467) n (%)
眼瞼腫脹	1 (0.4)	0 (0.0)	1 (0.2)
霧視	0 (0.0)	1 (0.4)	1 (0.2)
生殖系および乳房障害	1 (0.4)	5 (2.1)	6 (1.3)
勃起不全	0 (0.0)	2 (0.8)	2 (0.4)
乳房血腫	0 (0.0)	1 (0.4)	1 (0.2)
骨盤血腫	0 (0.0)	1 (0.4)	1 (0.2)
骨盤痛	1 (0.4)	0 (0.0)	1 (0.2)
陰嚢浮腫	0 (0.0)	1 (0.4)	1 (0.2)
精神障害	2 (0.9)	2 (0.8)	4 (0.9)
不眠症	1 (0.4)	2 (0.8)	3 (0.6)
抑うつ気分	1 (0.4)	0 (0.0)	1 (0.2)
肝胆道系障害	0 (0.0)	2 (0.8)	2 (0.4)
肝腫大	0 (0.0)	1 (0.4)	1 (0.2)
結節性再生性過形成	0 (0.0)	1 (0.4)	1 (0.2)

Source: Table 14.3.1.2.6.1.1 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
Abbreviations: AE, adverse event; B, Bendamustine; R, Rituximab; BR, Bendamustine and Rituximab; TEAE, treatment-emergent adverse event.
Notes: Adverse events were classified based on MedDRA Version 24.0
TEAE is defined as an AE that had an onset date or was worsening in severity from baseline (pretreatment) on or after the first dose of study drug up to 30 days after the last dose of zanubrutinib for zanubrutinib arm A and 90 days after the last dose of B or R (Arm B) following study drug discontinuation or the start of new anticancer therapy (including the zanubrutinib for Arm B patients crossed over), whichever comes first.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively. Events were sorted by descending order within System Organ Class, and by Preferred Term within System Organ Class in the Treatment-Emergent Total column.
Treatment-related AEs included AEs related to either B or R in Arm B and zanubrutinib in Arm A.

表 49： 投与に関連のある TEAE：器官別大分類別及び基本語別、ザヌブルチニブ群（BGB-3111-304 試験、安全性解析対象集団）

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
Patients With at Least One Treatment-Related TEAE	178 (74.2)	82 (73.9)	260 (74.1)
皮膚および皮下組織障害	64 (26.7)	25 (22.5)	89 (25.4)
点状出血	18 (7.5)	5 (4.5)	23 (6.6)
発疹	14 (5.8)	3 (2.7)	17 (4.8)
斑状出血	5 (2.1)	5 (4.5)	10 (2.8)
そう痒症	6 (2.5)	4 (3.6)	10 (2.8)
紅斑	4 (1.7)	2 (1.8)	6 (1.7)
紫斑	3 (1.3)	3 (2.7)	6 (1.7)
斑状丘疹状皮疹	5 (2.1)	1 (0.9)	6 (1.7)
皮膚乾燥	5 (2.1)	0 (0.0)	5 (1.4)
爪破損	2 (0.8)	1 (0.9)	3 (0.9)
皮膚病変	2 (0.8)	1 (0.9)	3 (0.9)
蕁麻疹	3 (1.3)	0 (0.0)	3 (0.9)
脱毛症	2 (0.8)	0 (0.0)	2 (0.6)
皮膚炎	1 (0.4)	1 (0.9)	2 (0.6)
ざ瘡様皮膚炎	2 (0.8)	0 (0.0)	2 (0.6)
皮膚変色	2 (0.8)	0 (0.0)	2 (0.6)
皮膚出血	2 (0.8)	0 (0.0)	2 (0.6)
水疱	1 (0.4)	0 (0.0)	1 (0.3)
手皮膚炎	1 (0.4)	0 (0.0)	1 (0.3)
虚血性皮膚潰瘍	1 (0.4)	0 (0.0)	1 (0.3)
斑	1 (0.4)	0 (0.0)	1 (0.3)
皮膚粘膜出血	0 (0.0)	1 (0.9)	1 (0.3)
爪床出血	1 (0.4)	0 (0.0)	1 (0.3)
好中球性皮膚症	0 (0.0)	1 (0.9)	1 (0.3)
寝汗	1 (0.4)	0 (0.0)	1 (0.3)
脂肪織炎	0 (0.0)	1 (0.9)	1 (0.3)
光線過敏性反応	1 (0.4)	0 (0.0)	1 (0.3)
足底紅斑	0 (0.0)	1 (0.9)	1 (0.3)
丘疹性皮疹	1 (0.4)	0 (0.0)	1 (0.3)
そう痒性皮疹	0 (0.0)	1 (0.9)	1 (0.3)
酒さ	1 (0.4)	0 (0.0)	1 (0.3)
皮膚剥脱	1 (0.4)	0 (0.0)	1 (0.3)
皮膚潰瘍	0 (0.0)	1 (0.9)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
感染症および寄生虫症	53 (22.1)	29 (26.1)	82 (23.4)
肺炎	9 (3.8)	7 (6.3)	16 (4.6)
上気道感染	10 (4.2)	6 (5.4)	16 (4.6)
尿路感染	7 (2.9)	2 (1.8)	9 (2.6)
COVID-19	5 (2.1)	2 (1.8)	7 (2.0)
気道感染	3 (1.3)	3 (2.7)	6 (1.7)
気管支炎	3 (1.3)	2 (1.8)	5 (1.4)
蜂巣炎	5 (2.1)	0 (0.0)	5 (1.4)
下気道感染	4 (1.7)	0 (0.0)	4 (1.1)
上咽頭炎	2 (0.8)	1 (0.9)	3 (0.9)
口腔ヘルペス	2 (0.8)	1 (0.9)	3 (0.9)
副鼻腔炎	2 (0.8)	1 (0.9)	3 (0.9)
皮膚感染	3 (1.3)	0 (0.0)	3 (0.9)
COVID-19 肺炎	1 (0.4)	1 (0.9)	2 (0.6)
B 型肝炎再活性化	2 (0.8)	0 (0.0)	2 (0.6)
帯状疱疹	2 (0.8)	0 (0.0)	2 (0.6)
感染	0 (0.0)	2 (1.8)	2 (0.6)
口腔カンジダ症	2 (0.8)	0 (0.0)	2 (0.6)
尿路性敗血症	1 (0.4)	1 (0.9)	2 (0.6)
急性副鼻腔炎	1 (0.4)	0 (0.0)	1 (0.3)
異型肺炎	0 (0.0)	1 (0.9)	1 (0.3)
感染性胆嚢炎	0 (0.0)	1 (0.9)	1 (0.3)
結膜炎	0 (0.0)	1 (0.9)	1 (0.3)
皮膚真菌感染	1 (0.4)	0 (0.0)	1 (0.3)
赤痢菌性胃腸炎	1 (0.4)	0 (0.0)	1 (0.3)
歯肉炎	1 (0.4)	0 (0.0)	1 (0.3)
肛径部膿瘍	0 (0.0)	1 (0.9)	1 (0.3)
麦粒腫	0 (0.0)	1 (0.9)	1 (0.3)
迷路炎	1 (0.4)	0 (0.0)	1 (0.3)
限局性感染	1 (0.4)	0 (0.0)	1 (0.3)
真菌性下気道感染	1 (0.4)	0 (0.0)	1 (0.3)
クリプトコッカス性髄膜炎	0 (0.0)	1 (0.9)	1 (0.3)
モルガネラ感染	1 (0.4)	0 (0.0)	1 (0.3)
鼻ヘルペス	1 (0.4)	0 (0.0)	1 (0.3)
中耳炎	0 (0.0)	1 (0.9)	1 (0.3)
パラインフルエンザウイルス気管支炎	1 (0.4)	0 (0.0)	1 (0.3)
爪囲炎	1 (0.4)	0 (0.0)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	1 (0.4)	0 (0.0)	1 (0.3)
シュードモナス性敗血症	0 (0.0)	1 (0.9)	1 (0.3)
敗血症	1 (0.4)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
敗血症性ショック	1 (0.4)	0 (0.0)	1 (0.3)
真菌性副鼻腔炎	1 (0.4)	0 (0.0)	1 (0.3)
胃腸障害	53 (22.1)	24 (21.6)	77 (21.9)
下痢	15 (6.3)	10 (9.0)	25 (7.1)
悪心	10 (4.2)	5 (4.5)	15 (4.3)
便秘	5 (2.1)	3 (2.7)	8 (2.3)
口腔内潰瘍形成	4 (1.7)	2 (1.8)	6 (1.7)
上腹部痛	3 (1.3)	2 (1.8)	5 (1.4)
消化不良	3 (1.3)	1 (0.9)	4 (1.1)
口腔内出血	4 (1.7)	0 (0.0)	4 (1.1)
嘔吐	2 (0.8)	2 (1.8)	4 (1.1)
腹部膨満	3 (1.3)	0 (0.0)	3 (0.9)
鼓腸	3 (1.3)	0 (0.0)	3 (0.9)
胃食道逆流性疾患	1 (0.4)	2 (1.8)	3 (0.9)
歯肉出血	2 (0.8)	1 (0.9)	3 (0.9)
口内炎	3 (1.3)	0 (0.0)	3 (0.9)
腹痛	1 (0.4)	1 (0.9)	2 (0.6)
腹壁血腫	1 (0.4)	0 (0.0)	1 (0.3)
口内乾燥	1 (0.4)	0 (0.0)	1 (0.3)
軟便	1 (0.4)	0 (0.0)	1 (0.3)
排便回数増加	1 (0.4)	0 (0.0)	1 (0.3)
出血性胃潰瘍	1 (0.4)	0 (0.0)	1 (0.3)
胃炎	1 (0.4)	0 (0.0)	1 (0.3)
歯肉浮腫	1 (0.4)	0 (0.0)	1 (0.3)
痔核	0 (0.0)	1 (0.9)	1 (0.3)
口腔白斑症	0 (0.0)	1 (0.9)	1 (0.3)
口唇水疱	0 (0.0)	1 (0.9)	1 (0.3)
嚥下痛	1 (0.4)	0 (0.0)	1 (0.3)
口腔血性水疱	0 (0.0)	1 (0.9)	1 (0.3)
舌障害	1 (0.4)	0 (0.0)	1 (0.3)
上部消化管出血	1 (0.4)	0 (0.0)	1 (0.3)
食道静脈瘤	1 (0.4)	0 (0.0)	1 (0.3)
傷害、中毒および処置合併症	46 (19.2)	24 (21.6)	70 (19.9)
挫傷	40 (16.7)	19 (17.1)	59 (16.8)
皮下血腫	4 (1.7)	1 (0.9)	5 (1.4)
処置後出血	3 (1.3)	1 (0.9)	4 (1.1)
転倒	1 (0.4)	0 (0.0)	1 (0.3)
眼窩周囲出血	0 (0.0)	1 (0.9)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
処置後挫傷	0 (0.0)	1 (0.9)	1 (0.3)
陰嚢血腫	1 (0.4)	0 (0.0)	1 (0.3)
皮膚創傷	0 (0.0)	1 (0.9)	1 (0.3)
硬膜下出血	1 (0.4)	0 (0.0)	1 (0.3)
血液およびリンパ系障害	39 (16.3)	20 (18.0)	59 (16.8)
好中球減少症	24 (10.0)	9 (8.1)	33 (9.4)
貧血	6 (2.5)	4 (3.6)	10 (2.8)
血小板減少症	7 (2.9)	2 (1.8)	9 (2.6)
内出血発生の増加傾向	3 (1.3)	3 (2.7)	6 (1.7)
発熱性好中球減少症	1 (0.4)	1 (0.9)	2 (0.6)
失血性貧血	1 (0.4)	0 (0.0)	1 (0.3)
好酸球増加症	1 (0.4)	0 (0.0)	1 (0.3)
溶血	1 (0.4)	0 (0.0)	1 (0.3)
出血性素因	0 (0.0)	1 (0.9)	1 (0.3)
白血球減少症	1 (0.4)	0 (0.0)	1 (0.3)
リンパ節症	1 (0.4)	0 (0.0)	1 (0.3)
リンパ球減少症	1 (0.4)	0 (0.0)	1 (0.3)
汎血球減少症	1 (0.4)	0 (0.0)	1 (0.3)
一般・全身障害および投与部位の状態	32 (13.3)	10 (9.0)	42 (12.0)
疲労	20 (8.3)	6 (5.4)	26 (7.4)
末梢性浮腫	5 (2.1)	1 (0.9)	6 (1.7)
無力症	3 (1.3)	2 (1.8)	5 (1.4)
発熱	3 (1.3)	1 (0.9)	4 (1.1)
悪寒	1 (0.4)	1 (0.9)	2 (0.6)
顔面浮腫	2 (0.8)	0 (0.0)	2 (0.6)
熱感	1 (0.4)	0 (0.0)	1 (0.3)
注射部位血腫	0 (0.0)	1 (0.9)	1 (0.3)
倦怠感	0 (0.0)	1 (0.9)	1 (0.3)
末梢腫脹	1 (0.4)	0 (0.0)	1 (0.3)
血管穿刺部位内出血	1 (0.4)	0 (0.0)	1 (0.3)
乾燥症	0 (0.0)	1 (0.9)	1 (0.3)
血管障害	28 (11.7)	10 (9.0)	38 (10.8)
高血圧	15 (6.3)	5 (4.5)	20 (5.7)
血腫	11 (4.6)	7 (6.3)	18 (5.1)
ほてり	0 (0.0)	1 (0.9)	1 (0.3)
高血圧クリーゼ	1 (0.4)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
血管破裂	1 (0.4)	0 (0.0)	1 (0.3)
白衣性高血圧	1 (0.4)	0 (0.0)	1 (0.3)
筋骨格系および結合組織障害	27 (11.3)	10 (9.0)	37 (10.5)
関節痛	12 (5.0)	4 (3.6)	16 (4.6)
筋痙縮	5 (2.1)	3 (2.7)	8 (2.3)
筋肉痛	2 (0.8)	4 (3.6)	6 (1.7)
四肢痛	3 (1.3)	1 (0.9)	4 (1.1)
関節炎	2 (0.8)	0 (0.0)	2 (0.6)
骨痛	1 (0.4)	1 (0.9)	2 (0.6)
関節腫脹	1 (0.4)	0 (0.0)	1 (0.3)
筋力低下	1 (0.4)	0 (0.0)	1 (0.3)
筋骨格系胸痛	1 (0.4)	0 (0.0)	1 (0.3)
筋骨格痛	0 (0.0)	1 (0.9)	1 (0.3)
筋炎	1 (0.4)	0 (0.0)	1 (0.3)
軟部組織出血	1 (0.4)	0 (0.0)	1 (0.3)
呼吸器、胸郭および縦隔障害	24 (10.0)	12 (10.8)	36 (10.3)
鼻出血	10 (4.2)	4 (3.6)	14 (4.0)
咳嗽	4 (1.7)	2 (1.8)	6 (1.7)
呼吸困難	2 (0.8)	3 (2.7)	5 (1.4)
口腔咽頭痛	1 (0.4)	2 (1.8)	3 (0.9)
胸水	2 (0.8)	1 (0.9)	3 (0.9)
肺臓炎	2 (0.8)	1 (0.9)	3 (0.9)
労作性呼吸困難	1 (0.4)	1 (0.9)	2 (0.6)
急性呼吸不全	1 (0.4)	0 (0.0)	1 (0.3)
前屈呼吸困難	0 (0.0)	1 (0.9)	1 (0.3)
咽喉乾燥	1 (0.4)	0 (0.0)	1 (0.3)
喀血	0 (0.0)	1 (0.9)	1 (0.3)
肺浸潤	1 (0.4)	0 (0.0)	1 (0.3)
湿性咳嗽	0 (0.0)	1 (0.9)	1 (0.3)
肺線維症	1 (0.4)	0 (0.0)	1 (0.3)
呼吸不全	1 (0.4)	0 (0.0)	1 (0.3)
上気道の炎症	0 (0.0)	1 (0.9)	1 (0.3)
上気道咳症候群	1 (0.4)	0 (0.0)	1 (0.3)
心臓障害	24 (10.0)	8 (7.2)	32 (9.1)
心房細動	10 (4.2)	6 (5.4)	16 (4.6)
動悸	6 (2.5)	2 (1.8)	8 (2.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
心筋梗塞	2 (0.8)	0 (0.0)	2 (0.6)
狭心症	1 (0.4)	0 (0.0)	1 (0.3)
心房粗動	1 (0.4)	0 (0.0)	1 (0.3)
房室ブロック	0 (0.0)	1 (0.9)	1 (0.3)
徐脈	1 (0.4)	0 (0.0)	1 (0.3)
左脚ブロック	1 (0.4)	0 (0.0)	1 (0.3)
心不全	0 (0.0)	1 (0.9)	1 (0.3)
急性心不全	1 (0.4)	0 (0.0)	1 (0.3)
左室肥大	0 (0.0)	1 (0.9)	1 (0.3)
心筋炎	1 (0.4)	0 (0.0)	1 (0.3)
心嚢液貯留	1 (0.4)	0 (0.0)	1 (0.3)
洞性徐脈	1 (0.4)	0 (0.0)	1 (0.3)
頻脈	1 (0.4)	0 (0.0)	1 (0.3)
心室性不整脈	0 (0.0)	1 (0.9)	1 (0.3)
心室性期外収縮	1 (0.4)	0 (0.0)	1 (0.3)
心室性頻脈	1 (0.4)	0 (0.0)	1 (0.3)
臨床検査	17 (7.1)	14 (12.6)	31 (8.8)
好中球数減少	7 (2.9)	7 (6.3)	14 (4.0)
アラニンアミノトランスフェラーゼ増加	5 (2.1)	0 (0.0)	5 (1.4)
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.3)	0 (0.0)	3 (0.9)
血中ビリルビン増加	2 (0.8)	1 (0.9)	3 (0.9)
血中クレアチニン増加	1 (0.4)	1 (0.9)	2 (0.6)
γーグルタミルトランスフェラーゼ増加	2 (0.8)	0 (0.0)	2 (0.6)
血小板数減少	0 (0.0)	2 (1.8)	2 (0.6)
体重減少	1 (0.4)	1 (0.9)	2 (0.6)
出血時間延長	1 (0.4)	0 (0.0)	1 (0.3)
血中アルカリホスファターゼ増加	1 (0.4)	0 (0.0)	1 (0.3)
血中乳酸脱水素酵素増加	1 (0.4)	0 (0.0)	1 (0.3)
血圧上昇	0 (0.0)	1 (0.9)	1 (0.3)
糸球体濾過率減少	1 (0.4)	0 (0.0)	1 (0.3)
心拍数増加	0 (0.0)	1 (0.9)	1 (0.3)
心拍数不整	0 (0.0)	1 (0.9)	1 (0.3)
ヒトライノウイルス検査陽性	1 (0.4)	0 (0.0)	1 (0.3)
リンパ球数減少	1 (0.4)	0 (0.0)	1 (0.3)
トランスアミナーゼ上昇	0 (0.0)	1 (0.9)	1 (0.3)
トロポニン増加	1 (0.4)	0 (0.0)	1 (0.3)
神経系障害	20 (8.3)	9 (8.1)	29 (8.3)
頭痛	11 (4.6)	3 (2.7)	14 (4.0)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
浮動性めまい	3 (1.3)	1 (0.9)	4 (1.1)
末梢性感覚ニューロパチー	1 (0.4)	2 (1.8)	3 (0.9)
健忘	0 (0.0)	1 (0.9)	1 (0.3)
味覚不全	0 (0.0)	1 (0.9)	1 (0.3)
卒中の出血性変化	1 (0.4)	0 (0.0)	1 (0.3)
水頭症	0 (0.0)	1 (0.9)	1 (0.3)
感覚鈍麻	1 (0.4)	0 (0.0)	1 (0.3)
ラクナ梗塞	1 (0.4)	0 (0.0)	1 (0.3)
嗜眠	1 (0.4)	0 (0.0)	1 (0.3)
末梢性感覚運動ニューロパチー	1 (0.4)	0 (0.0)	1 (0.3)
くも膜下出血	1 (0.4)	0 (0.0)	1 (0.3)
失神	0 (0.0)	1 (0.9)	1 (0.3)
振戦	1 (0.4)	0 (0.0)	1 (0.3)
腎および尿路障害	12 (5.0)	7 (6.3)	19 (5.4)
血尿	9 (3.8)	5 (4.5)	14 (4.0)
慢性腎臓病	1 (0.4)	0 (0.0)	1 (0.3)
水腎症	1 (0.4)	0 (0.0)	1 (0.3)
尿意切迫	1 (0.4)	0 (0.0)	1 (0.3)
腎機能障害	0 (0.0)	1 (0.9)	1 (0.3)
尿失禁	1 (0.4)	0 (0.0)	1 (0.3)
尿閉	0 (0.0)	1 (0.9)	1 (0.3)
代謝および栄養障害	15 (6.3)	2 (1.8)	17 (4.8)
低ナトリウム血症	3 (1.3)	1 (0.9)	4 (1.1)
食欲減退	2 (0.8)	0 (0.0)	2 (0.6)
痛風	2 (0.8)	0 (0.0)	2 (0.6)
高血糖	1 (0.4)	1 (0.9)	2 (0.6)
高尿酸血症	2 (0.8)	0 (0.0)	2 (0.6)
低カルシウム血症	2 (0.8)	0 (0.0)	2 (0.6)
コントロール不良の糖尿病	1 (0.4)	0 (0.0)	1 (0.3)
耐糖能障害	1 (0.4)	0 (0.0)	1 (0.3)
高コレステロール血症	1 (0.4)	0 (0.0)	1 (0.3)
高脂血症	1 (0.4)	0 (0.0)	1 (0.3)
血液量減少症	1 (0.4)	0 (0.0)	1 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (2.9)	4 (3.6)	11 (3.1)
基底細胞癌	3 (1.3)	1 (0.9)	4 (1.1)
肛門扁平上皮癌	1 (0.4)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
遠隔転移を伴う扁平上皮癌	1 (0.4)	0 (0.0)	1 (0.3)
皮膚癌	1 (0.4)	0 (0.0)	1 (0.3)
肺扁平上皮癌	1 (0.4)	0 (0.0)	1 (0.3)
皮膚有棘細胞癌	0 (0.0)	1 (0.9)	1 (0.3)
腎盂および尿管移行上皮癌	0 (0.0)	1 (0.9)	1 (0.3)
腫瘍フレア	0 (0.0)	1 (0.9)	1 (0.3)
眼障害	5 (2.1)	4 (3.6)	9 (2.6)
ドライアイ	3 (1.3)	0 (0.0)	3 (0.9)
眼瞼炎	0 (0.0)	1 (0.9)	1 (0.3)
白内障	0 (0.0)	1 (0.9)	1 (0.3)
結膜出血	0 (0.0)	1 (0.9)	1 (0.3)
眼出血	1 (0.4)	0 (0.0)	1 (0.3)
眼そう痒症	1 (0.4)	0 (0.0)	1 (0.3)
眼部腫脹	0 (0.0)	1 (0.9)	1 (0.3)
網膜出血	1 (0.4)	0 (0.0)	1 (0.3)
霧視	1 (0.4)	0 (0.0)	1 (0.3)
耳および迷路障害	6 (2.5)	1 (0.9)	7 (2.0)
回転性めまい	2 (0.8)	1 (0.9)	3 (0.9)
難聴	1 (0.4)	0 (0.0)	1 (0.3)
耳出血	1 (0.4)	0 (0.0)	1 (0.3)
耳痛	1 (0.4)	0 (0.0)	1 (0.3)
前庭障害	1 (0.4)	0 (0.0)	1 (0.3)
生殖系および乳房障害	5 (2.1)	0 (0.0)	5 (1.4)
勃起不全	2 (0.8)	0 (0.0)	2 (0.6)
乳房血腫	1 (0.4)	0 (0.0)	1 (0.3)
骨盤血腫	1 (0.4)	0 (0.0)	1 (0.3)
陰嚢浮腫	1 (0.4)	0 (0.0)	1 (0.3)
精神障害	2 (0.8)	2 (1.8)	4 (1.1)
不眠症	2 (0.8)	0 (0.0)	2 (0.6)
うつ病	0 (0.0)	1 (0.9)	1 (0.3)
睡眠時驚愕	0 (0.0)	1 (0.9)	1 (0.3)
肝胆道系障害	2 (0.8)	0 (0.0)	2 (0.6)
肝腫大	1 (0.4)	0 (0.0)	1 (0.3)
結節性再生性過形成	1 (0.4)	0 (0.0)	1 (0.3)

System Organ Class Preferred Term	Zanubrutinib (Arm A) (N = 240) n (%)	Zanubrutinib (Arm C) (N = 111) n (%)	Total (Arm A + Arm C) (N = 351) n (%)
免疫系障害	1 (0.4)	0 (0.0)	1 (0.3)
低γグロブリン血症	1 (0.4)	0 (0.0)	1 (0.3)

Source: Table 14.3.1.2.6.1.3 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
Abbreviations: AE, adverse event; TEAE, treatment-emergent adverse event.
Notes: Adverse events were classified based on MedDRA Version 24.0
TEAE is defined as an AE that had an onset date or was worsening in severity from baseline (pretreatment) on or after the first dose of study drug up to 30 days after the last dose of zanubrutinib for zanubrutinib arms (A and C) following study drug discontinuation or the start of new anticancer therapy (including the zanubrutinib for Arm B patients crossed over), whichever comes first.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively. Events were sorted by descending order within System Organ Class, and by Preferred Term within System Organ Class in the Total column.
Treatment-related AEs included AEs related to zanubrutinib in Arms A and C.

表 50： 治療下で発現した有害事象、及び治療下で発現した有害事象＋治験薬投与期間終了後に発現した有害事象：器官別大分類別及び基本語別、中国の治験実施施設の被験者（コホート 1a）（BGB-3111-304 試験、安全性解析対象集団）

	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
System Organ Class Preferred Term	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
Patients With at Least One AE	38 (100.0)	38 (100.0)	40 (100.0)	40 (100.0)	78 (100.0)	78 (100.0)
臨床検査	37 (97.4)	37 (97.4)	23 (57.5)	23 (57.5)	60 (76.9)	60 (76.9)
好中球数減少	28 (73.7)	30 (78.9)	7 (17.5)	7 (17.5)	35 (44.9)	37 (47.4)
血小板数減少	19 (50.0)	19 (50.0)	9 (22.5)	9 (22.5)	28 (35.9)	28 (35.9)
アスパラギン酸アミノトランスフェラーゼ増加	6 (15.8)	7 (18.4)	6 (15.0)	6 (15.0)	12 (15.4)	13 (16.7)
アラニンアミノトランスフェラーゼ増加	4 (10.5)	4 (10.5)	5 (12.5)	5 (12.5)	9 (11.5)	9 (11.5)
血中クレアチニン増加	5 (13.2)	5 (13.2)	4 (10.0)	4 (10.0)	9 (11.5)	9 (11.5)
白血球数減少	6 (15.8)	6 (15.8)	0 (0.0)	0 (0.0)	6 (7.7)	6 (7.7)
体重増加	0 (0.0)	2 (5.3)	4 (10.0)	4 (10.0)	4 (5.1)	6 (7.7)
血中ビリルビン増加	1 (2.6)	1 (2.6)	4 (10.0)	4 (10.0)	5 (6.4)	5 (6.4)
血中アルカリホスファターゼ増加	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
血中乳酸脱水素酵素増加	2 (5.3)	2 (5.3)	1 (2.5)	1 (2.5)	3 (3.8)	3 (3.8)
グロブリン減少	2 (5.3)	2 (5.3)	1 (2.5)	1 (2.5)	3 (3.8)	3 (3.8)
血中ブドウ糖増加	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
免疫グロブリン減少	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
総胆汁酸増加	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
体重減少	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
リンパ球数減少	1 (2.6)	2 (5.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.6)
抱合ビリルビン増加	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
血中非抱合ビリルビン増加	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
血圧上昇	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
血中甲状腺刺激ホルモン減少	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
血中尿素増加	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
血中尿酸増加	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
心電図異常 T 波	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
γーグルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
ヘモグロビン減少	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
ヘモグロビン増加	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
感染症および寄生虫症	21 (55.3)	25 (65.8)	27 (67.5)	27 (67.5)	48 (61.5)	52 (66.7)
上気道感染	7 (18.4)	11 (28.9)	13 (32.5)	13 (32.5)	20 (25.6)	24 (30.8)
肺炎	8 (21.1)	11 (28.9)	6 (15.0)	6 (15.0)	14 (17.9)	17 (21.8)
帯状疱疹	3 (7.9)	4 (10.5)	1 (2.5)	1 (2.5)	4 (5.1)	5 (6.4)
皮膚感染	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
気管支炎	2 (5.3)	3 (7.9)	0 (0.0)	0 (0.0)	2 (2.6)	3 (3.8)
ヘルペスウイルス感染	0 (0.0)	1 (2.6)	2 (5.0)	2 (5.0)	2 (2.6)	3 (3.8)
上咽頭炎	0 (0.0)	1 (2.6)	2 (5.0)	2 (5.0)	2 (2.6)	3 (3.8)
副鼻腔炎	1 (2.6)	2 (5.3)	1 (2.5)	1 (2.5)	2 (2.6)	3 (3.8)
結膜炎	1 (2.6)	3 (7.9)	0 (0.0)	0 (0.0)	1 (1.3)	3 (3.8)
肛門膿瘍	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
慢性副鼻腔炎	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
歯肉炎	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
B 型肝炎再活性化	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
インフルエンザ	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
中耳炎	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
敗血症	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
軟部組織感染	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
尿路感染	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
ヘリコバクター感染	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
咽頭炎	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
扁桃炎	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
細菌感染	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
膀胱炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
丹毒	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
眼感染	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
熱性感染症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
毛包炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
皮膚真菌感染	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
感染	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
咽喉頭炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
リンパ管炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
眼帯状疱疹	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
細菌性肺炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
歯髄炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
鼻炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
足部白癬	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
ウイルス感染	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
創傷感染	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
口腔ヘルペス	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
歯周炎	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
代謝および栄養障害	24 (63.2)	26 (68.4)	20 (50.0)	20 (50.0)	44 (56.4)	46 (59.0)
高尿酸血症	8 (21.1)	11 (28.9)	7 (17.5)	7 (17.5)	15 (19.2)	18 (23.1)
低カリウム血症	11 (28.9)	11 (28.9)	6 (15.0)	6 (15.0)	17 (21.8)	17 (21.8)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
低アルブミン血症	7 (18.4)	7 (18.4)	3 (7.5)	3 (7.5)	10 (12.8)	10 (12.8)
高血糖	6 (15.8)	8 (21.1)	1 (2.5)	1 (2.5)	7 (9.0)	9 (11.5)
低カルシウム血症	6 (15.8)	6 (15.8)	2 (5.0)	2 (5.0)	8 (10.3)	8 (10.3)
食欲減退	3 (7.9)	3 (7.9)	2 (5.0)	2 (5.0)	5 (6.4)	5 (6.4)
低ナトリウム血症	3 (7.9)	3 (7.9)	2 (5.0)	2 (5.0)	5 (6.4)	5 (6.4)
低蛋白血症	2 (5.3)	2 (5.3)	2 (5.0)	2 (5.0)	4 (5.1)	4 (5.1)
高トリグリセリド血症	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
痛風	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
高カリウム血症	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
低マグネシウム血症	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
低リン血症	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
電解質失調	1 (2.6)	1 (2.6)	0 (0.0)	1 (2.5)	1 (1.3)	2 (2.6)
糖尿病	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
耐糖能障害	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
高コレステロール血症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
高脂血症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
空腹時血中ブドウ糖不良	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
腫瘍崩壊症候群	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胃腸障害	19 (50.0)	26 (68.4)	20 (50.0)	20 (50.0)	39 (50.0)	46 (59.0)
便秘	9 (23.7)	9 (23.7)	2 (5.0)	2 (5.0)	11 (14.1)	11 (14.1)
悪心	8 (21.1)	8 (21.1)	3 (7.5)	3 (7.5)	11 (14.1)	11 (14.1)
下痢	1 (2.6)	3 (7.9)	5 (12.5)	5 (12.5)	6 (7.7)	8 (10.3)
口腔内潰瘍形成	1 (2.6)	4 (10.5)	2 (5.0)	2 (5.0)	3 (3.8)	6 (7.7)
上腹部痛	1 (2.6)	2 (5.3)	3 (7.5)	3 (7.5)	4 (5.1)	5 (6.4)
歯痛	1 (2.6)	1 (2.6)	3 (7.5)	3 (7.5)	4 (5.1)	4 (5.1)

System Organ Class Preferred Term	BR (N = 38) Treatment-Emergent n (%)	BR (N = 38) Treatment-Emergent and Post-treatment n (%)	Zanubrutinib (N = 40) Treatment-Emergent n (%)	Zanubrutinib (N = 40) Treatment-Emergent and Post-treatment n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent and Post-treatment n (%)
嘔吐	3 (7.9)	3 (7.9)	1 (2.5)	1 (2.5)	4 (5.1)	4 (5.1)
腹部膨満	2 (5.3)	2 (5.3)	1 (2.5)	1 (2.5)	3 (3.8)	3 (3.8)
鼓腸	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
痔核	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
腹部不快感	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
消化不良	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
胃炎	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
歯肉出血	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
口内炎	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
大腸ポリープ	0 (0.0)	2 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)
腹痛	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
下腹部痛	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
アフタ性潰瘍	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
慢性胃炎	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
口内乾燥	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
小腸炎	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
びらん性胃炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胃腸管瘻	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胃腸の炎症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胃食道逆流性疾患	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
口の錯感覚	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
歯周病	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
舌乾燥	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
埋伏歯	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
便習慣変化	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
大腸炎	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38) Treatment-Emergent n (%)	BR (N = 38) Treatment-Emergent and Post-treatment n (%)	Zanubrutinib (N = 40) Treatment-Emergent n (%)	Zanubrutinib (N = 40) Treatment-Emergent and Post-treatment n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent and Post-treatment n (%)
歯肉痛	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
口腔内出血	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
胃閉塞	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
血液およびリンパ系障害	23 (60.5)	23 (60.5)	15 (37.5)	15 (37.5)	38 (48.7)	38 (48.7)
貧血	20 (52.6)	20 (52.6)	9 (22.5)	9 (22.5)	29 (37.2)	29 (37.2)
血小板減少症	13 (34.2)	13 (34.2)	4 (10.0)	4 (10.0)	17 (21.8)	17 (21.8)
好中球減少症	8 (21.1)	10 (26.3)	3 (7.5)	3 (7.5)	11 (14.1)	13 (16.7)
発熱性好中球減少症	2 (5.3)	2 (5.3)	1 (2.5)	1 (2.5)	3 (3.8)	3 (3.8)
白血球減少症	3 (7.9)	3 (7.9)	0 (0.0)	0 (0.0)	3 (3.8)	3 (3.8)
低グロブリン血症	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
リンパ節炎	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
鉄欠乏性貧血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
免疫性血小板減少症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
一般・全身障害および投与部位の状態	20 (52.6)	22 (57.9)	14 (35.0)	14 (35.0)	34 (43.6)	36 (46.2)
発熱	14 (36.8)	14 (36.8)	4 (10.0)	4 (10.0)	18 (23.1)	18 (23.1)
末梢性浮腫	3 (7.9)	3 (7.9)	4 (10.0)	4 (10.0)	7 (9.0)	7 (9.0)
顔面浮腫	2 (5.3)	2 (5.3)	3 (7.5)	3 (7.5)	5 (6.4)	5 (6.4)
悪寒	4 (10.5)	4 (10.5)	0 (0.0)	0 (0.0)	4 (5.1)	4 (5.1)
倦怠感	1 (2.6)	2 (5.3)	1 (2.5)	1 (2.5)	2 (2.6)	3 (3.8)
疲労	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
無力症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
カテーテル留置部位血栓症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
胸部不快感	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胸痛	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
腫瘤	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
非心臓性胸痛	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
疼痛	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
末梢腫脹	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
セルフケア障害	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
皮膚および皮下組織障害	14 (36.8)	15 (39.5)	19 (47.5)	19 (47.5)	33 (42.3)	34 (43.6)
発疹	6 (15.8)	7 (18.4)	5 (12.5)	5 (12.5)	11 (14.1)	12 (15.4)
点状出血	0 (0.0)	0 (0.0)	7 (17.5)	7 (17.5)	7 (9.0)	7 (9.0)
そう痒症	5 (13.2)	5 (13.2)	1 (2.5)	1 (2.5)	6 (7.7)	6 (7.7)
皮膚炎	1 (2.6)	3 (7.9)	1 (2.5)	1 (2.5)	2 (2.6)	4 (5.1)
湿疹	1 (2.6)	4 (10.5)	0 (0.0)	0 (0.0)	1 (1.3)	4 (5.1)
紫斑	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	3 (3.8)	3 (3.8)
斑状出血	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
紅斑	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
皮下出血	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
皮膚障害	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
皮膚腫瘤	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
脱毛症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
接触皮膚炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
薬疹	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
多汗症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
寝汗	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
斑状丘疹状皮疹	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
皮膚出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
丘疹状蕁麻疹	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
手皮膚炎	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
結節性発疹	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
呼吸器、胸郭および縦隔障害	12 (31.6)	14 (36.8)	10 (25.0)	10 (25.0)	22 (28.2)	24 (30.8)
口腔咽頭痛	2 (5.3)	2 (5.3)	4 (10.0)	4 (10.0)	6 (7.7)	6 (7.7)
咳嗽	2 (5.3)	3 (7.9)	2 (5.0)	2 (5.0)	4 (5.1)	5 (6.4)
呼吸困難	3 (7.9)	3 (7.9)	1 (2.5)	1 (2.5)	4 (5.1)	4 (5.1)
胸水	3 (7.9)	3 (7.9)	1 (2.5)	1 (2.5)	4 (5.1)	4 (5.1)
鼻出血	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	3 (3.8)	3 (3.8)
しゃっくり	2 (5.3)	2 (5.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)
鼻閉	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
肺腫瘤	1 (2.6)	2 (5.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.6)
鼻漏	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
息詰まり感	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
嚢胞性肺疾患	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
低酸素症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
間質性肺疾患	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
喉頭出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
口腔咽頭不快感	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
肺臓炎	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
湿性咳嗽	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
肺肉芽腫	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
呼吸不全	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
くしゃみ	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
咽喉刺激感	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
扁桃肥大	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
副鼻腔の炎症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
傷害、中毒および処置合併症	18 (47.4)	18 (47.4)	5 (12.5)	5 (12.5)	23 (29.5)	23 (29.5)
注入に伴う反応	14 (36.8)	14 (36.8)	0 (0.0)	0 (0.0)	14 (17.9)	14 (17.9)
輸血反応	4 (10.5)	4 (10.5)	0 (0.0)	0 (0.0)	4 (5.1)	4 (5.1)
交通事故	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
胸部損傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
挫傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
凍傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
四肢損傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
多発骨折	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
肉離れ	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
外傷性気胸	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
皮膚擦過傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
皮下血腫	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
舌損傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
外傷性頭蓋内出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
外傷性肺損傷	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
筋骨格系および結合組織障害	5 (13.2)	8 (21.1)	13 (32.5)	13 (32.5)	18 (23.1)	21 (26.9)
四肢痛	2 (5.3)	3 (7.9)	3 (7.5)	3 (7.5)	5 (6.4)	6 (7.7)
関節痛	2 (5.3)	2 (5.3)	2 (5.0)	2 (5.0)	4 (5.1)	4 (5.1)
筋骨格痛	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
筋肉痛	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
背部痛	1 (2.6)	2 (5.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.6)
骨肥厚	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38) Treatment-Emergent n (%)	BR (N = 38) Treatment-Emergent and Post-treatment n (%)	Zanubrutinib (N = 40) Treatment-Emergent n (%)	Zanubrutinib (N = 40) Treatment-Emergent and Post-treatment n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent and Post-treatment n (%)
椎間板突出	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
筋痙縮	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
筋攣縮	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
頚部痛	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
変形性関節症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
横紋筋融解症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
脊椎すべり症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
狭窄性腱鞘炎	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
側腹部痛	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
関節周囲炎	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
血管障害	8 (21.1)	12 (31.6)	8 (20.0)	8 (20.0)	16 (20.5)	20 (25.6)
高血圧	4 (10.5)	8 (21.1)	7 (17.5)	7 (17.5)	11 (14.1)	15 (19.2)
静脈炎	2 (5.3)	2 (5.3)	1 (2.5)	1 (2.5)	3 (3.8)	3 (3.8)
動脈瘤	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
深部静脈血栓症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
低血圧	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
ショック	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
末梢動脈閉塞性疾患	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
神経系障害	5 (13.2)	7 (18.4)	9 (22.5)	9 (22.5)	14 (17.9)	16 (20.5)
頭痛	2 (5.3)	3 (7.9)	2 (5.0)	2 (5.0)	4 (5.1)	5 (6.4)
浮動性めまい	1 (2.6)	1 (2.6)	3 (7.5)	3 (7.5)	4 (5.1)	4 (5.1)
感覚鈍麻	1 (2.6)	2 (5.3)	2 (5.0)	2 (5.0)	3 (3.8)	4 (5.1)
脳虚血	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
ヘルペス後神経痛	1 (2.6)	2 (5.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.6)

System Organ Class Preferred Term	BR (N = 38) Treatment-Emergent n (%)	BR (N = 38) Treatment-Emergent and Post-treatment n (%)	Zanubrutinib (N = 40) Treatment-Emergent n (%)	Zanubrutinib (N = 40) Treatment-Emergent and Post-treatment n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent and Post-treatment n (%)
脳出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
片頭痛	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
神経突起斑	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
頚動脈硬化症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
脳梗塞	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
腎および尿路障害	3 (7.9)	5 (13.2)	7 (17.5)	7 (17.5)	10 (12.8)	12 (15.4)
腎結石症	0 (0.0)	2 (5.3)	2 (5.0)	2 (5.0)	2 (2.6)	4 (5.1)
血尿	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
腎機能障害	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
膀胱結石	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
夜間頻尿	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
腎嚢胞	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
腎不全	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
尿失禁	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
尿閉	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
心臓障害	4 (10.5)	4 (10.5)	4 (10.0)	4 (10.0)	8 (10.3)	8 (10.3)
動悸	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
右脚ブロック	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
心不快感	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
心嚢液貯留	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
洞性徐脈	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
頻脈	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
肝胆道系障害	2 (5.3)	4 (10.5)	4 (10.0)	4 (10.0)	6 (7.7)	8 (10.3)

System Organ Class Preferred Term	BR (N = 38)		Zanubrutinib (N = 40)		Total (Cohort 1a) (N = 78)	
	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)	Treatment-Emergent n (%)	Treatment-Emergent and Post-treatment n (%)
肝機能異常	2 (5.3)	3 (7.9)	3 (7.5)	3 (7.5)	5 (6.4)	6 (7.7)
脂肪肝	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胆石症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
眼障害	4 (10.5)	4 (10.5)	3 (7.5)	3 (7.5)	7 (9.0)	7 (9.0)
白内障	2 (5.3)	3 (7.9)	1 (2.5)	1 (2.5)	3 (3.8)	4 (5.1)
後天性涙道狭窄	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
ドライアイ	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
眼瞼出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
眼窩周囲の炎症	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
糖尿病網膜症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
黄斑浮腫	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
硝子体出血	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
精神障害	1 (2.6)	5 (13.2)	2 (5.0)	2 (5.0)	3 (3.8)	7 (9.0)
不眠症	1 (2.6)	4 (10.5)	1 (2.5)	1 (2.5)	2 (2.6)	5 (6.4)
睡眠障害	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.5)	1 (1.3)	2 (2.6)
睡眠異常	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
耳および迷路障害	1 (2.6)	2 (5.3)	3 (7.5)	3 (7.5)	4 (5.1)	5 (6.4)
耳垢栓塞	1 (2.6)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
鼓室内出血	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
中耳の炎症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
耳鳴	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
回転性めまい	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
難聴	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38) Treatment-Emergent n (%)	BR (N = 38) Treatment-Emergent and Post-treatment n (%)	Zanubrutinib (N = 40) Treatment-Emergent n (%)	Zanubrutinib (N = 40) Treatment-Emergent and Post-treatment n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent n (%)	Total (Cohort 1a) (N = 78) Treatment-Emergent and Post-treatment n (%)
生殖系および乳房障害	0 (0.0)	2 (5.3)	3 (7.5)	3 (7.5)	3 (3.8)	5 (6.4)
良性前立腺肥大症	0 (0.0)	0 (0.0)	2 (5.0)	2 (5.0)	2 (2.6)	2 (2.6)
不規則月経	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
骨盤液貯留	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
前立腺炎	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
免疫系障害	1 (2.6)	1 (2.6)	2 (5.0)	2 (5.0)	3 (3.8)	3 (3.8)
薬物過敏症	1 (2.6)	1 (2.6)	1 (2.5)	1 (2.5)	2 (2.6)	2 (2.6)
低γグロブリン血症	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (2.6)	2 (5.0)	2 (5.0)	2 (2.6)	3 (3.8)
肛門性器疣贅	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
卵巣腺腫	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
胃癌	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
Uncoded	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)
Uncoded	0 (0.0)	0 (0.0)	1 (2.5)	1 (2.5)	1 (1.3)	1 (1.3)

Source: Table 14.3.1.2.2.1.2 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
Abbreviations: AE, adverse event; B, Bendamustine; R, Rituximab; BR, Bendamustine and Rituximab; TEAE, treatment-emergent adverse event.
Notes: Adverse events were classified based on MedDRA Version 24.0
TEAE is defined as an AE that had an onset date or was worsening in severity from baseline (pretreatment) on or after the first dose of study drug up to 30 days after the last dose of zanubrutinib for zanubrutinib arm A and 90 days after the last dose of B or R (Arm B) following study drug discontinuation or the start of new anticancer therapy (including the zanubrutinib for Arm B patients crossed over), whichever comes first.
Post-treatment AEs include AEs that had an onset date or was worsening in severity during the post-treatment follow-up phase, defined as from the day after the last dose (either zanubrutinib in Arm A, or B or R in Arm B) to the date of progressive disease, except for the events after patients in Arm B crossover to zanubrutinib.

Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively. Events were sorted by descending order within System Organ Class, and by Preferred Term within System Organ Class in the Treatment-Emergent Total column

表 51： 投与に関連のある TEAE：器官別大分類別及び基本語別、、中国の治験実施施設の被験者（コホート 1a）（BGB-3111-304 試験、安全性解析対象集団）

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)
Patients With at Least One Treatment-Related TEAE	38 (100.0)	37 (92.5)	75 (96.2)
臨床検査	37 (97.4)	17 (42.5)	54 (69.2)
好中球数減少	28 (73.7)	6 (15.0)	34 (43.6)
血小板数減少	19 (50.0)	8 (20.0)	27 (34.6)
アスパラギン酸アミノトランスフェラーゼ増加	5 (13.2)	4 (10.0)	9 (11.5)
アラニンアミノトランスフェラーゼ増加	4 (10.5)	3 (7.5)	7 (9.0)
白血球数減少	6 (15.8)	0 (0.0)	6 (7.7)
血中クレアチニン増加	3 (7.9)	2 (5.0)	5 (6.4)
血中ビリルビン増加	1 (2.6)	3 (7.5)	4 (5.1)
体重増加	0 (0.0)	3 (7.5)	3 (3.8)
血中アルカリホスファターゼ増加	1 (2.6)	1 (2.5)	2 (2.6)
血中乳酸脱水素酵素増加	2 (5.3)	0 (0.0)	2 (2.6)
グロブリン減少	1 (2.6)	1 (2.5)	2 (2.6)
免疫グロブリン減少	2 (5.3)	0 (0.0)	2 (2.6)
血圧上昇	1 (2.6)	0 (0.0)	1 (1.3)
血中尿素増加	0 (0.0)	1 (2.5)	1 (1.3)
血中尿酸増加	0 (0.0)	1 (2.5)	1 (1.3)
心電図異常 T 波	1 (2.6)	0 (0.0)	1 (1.3)
ヘモグロビン減少	1 (2.6)	0 (0.0)	1 (1.3)
ヘモグロビン増加	0 (0.0)	1 (2.5)	1 (1.3)
リンパ球数減少	1 (2.6)	0 (0.0)	1 (1.3)
総胆汁酸増加	1 (2.6)	0 (0.0)	1 (1.3)
体重減少	1 (2.6)	0 (0.0)	1 (1.3)
血液およびリンパ系障害	23 (60.5)	12 (30.0)	35 (44.9)
貧血	20 (52.6)	6 (15.0)	26 (33.3)
血小板減少症	13 (34.2)	3 (7.5)	16 (20.5)
好中球減少症	8 (21.1)	2 (5.0)	10 (12.8)
発熱性好中球減少症	2 (5.3)	1 (2.5)	3 (3.8)
白血球減少症	3 (7.9)	0 (0.0)	3 (3.8)
低グロブリン血症	1 (2.6)	1 (2.5)	2 (2.6)
リンパ節炎	0 (0.0)	2 (5.0)	2 (2.6)
感染症および寄生虫症	17 (44.7)	16 (40.0)	33 (42.3)
上気道感染	5 (13.2)	8 (20.0)	13 (16.7)
肺炎	8 (21.1)	3 (7.5)	11 (14.1)
皮膚感染	1 (2.6)	2 (5.0)	3 (3.8)

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)
気管支炎	2 (5.3)	0 (0.0)	2 (2.6)
B 型肝炎再活性化	1 (2.6)	1 (2.5)	2 (2.6)
帯状疱疹	2 (5.3)	0 (0.0)	2 (2.6)
敗血症	1 (2.6)	1 (2.5)	2 (2.6)
軟部組織感染	1 (2.6)	1 (2.5)	2 (2.6)
肛門膿瘍	0 (0.0)	1 (2.5)	1 (1.3)
結膜炎	1 (2.6)	0 (0.0)	1 (1.3)
膀胱炎	0 (0.0)	1 (2.5)	1 (1.3)
丹毒	0 (0.0)	1 (2.5)	1 (1.3)
眼感染	1 (2.6)	0 (0.0)	1 (1.3)
熱性感染症	1 (2.6)	0 (0.0)	1 (1.3)
毛包炎	0 (0.0)	1 (2.5)	1 (1.3)
皮膚真菌感染	1 (2.6)	0 (0.0)	1 (1.3)
歯肉炎	1 (2.6)	0 (0.0)	1 (1.3)
感染	1 (2.6)	0 (0.0)	1 (1.3)
インフルエンザ	1 (2.6)	0 (0.0)	1 (1.3)
リンパ管炎	0 (0.0)	1 (2.5)	1 (1.3)
眼帯状疱疹	1 (2.6)	0 (0.0)	1 (1.3)
中耳炎	0 (0.0)	1 (2.5)	1 (1.3)
細菌性肺炎	0 (0.0)	1 (2.5)	1 (1.3)
足部白癬	0 (0.0)	1 (2.5)	1 (1.3)
扁桃炎	0 (0.0)	1 (2.5)	1 (1.3)
尿路感染	0 (0.0)	1 (2.5)	1 (1.3)
創傷感染	1 (2.6)	0 (0.0)	1 (1.3)
皮膚および皮下組織障害	11 (28.9)	16 (40.0)	27 (34.6)
発疹	5 (13.2)	3 (7.5)	8 (10.3)
点状出血	0 (0.0)	7 (17.5)	7 (9.0)
そう痒症	3 (7.9)	1 (2.5)	4 (5.1)
紫斑	0 (0.0)	3 (7.5)	3 (3.8)
紅斑	1 (2.6)	1 (2.5)	2 (2.6)
皮下出血	0 (0.0)	2 (5.0)	2 (2.6)
皮膚腫瘤	0 (0.0)	2 (5.0)	2 (2.6)
皮膚炎	1 (2.6)	0 (0.0)	1 (1.3)
薬疹	1 (2.6)	0 (0.0)	1 (1.3)
斑状出血	0 (0.0)	1 (2.5)	1 (1.3)
湿疹	1 (2.6)	0 (0.0)	1 (1.3)
多汗症	0 (0.0)	1 (2.5)	1 (1.3)
皮膚出血	0 (0.0)	1 (2.5)	1 (1.3)
代謝および栄養障害	17 (44.7)	9 (22.5)	26 (33.3)

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)
高尿酸血症	4 (10.5)	5 (12.5)	9 (11.5)
低カリウム血症	5 (13.2)	1 (2.5)	6 (7.7)
食欲減退	3 (7.9)	2 (5.0)	5 (6.4)
高血糖	5 (13.2)	0 (0.0)	5 (6.4)
低アルブミン血症	4 (10.5)	1 (2.5)	5 (6.4)
低カルシウム血症	2 (5.3)	1 (2.5)	3 (3.8)
低ナトリウム血症	1 (2.6)	2 (5.0)	3 (3.8)
高カリウム血症	2 (5.3)	0 (0.0)	2 (2.6)
低蛋白血症	2 (5.3)	0 (0.0)	2 (2.6)
高脂血症	1 (2.6)	0 (0.0)	1 (1.3)
低マグネシウム血症	0 (0.0)	1 (2.5)	1 (1.3)
腫瘍崩壊症候群	0 (0.0)	1 (2.5)	1 (1.3)
一般・全身障害および投与部位の状態	17 (44.7)	7 (17.5)	24 (30.8)
発熱	12 (31.6)	1 (2.5)	13 (16.7)
悪寒	4 (10.5)	0 (0.0)	4 (5.1)
顔面浮腫	2 (5.3)	2 (5.0)	4 (5.1)
末梢性浮腫	2 (5.3)	1 (2.5)	3 (3.8)
倦怠感	1 (2.6)	1 (2.5)	2 (2.6)
無力症	1 (2.6)	0 (0.0)	1 (1.3)
疲労	0 (0.0)	1 (2.5)	1 (1.3)
末梢腫脹	0 (0.0)	1 (2.5)	1 (1.3)
胃腸障害	15 (39.5)	8 (20.0)	23 (29.5)
便秘	6 (15.8)	1 (2.5)	7 (9.0)
悪心	7 (18.4)	0 (0.0)	7 (9.0)
嘔吐	3 (7.9)	0 (0.0)	3 (3.8)
腹部不快感	2 (5.3)	0 (0.0)	2 (2.6)
腹部膨満	1 (2.6)	1 (2.5)	2 (2.6)
歯肉出血	0 (0.0)	2 (5.0)	2 (2.6)
口腔内潰瘍形成	1 (2.6)	1 (2.5)	2 (2.6)
腹痛	1 (2.6)	0 (0.0)	1 (1.3)
上腹部痛	1 (2.6)	0 (0.0)	1 (1.3)
アフタ性潰瘍	1 (2.6)	0 (0.0)	1 (1.3)
下痢	0 (0.0)	1 (2.5)	1 (1.3)
消化不良	0 (0.0)	1 (2.5)	1 (1.3)
胃炎	1 (2.6)	0 (0.0)	1 (1.3)
胃腸の炎症	0 (0.0)	1 (2.5)	1 (1.3)
痔核	1 (2.6)	0 (0.0)	1 (1.3)
口の錯感覚	0 (0.0)	1 (2.5)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)
口内炎	1 (2.6)	0 (0.0)	1 (1.3)
歯痛	1 (2.6)	0 (0.0)	1 (1.3)
傷害、中毒および処置合併症	18 (47.4)	0 (0.0)	18 (23.1)
注入に伴う反応	14 (36.8)	0 (0.0)	14 (17.9)
輸血反応	4 (10.5)	0 (0.0)	4 (5.1)
皮下血腫	1 (2.6)	0 (0.0)	1 (1.3)
呼吸器、胸郭および縦隔障害	11 (28.9)	6 (15.0)	17 (21.8)
呼吸困難	3 (7.9)	1 (2.5)	4 (5.1)
鼻出血	0 (0.0)	3 (7.5)	3 (3.8)
胸水	3 (7.9)	0 (0.0)	3 (3.8)
しゃっくり	2 (5.3)	0 (0.0)	2 (2.6)
口腔咽頭痛	1 (2.6)	1 (2.5)	2 (2.6)
息詰まり感	1 (2.6)	0 (0.0)	1 (1.3)
咳嗽	1 (2.6)	0 (0.0)	1 (1.3)
低酸素症	1 (2.6)	0 (0.0)	1 (1.3)
間質性肺疾患	1 (2.6)	0 (0.0)	1 (1.3)
喉頭出血	0 (0.0)	1 (2.5)	1 (1.3)
肺臓炎	1 (2.6)	0 (0.0)	1 (1.3)
湿性咳嗽	1 (2.6)	0 (0.0)	1 (1.3)
肺肉芽腫	1 (2.6)	0 (0.0)	1 (1.3)
肺腫瘤	1 (2.6)	0 (0.0)	1 (1.3)
筋骨格系および結合組織障害	4 (10.5)	5 (12.5)	9 (11.5)
関節痛	2 (5.3)	2 (5.0)	4 (5.1)
四肢痛	2 (5.3)	1 (2.5)	3 (3.8)
筋骨格痛	0 (0.0)	2 (5.0)	2 (2.6)
筋肉痛	0 (0.0)	2 (5.0)	2 (2.6)
背部痛	1 (2.6)	0 (0.0)	1 (1.3)
血管障害	4 (10.5)	4 (10.0)	8 (10.3)
高血圧	2 (5.3)	4 (10.0)	6 (7.7)
静脈炎	2 (5.3)	0 (0.0)	2 (2.6)
低血圧	1 (2.6)	0 (0.0)	1 (1.3)
神経系障害	4 (10.5)	3 (7.5)	7 (9.0)
頭痛	2 (5.3)	1 (2.5)	3 (3.8)
脳出血	0 (0.0)	1 (2.5)	1 (1.3)
浮動性めまい	1 (2.6)	0 (0.0)	1 (1.3)
神経突起斑	0 (0.0)	1 (2.5)	1 (1.3)

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)
ヘルペス後神経痛	1 (2.6)	0 (0.0)	1 (1.3)
心臓障害	4 (10.5)	2 (5.0)	6 (7.7)
動悸	1 (2.6)	1 (2.5)	2 (2.6)
右脚ブロック	0 (0.0)	1 (2.5)	1 (1.3)
心不快感	1 (2.6)	0 (0.0)	1 (1.3)
心嚢液貯留	1 (2.6)	0 (0.0)	1 (1.3)
頻脈	1 (2.6)	0 (0.0)	1 (1.3)
腎および尿路障害	2 (5.3)	3 (7.5)	5 (6.4)
腎機能障害	1 (2.6)	1 (2.5)	2 (2.6)
血尿	0 (0.0)	1 (2.5)	1 (1.3)
腎結石症	0 (0.0)	1 (2.5)	1 (1.3)
腎不全	1 (2.6)	0 (0.0)	1 (1.3)
肝胆道系障害	2 (5.3)	2 (5.0)	4 (5.1)
肝機能異常	2 (5.3)	2 (5.0)	4 (5.1)
眼障害	2 (5.3)	1 (2.5)	3 (3.8)
ドライアイ	1 (2.6)	0 (0.0)	1 (1.3)
眼瞼出血	0 (0.0)	1 (2.5)	1 (1.3)
眼窩周囲の炎症	1 (2.6)	0 (0.0)	1 (1.3)
耳および迷路障害	0 (0.0)	1 (2.5)	1 (1.3)
鼓室内出血	0 (0.0)	1 (2.5)	1 (1.3)
中耳の炎症	0 (0.0)	1 (2.5)	1 (1.3)
免疫系障害	0 (0.0)	1 (2.5)	1 (1.3)
低γグロブリン血症	0 (0.0)	1 (2.5)	1 (1.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (2.5)	1 (1.3)
卵巣腺腫	0 (0.0)	1 (2.5)	1 (1.3)
生殖系および乳房障害	0 (0.0)	1 (2.5)	1 (1.3)
良性前立腺肥大症	0 (0.0)	1 (2.5)	1 (1.3)

Source: Table 14.3.1.2.6.1.2 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
Abbreviations: AE, adverse event; B, Bendamustine; R, Rituximab; BR, Bendamustine and Rituximab; TEAE, treatment-emergent adverse event.
Notes: Adverse events were classified based on MedDRA Version 24.0

System Organ Class Preferred Term	BR (N = 38) n (%)	Zanubrutinib (N = 40) n (%)	Total (Cohort 1a) (N = 78) n (%)

TEAE is defined as an AE that had an onset date or was worsening in severity from baseline (pretreatment) on or after the first dose of study drug up to 30 days after the last dose of zanubrutinib for zanubrutinib arm A and 90 days after the last dose of B or R (Arm B) following study drug discontinuation or the start of new anticancer therapy (including the zanubrutinib for Arm B patients crossed over), whichever comes first.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively. Events were sorted by descending order within System Organ Class, and by Preferred Term within System Organ Class in the Treatment-Emergent Total column.
Treatment-related AEs included AEs related to either B or R in Arm B, and zanubrutinib in Arm A.

表 52： 重篤な TEAE の一覧（死亡に至ったものを除く）、コホート 1（BGB-3111-304 試験、安全性解析対象集団）

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 5[redacted]/F	胃腸障害/ 嘔吐/ Vomiting	20[redacted] (30)/ 20[redacted] (32)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 悪心/ Nausea	20[redacted] (31)/ 20[redacted] (32)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 下痢/ Diarrhea	20[redacted] (31)/ 20[redacted] (39)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (10)/ 20[redacted] (14)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/F	血液およびリンパ系障害/ 発熱性好中球減少症/ Neutropenic Fever	20[redacted] (145)/ 20[redacted] (153)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ パラインフルエンザウイルス感染/ Parainfluenza Virus Iii Respiratory Infection	20[redacted] (226)/ 20[redacted] (260)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	眼障害/ 網膜剥離/ Right Retinal Detachment	20[redacted] (660)/ 20[redacted] (661)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 全身性炎症反応症候群/ Systemic Inflammatory Response Syndrome	20[redacted] (624)/ 20[redacted] (627)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	耳および迷路障害/ 回転性めまい/ Vertigo	20[redacted] (810)/ 20[redacted] (812)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 大腸菌性敗血症/ Sepsis/Bacteremia, E.Coli	20[redacted] (1291)/ 20[redacted] (1297)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (1291)/ 20[redacted] (1297)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路性敗血症/ Urosepsis	20[redacted] (1664)/ 20[redacted] (1668)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ ウイルス性胃腸炎/ Viral Gastroenteritis	20[redacted] (1811)/ 20[redacted] (1814)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	傷害、中毒および処置合併症/ 脊椎圧迫骨折/ Spinal Compression Fracture	20[redacted] (56)/ 20[redacted] (60)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	呼吸器、胸郭および縦隔障害/ 低酸素症/ Hypoxia	20[redacted] (211)/ 20[redacted] (220)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 蜂巣炎/ Cellulitis, Left Lower Extremity	20[redacted] (312)/ 20[redacted] (315)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (9)/ 20[redacted] (20)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	腎および尿路障害/ 急性腎障害/ Acute Kidney Injury	20[redacted] (623)/ 20[redacted] (626)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (91)/ 20[redacted] (96)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 皮膚感染/ Skin Infection	20[redacted] (642)/ 20[redacted] (645)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid-19 Infection	20[redacted] (926)/ 20[redacted] (932)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 狭心症/ Worsened Cardiac Chest Pain	20[redacted] (1030)/ 20[redacted] (1032)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (1565)/ 20[redacted] (1572)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 創傷感染/ Wound Infection	20[redacted] (8)/ 20[redacted] (9)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (8)/ 20[redacted] (23)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (12)/ 20[redacted] (25)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	傷害、中毒および処置合併症/ 膝蓋骨骨折/ Fractured Patella	20[redacted] (161)/ 20[redacted] (219)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (1382)/ 20[redacted] (1383)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	神経系障害/ 脳症/ Encephalopathy	20[redacted] (308)/ 20[redacted] (314)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ ウイルス性心膜炎/ Viral Pleuropericarditis	20[redacted] (989)/ 20[redacted] (992)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/ 疲労/ Worsening Fatigue	20[redacted] (1205)/ 20[redacted] (1207)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 6[redacted]/M	心臓障害/ 急性心筋梗塞/ Non-St-Elevation Myocardial Infarction	20[redacted] (189)/ 20[redacted] (190)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	心臓障害/ 心房細動/ Worsening Atrial Fibrillation	20[redacted] (16)/ 20[redacted] (19)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	神経系障害/ 一過性脳虚血発作/ Transient Ischemic Attack	20[redacted] (20)/ 20[redacted] (29)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE REDUCED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	血管障害/ 低血圧/ Hypotension	20[redacted] (28)/ 20[redacted] (31)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血管障害/ 低血圧/ Hypotension	20[redacted] (63)/ 20[redacted] (64)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ ダニ媒介熱/ Fevers Due To Tick-Borne Illness	20[redacted] (757)/ 20[redacted] (761)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (695)/ 20[redacted] (727)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Bilateral Pneumonia	20[redacted] (786)/ 20[redacted] (797)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 胸部損傷/ Blunt Chest Injury	20[redacted] (199)/ 20[redacted] (216)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 5[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (30)/ 20[redacted] (49)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/F	筋骨格系および結合組織障害/ 変形性関節症/ Osteoarthrosis Of The Right Hip Join	20[redacted] (1129)/ 20[redacted] (1131)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (1107)/ 20[redacted] (1112)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	傷害、中毒および処置合併症/ 骨盤骨折/ A Traumatic Fracture Of Superior Pubic Ramus (Right)	20[redacted] (13)/ 20[redacted] (79)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	血管障害/ 高血圧/ Worsening Of Arterial Hypertension	20[redacted] (239)/ 20[redacted] (248)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/F	感染症および寄生虫症/ ウイルス性肺炎/ Bilateral Viral Pneumonia	20[redacted] (526)/ 20[redacted] (536)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/F	臨床検査/ 血中クレアチニン増加/ Creatinine Increased	20[redacted] (14)/ 20[redacted] (21)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ COVID-19 肺炎/ Covid 19 Pneumonia	20[redacted] (821)/ 20[redacted] (835)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 倦怠感/ General Malaise	20[redacted] (31)/ 20[redacted] (33)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/ 発熱/ Non Neutropenic Fever	20[redacted] (166)/ 20[redacted] (167)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ Prostate Adenocarcinoma	20[redacted] (893)/ 20[redacted] (1107)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (8)/ 20[redacted] (21)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ ボーエン病/ In Situ Skin Epidermoid Carcinoma	20[redacted] (164)/ 20[redacted] (211)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	皮膚および皮下組織障害/ 中毒性皮疹/ Toxidermia	20[redacted] (30)/ 20[redacted] (32)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 心筋虚血/ Cardiac Ischemia	20[redacted] (1035)/ 20[redacted] (1043)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心筋虚血/ Cardiac Ischemia	20[redacted] (1042)/ 20[redacted] (1043)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	呼吸器、胸郭および縦隔障害/ 肺障害/ Pneumopathy	20[redacted] (31)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	肝胆道系障害/ 結節性再生性過形成/ Diffuse Nodular Regenerative Hyperplasia	20[redacted] (1295)/ Ongoing	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 8[redacted]/F	胃腸障害/ 腸閉塞/ Bowel Obstruction	20[redacted] (126)/ 20[redacted] (150)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 気管支炎/ Bronchitis	20[redacted] (164)/ 20[redacted] (169)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 消化管間質性腫瘍/ Gastrointestinal Stromal Tumor	20[redacted] (1214)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (17)/ 20[redacted] (29)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 憩室炎/ Diverticulitis	20[redacted] (17)/ 20[redacted] (30)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febril Neutropenia	20[redacted] (134)/ 20[redacted] (140)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Related Pneumonia	20[redacted] (1178)/ 20[redacted] (1231)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 注入に伴う反応/ Rituximab Infusion Reaction	20[redacted] (1)/ 20[redacted] (1)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (112)/ 20[redacted] (118)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (204)/ 20[redacted] (211)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ COVID-19/ Covid-19	20[redacted] (646)/ 20[redacted] (677)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/F	血管障害/ 動脈硬化症/ Arteriosclerosis No Further Information	20[redacted] (361)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 汎血球減少症/ Pantocytopenia	20[redacted] (2)/ 20[redacted] (10)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腫瘍フレア/ Increased Tumor Volume Malignant	20[redacted] (57)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
	感染症および寄生虫症/ 気管支肺アスペルギルス症/ Pulmonary Aspergillosis	20[redacted] (57)/ 20[redacted] (72)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	胃腸障害/ 閉塞性膵炎/ Acute Pancreatitis Of Billary Origin	20[redacted] (170)/ 20[redacted] (176)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	肝胆道系障害/ 胆管炎/ Cholangitis	20[redacted] (233)/ 20[redacted] (240)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	感染症および寄生虫症/ 気道感染/ Respiratory Infection	20[redacted] (24)/ 20[redacted] (29)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ ストーマ部ヘルニア/ Worsening Bricker Parestomal Hernia	20[redacted] (538)/ 20[redacted] (542)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Lung Infection (Covid-19 Positive)	20[redacted] (385)/ 20[redacted] (425)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (96)/ 20[redacted] (112)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 真菌性気道感染/ Respiratory Tract Infection By Aspergillus Niger	20[redacted] (160)/ 20[redacted] (176)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ シュードモナス性敗血症/ Sepsis Without Septic Shock Due To Pseudomonas Aeruginosa	20[redacted] (123)/ 20[redacted] (128)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/F	傷害、中毒および処置合併症/ 脊椎骨折/ Vertebral Fracture	20[redacted] (215)/ 20[redacted] (217)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion-Related Reactions	20[redacted] (31)/ 20[redacted] (33)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 再発肺扁平上皮癌/ Relapse Of Squamous Lung Carcinoma	20[redacted] (121)/ 20[redacted] (231)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 脊椎骨折/ Vertebral Fracture	20[redacted] (25)/ 20[redacted] (26)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	神経系障害/ 失神寸前の状態/ Presyncopal Episode With Nausea	20[redacted] (1000)/ 20[redacted] (1001)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 憩室炎/ Diverticulits	20[redacted] (220)/ 20[redacted] (225)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 腸憩室/ Diverticulosis On Colon	20[redacted] (731)/ 20[redacted] (736)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腎癌/ Renal Cancer	20[redacted] (591)/ 20[redacted] (596)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 喉頭肉芽腫/ Granuloma Vocal Cords	20[redacted]/ 20[redacted] (1541)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Lung Adenocarcinoma	20[redacted] (1353)/ 20[redacted] (1363)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腎細胞癌/ Renal Cell Carcinoma	20[redacted] (1353)/ 20[redacted] (1363)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (32)/ 20[redacted] (37)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	傷害、中毒および処置合併症/ 橈骨骨折/	20[redacted] (264)/	Yes/Grade 3: Severe or	NOT RELATED/ NOT APPLICABLE/	DRUG INTERRUPTED/ NOT APPLICABLE/	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	Left Radius Metaphyseal Fracture	20[redacted] (300)	medically significant	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 7[redacted]/M	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (286)/ 20[redacted] (289)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 前立腺炎/ Prostatitis	20[redacted] (322)/ 20[redacted] (331)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ インフルエンザ/ Influenza Virus A Infection	20[redacted] (6)/ 20[redacted] (13)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ インフルエンザ/ Influenza Virus A Infection	20[redacted] (38)/ 20[redacted] (48)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ クラミジア性肺炎/ Pneumonia Due To Chlamydia Pneumoniae Infection	20[redacted] (49)/ 20[redacted] (93)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (37)/ 20[redacted] (39)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					DOSE REDUCED/ NOT APPLICABLE			
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ RS ウイルス感染/ Respiratory Syncytial Virus Infection	20[redacted] (41)/ 20[redacted] (51)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腎癌/ Malignant Left Renal Neoformation	20[redacted] (67)/ 20[redacted] (73)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (333)/ 20[redacted] (340)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/M	腎および尿路障害/ 腎仙痛/ Right Renal Colic	20[redacted] (299)/ 20[redacted] (303)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (122)/ 20[redacted] (128)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	胃腸障害/ 腹痛/ Abdominal Pain	20[redacted] (29)/	Yes/Grade 3: Severe or	NOT APPLICABLE/ NOT RELATED/	NOT APPLICABLE/ DRUG WITHDRAWN/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
		20[redacted] (41)	medically significant	NOT RELATED/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE			
	胃腸障害/ 下痢/ Diarrhea	20[redacted] (29)/ 20[redacted] (41)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (29)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 菌血症/ Bacteremia	20[redacted] (49)/ 20[redacted] (52)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 蜂巣炎/ Worsening Of Left Arm Cellulitis	20[redacted] (88)/ 20[redacted] (93)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Adenocarcinomaof Pulmonary Origin	20[redacted] (659)/ 20[redacted] (697)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢	20[redacted] (91)/	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/	DOSE NOT CHANGED/	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	胞およびポリープを含む）/ 基底細胞癌/ Basal Cell Carcinoma	20[redacted] (155)		NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE		WITH SEQUELAE	
	腎および尿路障害/ 急性腎障害/ Acute Kidney Injury	20[redacted] (1024)/ 20[redacted] (1029)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 急性腎障害/ Acute Kidney Injury	20[redacted] (1033)/ 20[redacted] (1041)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 尿路感染/ Uti	20[redacted] (1196)/ 20[redacted] (1198)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 血尿/ Gross Hematuria	20[redacted] (1196)/ 20[redacted] (1198)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	感染症および寄生虫症/ 唾液腺膿瘍/ Left Submandibular Gland Abscess (Verbatim Ct Maxillofacial)	20[redacted] (103)/ 20[redacted] (141)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 唾液腺炎/ Left Submandibular Siadoadenitis	20[redacted] (103)/ 20[redacted] (141)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	胃腸障害/ 腹壁血腫/ Abdominal Wall Hematoma	20[redacted] (1128)/ 20[redacted] (1154)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Lung Adenocarcinoma	20[redacted] (428)/ 20[redacted] (432)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 胸水/ Pleural Effusion	20[redacted] (691)/ 20[redacted] (692)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERING/ RESOLVING	Yes
	呼吸器、胸郭および縦隔障害/ 胸水/ Pleural Effusion	20[redacted] (810)/ 20[redacted] (819)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERING/ RESOLVING	Yes
[redacted]/ 5[redacted]/M	胃腸障害/ 腹痛/ Worsening Abdominal Pain	20[redacted] (3)/ 20[redacted] (5)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (178)/ 20[redacted] (192)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (204)/ 20[redacted] (211)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted] 7[redacted]/M	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (1257)/ 20[redacted] (1399)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (1399)/ 20[redacted] (1407)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (1408)/ 20[redacted] (1426)	Yes/Grade 0: 0	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted] 7[redacted]/M	筋骨格系および結合組織障害/ 脊椎痛/ Vertebrogenic Algic Syndrome	20[redacted] (72)/ 20[redacted] (78)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia (Lung Infection)	20[redacted] (510)/ 20[redacted] (516)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	心臓障害/ 心筋梗塞/ Myocardial Infarction	20[redacted] (65)/ 20[redacted] (70)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (24)/ 20[redacted] (34)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 免疫性血小板減少症/ Immuno Thrombopenic Purpura	20[redacted] (44)/ 20[redacted] (49)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ COVID-19/ Covid 19 Infection	20[redacted] (1313)/ 20[redacted] (1324)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	臨床検査/ アラニンアミノトランスフェラーゼ増加/ Alt Elevation	20[redacted] (2)/ 20[redacted] (4)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	臨床検査/ アスパラギン酸アミノトランスフェラーゼ増加/ Ast Elevation	20[redacted] (2)/ 20[redacted] (4)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	臨床検査/ 血中アルカリホスファターゼ増加/ Alp Elevation	20[redacted] (29)/ 20[redacted] (33)	Yes/Grade 1: Mild	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	臨床検査/ γーグルタミルトランスフェラーゼ増加/ Ggt Elevation	20[redacted] (29)/ 20[redacted] (92)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	腎および尿路障害/ 尿路閉塞/ Urinary Tract Obstruction	20[redacted] (884)/ 20[redacted] (886)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	皮膚および皮下組織障害/ 発疹/ Skin Rash	20[redacted] (53)/ 20[redacted] (58)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 7[redacted]/M	皮膚および皮下組織障害/ 発疹/ Skin Rash	20[redacted] (29)/ 20[redacted] (39)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG WITHDRAWN/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infections	20[redacted] (1024)/ 20[redacted] (1030)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	腎および尿路障害/ 血尿/ Hematuria	20[redacted] (1024)/ 20[redacted] (1030)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infections	20[redacted] (1053)/ 20[redacted] (1060)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 血尿/ Hematuria	20[redacted] (1053)/ 20[redacted] (1060)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (1096)/ 20[redacted] (1102)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19 肺炎/ Bilateral Pneumonia Covid-19	20[redacted] (1195)/ 20[redacted] (1206)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (1195)/ 20[redacted] (1206)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	胃腸障害/ 下痢/ Diarrhoea	20[redacted] (211)/ 20[redacted] (214)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 心筋虚血/ Ischemic Heart Disease	20[redacted] (885)/ 20[redacted] (919)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心筋虚血/ Ischemic Heart Disease	20[redacted] (919)/ 20[redacted] (919)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid-19 Infection	20[redacted] (978)/ 20[redacted] (998)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ メレナ/ Melena	20[redacted] (1106)/ 20[redacted] (1111)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 食道潰瘍/ Oesophagus Ulcer	20[redacted] (1106)/ 20[redacted] (1111)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ COVID-19 肺炎/ Covid 19 Pneumonia	20[redacted] (1022)/ 20[redacted] (1053)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (521)/ 20[redacted] (528)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 後天性包茎/ Worsening Acquired Phimosis	20[redacted] (1057)/ 20[redacted] (1059)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 陰嚢血腫/ Scrotal Haematoma	20[redacted] (178)/ 20[redacted] (184)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心房細動/ Atrial Fibrilation	20[redacted] (1364)/ 20[redacted] (1387)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 急性膵炎/ Acute Pancreatitis	20[redacted] (1364)/ 20[redacted] (1387)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (1371)/ 20[redacted] (1380)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	胃腸障害/ 食道食物嵌入/ Esophageal Food Bolus Obstruction	20[redacted] (320)/ 20[redacted] (322)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	神経系障害/ 手根管症候群/ Carpal Tunnel Syndrome Right	20[redacted] (1133)/ 20[redacted] (1134)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 急性冠動脈症候群/ Acute Coronary Syndrome - Enzymatic Infarct	20[redacted] (425)/ 20[redacted] (429)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (560)/ 20[redacted] (566)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (844)/ 20[redacted] (851)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (1146)/ 20[redacted] (1149)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (1373)/ 20[redacted] (1403)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	神経系障害/ 顔面麻痺/ Peripheral Facial Paralysis (Right)	20[redacted] (200)/ 20[redacted] (209)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (299)/ 20[redacted] (310)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 脛骨骨折/ Stress Fracture Tibial Head (Left Knee)	20[redacted] (709)/ 20[redacted] (725)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19 肺炎/ Covid 19 Pneumonia	20[redacted] (858)/ 20[redacted] (869)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	皮膚および皮下組織障害/ 斑状丘疹状皮疹/ Maculopapular Exanthema (Torso)	20[redacted] (11)/ 20[redacted] (15)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 感染/ Infection (Unknown Origin)	20[redacted] (28)/ 20[redacted] (30)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	感染症および寄生虫症/ 軟部組織感染/ Soft Tissue Infection (Right Shoulder)	20[redacted] (281)/ 20[redacted] (287)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 後腹膜血腫/ Retroperitoneal Hematoma	20[redacted] (333)/ 20[redacted] (344)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿路閉塞/ Urinary Tract Obstruction	20[redacted] (333)/ 20[redacted] (344)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 良性前立腺肥大症/ Benign Prostatic Hyperplasia	20[redacted] (381)/ 20[redacted] (393)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 軟部組織感染/ Soft Tissue Infection (Left Shoulder)	20[redacted] (742)/ 20[redacted] (748)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	筋骨格系および結合組織障害/ 肩回旋筋腱板症候群/ Rotator Cuff Rupture	20[redacted] (742)/ 20[redacted] (748)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 骨髄増殖性新生物/ Chronic Myeloproliferative Neoplasm (Calr Positive)	20[redacted] (1128)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 6[redacted]/M	血液およびリンパ系障害/ 貧血/ Anaemia	20[redacted] (35)/ 20[redacted] (40)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ ニューモシスチス・イロベチイ肺炎/ Pcp Infection Pneumocystis Carinii Pneumonia	20[redacted] (1167)/ 20[redacted] (1186)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 低ナトリウム血症/ Hyponatraemia	20[redacted] (1194)/	Yes/Grade 3: Severe or	NOT RELATED/ NOT APPLICABLE/	DOSE NOT CHANGED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
		20[redacted] (1195)	medically significant	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	心臓障害/ 心筋梗塞/ Myocardial Infarction	20[redacted] (26)/ 20[redacted] (29)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	代謝および栄養障害/ 低ナトリウム血症/ Hyponatremia	20[redacted] (287)/ 20[redacted] (312)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN, DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ H3N2 インフルエンザ/ Influenza A Virus Consistent With Influenza A (H3)	20[redacted] (295)/ 20[redacted] (328)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (297)/ 20[redacted] (302)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Pyrexia With Rigors	20[redacted] (59)/ 20[redacted] (60)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	感染症および寄生虫症/	20[redacted] (31)/	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/	NOT APPLICABLE/ DOSE NOT	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染/ Suspected Infection Of Unknown Source - Diagnosis Unknown	20[redacted] (38)		RELATED/ NOT APPLICABLE	CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE			
	腎および尿路障害/ 急性腎障害/ Acute Kidney Injury Stage 2	20[redacted] (39)/ 20[redacted] (40)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 痛風/ Likely Gout Right Leg - Diagnosis Unknown	20[redacted] (39)/ 20[redacted] (44)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	一般・全身障害および投与部位の状態/ 発熱/ Pyrexia With Rigors	20[redacted] (58)/ 20[redacted] (60)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 注入に伴う反応/ Delayed Infusion-Related Reaction	20[redacted] (86)/ 20[redacted] (88)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Lung Infection (Covid-19)	20[redacted] (930)/ 20[redacted] (935)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 8[redacted]/M	心臓障害/ 心筋梗塞/ Mycardial Infraction	20[redacted] (281)/ 20[redacted] (288)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ Basal Cell Carcinoma	20[redacted] (8)/ 20[redacted] (127)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う扁平上皮癌/ Metastatic Squamous Cell Carcinoma Of Unknown Primary	20[redacted] (380)/ 20[redacted] (655)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (39)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/	20[redacted] (67)/	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	発熱/ Fever	20[redacted] (68)		RELATED/ NOT APPLICABLE	INTERRUPTED/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (336)/ 20[redacted] (337)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 下気道感染/ Chest Infection	20[redacted] (336)/ 20[redacted] (343)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱癌/ Bladder Carcinoma	20[redacted] (86)/ 20[redacted] (99)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 限局性感染/ Left Proximal Finger Infection	20[redacted] (1189)/ 20[redacted] (1218)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 7[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Pyrexia	20[redacted] (38)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	筋骨格系および結合組織障害/ 関節痛/ Arthralgia	20[redacted] (70)/ 20[redacted] (72)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					CHANGED/ NOT APPLICABLE			
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 外耳炎/ Otitis Externa	20[redacted] (214)/ 20[redacted] (221)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	感染症および寄生虫症/ 感染性皮膚潰瘍/ Infection To Right Calf - Related To Pre Existing Leg Ulceration.	20[redacted] (1)/ 20[redacted] (10)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ Clostridium Difficile Diarrhea	20[redacted] (35)/ 20[redacted] (46)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Uti	20[redacted] (35)/ 20[redacted] (46)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Fever (Non Neutropenic)	20[redacted] (11)/ 20[redacted] (14)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	皮膚および皮下組織障害/	20[redacted] (31)/	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/	NOT APPLICABLE/ DOSE NOT CHANGED/	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	斑状丘疹状皮疹/ Maculo-Papular Rash	20[redacted] (85)		RELATED/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE			
	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (114)/ 20[redacted] (116)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (13)/ 20[redacted] (16)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 敗血症/ Sepsis Unknown Origin	20[redacted] (59)/ 20[redacted] (62)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 心筋炎/ Myocarditis	20[redacted] (1052)/ 20[redacted] (1080)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 敗血症/ Sepsis Of Unknown Origin	20[redacted] (10)/ 20[redacted] (12)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/	20[redacted] (800)/	Yes/Grade 3: Severe or	NOT RELATED/ NOT APPLICABLE/	DRUG INTERRUPTED/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	COVID-19/ Covid 19 Infection	20[redacted] (820)	medically significant	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 7[redacted]/M	胃腸障害/ 膵炎/ Pancreatitis	20[redacted] (7)/ 20[redacted] (11)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	免疫系障害/ 薬物過敏症/ Allergic Reaction - Drug Allergy	20[redacted] (29)/ 20[redacted] (30)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 虫垂炎/ Appendicitis	20[redacted] (402)/ 20[redacted] (405)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/F	耳および迷路障害/ 回転性めまい/ Vertigo	20[redacted] (191)/ 20[redacted] (205)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (356)/ 20[redacted] (357)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 急性中耳炎/ Acute Otitis Media	20[redacted] (969)/ 20[redacted] (971)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/F	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (666)/ 20[redacted] (667)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	心臓障害/ 動悸/ Palpitations	20[redacted] (666)/ 20[redacted] (667)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	神経系障害/ 浮動性めまい/ Dizziness	20[redacted] (666)/ 20[redacted] (667)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid-19 Infection	20[redacted] (1313)/ 20[redacted] (1325)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	肝胆道系障害/ 鉄沈着再生肝結節/ Hepatic Steatotic Macro-Regenerative Nodule	20[redacted] (717)/ 20[redacted] (735)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (211)/ 20[redacted] (218)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					CHANGED/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ COVID-19/ Covid-19	20[redacted] (953)/ 20[redacted] (953)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (184)/ 20[redacted] (190)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (10)/ 20[redacted] (15)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (57)/ 20[redacted] (58)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (31)/ 20[redacted] (33)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	感染症および寄生虫症/ 神経ボレリア症/ Neuroborreliosis	20[redacted] (756)/ 20[redacted] (764)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/F	胃腸障害/ 悪心/ Nausea	20[redacted] (8)/ 20[redacted] (9)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 脱水/ Dehydration	20[redacted] (8)/ 20[redacted] (10)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	代謝および栄養障害/ 腫瘍崩壊症候群/ Tumor Lysis Syndrome	20[redacted] (7)/ 20[redacted] (10)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 丹毒/ Erysipelas Infection	20[redacted] (87)/ 20[redacted] (89)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺扁平上皮癌/ Squamous Cell Right Lung Cancer	20[redacted] (355)/ 20[redacted] (359)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢	20[redacted] (786)/	Yes/Grade 3: Severe or	NOT RELATED/ NOT APPLICABLE/	DRUG INTERRUPTED/	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	胞およびポリープを含む）/ 小脳腫瘍/ Tumor Of The Left Cerebellar Hemisphere, No Further Information	20[redacted] (791)	medically significant	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 四肢損傷/ Upper Left Limb Injury	20[redacted] (721)/ 20[redacted] (723)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 不安定狭心症/ Unstable Angina	20[redacted] (113)/ 20[redacted] (134)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN, DRUG INTERRUPTED/ DRUG WITHDRAWN, DRUG INTERRUPTED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	生殖系および乳房障害/ 子宮脱/ Descent Of The Reproductive Organs - Uterine Prolapse	20[redacted] (1024)/ 20[redacted] (1027)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	神経系障害/ くも膜下出血/ Subarachoid Hemorrhage	20[redacted] (1250)/ 20[redacted] (1263)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (10)/ 20[redacted] (14)	Yes/Grade 1: Mild	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	筋骨格系および結合組織障害/ 変性骨疾患/ Degenerative Changes Of Right Toe Bones	20[redacted] (849)/ 20[redacted] (861)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 4[redacted]/M	血液およびリンパ系障害/ 貧血/ Worsening Of Anemia	20[redacted] (10)/ 20[redacted] (14)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Worsening Of Anemia	20[redacted] (29)/ 20[redacted] (31)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Worsening Of Anemia	20[redacted] (66)/ 20[redacted] (69)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Worsening Of Anemia	20[redacted] (93)/ 20[redacted] (95)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	心臓障害/ 心筋虚血/ Ischemic Heart Disease	20[redacted] (700)/ 20[redacted] (701)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (1215)/ 20[redacted] (1249)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心筋梗塞/ Myocardial Infarction	20[redacted] (1224)/ 20[redacted] (1227)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	神経系障害/ 脳血管発作/ Stroke	20[redacted] (1276)/ 20[redacted] (1319)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 7[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (57)/ 20[redacted] (60)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	神経系障害/ 脳血管発作/ Cerebrovascular Accident	20[redacted] (519)/ 20[redacted] (529)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (5)/ 20[redacted] (12)	Yes/Grade 0: 0	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (29)/ 20[redacted] (36)	Yes/Grade 0: 0	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (31)/ 20[redacted] (36)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (57)/ 20[redacted] (61)	Yes/Grade 0: 0	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (133)/ 20[redacted] (145)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (233)/ 20[redacted] (241)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (304)/ 20[redacted] (313)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 上気道感染/ Upper Respiratory Tract Infection	20[redacted] (366)/ 20[redacted] (372)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	臨床検査/ アスパラギン酸アミノトランスフェラーゼ増加/ Aspartate Aminotransferase Increased	20[redacted] (1038)/ 20[redacted] (1045)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
	臨床検査/ アラニンアミノトランスフェラーゼ増加/ Alanine Aminotransferase Increased	20[redacted] (1038)/ 20[redacted] (1086)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	臨床検査/ アスパラギン酸アミノトランスフェラーゼ増加/ Aspartate Aminotransferase Increased	20[redacted] (1046)/ 20[redacted] (1058)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERING/ RESOLVING	Yes
	臨床検査/ アスパラギン酸アミノトランスフェラーゼ増加/ Aspartate	20[redacted] (1059)/ 20[redacted] (1086)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	Aminotransferase Increased							
[redacted]/ 7[redacted]/F	血液およびリンパ系障害/ 発熱性好中球減少症/ Neutropenic Fever	20[redacted] (32)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 心不全/ Cardiac Failura	20[redacted] (29)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ Pulmonary Embolism	20[redacted] (29)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 6[redacted]/F	心臓障害/ 心血管不全/ Worsening Circulatory Insufficiency	20[redacted] (10)/ 20[redacted] (18)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 感染/ Infection Of Unknown Site	20[redacted] (200)/ 20[redacted] (212)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 気道感染/ Respiratory Tract Infection	20[redacted] (29)/ 20[redacted] (36)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (177)/ 20[redacted] (182)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 血尿/ Hematuria	20[redacted] (177)/ 20[redacted] (189)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱の良性新生物/ Benign Neoplasm Of Bladder	20[redacted] (221)/ 20[redacted] (225)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 良性前立腺肥大症/ Prostatae Hyperplasia	20[redacted] (286)/ 20[redacted] (288)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ B 型肝炎再活性化/ Reactivation Hbv	20[redacted] (342)/ 20[redacted] (575)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid 19 Infections	20[redacted] (1037)/ 20[redacted] (1070)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (30)/ 20[redacted] (31)	Yes/Grade 1: Mild	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 口腔咽頭痛/ Sore Throat	20[redacted] (30)/ 20[redacted] (31)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	皮膚および皮下組織障害/ 発疹/ Rash On Neck, Chest And Forearms	20[redacted] (30)/ 20[redacted] (30)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Left-Side Pneumonia	20[redacted] (57)/ 20[redacted] (58)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	生殖系および乳房障害/ 会陰痛/ Worsening Of Pain Of The Perineum	20[redacted] (27)/ 20[redacted] (51)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Related Pneumonia	20[redacted] (683)/ 20[redacted] (710)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	血液およびリンパ系障害/ 貧血/ Anaemia	20[redacted] (31)/ 20[redacted] (35)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (58)/ 20[redacted] (61)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (86)/ 20[redacted] (91)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (111)/ 20[redacted] (115)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (140)/ 20[redacted] (143)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 感染/ Infection Of Unknown Origin	20[redacted] (31)/ 20[redacted] (50)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	筋骨格系および結合組織障害/ 椎間板障害/ Exacerbation Of Discopathy	20[redacted] (31)/ 20[redacted] (50)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
	筋骨格系および結合組織障害/ 背部痛/ Back Pain	20[redacted] (67)/ 20[redacted] (77)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/ 埋込み部位びらん/ Erosion Of Artificial Urinary Sphincter	20[redacted] (356)/ 20[redacted] (360)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	呼吸器、胸郭および縦隔障害/ 気胸/ Left Pneumothorax	20[redacted] (1168)/ 20[redacted] (1170)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERING/ RESOLVING	Yes
	代謝および栄養障害/ 低ナトリウム血症/ Hyponatremia	20[redacted] (1193)/ 20[redacted] (1195)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (30)/ 20[redacted] (37)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (57)/ 20[redacted] (58)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	代謝および栄養障害/ 腫瘍崩壊症候群/ Tumour Lysis Syndrome	20[redacted] (8)/ 20[redacted] (10)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (12)/ 20[redacted] (25)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19/ Covid 19 Infection	20[redacted] (1129)/ 20[redacted] (1136)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/F	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (18)/ 20[redacted] (22)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (18)/ 20[redacted] (36)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					INTERRUPTED/ NOT APPLICABLE			
[redacted]/ 5[redacted]/M	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ Thrombo-Embolic Event (Pulmonary Embolism)	20[redacted] (89)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 8[redacted]/M	心臓障害/ 心不全/ Decompensated Heart Failure	20[redacted] (39)/ 20[redacted] (41)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	胃腸障害/ 悪心/ Nausea	20[redacted] (949)/ 20[redacted] (952)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 嘔吐/ Vomiting	20[redacted] (949)/ 20[redacted] (952)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid 19	20[redacted] (949)/ 20[redacted] (964)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (972)/ 20[redacted] (976)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 5[redacted]/M	感染症および寄生虫症/ 上気道感染/ Urti	20[redacted] (66)/ 20[redacted] (77)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血管障害/ 末梢性虚血/ Worsening Ischemic Toe	20[redacted] (72)/ 20[redacted] (75)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid 19 Infection	20[redacted] (908)/ 20[redacted] (922)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness Of Breath	20[redacted] (808)/ 20[redacted] (814)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 硬膜下出血/ Traumatic Subdural Haemorrage	20[redacted] (836)/ 20[redacted] (960)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	神経系障害/ 脊髄症/ Cervical Myelopathy	20[redacted] (845)/ 20[redacted] (890)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (914)/ 20[redacted] (931)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 憩室炎/ Exacerbation Of Diverticulitis	20[redacted] (1093)/ 20[redacted] (1104)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 敗血症性ショック/ Septic Shock	20[redacted] (1150)/ 20[redacted] (1157)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	一般・全身障害および投与部位の状態/ 全身健康状態悪化/ General Physical Health Deterioration	20[redacted] (1159)/ 20[redacted] (1191)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	心臓障害/ 心室性頻脈/ Non Sustained Ventricular Tachycardia	20[redacted] (223)/ 20[redacted] (232)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 挫傷/ Bruising (Fingers)	20[redacted] (882)/ 20[redacted] (894)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 蜂巣炎/ Cellulitis	20[redacted] (1054)/ 20[redacted] (1068)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 蜂巣炎/ Cellulitis	20[redacted] (1309)/ 20[redacted] (1320)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心不全/ Heart Failure	20[redacted] (1343)/ 20[redacted] (1348)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
	心臓障害/ 心不全/ Heart Failure	20[redacted] (1353)/ 20[redacted] (1365)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/F	心臓障害/ 急性心筋梗塞/ Non-Stemi	20[redacted] (461)/ 20[redacted] (468)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	胃腸障害/ 腹痛/ Abdominal Pain-	20[redacted] (462)/ 20[redacted] (468)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (2)/ 20[redacted] (5)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	胃腸障害/ 直腸出血/ Rectal Bleeding	20[redacted] (396)/ 20[redacted] (397)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 直腸出血/ Rectal Bleeding	20[redacted] (400)/ 20[redacted] (401)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Related Reaction	20[redacted] (29)/ 20[redacted] (32)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN, DRUG INTERRUPTED/ DRUG WITHDRAWN/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 好中球減少性敗血症/ Neutropenic Sepsis	20[redacted] (17)/ 20[redacted] (21)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 下気道感染/ Lower Respiratory Tract Infection	20[redacted] (17)/ 20[redacted] (26)	Yes/Grade 2: Moderate	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ シュードモナス性菌血症/ Pseudomonas Bacteraemia	20[redacted] (24)/ 20[redacted] (58)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (162)/ 20[redacted] (168)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (162)/ 20[redacted] (175)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	神経系障害/ 頭痛/ Headache	20[redacted] (991)/ 20[redacted] (992)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	肝胆道系障害/ 胆管炎/ Cholangitis	20[redacted] (1204)/ 20[redacted] (1211)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	腎および尿路障害/ 血尿/ Painless Haematuria	20[redacted] (72)/ 20[redacted] (74)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	代謝および栄養障害/ 高カルシウム血症/ Hypercalcemia Due To Disease Progression	20[redacted] (90)/ 20[redacted] (113)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (30)/ 20[redacted] (33)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (59)/ 20[redacted] (79)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Related Reaction	20[redacted] (29)/ 20[redacted] (30)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Related Reaction	20[redacted] (57)/ 20[redacted] (58)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	肝胆道系障害/ 胆嚢炎/ Cholecystitis	20[redacted] (499)/ 20[redacted] (500)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 転倒/ Hospital Presentation - Presented To Ed After A Fall	20[redacted] (1248)/ 20[redacted] (1248)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	心臓障害/ 急性心筋梗塞/ Stemi/ Chest Pain	20[redacted] (1248)/ 20[redacted] (1251)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	心臓障害/ 急性冠動脈症候群/ Acute Coronary Syndrome	20[redacted] (44)/ 20[redacted] (70)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
	感染症および寄生虫症/ COVID-19 肺炎/ Covid 19 Positive Pneumonia	20[redacted] (1478)/ 20[redacted] (1593)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	血管障害/ 高血圧/ Hypertension	20[redacted] (224)/ 20[redacted] (227)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 感染による気管支拡張症の増悪/ Infective Exacerbation Bronchiectasis	20[redacted] (423)/ 20[redacted] (436)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 慢性副鼻腔炎/ Chronic Sinusitis	20[redacted] (528)/ 20[redacted] (529)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes
	感染症および寄生虫症/ 感染による気管支拡張症の増悪/ Infective Exacerbation Of Bronchiectasis	20[redacted] (831)/ 20[redacted] (846)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	血液およびリンパ系障害/ 貧血/ Anaemia	20[redacted] (453)/ 20[redacted] (470)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	免疫系障害/ 薬物過敏症/ Allergic Reaction “to Bendamustine” - Delayed	20[redacted] (59)/ 20[redacted] (64)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Reaction	20[redacted] (1)/ 20[redacted] (1)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	筋骨格系および結合組織障害/ ピロリン酸カルシウム結晶性軟骨石灰化症/	20[redacted] (25)/ 20[redacted] (36)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	Left Knee Swelling (Pseudo-Gout)							
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 感染/ Infection Of Unknown Origin	20[redacted] (11)/ 20[redacted] (16)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 直腸腺癌/ Adenocarcinoma Anorectal Junction	20[redacted] (476)/ 20[redacted] (476)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 直腸腺癌/ Invasive Adenocarcinoma Of Rectum With Mucinous Features	20[redacted] (798)/ 20[redacted] (955)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う肛門癌/ Metastatic Anal Adenocarcinoma	20[redacted] (1050)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	血管障害/ 大動脈壁内血腫/ Intramural Haematoma Of Distal Descending Aorta	20[redacted] (313)/ 20[redacted] (325)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	一般・全身障害および投与部位の状態/ 疲労/ Fatigue	20[redacted] (337)/ 20[redacted] (338)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	心臓障害/ 徐脈/ Bradycardia	20[redacted] (644)/ 20[redacted] (646)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	神経系障害/ 失神/ Syncope	20[redacted] (915)/ 20[redacted] (918)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	神経系障害/ 痙攣発作/ Seizures	20[redacted] (1183)/ 20[redacted] (1184)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	精神障害/ 自殺企図/ Attempted Suicide	20[redacted] (1411)/ 20[redacted] (1438)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever (Of Unknown Origin)	20[redacted] (118)/ 20[redacted] (124)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 閉塞性膵炎/ Gallstone Pancreatitis	20[redacted] (230)/ 20[redacted] (236)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (29)/ 20[redacted] (30)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (122)/ 20[redacted] (123)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う皮膚有棘細胞癌/ Metastatic Squamous Cell Carcinoma Of The Skin To The Left Postauricular Node	20[redacted] (51)/ 20[redacted] (1165)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	4	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 8[redacted]/F	血液およびリンパ系障害/	20[redacted] (62)/	Yes/Grade 4: Life-	RELATED/ NOT APPLICABLE/	DRUG INTERRUPTED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	好中球減少症/ Neutropenia	20[redacted] (76)	threatening or disabling	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 尿路性敗血症/ Urosepsis	20[redacted] (123)/ 20[redacted] (127)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (12)/ 20[redacted] (23)	Yes/Grade 1: Mild	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Micro-Invasive Adenocarcinoma Of Left Lower Lobe	20[redacted] (621)/ 20[redacted] (631)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 4[redacted]/M	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Related Reactions	20[redacted] (1)/ 20[redacted] (2)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted] (62)/ 20[redacted] (85)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious

Source: Listing 16.2.7.4.1 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE

Abbreviations: PT, Preferred Term; SOC, System Organ Class; TEAE, treatment-emergent adverse event; VT, verbatim term.

[a] Age is age at Informed Consent; Sex M = Male, F = Female.

[b] When stop date is missing then 'Ongoing' status is shown.

[c] Other action taken: 1 = none, 2 = concomitant medication, 3 = non-medication concomitant therapy or procedure, 4 = other.

Study Day = relative day with regard to first dose of study treatment, which is Study Day 1.

表 53： 重篤な TEAE の一覧（死亡に至ったものを除く）、コホート 2（BGB-3111-304 試験、安全性解析対象集団）

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Lung Infection - Covid-19 Pneumonia	20[redacted] (1223)/ 20[redacted] (1239)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN, DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 低ナトリウム血症/ Hyponatremia	20[redacted] (1246)/ 20[redacted] (1249)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19 肺炎/ Lung Infection - Covid-19 Pneumonia	20[redacted] (1247)/ 20[redacted] (1261)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 感染性胆嚢炎/ Gangrenous Cholecystitis	20[redacted] (280)/ 20[redacted] (289)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
	心臓障害/ 心房細動/ Rapid Ventricular Response (Atrial Fibrillation(Af))	20[redacted] (280)/ 20[redacted] (312)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 腹部敗血症/ Intra-Abdominal Sepsis	20[redacted] (282)/ 20[redacted] (284)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	胃腸障害/ 腹腔内血腫/ Pericholecystic Hematoma	20[redacted] (292)/ 20[redacted] (295)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 血液量増加症/ Hypervolemia	20[redacted] (301)/ 20[redacted] (302)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 胸水/ Right Pleural Effusion	20[redacted] (301)/ 20[redacted] (302)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Community-Acquired Pneumonia	20[redacted] (532)/ 20[redacted] (533)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	代謝および栄養障害/ 成人 FTT/ Failure To Thrive Due To Disease Progression	20[redacted] (175)/ 20[redacted] (248)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Worsening Pneumonia (Lung Infection)	20[redacted] (57)/ 20[redacted] (62)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 非小細胞肺癌/ Newly Diagnosed Nsclc	20[redacted] (383)/ 20[redacted] (482)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (267)/ 20[redacted] (272)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 気胸/ Pneumothorax	20[redacted] (267)/ 20[redacted] (272)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ Skin Squamous Cell Carcinoma On The Right Tibia	20[redacted] (369)/ 20[redacted] (383)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (894)/ 20[redacted] (904)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (734)/ 20[redacted] (753)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 5[redacted]/F	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonia	20[redacted] (1040)/ 20[redacted] (1053)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 大腸菌性尿路感染/ Escherichia Urinary Tract Infection	20[redacted] (23)/ 20[redacted] (25)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 7[redacted]/F	心臓障害/ 心室性不整脈/ Ventricular Arrhythmia	20[redacted] (1006)/ 20[redacted] (1052)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性黒色腫/ Melanoma	20[redacted] (191)/ 20[redacted] (1072)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	腎および尿路障害/ 腎結石症/ Renal Calculi	20[redacted] (97)/ 20[redacted] (98)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	神経系障害/ 水頭症/ Obstructive Hydrocephalus	20[redacted] (711)/ 20[redacted] (717)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED WITH SEQUELAE	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 8[redacted]/F	胃腸障害/ 出血性十二指腸潰瘍/ Digestive Bleeding From Duodenal Ulcer	20[redacted] (1435)/ 20[redacted] (1438)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎球菌性肺炎/ S. Pneumoniae Pneumonia	20[redacted] (130)/ 20[redacted] (147)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ 胃腸炎/ Acute Gastroenteritis	20[redacted] (221)/ 20[redacted] (227)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎/ Lung Infection (Pna)	20[redacted] (1072)/ 20[redacted] (1073)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (1072)/ 20[redacted] (1073)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	一般・全身障害および投与部位の状態/ 発熱/ Febrile	20[redacted] (199)/ 20[redacted] (219)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	一般・全身障害および投与部位の状態/ 発熱/ Febrile Due To Disease Progression	20[redacted] (223)/ 20[redacted] (234)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 虫垂炎/ Appendicitis	20[redacted] (292)/ 20[redacted] (298)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 大腸腺腫/ Colonadenom	20[redacted] (425)/ 20[redacted] (425)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (932)/ 20[redacted] (939)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心不全/ Cardiac Insufficiency	20[redacted] (943)/ 20[redacted] (951)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ COVID-19/ Covid 19 Infection	20[redacted] (957)/ 20[redacted] (961)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性黒色腫/ Malignant Melanoma	20[redacted] (1511)/ 20[redacted] (1534)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	筋骨格系および結合組織障害/ 筋肉痛/ Cervical Myalgia	20[redacted] (107)/ 20[redacted] (109)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	筋骨格系および結合組織障害/ 筋骨格系胸痛/ Musculoskeletal Chest Pain	20[redacted] (175)/ 20[redacted] (178)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	筋骨格系および結合組織障害/ 四肢痛/ Pain Left Arm	20[redacted] (186)/ 20[redacted] (189)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	神経系障害/ 手根管症候群/ Worsening Of Carpal Tunnel Syndrome	20[redacted] (437)/ 20[redacted] (442)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 腹痛/ Abdominal Pain	20[redacted] (749)/ 20[redacted] (750)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	傷害、中毒および処置合併症/ 骨挫傷/ Contusion Lumbar Vertebra Spine	20[redacted] (904)/ 20[redacted] (910)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 良性前立腺肥大症/ Benigne Enlargement Of The Prostate	20[redacted] (972)/ 20[redacted] (973)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pneumonia Lower Lobe Left	20[redacted] (976)/ 20[redacted] (981)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	生殖系および乳房障害/ 良性前立腺肥大症/ Benign Enlargement Of The Prostate	20[redacted] (1003)/ 20[redacted] (1007)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	神経系障害/ 失神/ Syncope	20[redacted] (1014)/ 20[redacted] (1016)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	生殖系および乳房障害/ 良性前立腺肥大症/ Worsening Of Prostatic Hypertrophy	20[redacted] (200)/ 20[redacted] (204)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性黒色腫/ Invasive Melanoma (Temporl Right Side)	20[redacted] (334)/ 20[redacted] (334)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 処置後出血/ Postoperative Hemorrhage	20[redacted] (334)/ 20[redacted] (335)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 4[redacted]/M	呼吸器、胸郭および縦隔障害/ 鼻出血/ Epistaxis	20[redacted] (2)/ 20[redacted] (4)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 下気道感染/ Bilateral Lower Respiratory Infection	20[redacted] (428)/ 20[redacted] (436)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 大腸感染/ Infectious Colitis	20[redacted] (906)/ 20[redacted] (919)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Suspected Adenocarcinoma Lung Diagnosis Unknown	20[redacted] (512)/ 20[redacted] (1086)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ Prostate Adenocarcinoma	20[redacted] (596)/ 20[redacted] (1233)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 8[redacted]/F	神経系障害/ 頭痛/ Headache	20[redacted] (45)/ 20[redacted] (64)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ COVID-19/ Infection, Covid-19	20[redacted] (1223)/ 20[redacted] (1227)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (3)/ 20[redacted] (11)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路感染/ Urinary Infection	20[redacted] (3)/ 20[redacted] (11)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	胃腸障害/ イレウス/ Small Intestinal Ileus	20[redacted] (597)/ 20[redacted] (603)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ COVID-19/ Sars Cov 2 Infection	20[redacted] (1035)/ 20[redacted] (1062)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	生殖系および乳房障害/ 良性前立腺肥大症/ Exacerbation Of Prostate Hypertrophy With Secondary Urinary Retention	20[redacted] (429)/ 20[redacted] (431)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 膀胱狭窄/ Stenosis Of The Bladder Neck	20[redacted] (519)/ 20[redacted] (522)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿道狭窄/ Stricture Of The Urethra	20[redacted] (574)/ 20[redacted] (577)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	腎および尿路障害/ 尿道狭窄/ Urethra Stenosis	20[redacted] (932)/ 20[redacted] (934)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	精神障害/ うつ病/ Depression Aggravated	20[redacted] (1213)/ 20[redacted] (1247)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 8[redacted]/F	傷害、中毒および処置合併症/ 大腿骨骨折/ Trochanteric Fracture Of The Femur	20[redacted] (833)/ 20[redacted] (941)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 貧血/ Anaemia	20[redacted] (16)/ 20[redacted] (17)	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	皮膚および皮下組織障害/ 紫斑/ Purpura	20[redacted] (16)/ 20[redacted] (43)	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anaemia	20[redacted] (20)/ 20[redacted] (22)	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	傷害、中毒および処置合併症/ 腰椎骨折/ Spinal Fracture At L1 And L4	20[redacted] (45)/ 20[redacted] (1211)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
	傷害、中毒および処置合併症/ 脊椎骨折/ Fracture At T11,t12,l1 And L5,t9	20[redacted] (57)/ 20[redacted] (1211)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ COVID-19 肺炎/ Covid-19 Pneumonitis	20[redacted] (1199)/ 20[redacted] (1210)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱癌/ Bladder Cancer	20[redacted] (565)/ 20[redacted] (566)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 高血糖/ Hyperglycaemia	20[redacted] (1205)/ 20[redacted] (1206)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (382)/ 20[redacted] (386)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (527)/ 20[redacted] (528)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (554)/ 20[redacted] (583)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (885)/ 20[redacted] (908)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (886)/ 20[redacted] (886)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性胸水/ Malignant Left Pleural Effusion	20[redacted] (26)/ 20[redacted] (54)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 転倒/ Collapse (Fall)	20[redacted] (812)/ 20[redacted] (814)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 尿路性敗血症/ Urosepsis	20[redacted] (816)/ 20[redacted] (818)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ 鼠径部膿瘍/ Right Inguinal Abscess	20[redacted] (435)/ 20[redacted] (442)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	神経系障害/ 脳血管発作/ Stroke	20[redacted] (617)/ 20[redacted] (620)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/F	皮膚および皮下組織障害/ 皮膚潰瘍/ Leg Ulcers	20[redacted] (58)/ 20[redacted] (151)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 虫垂炎/ Appendicitis	20[redacted] (84)/ 20[redacted] (90)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 虫垂炎/ Appendicitis	20[redacted] (136)/ 20[redacted] (148)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 頭部損傷/ Head Injury	20[redacted] (1368)/ 20[redacted] (1369)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	心臓障害/ 心房細動/ Rapid Atrial Fibrillation	20[redacted] (1402)/ 20[redacted] (1408)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED WITH SEQUELAE	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳癌/ Breast Cancer	20[redacted] (445)/ 20[redacted] (479)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 尿路性敗血症/ Urinary Sepsis	20[redacted] (141)/ 20[redacted] (146)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	腎および尿路障害/ 尿閉/ Urinary Retention	20[redacted] (261)/ 20[redacted] (265)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	筋骨格系および結合組織障害/ 背部痛/ Back Pain	20[redacted] (97)/ 20[redacted] (106)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腫瘍疼痛/ Tumour Pain Related To Disease Progression To Diffuse Large B Cell Lymphoma (Malingnant Neoplasm)	20[redacted] (125)/ 20[redacted] (222)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/	20[redacted] (1144)/ Ongoing	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/	3	NOT RECOVERED/ NOT RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	前立腺癌/ Prostate Cancer				NOT APPLICABLE/ NOT APPLICABLE			
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ Metastatic Adenocarcinoma Of Lung Origin In Spine-Vertebral Column	20[redacted] (1248)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 8[redacted]/M	感染症および寄生虫症/ クリプトコッカス性髄膜炎/ Cryptococcus Meningitis	20[redacted] (1620)/ 20[redacted] (1643)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN, DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
[redacted]/ 8[redacted]/F	傷害、中毒および処置合併症/ 大腿骨骨折/ Femur Fracture	20[redacted] (544)/ 20[redacted] (584)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	肝胆道系障害/ 胆道仙痛/ Biliary Colic	20[redacted] (10)/ 20[redacted] (22)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	胃腸障害/ 腹痛/ Abdominal Pain	20[redacted] (1256)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	NOT RECOVERED/ NOT RESOLVED	Yes
	感染症および寄生虫症/ 尿路性敗血症/ Urosepsis	20[redacted] (1291)/ 20[redacted] (1301)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	感染症および寄生虫症/ シュードモナス性敗血症/ Sepsis - Pseudomonas	20[redacted] (599)/ 20[redacted] (608)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	心臓障害/ 心房細動/ Atrial Fibrillation	20[redacted] (599)/ 20[redacted] (617)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱移行上皮癌/ Low Grade Papillary Urothelial Carcinoma - Bladder	20[redacted] (465)/ 20[redacted] (466)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 転倒/ Fall	20[redacted] (1318)/ 20[redacted] (1323)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	傷害、中毒および処置合併症/ 肋骨骨折/ Non Displaced Fractures Of The Right 9th And 11th Ribs.	20[redacted] (1379)/ 20[redacted] (1386)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	腎および尿路障害/ 腎結石症/ Translucent Renal Calculi	20[redacted] (25)/ 20[redacted] (27)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	筋骨格系および結合組織障害/ 脊柱管狭窄症/ Spinal Stenosis	20[redacted] (597)/ 20[redacted] (605)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
	神経系障害/ 頭痛/ Headache Secondary To Trigeminal Cephalagia	20[redacted] (809)/ 20[redacted] (820)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Subjective Fevers	20[redacted] (158)/ 20[redacted] (159)	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (129)/ 20[redacted] (139)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 尿路感染/ Urinary Tract Infection	20[redacted]-[redacted]-[redacted] (283)/ 20[redacted]-[redacted]-[redacted] (288)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	呼吸器、胸郭および縦隔障害/ 胸水/ Worsening Of Pleural Effusion	20[redacted]-[redacted]-[redacted] (392)/ 20[redacted]-[redacted]-[redacted] (489)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	腎および尿路障害/ 急性腎障害/ Acute Kidney Injury	20[redacted]-[redacted]-[redacted] (1236)/ 20[redacted]-[redacted]-[redacted] (1239)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	代謝および栄養障害/ 過小食/ Poor Nutritional Intake	20[redacted]-[redacted]-[redacted] (1236)/ 20[redacted]-[redacted]-[redacted] (1289)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	神経系障害/ 虚血性脳卒中/ Ischaemic Stroke	20[redacted]-[redacted]-[redacted] (1246)/ 20[redacted]-[redacted]-[redacted] (1289)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED WITH SEQUELAE	Yes

Source: Listing 16.2.7.4.3 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE

Abbreviations: PT, Preferred Term; SOC, System Organ Class; TEAE, treatment-emergent adverse event; VT, verbatim term.

[a] Age is age at Informed Consent; Sex M = Male, F = Female.

[b] When stop date is missing then 'Ongoing' status is shown.

[c] Other action taken: 1 = none, 2 = concomitant medication, 3 = non-medication concomitant therapy or procedure, 4 = other.

Study Day = relative day with regard to first dose of study treatment, which is Study Day 1.

表 54： 重篤な TEAE の一覧（死亡に至った者を除く）、中国の治験実施施設の被験者（コホート 1a）（BGB-3111-304 試験、安全性解析対象集団）

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	眼障害/ 白内障/ Cataract	20[redacted]-[redacted]-[redacted] (175)/ 20[redacted]-[redacted]-[redacted] (189)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	筋骨格系および結合組織障害/ 横紋筋融解症/ Rhabdomyolysis	20[redacted]-[redacted]-[redacted] (95)/ 20[redacted]-[redacted]-[redacted] (107)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted]-[redacted]-[redacted] (95)/ 20[redacted]-[redacted]-[redacted] (108)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 敗血症/ Bloodstream Infection	20[redacted]-[redacted]-[redacted] (95)/ 20[redacted]-[redacted]-[redacted] (108)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 上気道感染/ Acute Upper Respiratory Infection	20[redacted] (111)/ 20[redacted] (119)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (39)/ 20[redacted] (45)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (45)/ 20[redacted] (52)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (52)/ 20[redacted] (68)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (68)/ 20[redacted] (73)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (73)/ 20[redacted] (93)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DRUG	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					INTERRUPTED/ NOT APPLICABLE			
[redacted]/ 5[redacted]/M	臨床検査/ 血中クレアチニン増加/ Creatinine Increased	20[redacted] (941)/ Ongoing	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
	臨床検査/ アラニンアミノトランスフェラーゼ増加/ Alanine Aminotransferase Increased	20[redacted] (941)/ 20[redacted] (951)	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	代謝および栄養障害/ 高カリウム血症/ Hyperkalemia	20[redacted] (4)/ 20[redacted] (6)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	呼吸器、胸郭および縦隔障害/ 肺臓炎/ Pneumonitis	20[redacted] (29)/ 20[redacted] (45)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	呼吸器、胸郭および縦隔障害/ 肺臓炎/ Pneumonitis	20[redacted] (45)/ 20[redacted] (84)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/	20[redacted] (9)/ Ongoing	Yes/Grade 3: Severe or	NOT APPLICABLE/ NOT RELATED/	NOT APPLICABLE/ DOSE NOT CHANGED/	3	NOT RECOVERED/	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	肛門膿瘍/ Perianal Abscess		medically significant	NOT RELATED/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE		NOT RESOLVED	
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted]-[redacted]-[redacted] (55)/ 20[redacted]-[redacted]-[redacted] (57)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted]-[redacted]-[redacted] (114)/ 20[redacted]-[redacted]-[redacted] (115)	Yes/Grade 1: Mild	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted]-[redacted]-[redacted] (29)/ Ongoing	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	NOT RECOVERED/ NOT RESOLVED	Yes
	臨床検査/ 血小板数減少/ Platelet Count Decreased	20[redacted]-[redacted]-[redacted] (29)/ 20[redacted]-[redacted]-[redacted] (39)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	1	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 6[redacted]/F	臨床検査/ 血小板数減少/ Platelet Count Decreased	20[redacted] (4)/ 20[redacted] (5)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERING/ RESOLVING	Yes
	臨床検査/ 血小板数減少/ Platelet Count Decreased	20[redacted] (5)/ 20[redacted] (8)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (14)/ 20[redacted] (15)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	NOT RECOVERED/ NOT RESOLVED	Yes
	臨床検査/ 好中球数減少/ Neutrophil Count Decreased	20[redacted] (14)/ 20[redacted] (17)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (15)/ 20[redacted] (19)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERING/ RESOLVING	Yes
	臨床検査/ 好中球数減少/ Neutrophil Count Decreased	20[redacted] (17)/ 20[redacted] (19)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT	2	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					CHANGED/ NOT APPLICABLE			
	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (19)/ 20[redacted] (28)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	臨床検査/ 好中球数減少/ Neutrophil Count Decreased	20[redacted] (19)/ 20[redacted] (28)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (66)/ 20[redacted] (90)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (5)/ 20[redacted] (7)	Yes/Grade 1: Mild	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 8[redacted]/M	血液およびリンパ系障害/ リンパ節炎/ Acute Lymphadenitis	20[redacted] (167)/ 20[redacted] (185)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 敗血症/ Sepsis	20[redacted] (168)/ 20[redacted] (185)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					NOT APPLICABLE/ NOT APPLICABLE			
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (169)/ 20[redacted] (185)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (388)/ 20[redacted] (397)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (397)/ 20[redacted] (422)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (23)/ 20[redacted] (32)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	一般・全身障害および投与部位の状態/ 発熱/ Fever	20[redacted] (7)/ 20[redacted] (9)	Yes/Grade 1: Mild	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	肝胆道系障害/ 肝機能異常/ Abnormal Liver Function	20[redacted] (142)/ 20[redacted] (143)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT	2	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					CHANGED/ NOT APPLICABLE			
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 熱性感染症/ Infectious Fever	20[redacted] (31)/ 20[redacted] (39)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (8)/ 20[redacted] (12)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (100)/ 20[redacted] (107)	Yes/Grade 2: Moderate	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 卵巣腺腫/ Right Ovarian Serous Cystadenoma	20[redacted] (726)/ 20[redacted] (735)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	血液およびリンパ系障害/ 貧血/ Anemia	20[redacted] (12)/ 20[redacted] (21)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/F	代謝および栄養障害/ 腫瘍崩壊症候群/ Tumor Lysis Syndrome	20[redacted] (6)/	Yes/Grade 4: Life-	RELATED/ NOT APPLICABLE/	DRUG INTERRUPTED/ NOT APPLICABLE/	2	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
		20[redacted]-[redacted]-[redacted] (16)	threatening or disabling	NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE			
[redacted]/ 3[redacted]/M	感染症および寄生虫症/ 肛門膿瘍/ Perianal Abscess	20[redacted]-[redacted]-[redacted] (813)/ 20[redacted]-[redacted]-[redacted] (829)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted]-[redacted]-[redacted] (49)/ 20[redacted]-[redacted]-[redacted] (53)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 軟部組織感染/ Soft Tissue Infection	20[redacted]-[redacted]-[redacted] (61)/ 20[redacted]-[redacted]-[redacted] (90)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DOSE REDUCED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ リンパ節炎/ Lymph Node Phlogistic	20[redacted]-[redacted]-[redacted] (675)/ 20[redacted]-[redacted]-[redacted] (688)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 細菌性肺炎/ Bacterial Pneumonia	20[redacted]-[redacted]-[redacted] (675)/ 20[redacted]-[redacted]-[redacted] (688)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted]-[redacted]-[redacted] (118)/ 20[redacted]-[redacted]-[redacted] (138)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	感染症および寄生虫症/ 肺炎/ Pulmonary Infection	20[redacted] (166)/ 20[redacted] (175)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	胃腸障害/ 痔核/ Mixed Hemorrhoid	20[redacted] (651)/ 20[redacted] (662)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 皮膚感染/ Skin Infection Of Left Upper Limb	20[redacted] (731)/ 20[redacted] (749)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 軟部組織感染/ Soft Tissue Infection Of The Left Upper Limb	20[redacted] (731)/ 20[redacted] (749)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 5[redacted]/M	臨床検査/ 好中球数減少/ Neutrophil Counts Decreased	20[redacted] (4)/ 20[redacted] (105)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/M	呼吸器、胸郭および縦隔障害/ 胸水/ Pleural Effusion Worsening	20[redacted] (30)/ 20[redacted] (38)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 7[redacted]/F	一般・全身障害および投与部位の状態/ 腫瘤/ Right Thoracic Mass Of Unknown Nature	20[redacted]-[redacted]-[redacted] (192)/ 20[redacted]-[redacted]-[redacted] (197)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	傷害、中毒および処置合併症/ 交通事故/ Car Accident	20[redacted]-[redacted]-[redacted] (323)/ 20[redacted]-[redacted]-[redacted] (323)	Yes/Grade 2: Moderate	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 外傷性気胸/ Traumatic Pneumothorax	20[redacted]-[redacted]-[redacted] (323)/ 20[redacted]-[redacted]-[redacted] (355)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	臨床検査/ 血小板数減少/ Platelet Count Decreased(Aggravated)	20[redacted]-[redacted]-[redacted] (18)/ 20[redacted]-[redacted]-[redacted] (21)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	臨床検査/ 血小板数減少/ Platelet Count Decreased	20[redacted]-[redacted]-[redacted] (21)/ 20[redacted]-[redacted]-[redacted] (23)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	肝胆道系障害/ 肝機能異常/ Abnormal Liver Function	20[redacted]-[redacted]-[redacted] (43)/ 20[redacted]-[redacted]-[redacted] (49)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	4	RECOVERING/ RESOLVING	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile Neutropenia	20[redacted] (44)/ 20[redacted] (51)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 6[redacted]/F	感染症および寄生虫症/ リンパ管炎/ Lymphangiitis Of Left Lower Extremity	20[redacted] (236)/ 20[redacted] (245)	Yes/Grade 3: Severe or medically significant	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	感染症および寄生虫症/ 肺炎/ Pneumonia	20[redacted] (30)/ 20[redacted] (35)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 7[redacted]/M	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	20[redacted] (2)/ Ongoing	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	UNKNOWN	Yes
[redacted]/ 7[redacted]/M	傷害、中毒および処置合併症/ 交通事故/ Car Accident	20[redacted] (232)/ 20[redacted] (232)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	1	RECOVERED/ RESOLVED	Yes
	傷害、中毒および処置合併症/ 外傷性頭蓋内出血/ Traumatic Intracranial Hemorrhage	20[redacted] (232)/ 20[redacted] (302)	Yes/Grade 4: Life-threatening or disabling	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG INTERRUPTED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
[redacted]/ 5[redacted]/M	神経系障害/ 脳出血/ Parioccipital Cerebral Hemorrhage (Left)	20[redacted] (163)/ 20[redacted] (207)	Yes/Grade 4: Life-threatening or disabling	RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DRUG WITHDRAWN/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 7[redacted]/M	胃腸障害/ 腹痛/ Abdominal Pain	20[redacted] (10)/ 20[redacted] (13)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	血液およびリンパ系障害/ 好中球減少症/ Neutropenia	20[redacted] (29)/ 20[redacted] (30)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ NOT RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG INTERRUPTED/ DRUG INTERRUPTED, DOSE REDUCED/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (34)/ 20[redacted] (37)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (94)/ 20[redacted] (105)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT CHANGED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
	感染症および寄生虫症/ 肺炎/ Lung Infection	20[redacted] (192)/ 20[redacted] (203)	Yes/Grade 3: Severe or medically significant	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DOSE NOT CHANGED/ DOSE NOT	2	RECOVERED/ RESOLVED	Yes

Patient/ Age (y)/Sex [a]	SOC/PT/VT	AE Start Date (Study Day)/ AE Stop Date (Study Day) [b]	TEAE/ CTCAE Grade	Relationship: Zanu/Rit/Ben/Ven	Study Drug Action Taken: Zanu/Rit/Ben/Ven	Zanu Other Action Taken [c]	Outcome	Serious
					CHANGED/ NOT APPLICABLE			
[redacted]/ 6[redacted]/F	傷害、中毒および処置合併症/ 四肢損傷/ Shoulder Damage(Right Shoulder)(Unknow)	20[redacted]-[redacted]-[redacted] (192)/ 20[redacted]-[redacted]-[redacted] (200)	Yes/Grade 3: Severe or medically significant	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	3	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	神経系障害/ 脳虚血/ Ischemic Cerebrovascular Disease	20[redacted]-[redacted]-[redacted] (16)/ Ongoing	Yes/Grade 1: Mild	NOT RELATED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	DOSE NOT CHANGED/ NOT APPLICABLE/ NOT APPLICABLE/ NOT APPLICABLE	2	RECOVERING/ RESOLVING	Yes
[redacted]/ 6[redacted]/M	呼吸器、胸郭および縦隔障害/ 間質性肺疾患/ Interstitial Pneumonia	20[redacted]-[redacted]-[redacted] (82)/ 20[redacted]-[redacted]-[redacted] (100)	Yes/Grade 2: Moderate	NOT APPLICABLE/ RELATED/ NOT RELATED/ NOT APPLICABLE	NOT APPLICABLE/ NOT APPLICABLE/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes
[redacted]/ 5[redacted]/M	傷害、中毒および処置合併症/ 注入に伴う反応/ Infusion Related Reaction	20[redacted]-[redacted]-[redacted] (33)/ 20[redacted]-[redacted]-[redacted] (44)	Yes/Grade 4: Life-threatening or disabling	NOT APPLICABLE/ RELATED/ RELATED/ NOT APPLICABLE	NOT APPLICABLE/ DRUG WITHDRAWN/ DRUG INTERRUPTED/ NOT APPLICABLE	2	RECOVERED/ RESOLVED	Yes

Source: Listing 16.2.7.4.2 in BGB-3111-304 clinical study report (data cutoff date: 31 October 2022). Data cutoff: 31Oct2022; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE

Abbreviations: PT, Preferred Term; SOC, System Organ Class; TEAE, treatment-emergent adverse event; VT, verbatim term.

[a] Age is age at Informed Consent; Sex M = Male, F = Female.

[b] When stop date is missing then 'Ongoing' status is shown.

[c] Other action taken: 1 = none, 2 = concomitant medication, 3 = non-medication concomitant therapy or procedure, 4 = other.

Study Day = relative day with regard to first dose of study treatment, which is Study Day 1.

表 55： 治療下で発現した有害事象：器官別大分類別及び基本語別（BGB-3111-305 試験、安全性解析対象集団）

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
Patients With at Least One TEAE	318 (98.1)	321 (99.1)	639 (98.6)
感染症および寄生虫症	231 (71.3)	237 (73.1)	468 (72.2)
COVID-19	75 (23.1)	58 (17.9)	133 (20.5)
上気道感染	68 (21.0)	46 (14.2)	114 (17.6)
肺炎	34 (10.5)	40 (12.3)	74 (11.4)
尿路感染	31 (9.6)	30 (9.3)	61 (9.4)
COVID-19肺炎	25 (7.7)	14 (4.3)	39 (6.0)
気管支炎	13 (4.0)	19 (5.9)	32 (4.9)
副鼻腔炎	15 (4.6)	12 (3.7)	27 (4.2)
蜂巣炎	10 (3.1)	13 (4.0)	23 (3.5)
帯状疱疹	12 (3.7)	8 (2.5)	20 (3.1)
上咽頭炎	11 (3.4)	9 (2.8)	20 (3.1)
下気道感染	10 (3.1)	8 (2.5)	18 (2.8)
咽頭炎	6 (1.9)	11 (3.4)	17 (2.6)
皮膚感染	6 (1.9)	11 (3.4)	17 (2.6)
口腔ヘルペス	4 (1.2)	12 (3.7)	16 (2.5)
結膜炎	5 (1.5)	10 (3.1)	15 (2.3)
鼻炎	6 (1.9)	9 (2.8)	15 (2.3)
爪囲炎	4 (1.2)	10 (3.1)	14 (2.2)
限局性感染	6 (1.9)	6 (1.9)	12 (1.9)
気道感染	9 (2.8)	3 (0.9)	12 (1.9)
耳感染	8 (2.5)	2 (0.6)	10 (1.5)
胃腸炎	4 (1.2)	6 (1.9)	10 (1.5)
感染	5 (1.5)	4 (1.2)	9 (1.4)
毛包炎	4 (1.2)	4 (1.2)	8 (1.2)
せつ	4 (1.2)	4 (1.2)	8 (1.2)
ヘルペスウイルス感染	2 (0.6)	4 (1.2)	6 (0.9)
インフルエンザ	1 (0.3)	5 (1.5)	6 (0.9)
膿疱性皮疹	3 (0.9)	3 (0.9)	6 (0.9)
敗血症	4 (1.2)	2 (0.6)	6 (0.9)
歯膿瘍	4 (1.2)	2 (0.6)	6 (0.9)
創傷感染	3 (0.9)	3 (0.9)	6 (0.9)
慢性副鼻腔炎	5 (1.5)	0 (0.0)	5 (0.8)
大腸菌性尿路感染	1 (0.3)	4 (1.2)	5 (0.8)
眼感染	3 (0.9)	2 (0.6)	5 (0.8)
喉頭炎	3 (0.9)	2 (0.6)	5 (0.8)
歯周炎	3 (0.9)	2 (0.6)	5 (0.8)
急性COVID-19後症候群	2 (0.6)	3 (0.9)	5 (0.8)
皮膚細菌感染	1 (0.3)	4 (1.2)	5 (0.8)
歯感染	3 (0.9)	2 (0.6)	5 (0.8)
丹毒	3 (0.9)	1 (0.3)	4 (0.6)
歯肉炎	3 (0.9)	1 (0.3)	4 (0.6)
細菌性下気道感染	3 (0.9)	1 (0.3)	4 (0.6)
真菌性肺炎	2 (0.6)	2 (0.6)	4 (0.6)
扁桃炎	2 (0.6)	2 (0.6)	4 (0.6)
細菌性上気道感染	2 (0.6)	2 (0.6)	4 (0.6)
腟感染	4 (1.2)	0 (0.0)	4 (0.6)
ウイルス性上気道感染	2 (0.6)	2 (0.6)	4 (0.6)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
急性副鼻腔炎	1 (0.3)	2 (0.6)	3 (0.5)
虫垂炎	1 (0.3)	2 (0.6)	3 (0.5)
気管支肺アスペルギルス症	2 (0.6)	1 (0.3)	3 (0.5)
膀胱炎	1 (0.3)	2 (0.6)	3 (0.5)
憩室炎	1 (0.3)	2 (0.6)	3 (0.5)
皮膚真菌感染	1 (0.3)	2 (0.6)	3 (0.5)
B型肝炎	1 (0.3)	2 (0.6)	3 (0.5)
B型肝炎再活性化	2 (0.6)	1 (0.3)	3 (0.5)
単純ヘルペス	2 (0.6)	1 (0.3)	3 (0.5)
膿痂疹	3 (0.9)	0 (0.0)	3 (0.5)
爪感染	1 (0.3)	2 (0.6)	3 (0.5)
爪真菌症	1 (0.3)	2 (0.6)	3 (0.5)
口腔カンジダ症	1 (0.3)	2 (0.6)	3 (0.5)
ニューモシスチス・イロベチイ肺炎	1 (0.3)	2 (0.6)	3 (0.5)
細菌性肺炎	2 (0.6)	1 (0.3)	3 (0.5)
軟部組織感染	2 (0.6)	1 (0.3)	3 (0.5)
ウイルス感染	1 (0.3)	2 (0.6)	3 (0.5)
四肢膿瘍	0 (0.0)	2 (0.6)	2 (0.3)
肛門膿瘍	1 (0.3)	1 (0.3)	2 (0.3)
細菌性関節炎	1 (0.3)	1 (0.3)	2 (0.3)
異型肺炎	2 (0.6)	0 (0.0)	2 (0.3)
細菌性敗血症	1 (0.3)	1 (0.3)	2 (0.3)
細菌尿	1 (0.3)	1 (0.3)	2 (0.3)
ボレリア感染	0 (0.0)	2 (0.6)	2 (0.3)
カンピロバクター胃腸炎	0 (0.0)	2 (0.6)	2 (0.3)
感染性皮膚炎	0 (0.0)	2 (0.6)	2 (0.3)
遊走性紅斑	1 (0.3)	1 (0.3)	2 (0.3)
大腸菌性菌血症	1 (0.3)	1 (0.3)	2 (0.3)
熱性感染症	2 (0.6)	0 (0.0)	2 (0.3)
ウイルス性胃腸炎	0 (0.0)	2 (0.6)	2 (0.3)
ヘリコバクター感染	1 (0.3)	1 (0.3)	2 (0.3)
ヘルペス性皮膚炎	0 (0.0)	2 (0.6)	2 (0.3)
ヘルペス眼感染	0 (0.0)	2 (0.6)	2 (0.3)
麦粒腫	1 (0.3)	1 (0.3)	2 (0.3)
ウイルス性下気道感染	1 (0.3)	1 (0.3)	2 (0.3)
ライム病	2 (0.6)	0 (0.0)	2 (0.3)
乳様突起炎	0 (0.0)	2 (0.6)	2 (0.3)
鼻ヘルペス	2 (0.6)	0 (0.0)	2 (0.3)
口腔真菌感染	1 (0.3)	1 (0.3)	2 (0.3)
口腔感染	1 (0.3)	1 (0.3)	2 (0.3)
精巣炎	1 (0.3)	1 (0.3)	2 (0.3)
外耳炎	1 (0.3)	1 (0.3)	2 (0.3)
中耳炎	1 (0.3)	1 (0.3)	2 (0.3)
急性中耳炎	1 (0.3)	1 (0.3)	2 (0.3)
肺炎球菌性肺炎	1 (0.3)	1 (0.3)	2 (0.3)
膿疱	1 (0.3)	1 (0.3)	2 (0.3)
敗血症性ショック	0 (0.0)	2 (0.6)	2 (0.3)
唾液腺炎	1 (0.3)	1 (0.3)	2 (0.3)
皮下組織膿瘍	1 (0.3)	1 (0.3)	2 (0.3)
COVID-19の疑い	2 (0.6)	0 (0.0)	2 (0.3)
全身性感染	0 (0.0)	2 (0.6)	2 (0.3)
尿路性敗血症	2 (0.6)	0 (0.0)	2 (0.3)
アシネトバクター性菌血症	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
膿疱性ざ瘡	0 (0.0)	1 (0.3)	1 (0.2)
歯槽骨炎	0 (0.0)	1 (0.3)	1 (0.2)
感染性関節炎	1 (0.3)	0 (0.0)	1 (0.2)
細菌感染	1 (0.3)	0 (0.0)	1 (0.2)
細菌性鼻炎	1 (0.3)	0 (0.0)	1 (0.2)
感染性水疱	0 (0.0)	1 (0.3)	1 (0.2)
ヘモフィルス性気管支炎	1 (0.3)	0 (0.0)	1 (0.2)
よう	0 (0.0)	1 (0.3)	1 (0.2)
子宮頚管炎	1 (0.3)	0 (0.0)	1 (0.2)
クラミジア感染	0 (0.0)	1 (0.3)	1 (0.2)
クロストリジウム・ディフィシレ感染	1 (0.3)	0 (0.0)	1 (0.2)
涙嚢炎	1 (0.3)	0 (0.0)	1 (0.2)
耳垂感染	1 (0.3)	0 (0.0)	1 (0.2)
脳炎	1 (0.3)	0 (0.0)	1 (0.2)
精巣上体炎	0 (0.0)	1 (0.3)	1 (0.2)
エプスタイン・バーウイルス感染	0 (0.0)	1 (0.3)	1 (0.2)
大腸菌性敗血症	1 (0.3)	0 (0.0)	1 (0.2)
中枢神経系真菌性膿瘍	1 (0.3)	0 (0.0)	1 (0.2)
ウイルス性胃炎	1 (0.3)	0 (0.0)	1 (0.2)
大腸菌性胃腸炎	0 (0.0)	1 (0.3)	1 (0.2)
細菌性消化管感染	0 (0.0)	1 (0.3)	1 (0.2)
消化管感染	0 (0.0)	1 (0.3)	1 (0.2)
ウイルス性消化管感染	0 (0.0)	1 (0.3)	1 (0.2)
陰部ヘルペス	0 (0.0)	1 (0.3)	1 (0.2)
血腫感染	1 (0.3)	0 (0.0)	1 (0.2)
ヘモフィルス感染	0 (0.0)	1 (0.3)	1 (0.2)
ヘリコバクター性胃炎	0 (0.0)	1 (0.3)	1 (0.2)
帯状疱疹再燃	0 (0.0)	1 (0.3)	1 (0.2)
感染性腱鞘炎	0 (0.0)	1 (0.3)	1 (0.2)
頭蓋内感染	0 (0.0)	1 (0.3)	1 (0.2)
ウイルス性角膜炎	1 (0.3)	0 (0.0)	1 (0.2)
大腸感染	1 (0.3)	0 (0.0)	1 (0.2)
潜伏結核	1 (0.3)	0 (0.0)	1 (0.2)
口唇感染	0 (0.0)	1 (0.3)	1 (0.2)
細菌性リンパ節炎	0 (0.0)	1 (0.3)	1 (0.2)
髄膜炎	0 (0.0)	1 (0.3)	1 (0.2)
伝染性軟属腫	1 (0.3)	0 (0.0)	1 (0.2)
爪床感染	0 (0.0)	1 (0.3)	1 (0.2)
鼻前庭炎	1 (0.3)	0 (0.0)	1 (0.2)
眼帯状疱疹	0 (0.0)	1 (0.3)	1 (0.2)
真菌性骨髄炎	0 (0.0)	1 (0.3)	1 (0.2)
眼窩周囲蜂巣炎	1 (0.3)	0 (0.0)	1 (0.2)
クリプトコッカス性肺炎	1 (0.3)	0 (0.0)	1 (0.2)
ヘモフィルス性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
クレブシエラ菌性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
レジオネラ菌性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
シュードモナス性肺炎	1 (0.3)	0 (0.0)	1 (0.2)
RSウイルス肺炎	1 (0.3)	0 (0.0)	1 (0.2)
ウイルス性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
処置後感染	1 (0.3)	0 (0.0)	1 (0.2)
シュードモナス性皮膚感染	0 (0.0)	1 (0.3)	1 (0.2)
肺結核	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
歯髄炎	0 (0.0)	1 (0.3)	1 (0.2)
腎盂腎炎	0 (0.0)	1 (0.3)	1 (0.2)
細菌性気道感染	0 (0.0)	1 (0.3)	1 (0.2)
ウイルス性気道感染	0 (0.0)	1 (0.3)	1 (0.2)
皮膚カンジダ	1 (0.3)	0 (0.0)	1 (0.2)
植皮感染	1 (0.3)	0 (0.0)	1 (0.2)
スポロトリコーシス	1 (0.3)	0 (0.0)	1 (0.2)
ブドウ球菌性菌血症	0 (0.0)	1 (0.3)	1 (0.2)
ブドウ球菌感染	0 (0.0)	1 (0.3)	1 (0.2)
ブドウ球菌皮膚感染	0 (0.0)	1 (0.3)	1 (0.2)
レンサ球菌性菌血症	1 (0.3)	0 (0.0)	1 (0.2)
梅毒	1 (0.3)	0 (0.0)	1 (0.2)
全身性細菌感染	1 (0.3)	0 (0.0)	1 (0.2)
股部白癬	1 (0.3)	0 (0.0)	1 (0.2)
白癬感染	1 (0.3)	0 (0.0)	1 (0.2)
足部白癬	0 (0.0)	1 (0.3)	1 (0.2)
気管炎	0 (0.0)	1 (0.3)	1 (0.2)
上気道および上部消化管感染	1 (0.3)	0 (0.0)	1 (0.2)
尿道炎	0 (0.0)	1 (0.3)	1 (0.2)
水痘	1 (0.3)	0 (0.0)	1 (0.2)
皮膚ウイルス感染	1 (0.3)	0 (0.0)	1 (0.2)
外陰部腟カンジダ症	1 (0.3)	0 (0.0)	1 (0.2)
創部膿瘍	0 (0.0)	1 (0.3)	1 (0.2)
胃腸障害	163 (50.3)	179 (55.2)	342 (52.8)
下痢	52 (16.0)	78 (24.1)	130 (20.1)
悪心	26 (8.0)	31 (9.6)	57 (8.8)
便秘	22 (6.8)	24 (7.4)	46 (7.1)
嘔吐	19 (5.9)	26 (8.0)	45 (6.9)
消化不良	21 (6.5)	21 (6.5)	42 (6.5)
腹痛	19 (5.9)	16 (4.9)	35 (5.4)
胃食道逆流性疾患	15 (4.6)	14 (4.3)	29 (4.5)
口内炎	7 (2.2)	9 (2.8)	16 (2.5)
上腹部痛	11 (3.4)	4 (1.2)	15 (2.3)
口腔内潰瘍形成	5 (1.5)	10 (3.1)	15 (2.3)
胃炎	4 (1.2)	7 (2.2)	11 (1.7)
歯肉出血	7 (2.2)	4 (1.2)	11 (1.7)
歯痛	5 (1.5)	6 (1.9)	11 (1.7)
痔核	7 (2.2)	3 (0.9)	10 (1.5)
鼠径ヘルニア	4 (1.2)	6 (1.9)	10 (1.5)
口内乾燥	3 (0.9)	5 (1.5)	8 (1.2)
大腸ポリープ	3 (0.9)	4 (1.2)	7 (1.1)
嚥下障害	4 (1.2)	2 (0.6)	6 (0.9)
腹部膨満	2 (0.6)	3 (0.9)	5 (0.8)
齲歯	3 (0.9)	2 (0.6)	5 (0.8)
食道炎	1 (0.3)	4 (1.2)	5 (0.8)
口腔血性水疱	3 (0.9)	2 (0.6)	5 (0.8)
アフタ性潰瘍	2 (0.6)	2 (0.6)	4 (0.6)
びらん性胃炎	0 (0.0)	4 (1.2)	4 (0.6)
歯肉腫脹	3 (0.9)	1 (0.3)	4 (0.6)
裂孔ヘルニア	2 (0.6)	2 (0.6)	4 (0.6)
直腸出血	2 (0.6)	2 (0.6)	4 (0.6)
腹部不快感	0 (0.0)	3 (0.9)	3 (0.5)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
下腹部痛	2 (0.6)	1 (0.3)	3 (0.5)
慢性胃炎	1 (0.3)	2 (0.6)	3 (0.5)
大腸炎	2 (0.6)	1 (0.3)	3 (0.5)
胃腸障害	0 (0.0)	3 (0.9)	3 (0.5)
歯肉痛	3 (0.9)	0 (0.0)	3 (0.5)
血便排泄	2 (0.6)	1 (0.3)	3 (0.5)
口腔内出血	2 (0.6)	1 (0.3)	3 (0.5)
口腔粘膜水疱形成	3 (0.9)	0 (0.0)	3 (0.5)
腹部ヘルニア	0 (0.0)	2 (0.6)	2 (0.3)
憩室	1 (0.3)	1 (0.3)	2 (0.3)
腸憩室	2 (0.6)	0 (0.0)	2 (0.3)
腸炎	1 (0.3)	1 (0.3)	2 (0.3)
変色便	0 (0.0)	2 (0.6)	2 (0.3)
鼓腸	2 (0.6)	0 (0.0)	2 (0.3)
胃腸出血	0 (0.0)	2 (0.6)	2 (0.3)
痔出血	1 (0.3)	1 (0.3)	2 (0.3)
腹腔内血腫	0 (0.0)	2 (0.6)	2 (0.3)
口腔内痛	0 (0.0)	2 (0.6)	2 (0.3)
レッチング	2 (0.6)	0 (0.0)	2 (0.3)
舌出血	1 (0.3)	1 (0.3)	2 (0.3)
舌潰瘍	1 (0.3)	1 (0.3)	2 (0.3)
歯の障害	1 (0.3)	1 (0.3)	2 (0.3)
裂肛	0 (0.0)	1 (0.3)	1 (0.2)
口角口唇炎	0 (0.0)	1 (0.3)	1 (0.2)
腹水	1 (0.3)	0 (0.0)	1 (0.2)
便習慣変化	0 (0.0)	1 (0.3)	1 (0.2)
口唇炎	1 (0.3)	0 (0.0)	1 (0.2)
クローン病	0 (0.0)	1 (0.3)	1 (0.2)
便意切迫	0 (0.0)	1 (0.3)	1 (0.2)
十二指腸潰瘍	1 (0.3)	0 (0.0)	1 (0.2)
小腸炎	1 (0.3)	0 (0.0)	1 (0.2)
心窩部不快感	1 (0.3)	0 (0.0)	1 (0.2)
機能性胃腸障害	1 (0.3)	0 (0.0)	1 (0.2)
胃出血	0 (0.0)	1 (0.3)	1 (0.2)
胃粘膜紅斑	0 (0.0)	1 (0.3)	1 (0.2)
胃ポリープ	0 (0.0)	1 (0.3)	1 (0.2)
胃潰瘍	1 (0.3)	0 (0.0)	1 (0.2)
穿孔性胃潰瘍	0 (0.0)	1 (0.3)	1 (0.2)
消化管壊死	0 (0.0)	1 (0.3)	1 (0.2)
消化管壁肥厚	1 (0.3)	0 (0.0)	1 (0.2)
歯肉不快感	0 (0.0)	1 (0.3)	1 (0.2)
歯肉退縮	1 (0.3)	0 (0.0)	1 (0.2)
歯肉潰瘍	1 (0.3)	0 (0.0)	1 (0.2)
舌痛	1 (0.3)	0 (0.0)	1 (0.2)
吐血	1 (0.3)	0 (0.0)	1 (0.2)
口の感覚鈍麻	1 (0.3)	0 (0.0)	1 (0.2)
胃排出不全	1 (0.3)	0 (0.0)	1 (0.2)
過敏性腸症候群	1 (0.3)	0 (0.0)	1 (0.2)
口唇障害	0 (0.0)	1 (0.3)	1 (0.2)
口唇潰瘍	0 (0.0)	1 (0.3)	1 (0.2)
弛緩歯	1 (0.3)	0 (0.0)	1 (0.2)
メレナ	1 (0.3)	0 (0.0)	1 (0.2)
腸間膜脂肪織炎	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
非感染性歯肉炎	1 (0.3)	0 (0.0)	1 (0.2)
非感染性唾液腺炎	1 (0.3)	0 (0.0)	1 (0.2)
閉塞性膵炎	0 (0.0)	1 (0.3)	1 (0.2)
嚥下痛	1 (0.3)	0 (0.0)	1 (0.2)
食道食物嵌入	0 (0.0)	1 (0.3)	1 (0.2)
食道痛	1 (0.3)	0 (0.0)	1 (0.2)
口腔内不快感	0 (0.0)	1 (0.3)	1 (0.2)
口腔知覚不全	1 (0.3)	0 (0.0)	1 (0.2)
口腔内過角化	1 (0.3)	0 (0.0)	1 (0.2)
膵嚢胞	1 (0.3)	0 (0.0)	1 (0.2)
膵臓障害	1 (0.3)	0 (0.0)	1 (0.2)
膵炎	0 (0.0)	1 (0.3)	1 (0.2)
急性膵炎	0 (0.0)	1 (0.3)	1 (0.2)
耳下腺腫大	1 (0.3)	0 (0.0)	1 (0.2)
歯周病	1 (0.3)	0 (0.0)	1 (0.2)
腸壁気腫症	1 (0.3)	0 (0.0)	1 (0.2)
気腹	1 (0.3)	0 (0.0)	1 (0.2)
肛門周囲痛	1 (0.3)	0 (0.0)	1 (0.2)
直腸ポリープ	0 (0.0)	1 (0.3)	1 (0.2)
逆流性胃炎	0 (0.0)	1 (0.3)	1 (0.2)
唾液腺腫瘤	1 (0.3)	0 (0.0)	1 (0.2)
小腸閉塞	0 (0.0)	1 (0.3)	1 (0.2)
絞扼性臍ヘルニア	1 (0.3)	0 (0.0)	1 (0.2)
舌腫脹	1 (0.3)	0 (0.0)	1 (0.2)
舌障害	0 (0.0)	1 (0.3)	1 (0.2)
潰瘍性十二指腸炎	0 (0.0)	1 (0.3)	1 (0.2)
皮膚および皮下組織障害	138 (42.6)	144 (44.4)	282 (43.5)
発疹	33 (10.2)	40 (12.3)	73 (11.3)
点状出血	29 (9.0)	15 (4.6)	44 (6.8)
そう痒症	21 (6.5)	8 (2.5)	29 (4.5)
斑状丘疹状皮疹	12 (3.7)	7 (2.2)	19 (2.9)
紅斑	9 (2.8)	9 (2.8)	18 (2.8)
皮膚出血	9 (2.8)	9 (2.8)	18 (2.8)
光線角化症	7 (2.2)	9 (2.8)	16 (2.5)
皮膚病変	8 (2.5)	7 (2.2)	15 (2.3)
寝汗	7 (2.2)	7 (2.2)	14 (2.2)
斑状出血	4 (1.2)	9 (2.8)	13 (2.0)
紫斑	6 (1.9)	7 (2.2)	13 (2.0)
皮膚潰瘍	4 (1.2)	7 (2.2)	11 (1.7)
丘疹性皮疹	2 (0.6)	7 (2.2)	9 (1.4)
皮膚乾燥	3 (0.9)	5 (1.5)	8 (1.2)
皮下出血	3 (0.9)	5 (1.5)	8 (1.2)
皮膚亀裂	0 (0.0)	8 (2.5)	8 (1.2)
皮膚炎	4 (1.2)	3 (0.9)	7 (1.1)
アレルギー性皮膚炎	4 (1.2)	2 (0.6)	6 (0.9)
湿疹	6 (1.9)	0 (0.0)	6 (0.9)
多汗症	1 (0.3)	5 (1.5)	6 (0.9)
斑状皮疹	1 (0.3)	5 (1.5)	6 (0.9)
脱毛症	3 (0.9)	2 (0.6)	5 (0.8)
爪破損	2 (0.6)	3 (0.9)	5 (0.8)
紅斑性皮疹	4 (1.2)	1 (0.3)	5 (0.8)
皮膚腫瘤	2 (0.6)	3 (0.9)	5 (0.8)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
嵌入爪	1 (0.3)	3 (0.9)	4 (0.6)
血性水疱	0 (0.0)	3 (0.9)	3 (0.5)
ざ瘡様皮膚炎	2 (0.6)	1 (0.3)	3 (0.5)
接触皮膚炎	1 (0.3)	2 (0.6)	3 (0.5)
過角化	2 (0.6)	1 (0.3)	3 (0.5)
爪の障害	0 (0.0)	3 (0.9)	3 (0.5)
脂肪織炎	2 (0.6)	1 (0.3)	3 (0.5)
乾癬	2 (0.6)	1 (0.3)	3 (0.5)
酒さ	2 (0.6)	1 (0.3)	3 (0.5)
皮膚障害	2 (0.6)	1 (0.3)	3 (0.5)
皮膚色素過剰	2 (0.6)	1 (0.3)	3 (0.5)
薬疹	0 (0.0)	2 (0.6)	2 (0.3)
皮膚疼痛	0 (0.0)	2 (0.6)	2 (0.3)
丘疹	1 (0.3)	1 (0.3)	2 (0.3)
痂皮	0 (0.0)	2 (0.6)	2 (0.3)
皮膚剥脱	1 (0.3)	1 (0.3)	2 (0.3)
肌のきめ異常	1 (0.3)	1 (0.3)	2 (0.3)
日光黒子	1 (0.3)	1 (0.3)	2 (0.3)
蕁麻疹	2 (0.6)	0 (0.0)	2 (0.3)
ざ瘡	0 (0.0)	1 (0.3)	1 (0.2)
光線性口唇炎	0 (0.0)	1 (0.3)	1 (0.2)
急性熱性好中球性皮膚症	1 (0.3)	0 (0.0)	1 (0.2)
水疱	0 (0.0)	1 (0.3)	1 (0.2)
多形紅斑	0 (0.0)	1 (0.3)	1 (0.2)
ヘノッホ・シェーンライン紫斑病	0 (0.0)	1 (0.3)	1 (0.2)
斑	0 (0.0)	1 (0.3)	1 (0.2)
爪線状隆起	1 (0.3)	0 (0.0)	1 (0.2)
結節性発疹	0 (0.0)	1 (0.3)	1 (0.2)
手掌・足底発赤知覚不全症候群	0 (0.0)	1 (0.3)	1 (0.2)
不全角化	1 (0.3)	0 (0.0)	1 (0.2)
天疱瘡	1 (0.3)	0 (0.0)	1 (0.2)
陰茎潰瘍形成	1 (0.3)	0 (0.0)	1 (0.2)
光線過敏性反応	0 (0.0)	1 (0.3)	1 (0.2)
そう痒性皮疹	1 (0.3)	0 (0.0)	1 (0.2)
皮膚変色	1 (0.3)	0 (0.0)	1 (0.2)
皮膚脆弱性	0 (0.0)	1 (0.3)	1 (0.2)
皮膚刺激	1 (0.3)	0 (0.0)	1 (0.2)
皮膚反応	0 (0.0)	1 (0.3)	1 (0.2)
皮膚腫脹	0 (0.0)	1 (0.3)	1 (0.2)
うっ滞性皮膚炎	1 (0.3)	0 (0.0)	1 (0.2)
血液およびリンパ系障害	133 (41.0)	128 (39.5)	261 (40.3)
好中球減少症	74 (22.8)	59 (18.2)	133 (20.5)
貧血	49 (15.1)	51 (15.7)	100 (15.4)
血小板減少症	32 (9.9)	31 (9.6)	63 (9.7)
内出血発生の増加傾向	7 (2.2)	3 (0.9)	10 (1.5)
リンパ節症	5 (1.5)	4 (1.2)	9 (1.4)
発熱性好中球減少症	4 (1.2)	3 (0.9)	7 (1.1)
出血性素因	2 (0.6)	5 (1.5)	7 (1.1)
鉄欠乏性貧血	3 (0.9)	4 (1.2)	7 (1.1)
低グロブリン血症	1 (0.3)	3 (0.9)	4 (0.6)
リンパ球増加症	3 (0.9)	0 (0.0)	3 (0.5)
好酸球増加症	1 (0.3)	1 (0.3)	2 (0.3)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
顆粒球減少症	1 (0.3)	1 (0.3)	2 (0.3)
溶血性貧血	0 (0.0)	2 (0.6)	2 (0.3)
白血球減少症	0 (0.0)	2 (0.6)	2 (0.3)
リンパ節痛	2 (0.6)	0 (0.0)	2 (0.3)
無顆粒球症	0 (0.0)	1 (0.3)	1 (0.2)
失血性貧血	0 (0.0)	1 (0.3)	1 (0.2)
血球減少症	0 (0.0)	1 (0.3)	1 (0.2)
高γグロブリン血症	0 (0.0)	1 (0.3)	1 (0.2)
免疫性血小板減少症	1 (0.3)	0 (0.0)	1 (0.2)
白血球増加症	0 (0.0)	1 (0.3)	1 (0.2)
リンパ節炎	1 (0.3)	0 (0.0)	1 (0.2)
小球性貧血	1 (0.3)	0 (0.0)	1 (0.2)
腎性貧血	1 (0.3)	0 (0.0)	1 (0.2)
脾血腫	1 (0.3)	0 (0.0)	1 (0.2)
脾臓出血	0 (0.0)	1 (0.3)	1 (0.2)
脾臓梗塞	0 (0.0)	1 (0.3)	1 (0.2)
脾静脈瘤	0 (0.0)	1 (0.3)	1 (0.2)
筋骨格系および結合組織障害	119 (36.7)	130 (40.1)	249 (38.4)
関節痛	47 (14.5)	53 (16.4)	100 (15.4)
筋痙縮	10 (3.1)	41 (12.7)	51 (7.9)
背部痛	21 (6.5)	23 (7.1)	44 (6.8)
四肢痛	20 (6.2)	24 (7.4)	44 (6.8)
筋肉痛	10 (3.1)	12 (3.7)	22 (3.4)
関節腫脹	9 (2.8)	9 (2.8)	18 (2.8)
脊椎痛	6 (1.9)	5 (1.5)	11 (1.7)
変形性関節症	2 (0.6)	7 (2.2)	9 (1.4)
骨痛	1 (0.3)	7 (2.2)	8 (1.2)
頚部痛	5 (1.5)	3 (0.9)	8 (1.2)
側腹部痛	3 (0.9)	4 (1.2)	7 (1.1)
骨粗鬆症	6 (1.9)	1 (0.3)	7 (1.1)
変形性脊椎症	4 (1.2)	3 (0.9)	7 (1.1)
筋骨格系胸痛	4 (1.2)	2 (0.6)	6 (0.9)
筋骨格痛	4 (1.2)	2 (0.6)	6 (0.9)
関節炎	3 (0.9)	2 (0.6)	5 (0.8)
出血性関節症	2 (0.6)	1 (0.3)	3 (0.5)
筋力低下	2 (0.6)	1 (0.3)	3 (0.5)
鼡径部痛	1 (0.3)	1 (0.3)	2 (0.3)
筋肉内血腫	1 (0.3)	1 (0.3)	2 (0.3)
関節可動域低下	2 (0.6)	0 (0.0)	2 (0.3)
運動性低下	1 (0.3)	1 (0.3)	2 (0.3)
筋骨格不快感	1 (0.3)	1 (0.3)	2 (0.3)
顎痛	2 (0.6)	0 (0.0)	2 (0.3)
脊椎炎	1 (0.3)	1 (0.3)	2 (0.3)
腱炎	1 (0.3)	1 (0.3)	2 (0.3)
滑液包炎	0 (0.0)	1 (0.3)	1 (0.2)
ピロリン酸カルシウム結晶性軟骨石灰化症	0 (0.0)	1 (0.3)	1 (0.2)
肋軟骨炎	0 (0.0)	1 (0.3)	1 (0.2)
高クレアチン血症	1 (0.3)	0 (0.0)	1 (0.2)
椎間板圧迫	0 (0.0)	1 (0.3)	1 (0.2)
顎障害	1 (0.3)	0 (0.0)	1 (0.2)
関節滲出液	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
四肢不快感	0 (0.0)	1 (0.3)	1 (0.2)
筋不快感	1 (0.3)	0 (0.0)	1 (0.2)
筋肉疲労	1 (0.3)	0 (0.0)	1 (0.2)
筋緊張	0 (0.0)	1 (0.3)	1 (0.2)
ミオパチー	1 (0.3)	0 (0.0)	1 (0.2)
結節性変形性関節症	1 (0.3)	0 (0.0)	1 (0.2)
骨壊死	1 (0.3)	0 (0.0)	1 (0.2)
足底筋膜炎	0 (0.0)	1 (0.3)	1 (0.2)
乾癬性関節症	0 (0.0)	1 (0.3)	1 (0.2)
肩回旋筋腱板症候群	1 (0.3)	0 (0.0)	1 (0.2)
シェーグレン症候群	1 (0.3)	0 (0.0)	1 (0.2)
脊椎すべり症	1 (0.3)	0 (0.0)	1 (0.2)
軟骨下機能不全骨折	0 (0.0)	1 (0.3)	1 (0.2)
交感神経性後頚部症候群	1 (0.3)	0 (0.0)	1 (0.2)
顎関節症候群	1 (0.3)	0 (0.0)	1 (0.2)
腱障害	0 (0.0)	1 (0.3)	1 (0.2)
腱痛	1 (0.3)	0 (0.0)	1 (0.2)
一般・全身障害および投与部位の状態	107 (33.0)	129 (39.8)	236 (36.4)
疲労	31 (9.6)	43 (13.3)	74 (11.4)
発熱	27 (8.3)	33 (10.2)	60 (9.3)
末梢性浮腫	20 (6.2)	23 (7.1)	43 (6.6)
末梢腫脹	13 (4.0)	23 (7.1)	36 (5.6)
無力症	19 (5.9)	9 (2.8)	28 (4.3)
インフルエンザ様疾患	7 (2.2)	5 (1.5)	12 (1.9)
倦怠感	4 (1.2)	8 (2.5)	12 (1.9)
悪寒	4 (1.2)	4 (1.2)	8 (1.2)
非心臓性胸痛	6 (1.9)	2 (0.6)	8 (1.2)
疼痛	5 (1.5)	3 (0.9)	8 (1.2)
胸痛	1 (0.3)	4 (1.2)	5 (0.8)
歩行障害	3 (0.9)	2 (0.6)	5 (0.8)
死亡	2 (0.6)	2 (0.6)	4 (0.6)
多臓器機能不全症候群	2 (0.6)	1 (0.3)	3 (0.5)
軟部組織の炎症	2 (0.6)	1 (0.3)	3 (0.5)
胸部不快感	1 (0.3)	1 (0.3)	2 (0.3)
顔面浮腫	1 (0.3)	1 (0.3)	2 (0.3)
冷感	2 (0.6)	0 (0.0)	2 (0.3)
全身健康状態悪化	1 (0.3)	1 (0.3)	2 (0.3)
治癒不良	2 (0.6)	0 (0.0)	2 (0.3)
限局性浮腫	0 (0.0)	2 (0.6)	2 (0.3)
温度変化不耐症	1 (0.3)	1 (0.3)	2 (0.3)
適用部位発疹	0 (0.0)	1 (0.3)	1 (0.2)
腋窩痛	1 (0.3)	0 (0.0)	1 (0.2)
カテーテル留置部位血腫	0 (0.0)	1 (0.3)	1 (0.2)
医療機器関連合併症	1 (0.3)	0 (0.0)	1 (0.2)
医療機器関連血栓症	0 (0.0)	1 (0.3)	1 (0.2)
薬剤離脱症候群	0 (0.0)	1 (0.3)	1 (0.2)
運動耐性低下	1 (0.3)	0 (0.0)	1 (0.2)
熱感	0 (0.0)	1 (0.3)	1 (0.2)
ヘルニア	1 (0.3)	0 (0.0)	1 (0.2)
不明確な障害	1 (0.3)	0 (0.0)	1 (0.2)
注入部位反応	1 (0.3)	0 (0.0)	1 (0.2)
注射部位血腫	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
注射部位出血	0 (0.0)	1 (0.3)	1 (0.2)
腫瘤	1 (0.3)	0 (0.0)	1 (0.2)
恥骨上痛	0 (0.0)	1 (0.3)	1 (0.2)
顔面腫脹	0 (0.0)	1 (0.3)	1 (0.2)
呼吸器、胸郭および縦隔障害	109 (33.6)	117 (36.1)	226 (34.9)
咳嗽	38 (11.7)	34 (10.5)	72 (11.1)
鼻出血	24 (7.4)	22 (6.8)	46 (7.1)
呼吸困難	11 (3.4)	13 (4.0)	24 (3.7)
湿性咳嗽	11 (3.4)	9 (2.8)	20 (3.1)
口腔咽頭痛	9 (2.8)	10 (3.1)	19 (2.9)
鼻閉	6 (1.9)	4 (1.2)	10 (1.5)
鼻漏	7 (2.2)	3 (0.9)	10 (1.5)
労作性呼吸困難	4 (1.2)	5 (1.5)	9 (1.4)
アレルギー性鼻炎	7 (2.2)	2 (0.6)	9 (1.4)
喀血	2 (0.6)	6 (1.9)	8 (1.2)
胸水	3 (0.9)	5 (1.5)	8 (1.2)
肺腫瘤	3 (0.9)	5 (1.5)	8 (1.2)
喘息	5 (1.5)	2 (0.6)	7 (1.1)
慢性閉塞性肺疾患	3 (0.9)	4 (1.2)	7 (1.1)
カタル	3 (0.9)	3 (0.9)	6 (0.9)
肺浸潤	2 (0.6)	2 (0.6)	4 (0.6)
喘鳴	2 (0.6)	2 (0.6)	4 (0.6)
急性呼吸不全	1 (0.3)	2 (0.6)	3 (0.5)
発声障害	1 (0.3)	2 (0.6)	3 (0.5)
肺臓炎	1 (0.3)	2 (0.6)	3 (0.5)
呼吸不全	1 (0.3)	2 (0.6)	3 (0.5)
副鼻腔うっ血	1 (0.3)	2 (0.6)	3 (0.5)
副鼻腔痛	3 (0.9)	0 (0.0)	3 (0.5)
上気道咳症候群	1 (0.3)	2 (0.6)	3 (0.5)
しゃっくり	2 (0.6)	0 (0.0)	2 (0.3)
低酸素症	1 (0.3)	1 (0.3)	2 (0.3)
間質性肺疾患	2 (0.6)	0 (0.0)	2 (0.3)
肺障害	1 (0.3)	1 (0.3)	2 (0.3)
咽頭出血	1 (0.3)	1 (0.3)	2 (0.3)
気胸	1 (0.3)	1 (0.3)	2 (0.3)
肺塞栓症	1 (0.3)	1 (0.3)	2 (0.3)
睡眠時無呼吸症候群	1 (0.3)	1 (0.3)	2 (0.3)
上気道の炎症	1 (0.3)	1 (0.3)	2 (0.3)
アレルギー性咽頭炎	0 (0.0)	1 (0.3)	1 (0.2)
無気肺	1 (0.3)	0 (0.0)	1 (0.2)
気管支反応性亢進	1 (0.3)	0 (0.0)	1 (0.2)
慢性気管支炎	1 (0.3)	0 (0.0)	1 (0.2)
血胸	0 (0.0)	1 (0.3)	1 (0.2)
胸水症	1 (0.3)	0 (0.0)	1 (0.2)
特発性間質性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
喉頭痛	1 (0.3)	0 (0.0)	1 (0.2)
下気道うっ血	0 (0.0)	1 (0.3)	1 (0.2)
肺陰影	0 (0.0)	1 (0.3)	1 (0.2)
鼻痂皮	1 (0.3)	0 (0.0)	1 (0.2)
鼻部障害	1 (0.3)	0 (0.0)	1 (0.2)
鼻粘膜水疱形成	0 (0.0)	1 (0.3)	1 (0.2)
鼻潰瘍	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
副鼻腔の炎症	1 (0.3)	0 (0.0)	1 (0.2)
胸膜肥厚	0 (0.0)	1 (0.3)	1 (0.2)
胸膜痛	1 (0.3)	0 (0.0)	1 (0.2)
肺うっ血	0 (0.0)	1 (0.3)	1 (0.2)
肺高血圧症	0 (0.0)	1 (0.3)	1 (0.2)
肺水腫	1 (0.3)	0 (0.0)	1 (0.2)
ラ音	0 (0.0)	1 (0.3)	1 (0.2)
呼吸器症状	1 (0.3)	0 (0.0)	1 (0.2)
咽喉刺激感	1 (0.3)	0 (0.0)	1 (0.2)
扁桃の炎症	1 (0.3)	0 (0.0)	1 (0.2)
上気道うっ血	1 (0.3)	0 (0.0)	1 (0.2)
神経系障害	102 (31.5)	100 (30.9)	202 (31.2)
頭痛	28 (8.6)	31 (9.6)	59 (9.1)
浮動性めまい	27 (8.3)	23 (7.1)	50 (7.7)
失神	10 (3.1)	7 (2.2)	17 (2.6)
錯感覚	3 (0.9)	10 (3.1)	13 (2.0)
記憶障害	8 (2.5)	3 (0.9)	11 (1.7)
末梢性感覚ニューロパチー	4 (1.2)	6 (1.9)	10 (1.5)
坐骨神経痛	4 (1.2)	5 (1.5)	9 (1.4)
感覚鈍麻	2 (0.6)	5 (1.5)	7 (1.1)
嗜眠	3 (0.9)	3 (0.9)	6 (0.9)
ヘルペス後神経痛	5 (1.5)	0 (0.0)	5 (0.8)
健忘	1 (0.3)	3 (0.9)	4 (0.6)
脳血管発作	3 (0.9)	1 (0.3)	4 (0.6)
脳血管障害	2 (0.6)	2 (0.6)	4 (0.6)
失神寸前の状態	2 (0.6)	2 (0.6)	4 (0.6)
一過性脳虚血発作	2 (0.6)	2 (0.6)	4 (0.6)
脳梗塞	1 (0.3)	2 (0.6)	3 (0.5)
神経痛	1 (0.3)	2 (0.6)	3 (0.5)
傾眠	2 (0.6)	1 (0.3)	3 (0.5)
味覚障害	2 (0.6)	1 (0.3)	3 (0.5)
ベル麻痺	2 (0.6)	0 (0.0)	2 (0.3)
手根管症候群	0 (0.0)	2 (0.6)	2 (0.3)
認知障害	2 (0.6)	0 (0.0)	2 (0.3)
注意力障害	1 (0.3)	1 (0.3)	2 (0.3)
味覚不全	0 (0.0)	2 (0.6)	2 (0.3)
虚血性脳卒中	1 (0.3)	1 (0.3)	2 (0.3)
嗅覚錯誤	2 (0.6)	0 (0.0)	2 (0.3)
振戦	2 (0.6)	0 (0.0)	2 (0.3)
味覚消失	0 (0.0)	1 (0.3)	1 (0.2)
くも膜嚢胞	1 (0.3)	0 (0.0)	1 (0.2)
平衡障害	0 (0.0)	1 (0.3)	1 (0.2)
灼熱感	1 (0.3)	0 (0.0)	1 (0.2)
頚動脈閉塞	0 (0.0)	1 (0.3)	1 (0.2)
頚動脈狭窄	0 (0.0)	1 (0.3)	1 (0.2)
中枢神経系出血	0 (0.0)	1 (0.3)	1 (0.2)
脳出血	1 (0.3)	0 (0.0)	1 (0.2)
アルツハイマー型認知症	1 (0.3)	0 (0.0)	1 (0.2)
体位性めまい	1 (0.3)	0 (0.0)	1 (0.2)
構語障害	0 (0.0)	1 (0.3)	1 (0.2)
てんかん	0 (0.0)	1 (0.3)	1 (0.2)
本態性振戦	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
顔面麻痺	0 (0.0)	1 (0.3)	1 (0.2)
顔面痙攣	0 (0.0)	1 (0.3)	1 (0.2)
筋緊張低下	0 (0.0)	1 (0.3)	1 (0.2)
肋間神経痛	0 (0.0)	1 (0.3)	1 (0.2)
意識消失	0 (0.0)	1 (0.3)	1 (0.2)
片頭痛	1 (0.3)	0 (0.0)	1 (0.2)
不随意性筋収縮	1 (0.3)	0 (0.0)	1 (0.2)
筋痙直	1 (0.3)	0 (0.0)	1 (0.2)
脳神経炎	1 (0.3)	0 (0.0)	1 (0.2)
視神経炎	1 (0.3)	0 (0.0)	1 (0.2)
末梢性運動ニューロパチー	1 (0.3)	0 (0.0)	1 (0.2)
腓骨神経麻痺	1 (0.3)	0 (0.0)	1 (0.2)
多発ニューロパチー	0 (0.0)	1 (0.3)	1 (0.2)
精神運動亢進	0 (0.0)	1 (0.3)	1 (0.2)
上腕の神経根炎	1 (0.3)	0 (0.0)	1 (0.2)
神経根障害	1 (0.3)	0 (0.0)	1 (0.2)
下肢静止不能症候群	1 (0.3)	0 (0.0)	1 (0.2)
痙攣発作	0 (0.0)	1 (0.3)	1 (0.2)
昏迷	0 (0.0)	1 (0.3)	1 (0.2)
三叉神経痛	1 (0.3)	0 (0.0)	1 (0.2)
血管性認知症	0 (0.0)	1 (0.3)	1 (0.2)
椎骨動脈解離	0 (0.0)	1 (0.3)	1 (0.2)
椎骨脳底動脈不全	1 (0.3)	0 (0.0)	1 (0.2)
中枢神経系に起因する回転性めまい	1 (0.3)	0 (0.0)	1 (0.2)
臨床検査	99 (30.6)	101 (31.2)	200 (30.9)
好中球数減少	25 (7.7)	21 (6.5)	46 (7.1)
血小板数減少	13 (4.0)	20 (6.2)	33 (5.1)
体重減少	19 (5.9)	14 (4.3)	33 (5.1)
血中クレアチニン増加	15 (4.6)	8 (2.5)	23 (3.5)
アラニンアミノトランスフェラーゼ増加	9 (2.8)	13 (4.0)	22 (3.4)
血圧上昇	7 (2.2)	14 (4.3)	21 (3.2)
血中ビリルビン増加	8 (2.5)	9 (2.8)	17 (2.6)
アスパラギン酸アミノトランスフェラーゼ増加	3 (0.9)	11 (3.4)	14 (2.2)
γーグルタミルトランスフェラーゼ増加	7 (2.2)	7 (2.2)	14 (2.2)
血中アルカリホスファターゼ増加	4 (1.2)	6 (1.9)	10 (1.5)
血中乳酸脱水素酵素増加	5 (1.5)	4 (1.2)	9 (1.4)
体重増加	5 (1.5)	4 (1.2)	9 (1.4)
心電図QT延長	6 (1.9)	0 (0.0)	6 (0.9)
白血球数減少	1 (0.3)	5 (1.5)	6 (0.9)
血中尿酸増加	1 (0.3)	4 (1.2)	5 (0.8)
心電図異常T波	1 (0.3)	4 (1.2)	5 (0.8)
グロブリン減少	3 (0.9)	2 (0.6)	5 (0.8)
総蛋白減少	2 (0.6)	3 (0.9)	5 (0.8)
血中ブドウ糖増加	2 (0.6)	1 (0.3)	3 (0.5)
血中尿素増加	2 (0.6)	1 (0.3)	3 (0.5)
駆出率減少	1 (0.3)	2 (0.6)	3 (0.5)
心電図高電位	2 (0.6)	1 (0.3)	3 (0.5)
ヘモグロビン減少	1 (0.3)	2 (0.6)	3 (0.5)
心拍数増加	2 (0.6)	1 (0.3)	3 (0.5)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
免疫グロブリン減少	2 (0.6)	1 (0.3)	3 (0.5)
便潜血陽性	0 (0.0)	3 (0.9)	3 (0.5)
前立腺特異性抗原増加	3 (0.9)	0 (0.0)	3 (0.5)
トランスアミナーゼ上昇	2 (0.6)	1 (0.3)	3 (0.5)
抱合ビリルビン増加	0 (0.0)	2 (0.6)	2 (0.3)
血中非抱合ビリルビン増加	0 (0.0)	2 (0.6)	2 (0.3)
尿中血陽性	1 (0.3)	1 (0.3)	2 (0.3)
ヘモグロビン増加	2 (0.6)	0 (0.0)	2 (0.3)
心拍数不整	0 (0.0)	2 (0.6)	2 (0.3)
リンパ球数減少	1 (0.3)	1 (0.3)	2 (0.3)
尿中蛋白陽性	2 (0.6)	0 (0.0)	2 (0.3)
血清フェリチン減少	2 (0.6)	0 (0.0)	2 (0.3)
α1ミクログロブリン増加	0 (0.0)	1 (0.3)	1 (0.2)
αヒドロキシ酪酸脱水素酵素増加	0 (0.0)	1 (0.3)	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ減少	1 (0.3)	0 (0.0)	1 (0.2)
血中アルブミン減少	0 (0.0)	1 (0.3)	1 (0.2)
血中コレステロール増加	0 (0.0)	1 (0.3)	1 (0.2)
血中クレアチン増加	0 (0.0)	1 (0.3)	1 (0.2)
血中フィブリノゲン減少	0 (0.0)	1 (0.3)	1 (0.2)
血中葉酸減少	1 (0.3)	0 (0.0)	1 (0.2)
血中ブドウ糖異常	0 (0.0)	1 (0.3)	1 (0.2)
血中免疫グロブリンG減少	1 (0.3)	0 (0.0)	1 (0.2)
血中免疫グロブリンM減少	0 (0.0)	1 (0.3)	1 (0.2)
血中マグネシウム減少	0 (0.0)	1 (0.3)	1 (0.2)
血中リン減少	0 (0.0)	1 (0.3)	1 (0.2)
血圧低下	0 (0.0)	1 (0.3)	1 (0.2)
血中テストステロン減少	1 (0.3)	0 (0.0)	1 (0.2)
血中尿素窒素／クレアチニン比増加	1 (0.3)	0 (0.0)	1 (0.2)
C-反応性蛋白増加	0 (0.0)	1 (0.3)	1 (0.2)
カンジダ検査陽性	1 (0.3)	0 (0.0)	1 (0.2)
心雑音	1 (0.3)	0 (0.0)	1 (0.2)
シスタチンC増加	0 (0.0)	1 (0.3)	1 (0.2)
心電図異常P波	0 (0.0)	1 (0.3)	1 (0.2)
心電図PR延長	1 (0.3)	0 (0.0)	1 (0.2)
心電図ST-T変化	0 (0.0)	1 (0.3)	1 (0.2)
心電図ST-T部分下降	0 (0.0)	1 (0.3)	1 (0.2)
心電図T波逆転	0 (0.0)	1 (0.3)	1 (0.2)
検査結果偽陽性	1 (0.3)	0 (0.0)	1 (0.2)
γーグルタミルトランスフェラーゼ減少	0 (0.0)	1 (0.3)	1 (0.2)
糸球体濾過率減少	1 (0.3)	0 (0.0)	1 (0.2)
グルタチオン還元酵素活性上昇	0 (0.0)	1 (0.3)	1 (0.2)
肝酵素上昇	1 (0.3)	0 (0.0)	1 (0.2)
ヒト乳頭腫ウイルス検査陽性	0 (0.0)	1 (0.3)	1 (0.2)
A型インフルエンザウイルス検査陽性	0 (0.0)	1 (0.3)	1 (0.2)
B型インフルエンザウイルス検査陽性	0 (0.0)	1 (0.3)	1 (0.2)
リパーゼ増加	1 (0.3)	0 (0.0)	1 (0.2)
リポ蛋白増加	0 (0.0)	1 (0.3)	1 (0.2)
リンパ球数増加	1 (0.3)	0 (0.0)	1 (0.2)
乳房撮影異常	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
好中球数増加	0 (0.0)	1 (0.3)	1 (0.2)
酸素飽和度低下	0 (0.0)	1 (0.3)	1 (0.2)
身体的診察結果異常	0 (0.0)	1 (0.3)	1 (0.2)
血小板凝集異常	1 (0.3)	0 (0.0)	1 (0.2)
プロテウス検査陽性	0 (0.0)	1 (0.3)	1 (0.2)
QRS軸異常	0 (0.0)	1 (0.3)	1 (0.2)
SARS-CoV-2検査陽性	0 (0.0)	1 (0.3)	1 (0.2)
トロポニン増加	1 (0.3)	0 (0.0)	1 (0.2)
尿潜血陽性	1 (0.3)	0 (0.0)	1 (0.2)
ビタミンB12減少	0 (0.0)	1 (0.3)	1 (0.2)
肝胆道X線異常	1 (0.3)	0 (0.0)	1 (0.2)
血管障害	96 (29.6)	98 (30.2)	194 (29.9)
高血圧	71 (21.9)	64 (19.8)	135 (20.8)
血腫	15 (4.6)	16 (4.9)	31 (4.8)
低血圧	2 (0.6)	7 (2.2)	9 (1.4)
白衣性高血圧	2 (0.6)	3 (0.9)	5 (0.8)
大動脈硬化症	1 (0.3)	3 (0.9)	4 (0.6)
潮紅	3 (0.9)	1 (0.3)	4 (0.6)
深部静脈血栓症	3 (0.9)	0 (0.0)	3 (0.5)
末梢静脈疾患	1 (0.3)	2 (0.6)	3 (0.5)
静脈瘤	1 (0.3)	2 (0.6)	3 (0.5)
血圧変動	0 (0.0)	2 (0.6)	2 (0.3)
リンパ浮腫	1 (0.3)	1 (0.3)	2 (0.3)
末梢動脈閉塞性疾患	1 (0.3)	1 (0.3)	2 (0.3)
静脈炎	0 (0.0)	2 (0.6)	2 (0.3)
血栓性静脈炎	2 (0.6)	0 (0.0)	2 (0.3)
大動脈瘤破裂	1 (0.3)	0 (0.0)	1 (0.2)
ほてり	1 (0.3)	0 (0.0)	1 (0.2)
腸骨動脈解離	1 (0.3)	0 (0.0)	1 (0.2)
間欠性跛行	1 (0.3)	0 (0.0)	1 (0.2)
頚静脈血栓症	0 (0.0)	1 (0.3)	1 (0.2)
起立性低血圧	1 (0.3)	0 (0.0)	1 (0.2)
末梢動脈血栓症	1 (0.3)	0 (0.0)	1 (0.2)
末梢冷感	1 (0.3)	0 (0.0)	1 (0.2)
収縮期高血圧	1 (0.3)	0 (0.0)	1 (0.2)
表在性血栓性静脈炎	1 (0.3)	0 (0.0)	1 (0.2)
血管炎	0 (0.0)	1 (0.3)	1 (0.2)
四肢静脈血栓症	1 (0.3)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	97 (29.9)	86 (26.5)	183 (28.2)
挫傷	44 (13.6)	34 (10.5)	78 (12.0)
転倒	14 (4.3)	18 (5.6)	32 (4.9)
皮膚裂傷	11 (3.4)	3 (0.9)	14 (2.2)
四肢損傷	5 (1.5)	5 (1.5)	10 (1.5)
節足動物咬傷	5 (1.5)	3 (0.9)	8 (1.2)
皮下血腫	3 (0.9)	5 (1.5)	8 (1.2)
肋骨骨折	4 (1.2)	1 (0.3)	5 (0.8)
靭帯捻挫	2 (0.6)	2 (0.6)	4 (0.6)
処置後出血	0 (0.0)	4 (1.2)	4 (0.6)
歯牙破折	3 (0.9)	1 (0.3)	4 (0.6)
創傷	1 (0.3)	3 (0.9)	4 (0.6)
動物咬傷	1 (0.3)	2 (0.6)	3 (0.5)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
背部損傷	3 (0.9)	0 (0.0)	3 (0.5)
上腕骨骨折	3 (0.9)	0 (0.0)	3 (0.5)
腰椎骨折	1 (0.3)	2 (0.6)	3 (0.5)
交通事故	1 (0.3)	2 (0.6)	3 (0.5)
皮膚擦過傷	2 (0.6)	1 (0.3)	3 (0.5)
皮膚損傷	1 (0.3)	2 (0.6)	3 (0.5)
脊椎圧迫骨折	3 (0.9)	0 (0.0)	3 (0.5)
事故	0 (0.0)	2 (0.6)	2 (0.3)
鎖骨骨折	1 (0.3)	1 (0.3)	2 (0.3)
大腿骨骨折	1 (0.3)	1 (0.3)	2 (0.3)
足骨折	0 (0.0)	2 (0.6)	2 (0.3)
頭部損傷	2 (0.6)	0 (0.0)	2 (0.3)
股関節部骨折	0 (0.0)	2 (0.6)	2 (0.3)
半月板損傷	1 (0.3)	1 (0.3)	2 (0.3)
肉離れ	2 (0.6)	0 (0.0)	2 (0.3)
外傷後疼痛	1 (0.3)	1 (0.3)	2 (0.3)
処置による疼痛	1 (0.3)	1 (0.3)	2 (0.3)
橈骨骨折	1 (0.3)	1 (0.3)	2 (0.3)
脊椎骨折	1 (0.3)	1 (0.3)	2 (0.3)
硬膜下血腫	0 (0.0)	2 (0.6)	2 (0.3)
熱傷	1 (0.3)	1 (0.3)	2 (0.3)
ワクチン接種合併症	1 (0.3)	1 (0.3)	2 (0.3)
動物による引っかき傷	0 (0.0)	1 (0.3)	1 (0.2)
節足動物刺傷	0 (0.0)	1 (0.3)	1 (0.2)
骨挫傷	0 (0.0)	1 (0.3)	1 (0.2)
頭蓋脳損傷	1 (0.3)	0 (0.0)	1 (0.2)
歯科修復不成功	0 (0.0)	1 (0.3)	1 (0.2)
眼挫傷	1 (0.3)	0 (0.0)	1 (0.2)
気道内異物	1 (0.3)	0 (0.0)	1 (0.2)
移植部位出血	1 (0.3)	0 (0.0)	1 (0.2)
手骨折	1 (0.3)	0 (0.0)	1 (0.2)
注入に伴う反応	1 (0.3)	0 (0.0)	1 (0.2)
結膜損傷	0 (0.0)	1 (0.3)	1 (0.2)
靭帯断裂	1 (0.3)	0 (0.0)	1 (0.2)
下肢骨折	0 (0.0)	1 (0.3)	1 (0.2)
半月板嚢腫	0 (0.0)	1 (0.3)	1 (0.2)
筋損傷	1 (0.3)	0 (0.0)	1 (0.2)
筋骨格内異物	0 (0.0)	1 (0.3)	1 (0.2)
眼窩周囲出血	1 (0.3)	0 (0.0)	1 (0.2)
処置後合併症	1 (0.3)	0 (0.0)	1 (0.2)
処置後挫傷	0 (0.0)	1 (0.3)	1 (0.2)
処置後血腫	1 (0.3)	0 (0.0)	1 (0.2)
肩甲骨骨折	0 (0.0)	1 (0.3)	1 (0.2)
腱断裂	0 (0.0)	1 (0.3)	1 (0.2)
歯牙損傷	1 (0.3)	0 (0.0)	1 (0.2)
外傷性血腫	1 (0.3)	0 (0.0)	1 (0.2)
外傷性肝損傷	1 (0.3)	0 (0.0)	1 (0.2)
尺骨骨折	0 (0.0)	1 (0.3)	1 (0.2)
血管確保合併症	1 (0.3)	0 (0.0)	1 (0.2)
外陰腟損傷	0 (0.0)	1 (0.3)	1 (0.2)
創離開	1 (0.3)	0 (0.0)	1 (0.2)
手首関節骨折	0 (0.0)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
代謝および栄養障害	85 (26.2)	89 (27.5)	174 (26.9)
低カリウム血症	18 (5.6)	16 (4.9)	34 (5.2)
高尿酸血症	12 (3.7)	19 (5.9)	31 (4.8)
食欲減退	10 (3.1)	20 (6.2)	30 (4.6)
高血糖	9 (2.8)	6 (1.9)	15 (2.3)
痛風	3 (0.9)	10 (3.1)	13 (2.0)
低ナトリウム血症	4 (1.2)	8 (2.5)	12 (1.9)
高カリウム血症	7 (2.2)	3 (0.9)	10 (1.5)
低アルブミン血症	3 (0.9)	7 (2.2)	10 (1.5)
低マグネシウム血症	3 (0.9)	7 (2.2)	10 (1.5)
2型糖尿病	9 (2.8)	1 (0.3)	10 (1.5)
糖尿病	5 (1.5)	3 (0.9)	8 (1.2)
高カルシウム血症	4 (1.2)	4 (1.2)	8 (1.2)
低カルシウム血症	5 (1.5)	3 (0.9)	8 (1.2)
鉄欠乏	4 (1.2)	4 (1.2)	8 (1.2)
脱水	2 (0.6)	4 (1.2)	6 (0.9)
高コレステロール血症	3 (0.9)	3 (0.9)	6 (0.9)
高トリグリセリド血症	3 (0.9)	2 (0.6)	5 (0.8)
ビタミンD欠乏	3 (0.9)	0 (0.0)	3 (0.5)
耐糖能障害	0 (0.0)	2 (0.6)	2 (0.3)
高クレアチニン血症	1 (0.3)	1 (0.3)	2 (0.3)
高脂血症	2 (0.6)	0 (0.0)	2 (0.3)
低リン血症	0 (0.0)	2 (0.6)	2 (0.3)
マグネシウム欠乏	0 (0.0)	2 (0.6)	2 (0.3)
異常体重減少	0 (0.0)	1 (0.3)	1 (0.2)
食欲障害	1 (0.3)	0 (0.0)	1 (0.2)
悪液質	0 (0.0)	1 (0.3)	1 (0.2)
カルシウム欠乏	0 (0.0)	1 (0.3)	1 (0.2)
コントロール不良の糖尿病	1 (0.3)	0 (0.0)	1 (0.2)
脂質異常症	1 (0.3)	0 (0.0)	1 (0.2)
高フェリチン血症	0 (0.0)	1 (0.3)	1 (0.2)
高マグネシウム血症	0 (0.0)	1 (0.3)	1 (0.2)
高ナトリウム血症	1 (0.3)	0 (0.0)	1 (0.2)
高リン血症	1 (0.3)	0 (0.0)	1 (0.2)
低血糖	0 (0.0)	1 (0.3)	1 (0.2)
低蛋白血症	0 (0.0)	1 (0.3)	1 (0.2)
栄養障害	1 (0.3)	0 (0.0)	1 (0.2)
代謝性アシドーシス	1 (0.3)	0 (0.0)	1 (0.2)
肥満	0 (0.0)	1 (0.3)	1 (0.2)
腫瘍崩壊症候群	1 (0.3)	0 (0.0)	1 (0.2)
水中毒	1 (0.3)	0 (0.0)	1 (0.2)
心臓障害	69 (21.3)	96 (29.6)	165 (25.5)
心房細動	15 (4.6)	40 (12.3)	55 (8.5)
動悸	9 (2.8)	13 (4.0)	22 (3.4)
洞性徐脈	5 (1.5)	7 (2.2)	12 (1.9)
狭心症	4 (1.2)	7 (2.2)	11 (1.7)
心不全	5 (1.5)	6 (1.9)	11 (1.7)
第一度房室ブロック	5 (1.5)	3 (0.9)	8 (1.2)
上室性期外収縮	4 (1.2)	3 (0.9)	7 (1.1)
心室性期外収縮	3 (0.9)	3 (0.9)	6 (0.9)
心房粗動	2 (0.6)	3 (0.9)	5 (0.8)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
右脚ブロック	2 (0.6)	3 (0.9)	5 (0.8)
洞性頻脈	4 (1.2)	1 (0.3)	5 (0.8)
心筋梗塞	1 (0.3)	3 (0.9)	4 (0.6)
心筋虚血	3 (0.9)	1 (0.3)	4 (0.6)
不整脈	1 (0.3)	2 (0.6)	3 (0.5)
上室性不整脈	3 (0.9)	0 (0.0)	3 (0.5)
徐脈	0 (0.0)	3 (0.9)	3 (0.5)
左脚ブロック	3 (0.9)	0 (0.0)	3 (0.5)
心停止	0 (0.0)	3 (0.9)	3 (0.5)
心不快感	0 (0.0)	3 (0.9)	3 (0.5)
うっ血性心不全	1 (0.3)	2 (0.6)	3 (0.5)
うっ血性心筋症	0 (0.0)	3 (0.9)	3 (0.5)
冠動脈疾患	2 (0.6)	1 (0.3)	3 (0.5)
期外収縮	1 (0.3)	2 (0.6)	3 (0.5)
僧帽弁閉鎖不全症	1 (0.3)	2 (0.6)	3 (0.5)
上室性頻脈	2 (0.6)	1 (0.3)	3 (0.5)
頻脈	1 (0.3)	2 (0.6)	3 (0.5)
心室性不整脈	2 (0.6)	1 (0.3)	3 (0.5)
洞性不整脈	1 (0.3)	1 (0.3)	2 (0.3)
心室細動	0 (0.0)	2 (0.6)	2 (0.3)
急性冠動脈症候群	1 (0.3)	0 (0.0)	1 (0.2)
急性心筋梗塞	1 (0.3)	0 (0.0)	1 (0.2)
大動脈弁閉鎖不全症	0 (0.0)	1 (0.3)	1 (0.2)
大動脈弁狭窄	1 (0.3)	0 (0.0)	1 (0.2)
冠動脈硬化症	1 (0.3)	0 (0.0)	1 (0.2)
心房頻脈	0 (0.0)	1 (0.3)	1 (0.2)
房室ブロック	0 (0.0)	1 (0.3)	1 (0.2)
徐脈性不整脈	1 (0.3)	0 (0.0)	1 (0.2)
心障害	0 (0.0)	1 (0.3)	1 (0.2)
急性心不全	0 (0.0)	1 (0.3)	1 (0.2)
慢性心不全	0 (0.0)	1 (0.3)	1 (0.2)
冠動脈不全	1 (0.3)	0 (0.0)	1 (0.2)
心室内伝導障害	1 (0.3)	0 (0.0)	1 (0.2)
心房拡張	1 (0.3)	0 (0.0)	1 (0.2)
左房肥大	1 (0.3)	0 (0.0)	1 (0.2)
左室機能不全	1 (0.3)	0 (0.0)	1 (0.2)
左室不全	1 (0.3)	0 (0.0)	1 (0.2)
心筋線維症	1 (0.3)	0 (0.0)	1 (0.2)
心嚢液貯留	1 (0.3)	0 (0.0)	1 (0.2)
洞房ブロック	1 (0.3)	0 (0.0)	1 (0.2)
洞結節機能不全	0 (0.0)	1 (0.3)	1 (0.2)
心室壁運動低下	1 (0.3)	0 (0.0)	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	52 (16.0)	55 (17.0)	107 (16.5)
皮膚有棘細胞癌	12 (3.7)	14 (4.3)	26 (4.0)
基底細胞癌	11 (3.4)	12 (3.7)	23 (3.5)
ボーエン病	4 (1.2)	5 (1.5)	9 (1.4)
脂漏性角化症	5 (1.5)	2 (0.6)	7 (1.1)
皮膚乳頭腫	4 (1.2)	2 (0.6)	6 (0.9)
前立腺癌	2 (0.6)	3 (0.9)	5 (0.8)
脂肪腫	3 (0.9)	1 (0.3)	4 (0.6)
肺腺癌	1 (0.3)	2 (0.6)	3 (0.5)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
胃腺癌	0 (0.0)	2 (0.6)	2 (0.3)
結腸腺癌	1 (0.3)	1 (0.3)	2 (0.3)
膀胱移行上皮癌	2 (0.6)	0 (0.0)	2 (0.3)
大腸腺腫	1 (0.3)	1 (0.3)	2 (0.3)
結腸癌	1 (0.3)	1 (0.3)	2 (0.3)
乳管内増殖性病変	2 (0.6)	0 (0.0)	2 (0.3)
メラノサイト性母斑	1 (0.3)	1 (0.3)	2 (0.3)
神経内分泌癌	2 (0.6)	0 (0.0)	2 (0.3)
再発皮膚有棘細胞癌	1 (0.3)	1 (0.3)	2 (0.3)
肛門扁平上皮癌	0 (0.0)	1 (0.3)	1 (0.2)
乳房の良性新生物	1 (0.3)	0 (0.0)	1 (0.2)
肺の良性新生物	0 (0.0)	1 (0.3)	1 (0.2)
網膜の良性新生物	0 (0.0)	1 (0.3)	1 (0.2)
皮膚良性新生物	1 (0.3)	0 (0.0)	1 (0.2)
甲状腺の良性新生物	0 (0.0)	1 (0.3)	1 (0.2)
乳頭の良性新生物	1 (0.3)	0 (0.0)	1 (0.2)
軟部組織の良性新生物	0 (0.0)	1 (0.3)	1 (0.2)
脳新生物	0 (0.0)	1 (0.3)	1 (0.2)
乳癌	0 (0.0)	1 (0.3)	1 (0.2)
癌疼痛	0 (0.0)	1 (0.3)	1 (0.2)
脈絡膜黒色腫	1 (0.3)	0 (0.0)	1 (0.2)
嫌色素性腎細胞癌	0 (0.0)	1 (0.3)	1 (0.2)
腎明細胞癌	1 (0.3)	0 (0.0)	1 (0.2)
遠隔転移を伴う結腸癌	1 (0.3)	0 (0.0)	1 (0.2)
結腸直腸腺癌	0 (0.0)	1 (0.3)	1 (0.2)
結腸直腸癌	0 (0.0)	1 (0.3)	1 (0.2)
子宮内膜腺癌	1 (0.3)	0 (0.0)	1 (0.2)
外耳の悪性新生物	0 (0.0)	1 (0.3)	1 (0.2)
胃腸管腺腫	0 (0.0)	1 (0.3)	1 (0.2)
皮膚血管腫	0 (0.0)	1 (0.3)	1 (0.2)
浸潤性乳管癌	0 (0.0)	1 (0.3)	1 (0.2)
再発喉頭癌	1 (0.3)	0 (0.0)	1 (0.2)
口唇扁平上皮癌	0 (0.0)	1 (0.3)	1 (0.2)
肺新生物	0 (0.0)	1 (0.3)	1 (0.2)
悪性黒色腫	1 (0.3)	0 (0.0)	1 (0.2)
髄膜腫	0 (0.0)	1 (0.3)	1 (0.2)
唾液腺粘液性類表皮癌	0 (0.0)	1 (0.3)	1 (0.2)
神経内分泌腫瘍	1 (0.3)	0 (0.0)	1 (0.2)
口腔血管腫	0 (0.0)	1 (0.3)	1 (0.2)
口腔乳頭腫	0 (0.0)	1 (0.3)	1 (0.2)
下垂体の良性腫瘍	1 (0.3)	0 (0.0)	1 (0.2)
化膿性肉芽腫	1 (0.3)	0 (0.0)	1 (0.2)
直腸癌	1 (0.3)	0 (0.0)	1 (0.2)
皮膚癌	0 (0.0)	1 (0.3)	1 (0.2)
遠隔転移を伴う皮膚有棘細胞癌	0 (0.0)	1 (0.3)	1 (0.2)
遠隔転移を伴う小細胞肺癌	1 (0.3)	0 (0.0)	1 (0.2)
肺扁平上皮癌	1 (0.3)	0 (0.0)	1 (0.2)
口腔内扁平上皮癌	1 (0.3)	0 (0.0)	1 (0.2)
表在拡大型黒色腫第2期	0 (0.0)	1 (0.3)	1 (0.2)
再発悪性胸腺腫	0 (0.0)	1 (0.3)	1 (0.2)
腎盂および尿管移行上皮癌	0 (0.0)	1 (0.3)	1 (0.2)
移行上皮癌	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
腎および尿路障害	41 (12.7)	46 (14.2)	87 (13.4)
血尿	15 (4.6)	13 (4.0)	28 (4.3)
急性腎障害	5 (1.5)	4 (1.2)	9 (1.4)
慢性腎臓病	2 (0.6)	6 (1.9)	8 (1.2)
頻尿	5 (1.5)	3 (0.9)	8 (1.2)
排尿困難	3 (0.9)	2 (0.6)	5 (0.8)
尿閉	2 (0.6)	3 (0.9)	5 (0.8)
非感染性膀胱炎	2 (0.6)	2 (0.6)	4 (0.6)
腎結石症	2 (0.6)	2 (0.6)	4 (0.6)
腎不全	2 (0.6)	2 (0.6)	4 (0.6)
腎機能障害	2 (0.6)	2 (0.6)	4 (0.6)
尿失禁	4 (1.2)	0 (0.0)	4 (0.6)
尿意切迫	2 (0.6)	1 (0.3)	3 (0.5)
夜間頻尿	2 (0.6)	1 (0.3)	3 (0.5)
蛋白尿	2 (0.6)	1 (0.3)	3 (0.5)
腎嚢胞	1 (0.3)	2 (0.6)	3 (0.5)
着色尿	0 (0.0)	2 (0.6)	2 (0.3)
腎仙痛	0 (0.0)	2 (0.6)	2 (0.3)
腎臓痛	2 (0.6)	0 (0.0)	2 (0.3)
尿路出血	1 (0.3)	0 (0.0)	1 (0.2)
緊張性膀胱	0 (0.0)	1 (0.3)	1 (0.2)
多尿	0 (0.0)	1 (0.3)	1 (0.2)
腎腫瘤	0 (0.0)	1 (0.3)	1 (0.2)
尿管拡張	0 (0.0)	1 (0.3)	1 (0.2)
尿道症候群	0 (0.0)	1 (0.3)	1 (0.2)
排尿躊躇	0 (0.0)	1 (0.3)	1 (0.2)
尿路閉塞	0 (0.0)	1 (0.3)	1 (0.2)
精神障害	39 (12.0)	44 (13.6)	83 (12.8)
不眠症	16 (4.9)	17 (5.2)	33 (5.1)
不安	10 (3.1)	11 (3.4)	21 (3.2)
うつ病	10 (3.1)	8 (2.5)	18 (2.8)
睡眠障害	2 (0.6)	3 (0.9)	5 (0.8)
激越	1 (0.3)	3 (0.9)	4 (0.6)
錯乱状態	0 (0.0)	2 (0.6)	2 (0.3)
抑うつ気分	2 (0.6)	0 (0.0)	2 (0.3)
失見当識	0 (0.0)	2 (0.6)	2 (0.3)
異常な夢	0 (0.0)	1 (0.3)	1 (0.2)
抑うつ気分を伴う適応障害	1 (0.3)	0 (0.0)	1 (0.2)
感情障害	0 (0.0)	1 (0.3)	1 (0.2)
不安障害	0 (0.0)	1 (0.3)	1 (0.2)
双極性障害	1 (0.3)	0 (0.0)	1 (0.2)
燃え尽き症候群	1 (0.3)	0 (0.0)	1 (0.2)
譫妄	0 (0.0)	1 (0.3)	1 (0.2)
幻覚	0 (0.0)	1 (0.3)	1 (0.2)
易刺激性	1 (0.3)	0 (0.0)	1 (0.2)
神経症	1 (0.3)	0 (0.0)	1 (0.2)
悪夢	1 (0.3)	0 (0.0)	1 (0.2)
器質性脳症候群	0 (0.0)	1 (0.3)	1 (0.2)
身体症状症	1 (0.3)	0 (0.0)	1 (0.2)
夢遊症	0 (0.0)	1 (0.3)	1 (0.2)
ストレス	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
自殺行為	0 (0.0)	1 (0.3)	1 (0.2)
眼障害	43 (13.3)	33 (10.2)	76 (11.7)
白内障	11 (3.4)	8 (2.5)	19 (2.9)
結膜出血	6 (1.9)	2 (0.6)	8 (1.2)
視力障害	2 (0.6)	5 (1.5)	7 (1.1)
霧視	2 (0.6)	3 (0.9)	5 (0.8)
緑内障	3 (0.9)	0 (0.0)	3 (0.5)
硝子体出血	2 (0.6)	1 (0.3)	3 (0.5)
ドライアイ	1 (0.3)	1 (0.3)	2 (0.3)
眼出血	1 (0.3)	1 (0.3)	2 (0.3)
眼の炎症	0 (0.0)	2 (0.6)	2 (0.3)
眼痛	0 (0.0)	2 (0.6)	2 (0.3)
眼充血	1 (0.3)	1 (0.3)	2 (0.3)
弱視	1 (0.3)	0 (0.0)	1 (0.2)
失明	0 (0.0)	1 (0.3)	1 (0.2)
核性白内障	0 (0.0)	1 (0.3)	1 (0.2)
霰粒腫	0 (0.0)	1 (0.3)	1 (0.2)
網脈絡膜症	0 (0.0)	1 (0.3)	1 (0.2)
脈絡膜滲出	1 (0.3)	0 (0.0)	1 (0.2)
結膜充血	1 (0.3)	0 (0.0)	1 (0.2)
アレルギー性結膜炎	1 (0.3)	0 (0.0)	1 (0.2)
皮質性視力障害	0 (0.0)	1 (0.3)	1 (0.2)
後天性涙道狭窄	1 (0.3)	0 (0.0)	1 (0.2)
複視	0 (0.0)	1 (0.3)	1 (0.2)
眼瞼内反	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼紅斑	1 (0.3)	0 (0.0)	1 (0.2)
眼のアレルギー	0 (0.0)	1 (0.3)	1 (0.2)
眼血腫	1 (0.3)	0 (0.0)	1 (0.2)
眼刺激	0 (0.0)	1 (0.3)	1 (0.2)
眼そう痒症	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼出血	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼血腫	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼浮腫	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼発疹	1 (0.3)	0 (0.0)	1 (0.2)
角膜炎	1 (0.3)	0 (0.0)	1 (0.2)
円錐角膜	0 (0.0)	1 (0.3)	1 (0.2)
眼部不快感	0 (0.0)	1 (0.3)	1 (0.2)
眼窩周囲浮腫	0 (0.0)	1 (0.3)	1 (0.2)
眼窩周囲腫脹	0 (0.0)	1 (0.3)	1 (0.2)
羞明	0 (0.0)	1 (0.3)	1 (0.2)
翼状片	0 (0.0)	1 (0.3)	1 (0.2)
網膜出血	1 (0.3)	0 (0.0)	1 (0.2)
強膜出血	1 (0.3)	0 (0.0)	1 (0.2)
潰瘍性角膜炎	1 (0.3)	0 (0.0)	1 (0.2)
ぶどう膜炎	0 (0.0)	1 (0.3)	1 (0.2)
視野欠損	1 (0.3)	0 (0.0)	1 (0.2)
硝子体障害	1 (0.3)	0 (0.0)	1 (0.2)
耳および迷路障害	28 (8.6)	14 (4.3)	42 (6.5)
回転性めまい	10 (3.1)	5 (1.5)	15 (2.3)
耳痛	7 (2.2)	3 (0.9)	10 (1.5)
耳鳴	5 (1.5)	1 (0.3)	6 (0.9)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
耳不快感	2 (0.6)	1 (0.3)	3 (0.5)
耳出血	2 (0.6)	0 (0.0)	2 (0.3)
中耳の炎症	2 (0.6)	0 (0.0)	2 (0.3)
難聴	1 (0.3)	0 (0.0)	1 (0.2)
感音性難聴	0 (0.0)	1 (0.3)	1 (0.2)
一過性難聴	1 (0.3)	0 (0.0)	1 (0.2)
耳閉	1 (0.3)	0 (0.0)	1 (0.2)
耳そう痒症	1 (0.3)	0 (0.0)	1 (0.2)
外耳の炎症	0 (0.0)	1 (0.3)	1 (0.2)
鼓室内出血	0 (0.0)	1 (0.3)	1 (0.2)
聴力低下	0 (0.0)	1 (0.3)	1 (0.2)
免疫系障害	20 (6.2)	14 (4.3)	34 (5.2)
低γグロブリン血症	11 (3.4)	7 (2.2)	18 (2.8)
季節性アレルギー	3 (0.9)	1 (0.3)	4 (0.6)
節足動物咬傷アレルギー	1 (0.3)	1 (0.3)	2 (0.3)
造影剤アレルギー	2 (0.6)	0 (0.0)	2 (0.3)
薬物過敏症	1 (0.3)	1 (0.3)	2 (0.3)
免疫反応	2 (0.6)	0 (0.0)	2 (0.3)
続発性免疫不全症	0 (0.0)	2 (0.6)	2 (0.3)
節足動物刺傷アレルギー	0 (0.0)	1 (0.3)	1 (0.2)
ワクチンアレルギー	0 (0.0)	1 (0.3)	1 (0.2)
サルコイドーシス	1 (0.3)	0 (0.0)	1 (0.2)
生殖系および乳房障害	24 (7.4)	9 (2.8)	33 (5.1)
良性前立腺肥大症	4 (1.2)	2 (0.6)	6 (0.9)
勃起不全	2 (0.6)	1 (0.3)	3 (0.5)
前立腺炎	1 (0.3)	1 (0.3)	2 (0.3)
前立腺腫大	0 (0.0)	2 (0.6)	2 (0.3)
子宮ポリープ	2 (0.6)	0 (0.0)	2 (0.3)
後天性包茎	1 (0.3)	0 (0.0)	1 (0.2)
乳房血腫	1 (0.3)	0 (0.0)	1 (0.2)
乳房出血	0 (0.0)	1 (0.3)	1 (0.2)
乳房腫瘤	0 (0.0)	1 (0.3)	1 (0.2)
乳房痛	1 (0.3)	0 (0.0)	1 (0.2)
子宮頚部上皮異形成	1 (0.3)	0 (0.0)	1 (0.2)
膀胱瘤	1 (0.3)	0 (0.0)	1 (0.2)
子宮内膜増殖症	1 (0.3)	0 (0.0)	1 (0.2)
乳頭の炎症	0 (0.0)	1 (0.3)	1 (0.2)
乳頭浮腫	0 (0.0)	1 (0.3)	1 (0.2)
乳頭痛	1 (0.3)	0 (0.0)	1 (0.2)
卵巣嚢胞	1 (0.3)	0 (0.0)	1 (0.2)
骨盤脱	1 (0.3)	0 (0.0)	1 (0.2)
陰茎血腫	1 (0.3)	0 (0.0)	1 (0.2)
陰茎浮腫	1 (0.3)	0 (0.0)	1 (0.2)
精巣不快感	1 (0.3)	0 (0.0)	1 (0.2)
子宮脱	1 (0.3)	0 (0.0)	1 (0.2)
腟分泌物	1 (0.3)	0 (0.0)	1 (0.2)
腟出血	1 (0.3)	0 (0.0)	1 (0.2)
外陰嚢胞	1 (0.3)	0 (0.0)	1 (0.2)
外陰腟の炎症	1 (0.3)	0 (0.0)	1 (0.2)
外陰腟そう痒症	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
肝胆道系障害	16 (4.9)	13 (4.0)	29 (4.5)
胆嚢炎	2 (0.6)	2 (0.6)	4 (0.6)
肝機能異常	2 (0.6)	2 (0.6)	4 (0.6)
高ビリルビン血症	2 (0.6)	2 (0.6)	4 (0.6)
肝嚢胞	2 (0.6)	1 (0.3)	3 (0.5)
脂肪肝	3 (0.9)	0 (0.0)	3 (0.5)
胆石症	0 (0.0)	2 (0.6)	2 (0.3)
肝腫大	2 (0.6)	0 (0.0)	2 (0.3)
黄疸	1 (0.3)	1 (0.3)	2 (0.3)
急性胆嚢炎	1 (0.3)	0 (0.0)	1 (0.2)
肝腫瘤	0 (0.0)	1 (0.3)	1 (0.2)
肝炎	0 (0.0)	1 (0.3)	1 (0.2)
肝毒性	0 (0.0)	1 (0.3)	1 (0.2)
高トランスアミナーゼ血症	0 (0.0)	1 (0.3)	1 (0.2)
肝損傷	1 (0.3)	0 (0.0)	1 (0.2)
門脈圧亢進症	0 (0.0)	1 (0.3)	1 (0.2)
内分泌障害	3 (0.9)	2 (0.6)	5 (0.8)
甲状腺機能低下症	2 (0.6)	0 (0.0)	2 (0.3)
甲状腺腫	1 (0.3)	0 (0.0)	1 (0.2)
副甲状腺機能亢進症	0 (0.0)	1 (0.3)	1 (0.2)
甲状腺腫瘤	0 (0.0)	1 (0.3)	1 (0.2)
先天性、家族性および遺伝性障害	0 (0.0)	2 (0.6)	2 (0.3)
気管支原性嚢胞	0 (0.0)	1 (0.3)	1 (0.2)
汗孔角化症	0 (0.0)	1 (0.3)	1 (0.2)

Source: Table 14.3.1.2.2.1 in BGB-3111-305 clinical study report (data cutoff date: 08 August 2022). Data cutoff: 08AUG2022. Data extraction: [redacted] 20[redacted].
Abbreviation: TEAE, treatment-emergent adverse event.
TEAE is defined as an AE that has an onset date on or after the first dose of study drug up to 30 days after the last dose of study drug or the day prior to initiation of a new CLL/SLL therapy, whichever occurs first. If a TEAE worsens to Grade 5 more than 30 days after last dose of study drug and prior to initiation of a new CLL/SLL therapy, the Grade 5 AE will be treatment-emergent.
Notes: Adverse events were classified based on MedDRA Version 24.0.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively.
Events were sorted by decreasing frequency of System Organ Class and Preferred Term in the Total group.

表 56： 投与と関連のある TEAE：器官別大分類別及び基本語別（BGB-3111-305 試験、安全性解析対象集団）

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
Patients With at Least One Treatment-Related TEAE	243 (75.0)	267 (82.4)	510 (78.7)
血液およびリンパ系障害	98 (30.2)	97 (29.9)	195 (30.1)
好中球減少症	60 (18.5)	50 (15.4)	110 (17.0)
貧血	29 (9.0)	29 (9.0)	58 (9.0)
血小板減少症	17 (5.2)	20 (6.2)	37 (5.7)
内出血発生の増加傾向	6 (1.9)	3 (0.9)	9 (1.4)
出血性素因	2 (0.6)	5 (1.5)	7 (1.1)
発熱性好中球減少症	4 (1.2)	2 (0.6)	6 (0.9)
好酸球増加症	1 (0.3)	1 (0.3)	2 (0.3)
顆粒球減少症	1 (0.3)	1 (0.3)	2 (0.3)
鉄欠乏性貧血	0 (0.0)	2 (0.6)	2 (0.3)
白血球減少症	0 (0.0)	2 (0.6)	2 (0.3)
リンパ球増加症	2 (0.6)	0 (0.0)	2 (0.3)
無顆粒球症	0 (0.0)	1 (0.3)	1 (0.2)
白血球増加症	0 (0.0)	1 (0.3)	1 (0.2)
リンパ節痛	1 (0.3)	0 (0.0)	1 (0.2)
リンパ節炎	1 (0.3)	0 (0.0)	1 (0.2)
リンパ節症	0 (0.0)	1 (0.3)	1 (0.2)
脾臓梗塞	0 (0.0)	1 (0.3)	1 (0.2)
脾静脈瘤	0 (0.0)	1 (0.3)	1 (0.2)
感染症および寄生虫症	87 (26.9)	83 (25.6)	170 (26.2)
肺炎	16 (4.9)	23 (7.1)	39 (6.0)
上気道感染	24 (7.4)	13 (4.0)	37 (5.7)
尿路感染	11 (3.4)	11 (3.4)	22 (3.4)
気管支炎	5 (1.5)	4 (1.2)	9 (1.4)
口腔ヘルペス	3 (0.9)	6 (1.9)	9 (1.4)
COVID-19	7 (2.2)	1 (0.3)	8 (1.2)
副鼻腔炎	3 (0.9)	5 (1.5)	8 (1.2)
帯状疱疹	4 (1.2)	3 (0.9)	7 (1.1)
下気道感染	4 (1.2)	3 (0.9)	7 (1.1)
皮膚感染	4 (1.2)	3 (0.9)	7 (1.1)
蜂巣炎	2 (0.6)	4 (1.2)	6 (0.9)
COVID-19肺炎	2 (0.6)	3 (0.9)	5 (0.8)
結膜炎	4 (1.2)	1 (0.3)	5 (0.8)
限局性感染	3 (0.9)	2 (0.6)	5 (0.8)
膿疱性皮疹	3 (0.9)	2 (0.6)	5 (0.8)
せつ	2 (0.6)	2 (0.6)	4 (0.6)
爪囲炎	0 (0.0)	4 (1.2)	4 (0.6)
咽頭炎	1 (0.3)	3 (0.9)	4 (0.6)
気道感染	3 (0.9)	1 (0.3)	4 (0.6)
鼻炎	1 (0.3)	3 (0.9)	4 (0.6)
B型肝炎	1 (0.3)	2 (0.6)	3 (0.5)
ヘルペスウイルス感染	1 (0.3)	2 (0.6)	3 (0.5)
皮膚細菌感染	1 (0.3)	2 (0.6)	3 (0.5)
虫垂炎	0 (0.0)	2 (0.6)	2 (0.3)
細菌尿	1 (0.3)	1 (0.3)	2 (0.3)
耳感染	2 (0.6)	0 (0.0)	2 (0.3)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
B型肝炎再活性化	2 (0.6)	0 (0.0)	2 (0.3)
膿痂疹	2 (0.6)	0 (0.0)	2 (0.3)
インフルエンザ	0 (0.0)	2 (0.6)	2 (0.3)
細菌性下気道感染	1 (0.3)	1 (0.3)	2 (0.3)
上咽頭炎	1 (0.3)	1 (0.3)	2 (0.3)
歯周炎	0 (0.0)	2 (0.6)	2 (0.3)
ニューモシスチス・イロベチイ肺炎	1 (0.3)	1 (0.3)	2 (0.3)
敗血症	2 (0.6)	0 (0.0)	2 (0.3)
細菌性上気道感染	1 (0.3)	1 (0.3)	2 (0.3)
四肢膿瘍	0 (0.0)	1 (0.3)	1 (0.2)
肛門膿瘍	1 (0.3)	0 (0.0)	1 (0.2)
細菌感染	1 (0.3)	0 (0.0)	1 (0.2)
細菌性鼻炎	1 (0.3)	0 (0.0)	1 (0.2)
細菌性敗血症	0 (0.0)	1 (0.3)	1 (0.2)
気管支肺アスペルギルス症	0 (0.0)	1 (0.3)	1 (0.2)
カンピロバクター胃腸炎	0 (0.0)	1 (0.3)	1 (0.2)
涙嚢炎	1 (0.3)	0 (0.0)	1 (0.2)
感染性皮膚炎	0 (0.0)	1 (0.3)	1 (0.2)
憩室炎	1 (0.3)	0 (0.0)	1 (0.2)
大腸菌性菌血症	1 (0.3)	0 (0.0)	1 (0.2)
大腸菌性敗血症	1 (0.3)	0 (0.0)	1 (0.2)
熱性感染症	1 (0.3)	0 (0.0)	1 (0.2)
皮膚真菌感染	0 (0.0)	1 (0.3)	1 (0.2)
ウイルス性胃炎	1 (0.3)	0 (0.0)	1 (0.2)
胃腸炎	1 (0.3)	0 (0.0)	1 (0.2)
細菌性消化管感染	0 (0.0)	1 (0.3)	1 (0.2)
陰部ヘルペス	0 (0.0)	1 (0.3)	1 (0.2)
歯肉炎	1 (0.3)	0 (0.0)	1 (0.2)
血腫感染	1 (0.3)	0 (0.0)	1 (0.2)
ヘルペス性皮膚炎	0 (0.0)	1 (0.3)	1 (0.2)
単純ヘルペス	1 (0.3)	0 (0.0)	1 (0.2)
感染	0 (0.0)	1 (0.3)	1 (0.2)
感染性腱鞘炎	0 (0.0)	1 (0.3)	1 (0.2)
頭蓋内感染	0 (0.0)	1 (0.3)	1 (0.2)
喉頭炎	1 (0.3)	0 (0.0)	1 (0.2)
ウイルス性下気道感染	1 (0.3)	0 (0.0)	1 (0.2)
乳様突起炎	0 (0.0)	1 (0.3)	1 (0.2)
髄膜炎	0 (0.0)	1 (0.3)	1 (0.2)
爪床感染	0 (0.0)	1 (0.3)	1 (0.2)
爪感染	1 (0.3)	0 (0.0)	1 (0.2)
鼻ヘルペス	1 (0.3)	0 (0.0)	1 (0.2)
鼻前庭炎	1 (0.3)	0 (0.0)	1 (0.2)
眼帯状疱疹	0 (0.0)	1 (0.3)	1 (0.2)
口腔カンジダ症	0 (0.0)	1 (0.3)	1 (0.2)
口腔真菌感染	0 (0.0)	1 (0.3)	1 (0.2)
細菌性肺炎	1 (0.3)	0 (0.0)	1 (0.2)
真菌性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
レジオネラ菌性肺炎	0 (0.0)	1 (0.3)	1 (0.2)
肺結核	0 (0.0)	1 (0.3)	1 (0.2)
膿疱	1 (0.3)	0 (0.0)	1 (0.2)
皮膚カンジダ	1 (0.3)	0 (0.0)	1 (0.2)
軟部組織感染	1 (0.3)	0 (0.0)	1 (0.2)
スポロトリコーシス	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
全身性細菌感染	1 (0.3)	0 (0.0)	1 (0.2)
尿道炎	0 (0.0)	1 (0.3)	1 (0.2)
胃腸障害	69 (21.3)	98 (30.2)	167 (25.8)
下痢	26 (8.0)	46 (14.2)	72 (11.1)
悪心	13 (4.0)	17 (5.2)	30 (4.6)
消化不良	6 (1.9)	9 (2.8)	15 (2.3)
口内炎	5 (1.5)	6 (1.9)	11 (1.7)
便秘	1 (0.3)	8 (2.5)	9 (1.4)
胃食道逆流性疾患	4 (1.2)	5 (1.5)	9 (1.4)
歯肉出血	5 (1.5)	4 (1.2)	9 (1.4)
嘔吐	2 (0.6)	7 (2.2)	9 (1.4)
腹痛	3 (0.9)	2 (0.6)	5 (0.8)
口腔内潰瘍形成	3 (0.9)	1 (0.3)	4 (0.6)
口腔血性水疱	3 (0.9)	1 (0.3)	4 (0.6)
上腹部痛	1 (0.3)	2 (0.6)	3 (0.5)
アフタ性潰瘍	1 (0.3)	2 (0.6)	3 (0.5)
口内乾燥	2 (0.6)	1 (0.3)	3 (0.5)
胃炎	1 (0.3)	1 (0.3)	2 (0.3)
歯肉腫脹	1 (0.3)	1 (0.3)	2 (0.3)
血便排泄	2 (0.6)	0 (0.0)	2 (0.3)
口腔内出血	1 (0.3)	1 (0.3)	2 (0.3)
口腔粘膜水疱形成	2 (0.6)	0 (0.0)	2 (0.3)
直腸出血	0 (0.0)	2 (0.6)	2 (0.3)
腹部不快感	0 (0.0)	1 (0.3)	1 (0.2)
腹部膨満	0 (0.0)	1 (0.3)	1 (0.2)
便習慣変化	0 (0.0)	1 (0.3)	1 (0.2)
口唇炎	1 (0.3)	0 (0.0)	1 (0.2)
大腸炎	1 (0.3)	0 (0.0)	1 (0.2)
十二指腸潰瘍	1 (0.3)	0 (0.0)	1 (0.2)
嚥下障害	1 (0.3)	0 (0.0)	1 (0.2)
機能性胃腸障害	1 (0.3)	0 (0.0)	1 (0.2)
びらん性胃炎	0 (0.0)	1 (0.3)	1 (0.2)
歯肉痛	1 (0.3)	0 (0.0)	1 (0.2)
舌痛	1 (0.3)	0 (0.0)	1 (0.2)
腹腔内血腫	0 (0.0)	1 (0.3)	1 (0.2)
大腸ポリープ	0 (0.0)	1 (0.3)	1 (0.2)
口唇潰瘍	0 (0.0)	1 (0.3)	1 (0.2)
メレナ	1 (0.3)	0 (0.0)	1 (0.2)
腸間膜脂肪織炎	0 (0.0)	1 (0.3)	1 (0.2)
口腔内不快感	0 (0.0)	1 (0.3)	1 (0.2)
口腔内過角化	1 (0.3)	0 (0.0)	1 (0.2)
歯周病	1 (0.3)	0 (0.0)	1 (0.2)
直腸ポリープ	0 (0.0)	1 (0.3)	1 (0.2)
唾液腺腫瘤	1 (0.3)	0 (0.0)	1 (0.2)
舌腫脹	1 (0.3)	0 (0.0)	1 (0.2)
舌出血	1 (0.3)	0 (0.0)	1 (0.2)
舌潰瘍	0 (0.0)	1 (0.3)	1 (0.2)
歯痛	0 (0.0)	1 (0.3)	1 (0.2)
潰瘍性十二指腸炎	0 (0.0)	1 (0.3)	1 (0.2)
皮膚および皮下組織障害	78 (24.1)	85 (26.2)	163 (25.2)
発疹	16 (4.9)	24 (7.4)	40 (6.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
点状出血	22 (6.8)	13 (4.0)	35 (5.4)
皮膚出血	9 (2.8)	7 (2.2)	16 (2.5)
そう痒症	11 (3.4)	3 (0.9)	14 (2.2)
紫斑	5 (1.5)	7 (2.2)	12 (1.9)
斑状出血	4 (1.2)	6 (1.9)	10 (1.5)
斑状丘疹状皮疹	5 (1.5)	4 (1.2)	9 (1.4)
皮下出血	3 (0.9)	5 (1.5)	8 (1.2)
紅斑	4 (1.2)	3 (0.9)	7 (1.1)
皮膚乾燥	2 (0.6)	3 (0.9)	5 (0.8)
斑状皮疹	1 (0.3)	4 (1.2)	5 (0.8)
爪破損	2 (0.6)	2 (0.6)	4 (0.6)
皮膚亀裂	0 (0.0)	4 (1.2)	4 (0.6)
皮膚腫瘤	2 (0.6)	2 (0.6)	4 (0.6)
脱毛症	1 (0.3)	2 (0.6)	3 (0.5)
皮膚潰瘍	1 (0.3)	2 (0.6)	3 (0.5)
光線角化症	2 (0.6)	0 (0.0)	2 (0.3)
血性水疱	0 (0.0)	2 (0.6)	2 (0.3)
皮膚炎	1 (0.3)	1 (0.3)	2 (0.3)
ざ瘡様皮膚炎	1 (0.3)	1 (0.3)	2 (0.3)
爪の障害	0 (0.0)	2 (0.6)	2 (0.3)
皮膚疼痛	0 (0.0)	2 (0.6)	2 (0.3)
脂肪織炎	1 (0.3)	1 (0.3)	2 (0.3)
紅斑性皮疹	1 (0.3)	1 (0.3)	2 (0.3)
丘疹性皮疹	0 (0.0)	2 (0.6)	2 (0.3)
皮膚障害	1 (0.3)	1 (0.3)	2 (0.3)
皮膚病変	2 (0.6)	0 (0.0)	2 (0.3)
アレルギー性皮膚炎	0 (0.0)	1 (0.3)	1 (0.2)
接触皮膚炎	1 (0.3)	0 (0.0)	1 (0.2)
薬疹	0 (0.0)	1 (0.3)	1 (0.2)
湿疹	1 (0.3)	0 (0.0)	1 (0.2)
多形紅斑	0 (0.0)	1 (0.3)	1 (0.2)
ヘノッホ・シェーンライン紫斑病	0 (0.0)	1 (0.3)	1 (0.2)
爪線状隆起	1 (0.3)	0 (0.0)	1 (0.2)
結節性発疹	0 (0.0)	1 (0.3)	1 (0.2)
手掌・足底発赤知覚不全症候群	0 (0.0)	1 (0.3)	1 (0.2)
丘疹	0 (0.0)	1 (0.3)	1 (0.2)
そう痒性皮疹	1 (0.3)	0 (0.0)	1 (0.2)
皮膚脆弱性	0 (0.0)	1 (0.3)	1 (0.2)
皮膚色素過剰	1 (0.3)	0 (0.0)	1 (0.2)
皮膚反応	0 (0.0)	1 (0.3)	1 (0.2)
肌のきめ異常	0 (0.0)	1 (0.3)	1 (0.2)
蕁麻疹	1 (0.3)	0 (0.0)	1 (0.2)
臨床検査	49 (15.1)	55 (17.0)	104 (16.0)
好中球数減少	23 (7.1)	19 (5.9)	42 (6.5)
血小板数減少	11 (3.4)	13 (4.0)	24 (3.7)
アラニンアミノトランスフェラーゼ増加	6 (1.9)	9 (2.8)	15 (2.3)
血圧上昇	3 (0.9)	8 (2.5)	11 (1.7)
体重減少	6 (1.9)	4 (1.2)	10 (1.5)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.6)	7 (2.2)	9 (1.4)
血中クレアチニン増加	6 (1.9)	3 (0.9)	9 (1.4)
血中ビリルビン増加	1 (0.3)	7 (2.2)	8 (1.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
γ－グルタミルトランスフェラーゼ増加	4 (1.2)	4 (1.2)	8 (1.2)
白血球数減少	1 (0.3)	4 (1.2)	5 (0.8)
血中乳酸脱水素酵素増加	2 (0.6)	2 (0.6)	4 (0.6)
心電図QT延長	4 (1.2)	0 (0.0)	4 (0.6)
心電図異常T波	1 (0.3)	3 (0.9)	4 (0.6)
血中アルカリホスファターゼ増加	1 (0.3)	2 (0.6)	3 (0.5)
心電図高電位	2 (0.6)	1 (0.3)	3 (0.5)
血中非抱合ビリルビン増加	0 (0.0)	2 (0.6)	2 (0.3)
血中尿酸増加	0 (0.0)	2 (0.6)	2 (0.3)
駆出率減少	1 (0.3)	1 (0.3)	2 (0.3)
グロブリン減少	1 (0.3)	1 (0.3)	2 (0.3)
ヘモグロビン減少	1 (0.3)	1 (0.3)	2 (0.3)
便潜血陽性	0 (0.0)	2 (0.6)	2 (0.3)
尿中蛋白陽性	2 (0.6)	0 (0.0)	2 (0.3)
αヒドロキシ酪酸脱水素酵素増加	0 (0.0)	1 (0.3)	1 (0.2)
抱合ビリルビン増加	0 (0.0)	1 (0.3)	1 (0.2)
血中アルブミン減少	0 (0.0)	1 (0.3)	1 (0.2)
血中ブドウ糖増加	0 (0.0)	1 (0.3)	1 (0.2)
血中免疫グロブリンG減少	1 (0.3)	0 (0.0)	1 (0.2)
血中免疫グロブリンM減少	0 (0.0)	1 (0.3)	1 (0.2)
血中尿素増加	1 (0.3)	0 (0.0)	1 (0.2)
血中尿素窒素／クレアチニン比増加	1 (0.3)	0 (0.0)	1 (0.2)
心電図異常P波	0 (0.0)	1 (0.3)	1 (0.2)
心電図PR延長	1 (0.3)	0 (0.0)	1 (0.2)
心電図ST-T変化	0 (0.0)	1 (0.3)	1 (0.2)
心電図ST-T部分下降	0 (0.0)	1 (0.3)	1 (0.2)
γ－グルタミルトランスフェラーゼ減少	0 (0.0)	1 (0.3)	1 (0.2)
グルタチオン還元酵素活性上昇	0 (0.0)	1 (0.3)	1 (0.2)
ヘモグロビン増加	1 (0.3)	0 (0.0)	1 (0.2)
心拍数増加	0 (0.0)	1 (0.3)	1 (0.2)
心拍数不整	0 (0.0)	1 (0.3)	1 (0.2)
免疫グロブリン減少	1 (0.3)	0 (0.0)	1 (0.2)
リポ蛋白増加	0 (0.0)	1 (0.3)	1 (0.2)
リンパ球数減少	0 (0.0)	1 (0.3)	1 (0.2)
リンパ球数増加	1 (0.3)	0 (0.0)	1 (0.2)
好中球数増加	0 (0.0)	1 (0.3)	1 (0.2)
身体的診察結果異常	0 (0.0)	1 (0.3)	1 (0.2)
血小板凝集異常	1 (0.3)	0 (0.0)	1 (0.2)
総蛋白減少	0 (0.0)	1 (0.3)	1 (0.2)
QRS軸異常	0 (0.0)	1 (0.3)	1 (0.2)
尿潜血陽性	1 (0.3)	0 (0.0)	1 (0.2)
体重増加	0 (0.0)	1 (0.3)	1 (0.2)
血管障害	52 (16.0)	43 (13.3)	95 (14.7)
高血圧	38 (11.7)	29 (9.0)	67 (10.3)
血腫	13 (4.0)	11 (3.4)	24 (3.7)
血圧変動	0 (0.0)	2 (0.6)	2 (0.3)
大動脈瘤破裂	1 (0.3)	0 (0.0)	1 (0.2)
低血圧	0 (0.0)	1 (0.3)	1 (0.2)
リンパ浮腫	1 (0.3)	0 (0.0)	1 (0.2)
末梢動脈血栓症	1 (0.3)	0 (0.0)	1 (0.2)
末梢静脈疾患	1 (0.3)	0 (0.0)	1 (0.2)
収縮期高血圧	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
白衣性高血圧	0 (0.0)	1 (0.3)	1 (0.2)
心臓障害	31 (9.6)	61 (18.8)	92 (14.2)
心房細動	8 (2.5)	32 (9.9)	40 (6.2)
動悸	2 (0.6)	9 (2.8)	11 (1.7)
心不全	1 (0.3)	5 (1.5)	6 (0.9)
洞性徐脈	2 (0.6)	4 (1.2)	6 (0.9)
上室性期外収縮	4 (1.2)	2 (0.6)	6 (0.9)
第一度房室ブロック	2 (0.6)	3 (0.9)	5 (0.8)
心室性期外収縮	2 (0.6)	3 (0.9)	5 (0.8)
心房粗動	1 (0.3)	3 (0.9)	4 (0.6)
不整脈	1 (0.3)	2 (0.6)	3 (0.5)
上室性不整脈	3 (0.9)	0 (0.0)	3 (0.5)
洞性頻脈	3 (0.9)	0 (0.0)	3 (0.5)
狭心症	0 (0.0)	2 (0.6)	2 (0.3)
左脚ブロック	2 (0.6)	0 (0.0)	2 (0.3)
右脚ブロック	1 (0.3)	1 (0.3)	2 (0.3)
うっ血性心筋症	0 (0.0)	2 (0.6)	2 (0.3)
期外収縮	1 (0.3)	1 (0.3)	2 (0.3)
頻脈	1 (0.3)	1 (0.3)	2 (0.3)
心室性不整脈	1 (0.3)	1 (0.3)	2 (0.3)
心室細動	0 (0.0)	2 (0.6)	2 (0.3)
心房頻脈	0 (0.0)	1 (0.3)	1 (0.2)
徐脈性不整脈	1 (0.3)	0 (0.0)	1 (0.2)
心停止	0 (0.0)	1 (0.3)	1 (0.2)
心不快感	0 (0.0)	1 (0.3)	1 (0.2)
慢性心不全	0 (0.0)	1 (0.3)	1 (0.2)
心室内伝導障害	1 (0.3)	0 (0.0)	1 (0.2)
心房拡張	1 (0.3)	0 (0.0)	1 (0.2)
左房肥大	1 (0.3)	0 (0.0)	1 (0.2)
心筋虚血	0 (0.0)	1 (0.3)	1 (0.2)
洞房ブロック	1 (0.3)	0 (0.0)	1 (0.2)
洞性不整脈	1 (0.3)	0 (0.0)	1 (0.2)
洞結節機能不全	0 (0.0)	1 (0.3)	1 (0.2)
上室性頻脈	0 (0.0)	1 (0.3)	1 (0.2)
筋骨格系および結合組織障害	27 (8.3)	59 (18.2)	86 (13.3)
関節痛	8 (2.5)	22 (6.8)	30 (4.6)
筋痙縮	4 (1.2)	26 (8.0)	30 (4.6)
筋肉痛	6 (1.9)	7 (2.2)	13 (2.0)
四肢痛	3 (0.9)	8 (2.5)	11 (1.7)
関節腫脹	3 (0.9)	2 (0.6)	5 (0.8)
背部痛	0 (0.0)	2 (0.6)	2 (0.3)
骨痛	0 (0.0)	2 (0.6)	2 (0.3)
出血性関節症	2 (0.6)	0 (0.0)	2 (0.3)
筋肉内血腫	1 (0.3)	1 (0.3)	2 (0.3)
筋骨格痛	0 (0.0)	2 (0.6)	2 (0.3)
関節炎	0 (0.0)	1 (0.3)	1 (0.2)
鼡径部痛	1 (0.3)	0 (0.0)	1 (0.2)
筋骨格系胸痛	0 (0.0)	1 (0.3)	1 (0.2)
結節性変形性関節症	1 (0.3)	0 (0.0)	1 (0.2)
顎痛	1 (0.3)	0 (0.0)	1 (0.2)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
傷害、中毒および処置合併症	36 (11.1)	32 (9.9)	68 (10.5)
挫傷	29 (9.0)	25 (7.7)	54 (8.3)
皮下血腫	2 (0.6)	3 (0.9)	5 (0.8)
処置後出血	0 (0.0)	3 (0.9)	3 (0.5)
皮膚裂傷	2 (0.6)	0 (0.0)	2 (0.3)
動物による引っかき傷	0 (0.0)	1 (0.3)	1 (0.2)
節足動物咬傷	1 (0.3)	0 (0.0)	1 (0.2)
転倒	1 (0.3)	0 (0.0)	1 (0.2)
四肢損傷	0 (0.0)	1 (0.3)	1 (0.2)
眼窩周囲出血	1 (0.3)	0 (0.0)	1 (0.2)
処置後挫傷	0 (0.0)	1 (0.3)	1 (0.2)
創傷	1 (0.3)	0 (0.0)	1 (0.2)
一般・全身障害および投与部位の状態	23 (7.1)	40 (12.3)	63 (9.7)
疲労	10 (3.1)	15 (4.6)	25 (3.9)
発熱	5 (1.5)	6 (1.9)	11 (1.7)
末梢性浮腫	1 (0.3)	9 (2.8)	10 (1.5)
無力症	4 (1.2)	4 (1.2)	8 (1.2)
末梢腫脹	4 (1.2)	4 (1.2)	8 (1.2)
インフルエンザ様疾患	1 (0.3)	2 (0.6)	3 (0.5)
限局性浮腫	0 (0.0)	2 (0.6)	2 (0.3)
薬剤離脱症候群	0 (0.0)	1 (0.3)	1 (0.2)
顔面浮腫	1 (0.3)	0 (0.0)	1 (0.2)
倦怠感	0 (0.0)	1 (0.3)	1 (0.2)
疼痛	0 (0.0)	1 (0.3)	1 (0.2)
軟部組織の炎症	0 (0.0)	1 (0.3)	1 (0.2)
顔面腫脹	0 (0.0)	1 (0.3)	1 (0.2)
神経系障害	25 (7.7)	36 (11.1)	61 (9.4)
頭痛	6 (1.9)	13 (4.0)	19 (2.9)
浮動性めまい	8 (2.5)	9 (2.8)	17 (2.6)
末梢性感覚ニューロパチー	0 (0.0)	5 (1.5)	5 (0.8)
嗜眠	2 (0.6)	1 (0.3)	3 (0.5)
錯感覚	0 (0.0)	3 (0.9)	3 (0.5)
ヘルペス後神経痛	3 (0.9)	0 (0.0)	3 (0.5)
感覚鈍麻	0 (0.0)	2 (0.6)	2 (0.3)
傾眠	1 (0.3)	1 (0.3)	2 (0.3)
失神	1 (0.3)	1 (0.3)	2 (0.3)
味覚障害	1 (0.3)	1 (0.3)	2 (0.3)
脳梗塞	0 (0.0)	1 (0.3)	1 (0.2)
脳血管障害	1 (0.3)	0 (0.0)	1 (0.2)
味覚不全	0 (0.0)	1 (0.3)	1 (0.2)
てんかん	0 (0.0)	1 (0.3)	1 (0.2)
顔面痙攣	0 (0.0)	1 (0.3)	1 (0.2)
肋間神経痛	0 (0.0)	1 (0.3)	1 (0.2)
不随意性筋収縮	1 (0.3)	0 (0.0)	1 (0.2)
嗅覚錯誤	1 (0.3)	0 (0.0)	1 (0.2)
精神運動亢進	0 (0.0)	1 (0.3)	1 (0.2)
代謝および栄養障害	27 (8.3)	29 (9.0)	56 (8.6)
高尿酸血症	7 (2.2)	10 (3.1)	17 (2.6)
低カリウム血症	5 (1.5)	6 (1.9)	11 (1.7)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
食欲減退	4 (1.2)	6 (1.9)	10 (1.5)
低マグネシウム血症	1 (0.3)	4 (1.2)	5 (0.8)
高カリウム血症	3 (0.9)	1 (0.3)	4 (0.6)
痛風	1 (0.3)	2 (0.6)	3 (0.5)
低ナトリウム血症	1 (0.3)	2 (0.6)	3 (0.5)
高コレステロール血症	1 (0.3)	1 (0.3)	2 (0.3)
高血糖	2 (0.6)	0 (0.0)	2 (0.3)
低アルブミン血症	1 (0.3)	1 (0.3)	2 (0.3)
低カルシウム血症	2 (0.6)	0 (0.0)	2 (0.3)
マグネシウム欠乏	0 (0.0)	2 (0.6)	2 (0.3)
異常体重減少	0 (0.0)	1 (0.3)	1 (0.2)
脱水	1 (0.3)	0 (0.0)	1 (0.2)
糖尿病	1 (0.3)	0 (0.0)	1 (0.2)
コントロール不良の糖尿病	1 (0.3)	0 (0.0)	1 (0.2)
耐糖能障害	0 (0.0)	1 (0.3)	1 (0.2)
高リン血症	1 (0.3)	0 (0.0)	1 (0.2)
低リン血症	0 (0.0)	1 (0.3)	1 (0.2)
鉄欠乏	1 (0.3)	0 (0.0)	1 (0.2)
代謝性アシドーシス	1 (0.3)	0 (0.0)	1 (0.2)
腫瘍崩壊症候群	1 (0.3)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害	19 (5.9)	36 (11.1)	55 (8.5)
鼻出血	13 (4.0)	15 (4.6)	28 (4.3)
湿性咳嗽	1 (0.3)	4 (1.2)	5 (0.8)
咳嗽	2 (0.6)	2 (0.6)	4 (0.6)
喀血	1 (0.3)	3 (0.9)	4 (0.6)
労作性呼吸困難	1 (0.3)	1 (0.3)	2 (0.3)
肺浸潤	0 (0.0)	2 (0.6)	2 (0.3)
口腔咽頭痛	0 (0.0)	2 (0.6)	2 (0.3)
肺腫瘤	0 (0.0)	2 (0.6)	2 (0.3)
急性呼吸不全	0 (0.0)	1 (0.3)	1 (0.2)
慢性閉塞性肺疾患	0 (0.0)	1 (0.3)	1 (0.2)
呼吸困難	0 (0.0)	1 (0.3)	1 (0.2)
血胸	0 (0.0)	1 (0.3)	1 (0.2)
鼻痂皮	1 (0.3)	0 (0.0)	1 (0.2)
鼻部障害	1 (0.3)	0 (0.0)	1 (0.2)
咽頭出血	0 (0.0)	1 (0.3)	1 (0.2)
肺臓炎	0 (0.0)	1 (0.3)	1 (0.2)
上気道咳症候群	0 (0.0)	1 (0.3)	1 (0.2)
腎および尿路障害	11 (3.4)	13 (4.0)	24 (3.7)
血尿	8 (2.5)	9 (2.8)	17 (2.6)
蛋白尿	2 (0.6)	1 (0.3)	3 (0.5)
腎不全	1 (0.3)	1 (0.3)	2 (0.3)
急性腎障害	1 (0.3)	0 (0.0)	1 (0.2)
排尿困難	1 (0.3)	0 (0.0)	1 (0.2)
腎嚢胞	0 (0.0)	1 (0.3)	1 (0.2)
腎機能障害	0 (0.0)	1 (0.3)	1 (0.2)
腎腫瘤	0 (0.0)	1 (0.3)	1 (0.2)
尿失禁	1 (0.3)	0 (0.0)	1 (0.2)
眼障害	15 (4.6)	7 (2.2)	22 (3.4)
結膜出血	3 (0.9)	2 (0.6)	5 (0.8)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
視力障害	1 (0.3)	2 (0.6)	3 (0.5)
眼出血	1 (0.3)	1 (0.3)	2 (0.3)
脈絡膜滲出	1 (0.3)	0 (0.0)	1 (0.2)
アレルギー性結膜炎	1 (0.3)	0 (0.0)	1 (0.2)
後天性涙道狭窄	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼紅斑	1 (0.3)	0 (0.0)	1 (0.2)
眼血腫	1 (0.3)	0 (0.0)	1 (0.2)
眼の炎症	0 (0.0)	1 (0.3)	1 (0.2)
眼瞼出血	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼浮腫	1 (0.3)	0 (0.0)	1 (0.2)
眼瞼発疹	1 (0.3)	0 (0.0)	1 (0.2)
網膜出血	1 (0.3)	0 (0.0)	1 (0.2)
強膜出血	1 (0.3)	0 (0.0)	1 (0.2)
霧視	1 (0.3)	0 (0.0)	1 (0.2)
硝子体障害	1 (0.3)	0 (0.0)	1 (0.2)
硝子体出血	0 (0.0)	1 (0.3)	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5 (1.5)	10 (3.1)	15 (2.3)
皮膚有棘細胞癌	2 (0.6)	5 (1.5)	7 (1.1)
基底細胞癌	1 (0.3)	1 (0.3)	2 (0.3)
ボーエン病	0 (0.0)	1 (0.3)	1 (0.2)
脳新生物	0 (0.0)	1 (0.3)	1 (0.2)
癌疼痛	0 (0.0)	1 (0.3)	1 (0.2)
結腸癌	0 (0.0)	1 (0.3)	1 (0.2)
乳管内増殖性病変	1 (0.3)	0 (0.0)	1 (0.2)
口唇扁平上皮癌	0 (0.0)	1 (0.3)	1 (0.2)
肺腺癌	0 (0.0)	1 (0.3)	1 (0.2)
唾液腺粘液性類表皮癌	0 (0.0)	1 (0.3)	1 (0.2)
脂漏性角化症	1 (0.3)	0 (0.0)	1 (0.2)
皮膚乳頭腫	1 (0.3)	0 (0.0)	1 (0.2)
遠隔転移を伴う皮膚有棘細胞癌	0 (0.0)	1 (0.3)	1 (0.2)
表在拡大型黒色腫第2期	0 (0.0)	1 (0.3)	1 (0.2)
肝胆道系障害	5 (1.5)	6 (1.9)	11 (1.7)
高ビリルビン血症	2 (0.6)	2 (0.6)	4 (0.6)
肝機能異常	1 (0.3)	1 (0.3)	2 (0.3)
脂肪肝	1 (0.3)	0 (0.0)	1 (0.2)
肝毒性	0 (0.0)	1 (0.3)	1 (0.2)
高トランスアミナーゼ血症	0 (0.0)	1 (0.3)	1 (0.2)
肝損傷	1 (0.3)	0 (0.0)	1 (0.2)
門脈圧亢進症	0 (0.0)	1 (0.3)	1 (0.2)
生殖系および乳房障害	4 (1.2)	2 (0.6)	6 (0.9)
乳房痛	1 (0.3)	0 (0.0)	1 (0.2)
勃起不全	1 (0.3)	0 (0.0)	1 (0.2)
乳頭浮腫	0 (0.0)	1 (0.3)	1 (0.2)
陰茎血腫	1 (0.3)	0 (0.0)	1 (0.2)
前立腺炎	0 (0.0)	1 (0.3)	1 (0.2)
腟出血	1 (0.3)	0 (0.0)	1 (0.2)
免疫系障害	4 (1.2)	1 (0.3)	5 (0.8)
低γグロブリン血症	3 (0.9)	0 (0.0)	3 (0.5)

System Organ Class Preferred Term	Zanubrutinib (N = 324) n (%)	Ibrutinib (N = 324) n (%)	Total (N = 648) n (%)
薬物過敏症	1 (0.3)	0 (0.0)	1 (0.2)
続発性免疫不全症	0 (0.0)	1 (0.3)	1 (0.2)
精神障害	3 (0.9)	2 (0.6)	5 (0.8)
不眠症	1 (0.3)	1 (0.3)	2 (0.3)
激越	1 (0.3)	0 (0.0)	1 (0.2)
錯乱状態	0 (0.0)	1 (0.3)	1 (0.2)
神経症	1 (0.3)	0 (0.0)	1 (0.2)
耳および迷路障害	2 (0.6)	2 (0.6)	4 (0.6)
耳出血	1 (0.3)	0 (0.0)	1 (0.2)
耳痛	0 (0.0)	1 (0.3)	1 (0.2)
鼓室内出血	0 (0.0)	1 (0.3)	1 (0.2)
回転性めまい	1 (0.3)	0 (0.0)	1 (0.2)
先天性、家族性および遺伝性障害	0 (0.0)	1 (0.3)	1 (0.2)
汗孔角化症	0 (0.0)	1 (0.3)	1 (0.2)

Source: Table 14.3.1.2.2.6 in BGB-3111-305 clinical study report (data cutoff date: 08 August 2022). Data cutoff: 08AUG2022. Data extraction: [redacted] 20[redacted].
Abbreviation: TEAE, treatment-emergent adverse event.
TEAE is defined as an AE that has an onset date on or after the first dose of study drug up to 30 days after the last dose of study drug or the day prior to initiation of a new CLL/SLL therapy, whichever occurs first. If a TEAE worsens to Grade 5 more than 30 days after last dose of study drug and prior to initiation of a new CLL/SLL therapy, the Grade 5 AE will be treatment-emergent.
Notes: Adverse events were classified based on MedDRA Version 24.0.
Patients with multiple events for a given Preferred Term and System Organ Class were counted only once for each Preferred Term and System Organ Class, respectively.
Events were sorted by decreasing frequency of System Organ Class and Preferred Term in the Total group.

表 57： 重篤な有害事象の一覧（BGB-3111-305 試験、安全性解析対象集団）

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (422)/ [redacted]20[redacted] (423)	一般・全身障害および投与部位の状態/ 非心臓性胸痛/ NON-CARDIAC CHEST PAIN	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (427)/ [redacted]20[redacted] (428)	一般・全身障害および投与部位の状態/ 非心臓性胸痛/ NON-CARDIAC CHEST PAIN	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (90)/ [redacted]20[redacted] (93)	筋骨格系および結合組織障害/ 四肢痛/ LEFT LEG PAIN	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (156)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 再発悪性胸腺腫/ LEFT LUNG MASS RECURENCE (METASTATIC RECURRENT THYMOMA)	Yes/ 2/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (1118)/ [redacted]20[redacted] (1132)	肝胆道系障害/ 胆嚢炎/ CHOLECYSTITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (883)/ [redacted]20[redacted] (1122)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATE ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (153)/ [redacted]20[redacted] (154)	神経系障害/ 脳血管発作/ CEREBROVASCULAR ACCIDENT (CVA)	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (735)/ [redacted]20[redacted] (765)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性黒色腫/ MALIGNANT MELANOMA, LEFT INFRACLAVICULAR CHEST	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (260)/ [redacted]20[redacted] (273)	血液およびリンパ系障害/ 脾臓出血/ SPLENIC HEMORRHAGE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (260)/ [redacted]20[redacted] (273)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ HYPOXIC RESPIRATORY FAILURE	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (262)/ [redacted]20[redacted] (263)	心臓障害/ 心房細動/ ATRIAL FIBRILLATION	Yes/ 3/ RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (857)/ [redacted]20[redacted] (857)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 移行上皮癌/ PAPILLARY UROTHELIAL CARCINOMA, LOW-GRADE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (861)/ [redacted]20[redacted] (866)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (684)/ [redacted]20[redacted] (731)	傷害、中毒および処置合併症/ 外傷性肝損傷/ HEPATIC LACERATION	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (296)/ [redacted]20[redacted] (346)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ BASAL CELL CARCINOMA, LEFT FOREHEAD	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (56)/ [redacted]20[redacted] (75)	感染症および寄生虫症/ インフルエンザ/ INFECTION, INFLUENZA A	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (56)/ [redacted]20[redacted] (75)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 5/ FATAL
	Yes	[redacted]20[redacted] (75)/ [redacted]20[redacted] (75)	感染症および寄生虫症/ インフルエンザ/ INFECTION, INFLUENZA A	Yes/ 5/ RELATED	DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (75)/ [redacted]20[redacted] (75)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 5/ FATAL
[redacted]	Yes	[redacted]20[redacted] (382)/ [redacted]20[redacted] (382)	心臓障害/ 心停止/ CARDIAC ARREST	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (382)/ [redacted]20[redacted] (386)	心臓障害/ 心室細動/ VENTRICULAR FIBRILLATION	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (749)/ [redacted]20[redacted] (764)	感染症および寄生虫症/ 虫垂炎/ APPENDICITIS WITHOUT PERFORATION	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (183)/ [redacted]20[redacted] (185)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (266)/ [redacted]20[redacted] (269)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (54)/ [redacted]20[redacted] (58)	傷害、中毒および処置合併症/ 硬膜下血腫/ SUBDURAL HEMATOMA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 1/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-11)/ [redacted]20[redacted] (-9)	血液およびリンパ系障害/ 発熱性好中球減少症/ FEBRILE NEUTROPENIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (29)/ [redacted]20[redacted] (33)	血液およびリンパ系障害/ 溶血性貧血/ HEMOLYTIC ANEMIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (52)/ [redacted]20[redacted] (57)	感染症および寄生虫症/ 憩室炎/ DIVERTICULITIS	Yes/ 3/ RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (52)/ [redacted]20[redacted] (155)	感染症および寄生虫症/ 気管支肺アスペルギルス症/ INVASIVE PULMONARY ASPERGILLOSIS	Yes/ 3/ RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (5)/ [redacted] 20[redacted] (10)	代謝および栄養障害/ 腫瘍崩壊症候群/ TUMOR LYSIS SYNDROME	Yes/ 4/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (8)/ [redacted] 20[redacted] (10)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (20)/ [redacted] 20[redacted] (23)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (242)/ [redacted] 20[redacted] (245)	感染症および寄生虫症/ 大腸菌性菌血症/ INFECTION (E. COLI BACTEREMIA)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (82)/ [redacted] 20[redacted] (115)	神経系障害/ 脳血管発作/ STROKE	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (82)/ [redacted] 20[redacted] (303)	血管障害/ 高血圧/ WORSENED HYPERTENSION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (445)/ [redacted] 20[redacted] (1022)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ SECONDARY CANCER - NON-SMALL CELL LUNG CANCER - ADENOCARCINOMA	Yes/ 3/ RELATED	NOT APPLICABLE/ 2;3/ FATAL
	No	[redacted] 20[redacted] (1023)/ [redacted] 20[redacted] (1027)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ SECONDARY CANCER - NON-SMALL CELL LUNG CANCER - ADENOCARCINOMA	Yes/ 4/ RELATED	NOT APPLICABLE/ 2;3/ FATAL
	No	[redacted] 20[redacted] (1028)/ [redacted] 20[redacted] (1028)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ SECONDARY CANCER - NON-SMALL CELL LUNG CANCER - ADENOCARCINOMA	Yes/ 5/ RELATED	NOT APPLICABLE/ 2;3/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (97)/ [redacted] 20[redacted] (111)	感染症および寄生虫症/ RSウイルス肺炎/ RSV PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (267)/ [redacted] 20[redacted] (270)	感染症および寄生虫症/ 肺炎球菌性肺炎/ BILATERAL PNEUMONIA (STREPTOCOCCUS PNEUMONIAE)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (267)/ [redacted] 20[redacted] (279)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (7)/ [redacted] 20[redacted] (10)	呼吸器、胸郭および縦隔障害/ 胸水/ SHORTNESS OF BREATH (RELATED TO RIGHT PLEURAL EFFUSION, RELATED TO CLL)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (66)/ [redacted] 20[redacted] (66)	心臓障害/ 心停止/ CARDIAC ARREST	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	No	[redacted] 20[redacted] (524)/ [redacted] 20[redacted] (524)	一般・全身障害および投与部位の状態/ 死亡/ DEATH	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (224)/ [redacted] 20[redacted] (224)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 嫌色素性腎細胞癌/ CHROMOPHOBE RCC (LOWER POLE RIGHT KIDNEY)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (1136)/ [redacted]20[redacted] (1138)	感染症および寄生虫症/ COVID-19/ COVID - 19 INFECTION	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
	Yes	[redacted]20[redacted] (1138)/ [redacted]20[redacted] (1138)	感染症および寄生虫症/ COVID-19/ COVID - 19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (182)/ [redacted]20[redacted] (185)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (566)/ [redacted]20[redacted] (582)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸癌/ COLON CANCER NEW PRIMARY	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (867)/ [redacted]20[redacted] (1040)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う結腸癌/ LIVER METASTASIS OF COLON CANCER-RECURRENCE	Yes/ 2/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (913)/ [redacted]20[redacted] (915)	胃腸障害/ 下痢/ DIARRHEA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ NOT RECOVERED/NOT RESOLVED
	No	[redacted]20[redacted] (1040)/ [redacted]20[redacted] (1040)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (246)/ [redacted]20[redacted] (248)	胃腸障害/ 小腸閉塞/ PARTIAL SMALL BOWEL OBSTRUCTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (265)/ [redacted]20[redacted] (265)	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ MULTI-ORGAN FAILURE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (946)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATE CANCER PROGRESSION	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (112)/ [redacted]20[redacted] (113)	神経系障害/ 頚動脈閉塞/ RT CAROTID ARTERY BLOCK	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (594)/ [redacted]20[redacted] (637)	血管障害/ 血腫/ HEMATOMA RIGHT LOWER LEG	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (754)/ [redacted]20[redacted] (755)	傷害、中毒および処置合併症/ 硬膜下血腫/ LARGE LEFT SUBDURAL HEMATOMA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (154)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 浸潤性乳管癌/ INVASIVE DUCTAL CARCINOMA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (286)/ [redacted]20[redacted] (292)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
	Yes	[redacted]20[redacted] (286)/ [redacted]20[redacted] (293)	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ ACUTE RESPIRATORY FAILURE	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (293)/ [redacted]20[redacted] (293)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
[redacted]	No	[redacted]20[redacted] (-10)/ [redacted]20[redacted] (2)	血液およびリンパ系障害/ 自己免疫性溶血性貧血/ WORSENING AUTOIMMUNE HEMOLYTIC ANEMIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (895)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腎明細胞癌/ CLEAR CELL CARCINOMA OF LEFT KIDNEY	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (617)/ [redacted]20[redacted] (653)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳癌/ NEOPLASM, MALIGNANT-OTHER, BREAST	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (697)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ NEOPLASM, LUNG ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERING/RESOLVING

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (889)/ [redacted]20[redacted] (894)	感染症および寄生虫症/ レンサ球菌性菌血症/ INFECTIONS AND INFESTATIONS - OTHER, BACTEREMIA-STREPTOCOCCUS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (384)/ [redacted]20[redacted] (408)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA R/T COVID-19	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (272)/ [redacted]20[redacted] (279)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (730)/ [redacted]20[redacted] (731)	神経系障害/ 一過性脳虚血発作/ TRANSIENT ISCHEMIC ATTACK	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (852)/ [redacted]20[redacted] (853)	神経系障害/ 失神/ SYNCOPE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (21)/ [redacted]20[redacted] (26)	感染症および寄生虫症/ ブドウ球菌性菌血症/ STAPH AUREUS BACTEREMIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (727)/ [redacted]20[redacted] (729)	感染症および寄生虫症/ 蜂巣炎/ CELLULITIS RIGHT LOWER EXTREMITY	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted]20[redacted] (-45)/ [redacted]20[redacted] (-42)	感染症および寄生虫症/ 蜂巣炎/ CELLULITIS OF RIGHT HAND	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (503)/ [redacted]20[redacted] (505)	腎および尿路障害/ 血尿/ HEMATURIA	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (590)/ [redacted]20[redacted] (593)	感染症および寄生虫症/ COVID-19肺炎/ COVID 19 PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (25)/ [redacted]20[redacted] (30)	血管障害/ 末梢動脈血栓症/ ARTERIAL THROMBOSIS OF THE RIGHT TOE	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (588)/ [redacted]20[redacted] (605)	感染症および寄生虫症/ COVID-19肺炎/ COVID PNEUMONIA	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (770)/ [redacted]20[redacted] (804)	感染症および寄生虫症/ COVID-19/ COVID 19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (93)/ [redacted] 20[redacted] (113)	血液およびリンパ系障害/ リンパ節症/ LEFT AXILLARY LYMPHADENOPATHY	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (175)/ [redacted] 20[redacted] (175)	血液およびリンパ系障害/ リンパ節症/ LEFT AXILLARY LYMPHADENOPATHY	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (315)/ [redacted] 20[redacted] (317)	感染症および寄生虫症/ 大腸菌性尿路感染/ E. COLI (UTI)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (318)/ [redacted] 20[redacted] (319)	心臓障害/ 心房細動/ ATRIAL FIBRILLATION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (449)/ [redacted] 20[redacted] (512)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ BASAL CELL CARCINOMA NOSE LEFT SIDE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (511)/ [redacted] 20[redacted] (513)	血液およびリンパ系障害/ 脾臓梗塞/ SPLEEN INFARCTION	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (667)/ [redacted] 20[redacted] (674)	感染症および寄生虫症/ 肺炎/ IDIOPATHIC PNEUMONIA	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (792)/ [redacted] 20[redacted] (803)	筋骨格系および結合組織障害/ 筋肉内血腫/ PSOAS HEMATOMA	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted]20[redacted] (807)/ [redacted]20[redacted] (808)	傷害、中毒および処置合併症/ 注入に伴う反応/ INFUSION RELATED REACTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (837)/ [redacted]20[redacted] (849)	感染症および寄生虫症/ 肺炎/ PNEUMONIA (ETIOLOGY UNKNOWN)	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
	No	[redacted]20[redacted] (849)/ [redacted]20[redacted] (849)	感染症および寄生虫症/ 肺炎/ PNEUMONIA (ETIOLOGY UNKNOWN)	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (988)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ RECURRENT BASAL CELL CARCINOMA (FRONTAL RIGHT FACE)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (988)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ RECURRENT BASAL CELL CARCINOMA (TEMPORAL LEFT)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (17)/ [redacted]20[redacted] (29)	筋骨格系および結合組織障害/ 出血性関節症/ HEMATOMA IN RIGHT KNEE	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (244)/ [redacted]20[redacted] (253)	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (189)/ [redacted] 20[redacted] (189)	一般・全身障害および投与部位の状態/ 死亡/ DEATH (UNDERLYING EVENT UNKNOWN)	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (863)/ [redacted] 20[redacted] (866)	胃腸障害/ 食道食物嵌入/ FOOD IMPACTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (253)/ [redacted] 20[redacted] (291)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ EPIDERMOID CARCINOMA OF SKIN ON RIGHT TEMPLE	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (267)/ [redacted] 20[redacted] (281)	腎および尿路障害/ 腎不全/ WORSENING OF RENAL INSUFFICIENCY	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted] 20[redacted] (327)/ [redacted] 20[redacted] (341)	腎および尿路障害/ 腎不全/ WORSENING OF RENAL INSUFFICIENCY	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (236)/ [redacted] 20[redacted] (364)	心臓障害/ 心不全/ CARDIAC HEART FAILURE	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (163)/ [redacted]20[redacted] (169)	一般・全身障害および投与部位の状態/ 発熱/ FEVER - NO FURTHER INFORMATION	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (34)/ [redacted]20[redacted] (36)	心臓障害/ 心房粗動/ WORSENING ATRIAL FLUTTER	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (236)/ [redacted]20[redacted] (236)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ RIGHT FOREHEAD INFILTRANT EPIDERMOID CARCINOMA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (236)/ [redacted]20[redacted] (236)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ RIGHT TEMPORAL INFILTRANT EPIDERMOID CARCINOMA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (236)/ [redacted]20[redacted] (328)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 神経内分泌癌/ SECOND MALIGNANCY NEURO-ENDOCRIN TUMOR - LEFT CERVICAL	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (329)/ [redacted]20[redacted] (329)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 神経内分泌癌/ SECOND MALIGNANCY NEURO-ENDOCRIN TUMOR - LEFT CERVICAL	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (665)/ [redacted]20[redacted] (816)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 胃腸管腺腫/ ANAL TUBULOVILLOUS ADENOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (1116)/ [redacted]20[redacted] (1116)	心臓障害/ 心停止/ CARDIAC ARREST	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (658)/ [redacted]20[redacted] (664)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA COVID19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (134)/ [redacted]20[redacted] (141)	血液およびリンパ系障害/ 脾血腫/ SPLENIC HEMATOMA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-9)/ [redacted]20[redacted] (1)	感染症および寄生虫症/ 口腔ヘルペス/ HERPES SIMPLEX IN THE LOWER LIP	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (654)/ [redacted]20[redacted] (658)	筋骨格系および結合組織障害/ 背部痛/ LUMBAR PAIN	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (794)/ [redacted]20[redacted] (801)	腎および尿路障害/ 急性腎障害/ ACUTE RENAL FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (1002)/ [redacted]20[redacted] (1003)	胃腸障害/ 下痢/ DIARRHEA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (1002)/ [redacted]20[redacted] (1003)	腎および尿路障害/ 急性腎障害/ ACUTE RENAL FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (118)/ [redacted]20[redacted] (119)	呼吸器、胸郭および縦隔障害/ 胸水/ PLEURAL EFFUSION	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (355)/ [redacted]20[redacted] (355)	腎および尿路障害/ 急性腎障害/ ACUTE RENAL FAILURE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (477)/ [redacted]20[redacted] (479)	神経系障害/ 痙攣発作/ CONVULSIONS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (550)/ [redacted]20[redacted] (568)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (504)/ [redacted] 20[redacted] (521)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (449)/ [redacted] 20[redacted] (462)	感染症および寄生虫症/ 帯状疱疹/ HERPES ZOSTER IN LEFT HEMITHORAX	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (716)/ [redacted] 20[redacted] (823)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 直腸癌/ NEW PRIMARY CANCER, RECTUM CANCER	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (150)/ [redacted] 20[redacted] (150)	感染症および寄生虫症/ 肛門膿瘍/ PERIANAL ABSCESS (PATHOGEN UNKNOWN	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (150)/ [redacted] 20[redacted] (207)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (-14)/ [redacted] 20[redacted] (9)	一般・全身障害および投与部位の状態/ 発熱/ FEVER OF UNKNOWN ORIGIN	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (916)/ [redacted] 20[redacted] (918)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (1009)/ [redacted]20[redacted] (1018)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (611)/ [redacted]20[redacted] (622)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (623)/ [redacted]20[redacted] (623)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (406)/ [redacted]20[redacted] (434)	感染症および寄生虫症/ 皮膚細菌感染/ BACTERIAL SKIN AND SOFT TISSUE INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (733)/ [redacted]20[redacted] (773)	感染症および寄生虫症/ 肺炎/ PNEUMONIA (UNKNOWN PATHOGEN).	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (757)/ [redacted]20[redacted] (772)	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ MULTI-ORGAN FAILURE	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	No	[redacted]20[redacted] (773)/ [redacted]20[redacted] (773)	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ MULTI-ORGAN FAILURE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (386)/ [redacted]20[redacted] (393)	心臓障害/ 心房細動/ ATRIAL FIBRILLATION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (38)/ [redacted]20[redacted] (49)	感染症および寄生虫症/ 真菌性肺炎/ FUNGAL PNEUMONIA	Yes/ 2/ NOT RELATED	DRUG WITHDRAWN/ 2;5/ FATAL
	Yes	[redacted]20[redacted] (49)/ [redacted]20[redacted] (49)	感染症および寄生虫症/ 真菌性肺炎/ FUNGAL PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;5/ FATAL
[redacted]	Yes	[redacted]20[redacted] (267)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺腺癌/ LUNG ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (340)/ [redacted]20[redacted] (357)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 神経内分泌癌/ HEPATIC LOCALIZATION OF POORLY DIFFERENTIATED NEUROENDOCRINE CARCINOMA (NEC G3)	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted]20[redacted] (358)/ [redacted]20[redacted] (358)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 神経内分泌癌/ HEPATIC LOCALIZATION OF POORLY DIFFERENTIATED NEUROENDOCRINE CARCINOMA (NEC G3)	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (332)/ [redacted]20[redacted] (344)	傷害、中毒および処置合併症/ 大腿骨骨折/ FEMUR FRACTURE (LEFT)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (301)/ [redacted] 20[redacted] (304)	傷害、中毒および処置合併症/ 鎖骨骨折/ CLAVICLE FRACTURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (301)/ [redacted] 20[redacted] (304)	傷害、中毒および処置合併症/ 肋骨骨折/ RIBS FRACTURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (301)/ [redacted] 20[redacted] (304)	傷害、中毒および処置合併症/ 交通事故/ ROAD TRAFFIC ACCIDENT	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (301)/ [redacted] 20[redacted] (304)	傷害、中毒および処置合併症/ 肩甲骨骨折/ ACROMION FRACTURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted] 20[redacted] (472)/ [redacted] 20[redacted] (594)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳管内増殖性病変/ DUCTAL BREAST ADENOCARCINOMA IN SITU WITH HIGH GRADE DYSPLASIA	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (45)/ [redacted] 20[redacted] (57)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (245)/ [redacted]20[redacted] (252)	一般・全身障害および投与部位の状態/ 疲労/ FATIGUE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (245)/ [redacted]20[redacted] (252)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-3)/ [redacted]20[redacted] (-1)	感染症および寄生虫症/ 敗血症/ INFECTIONS AND INFESTATIONS- OTHER, BLOOD INFECTION OF UNKNOWN CAUSE	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (6)/ [redacted]20[redacted] (21)	筋骨格系および結合組織障害/ 出血性関節症/ HAEMARTHROSIS R KNEE	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (917)/ [redacted]20[redacted] (921)	感染症および寄生虫症/ COVID-19/ COVID 19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (929)/ [redacted]20[redacted] (942)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (942)/ [redacted]20[redacted] (944)	呼吸器、胸郭および縦隔障害/ 低酸素症/ HYPOXIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (271)/ [redacted]20[redacted] (273)	胃腸障害/ 便秘/ CONSTIPATION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (314)/ [redacted]20[redacted] (320)	感染症および寄生虫症/ カンピロバクター胃腸炎/ DIARRHOEA CAMPYLOBACTER POSITIVE	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (494)/ [redacted]20[redacted] (521)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (228)/ [redacted]20[redacted] (506)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸直腸癌/ COLORECTAL CANCER	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (279)/ [redacted]20[redacted] (286)	胃腸障害/ 膵炎/ PANCREATITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (279)/ [redacted]20[redacted] (387)	肝胆道系障害/ 胆石症/ GALLSTONES	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (350)/ [redacted]20[redacted] (352)	胃腸障害/ 閉塞性膵炎/ RECURRANCE OF GALLSTONE PANCREATITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (810)/ [redacted]20[redacted] (814)	感染症および寄生虫症/ COVID-19/ COVID19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (1028)/ [redacted] 20[redacted] (1046)	感染症および寄生虫症/ COVID-19/ UPPER RESPIRATORY INFECTION (COVID-19)	Yes/ 3/ RELATED	DRUG WITHDRAWN/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (73)/ [redacted] 20[redacted] (80)	神経系障害/ 失神/ SYNCOPE	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (160)/ [redacted] 20[redacted] (171)	一般・全身障害および投与部位の状態/ 倦怠感/ GENERAL DISORDERS OTHER: GENERALLY UNWELL	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted] 20[redacted] (171)/ [redacted] 20[redacted] (171)	一般・全身障害および投与部位の状態/ 倦怠感/ GENERAL DISORDERS OTHER: GENERALLY UNWELL	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (812)/ [redacted] 20[redacted] (822)	呼吸器、胸郭および縦隔障害/ 胸水/ WORSENING BILATERAL PLEURAL EFFUSION	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (350)/ [redacted] 20[redacted] (360)	感染症および寄生虫症/ 肺炎/ PNEUMONIA (RIGHT LUNG)	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (379)/ [redacted] 20[redacted] (489)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 骨髄異形成症候群/ MYELODYSPLASTIC SYNDROME	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted] 20[redacted] (467)/ [redacted] 20[redacted] (477)	呼吸器、胸郭および縦隔障害/ 慢性閉塞性肺疾患/ EXACERBATION OF COPD	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (489)/ [redacted] 20[redacted] (489)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 骨髄異形成症候群/ MYELODYSPLASTIC SYNDROME	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (589)/ [redacted] 20[redacted] (631)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 口唇扁平上皮癌/ SKIN AND SUBCUTANEOUS TISSUE DISORDERS - SKIN LESION - RIGHT LOWER LIP: SQUAMOUS CELL CARCINOMA	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (632)/ [redacted] 20[redacted] (632)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 口唇扁平上皮癌/ SKIN AND SUBCUTANEOUS TISSUE DISORDERS - SKIN LESION - RIGHT LOWER LIP: SQUAMOUS CELL CARCINOMA	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (673)/ [redacted] 20[redacted] (694)	傷害、中毒および処置合併症/ 転倒/ FALL	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;5/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (580)/ [redacted] 20[redacted] (585)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (238)/ [redacted] 20[redacted] (244)	眼障害/ 後天性涙道狭窄/ LACRIMAL DUCT BLOCKAGE	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERING/RESOLVING
	Yes	[redacted] 20[redacted] (241)/ [redacted] 20[redacted] (660)	感染症および寄生虫症/ 涙嚢炎/ INTERMITTENT EYE INFECTION (INFECTION OF THE LACRIMAL SAC)	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (928)/ [redacted] 20[redacted] (929)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION (PATHOGEN UNKNOWN)	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (19)/ [redacted] 20[redacted] (21)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (19)/ [redacted] 20[redacted] (21)	感染症および寄生虫症/ ウイルス性胃炎/ VIRAL GASTRITIS	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (426)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う小細胞肺癌/ METASTATIC SMALL CELL LUNG CANCER	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (1038)/ [redacted]20[redacted] (1048)	感染症および寄生虫症/ COVID-19肺炎/ LUNG INFECTION (COVID 19)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (1002)/ [redacted]20[redacted] (1041)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (1041)/ [redacted]20[redacted] (1041)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	No	[redacted]20[redacted] (-14)/ [redacted]20[redacted] (-9)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (229)/ [redacted]20[redacted] (230)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (229)/ [redacted]20[redacted] (239)	筋骨格系および結合組織障害/ 椎間板圧迫/ LOW BACK PAIN DUE TO INTERVERTEBRAL DISC COMPRESSIONS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (617)/ [redacted]20[redacted] (623)	傷害、中毒および処置合併症/ 転倒/ FELL	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (944)/ [redacted]20[redacted] (945)	眼障害/ 眼窩周囲浮腫/ PERORBITAL EDEMA LEFT EYE	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 5/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-14)/ [redacted]20[redacted] (-4)	呼吸器、胸郭および縦隔障害/ 肺障害/ UNSPECIFIED LUNG DISEASE	Yes/ 1/ NOT RELATED	NOT APPLICABLE/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (301)/ [redacted]20[redacted] (302)	神経系障害/ 脳血管発作/ STROKE	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (435)/ [redacted]20[redacted] (442)	胃腸障害/ 大腸炎/ COLITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (435)/ [redacted]20[redacted] (442)	感染症および寄生虫症/ 尿路性敗血症/ UROSEPTICIMIA	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (670)/ [redacted]20[redacted] (673)	血液およびリンパ系障害/ 発熱性好中球減少症/ FEBRILE NEUTROPENIA	Yes/ 3/ RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (670)/ [redacted]20[redacted] (673)	胃腸障害/ 腸炎/ ENTEROCOLITIS	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (714)/ [redacted]20[redacted] (930)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 急性骨髄性白血病/ ACUTE MYELOID LEUKEMIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted] (931)/ [redacted] (931)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 急性骨髄性白血病/ ACUTE MYELOID LEUKEMIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] (542)/ [redacted] (565)	感染症および寄生虫症/ 虫垂炎/ APPENDICITIS	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] (542)/ [redacted] (565)	感染症および寄生虫症/ 細菌性敗血症/ SEPTICEMIA-E-COLI AND ENTEROCOCCUS FAECALIS	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] (5)/ [redacted] (7)	感染症および寄生虫症/ 処置後感染/ POST OP INFECTION ON THE FOREHEAD	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] (16)/ [redacted] (27)	血管障害/ 血腫/ RIGHT LOWER LEG HEMATOMA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] (56)/ [redacted] (67)	傷害、中毒および処置合併症/ 四肢損傷/ LEG WOUND	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] (403)/ [redacted] (408)	心臓障害/ 慢性心不全/ CHRONIC HEART FAILURE NYHA II	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERING/RESOLVING
	Yes	[redacted] (438)/ [redacted] (441)	心臓障害/ 心房細動/ PERSISTENT ATRIAL FIBRILLATION	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (451)/ [redacted]20[redacted] (452)	心臓障害/ 慢性心不全/ CHRONIC HEART FAILURE NYHA II	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERING/RESOLVING
	Yes	[redacted]20[redacted] (458)/ [redacted]20[redacted] (466)	呼吸器、胸郭および縦隔障害/ 血胸/ PLEURAL HEMATOMA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (1014)/ [redacted]20[redacted] (1022)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATIC CARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3;4;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (555)/ [redacted]20[redacted] (576)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA DUE TO SARS-COV-2 INFECTION	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (191)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 再発喉頭癌/ RECURRENT LARYNX CANCER	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (677)/ [redacted]20[redacted] (681)	心臓障害/ 心房細動/ PERSISTENT ATRIAL FIBRILLATION	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (389)/ [redacted]20[redacted] (389)	一般・全身障害および投与部位の状態/ 死亡/ DEATH WITH UNKNOWN REASON	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (956)/ [redacted] 20[redacted] (967)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (988)/ [redacted] 20[redacted] (988)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (85)/ [redacted] 20[redacted] (89)	血液およびリンパ系障害/ 失血性貧血/ HEMORRHAGIC ANEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (125)/ [redacted] 20[redacted] (152)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸癌/ COLONIC CACRINOMA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (29)/ [redacted] 20[redacted] (35)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (500)/ [redacted] 20[redacted] (500)	感染症および寄生虫症/ 気道感染/ RESPIRATORY TRACT INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (1)/ [redacted] 20[redacted] (4)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (983)/ [redacted]20[redacted] (998)	感染症および寄生虫症/ COVID-19肺炎/ BILATERAL PNEUMONIA IN THE COURSE OF COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (697)/ [redacted]20[redacted] (1037)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 唾液腺粘液性類表皮癌/ MUCOEPIDERMOID CARCINOMA (LEFT PAROTID)	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ UNKNOWN
	Yes	[redacted]20[redacted] (697)/ [redacted]20[redacted] (1037)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ CARCINOMA PLANOEPITHELIALE KERATODES (FOREHEAD)	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ UNKNOWN
	Yes	[redacted]20[redacted] (697)/ [redacted]20[redacted] (1037)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 表在拡大型黒色腫第2期/ SUPERFICIAL SPREADING MELANOMA GRADE II (RIGHT CHEEK)	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ UNKNOWN
	No	[redacted]20[redacted] (1037)/ [redacted]20[redacted] (1037)	一般・全身障害および投与部位の状態/ 死亡/ DEATH WITH UNKNOWN CAUSE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (95)/ [redacted] 20[redacted] (116)	感染症および寄生虫症/ 肺炎/ RIGHT-SIDED PNEUMONIA	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (452)/ [redacted] 20[redacted] (452)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;5/ FATAL
	Yes	[redacted] 20[redacted] (453)/ [redacted] 20[redacted] (453)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;5/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (589)/ [redacted] 20[redacted] (598)	感染症および寄生虫症/ 限局性感染/ INFECTION OF THE TOE (LEFT LEG)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (1094)/ [redacted] 20[redacted] (1094)	一般・全身障害および投与部位の状態/ 死亡/ DEATH WITH UNKNOWN CAUSE	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (366)/ [redacted] 20[redacted] (373)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (377)/ [redacted] 20[redacted] (381)	感染症および寄生虫症/ 胃腸炎/ ACUTE GASTROENTERITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (377)/ [redacted] 20[redacted] (381)	腎および尿路障害/ 慢性腎臓病/ CHRONIC KIDNEY DISEASE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (395)/ [redacted]20[redacted] (404)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (58)/ [redacted]20[redacted] (66)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFLECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (58)/ [redacted]20[redacted] (66)	腎および尿路障害/ 急性腎障害/ ACUTE PRERENAL RENAL FAILURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (20)/ [redacted]20[redacted] (25)	血液およびリンパ系障害/ 血小板減少症/ WORSENING OF THROMBOCYTOPENIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (819)/ [redacted]20[redacted] (827)	感染症および寄生虫症/ 蜂巣炎/ NECK PHLEGMON	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (963)/ [redacted]20[redacted] (963)	感染症および寄生虫症/ 肺炎/ UNILATERAL PNEUMONIA - ETIOLOGY UNKNOWN	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (963)/ [redacted]20[redacted] (963)	呼吸器、胸郭および縦隔障害/ 肺水腫/ PULMONARY EDEMA WITH FATAL OUTCOME	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (500)/ [redacted]20[redacted] (508)	眼障害/ 角膜炎/ RIGHT EYE KERATITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (609)/ [redacted]20[redacted] (624)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA (DUE TO COVID-19 INFECTION)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (219)/ [redacted]20[redacted] (220)	眼障害/ 核性白内障/ SENILE INTUMESCENT NUCLEAR CATARACT	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (133)/ -	血管障害/ 高血圧/ WORSENED HYPERTENSION	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (584)/ [redacted]20[redacted] (586)	心臓障害/ 心房細動/ PERSISTENT ATRIAL FIBRILLATION	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted]20[redacted] (409)/ [redacted]20[redacted] (417)	神経系障害/ 一過性脳虚血発作/ TRANSIENT ISCHEMIC ATTACK	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (818)/ [redacted]20[redacted] (828)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA IN THE COURSE OF SARS-COV-2 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (6)/ [redacted]20[redacted] (11)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (29)/ [redacted]20[redacted] (33)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (47)/ [redacted]20[redacted] (48)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (57)/ [redacted]20[redacted] (58)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (554)/ [redacted]20[redacted] (574)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (554)/ [redacted]20[redacted] (574)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
	Yes	[redacted]20[redacted] (575)/ [redacted]20[redacted] (575)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (575)/ [redacted]20[redacted] (575)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
[redacted]	Yes	[redacted]20[redacted] (9)/ [redacted]20[redacted] (16)	感染症および寄生虫症/ 細菌性リンパ節炎/ SUPPURATIVE LYMPHADENITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (507)/ [redacted]20[redacted] (529)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (507)/ [redacted]20[redacted] (530)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (530)/ [redacted]20[redacted] (530)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (784)/ [redacted]20[redacted] (791)	胃腸障害/ クローン病/ CROHN'S DISEASE	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;5/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (808)/ [redacted]20[redacted] (814)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
	Yes	[redacted]20[redacted] (815)/ [redacted]20[redacted] (815)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (972)/ [redacted]20[redacted] (984)	感染症および寄生虫症/ 乳様突起炎/ ACUTE MASTOIDITIS OF THE RIGHT TEMPORAL BONE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (972)/ [redacted]20[redacted] (984)	感染症および寄生虫症/ 急性中耳炎/ ACUTE OTITIS MEDIA OF THE RIGHT EAR	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (428)/ [redacted]20[redacted] (428)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (101)/ [redacted]20[redacted] (101)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 3/ FATAL
	Yes	[redacted]20[redacted] (102)/ [redacted]20[redacted] (102)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (534)/ [redacted]20[redacted] (541)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (638)/ [redacted]20[redacted] (641)	生殖系および乳房障害/ 子宮ポリープ/ ENDOMETRIAL POLYP OF THE UTERINE BODY	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (35)/ [redacted]20[redacted] (46)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
	Yes	[redacted]20[redacted] (47)/ [redacted]20[redacted] (47)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (341)/ [redacted]20[redacted] (346)	感染症および寄生虫症/ 創傷感染/ POST-TRAUMATIC INFECTION OF THE SKIN AND SUBCUTANEOUS TISSUE OF THE RIGHT LOWER LEG	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (506)/ [redacted]20[redacted] (521)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (506)/ [redacted]20[redacted] (521)	皮膚および皮下組織障害/ 皮膚潰瘍/ ULCERATION OF THE LOWER RIGHT LIMB	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (120)/ [redacted] 20[redacted] (134)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (121)/ [redacted] 20[redacted] (134)	感染症および寄生虫症/ COVID-19肺炎/ INTERSTITIAL PNEUMONIA - RELATED TO COVID-19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (128)/ [redacted] 20[redacted] (131)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA POSSIBLE COVID-19	Yes/ 2/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL
	Yes	[redacted] 20[redacted] (128)/ [redacted] 20[redacted] (135)	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;3;5/ FATAL
	Yes	[redacted] 20[redacted] (131)/ [redacted] 20[redacted] (133)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA POSSIBLE COVID-19	Yes/ 3/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL
	Yes	[redacted] 20[redacted] (133)/ [redacted] 20[redacted] (136)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA POSSIBLE COVID-19	Yes/ 4/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL
	Yes	[redacted] 20[redacted] (136)/ [redacted] 20[redacted] (136)	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2;3;5/ FATAL
	Yes	[redacted] 20[redacted] (136)/ [redacted] 20[redacted] (136)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA POSSIBLE COVID-19	Yes/ 5/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (429)/ [redacted] 20[redacted] (438)	感染症および寄生虫症/ COVID-19/ INFECTION SARS-COV-2	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	No	[redacted] 20[redacted] (287)/ [redacted] 20[redacted] (303)	感染症および寄生虫症/ 肺炎/ LEFT SIDE PNEUMONIA OF UNKNOWN ETIOLOGY	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;4/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (488)/ [redacted] 20[redacted] (491)	血液およびリンパ系障害/ リンパ節症/ PROGRESSIVE LIMPHADENOPATHY	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (601)/ [redacted] 20[redacted] (601)	一般・全身障害および投与部位の状態/ 死亡/ UNKNOWN CAUSE OF DEATH	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (8)/ [redacted] 20[redacted] (15)	感染症および寄生虫症/ 下気道感染/ CHEST INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (18)/ [redacted] 20[redacted] (31)	感染症および寄生虫症/ 副鼻腔炎/ PANSINUSITIS	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	No	[redacted] 20[redacted] (-20)/ [redacted] 20[redacted] (-14)	感染症および寄生虫症/ 肺炎/ LEFT SIDED PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (906)/ [redacted] 20[redacted] (906)	一般・全身障害および投与部位の状態/ 死亡/ DEATH OF UNKNOWN ORIGIN	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (245)/ [redacted]20[redacted] (253)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (441)/ [redacted]20[redacted] (443)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 脈絡膜黒色腫/ MALIGNANT MELANOMA OF THE LEFT EYE CHORIOID.	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (333)/ [redacted]20[redacted] (337)	神経系障害/ 頭痛/ HEADACHE	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (483)/ [redacted]20[redacted] (489)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted]20[redacted] (490)/ [redacted]20[redacted] (490)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (147)/ [redacted]20[redacted] (149)	腎および尿路障害/ 腎結石症/ WORSENING OF NEPHROLITHIASIS	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (295)/ [redacted]20[redacted] (382)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳管内増殖性病変/ INTRADUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (383)/ [redacted]20[redacted] (385)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳管内増殖性病変/ INTRADUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (693)/ [redacted]20[redacted] (739)	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (623)/ [redacted]20[redacted] (625)	胃腸障害/ 単径ヘルニア/ INGUINAL HERNIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 3;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (222)/ [redacted]20[redacted] (228)	感染症および寄生虫症/ 肺炎球菌性肺炎/ LEFT SIDED PNEUMONIA (STEREPTOCOCCUS PNEUMONIAE)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (634)/ [redacted]20[redacted] (644)	感染症および寄生虫症/ 肺炎球菌性肺炎/ STREPTOCOCCUS PNEUMONIAE PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (753)/ [redacted]20[redacted] (766)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 RELATED PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
	Yes	[redacted]20[redacted] (767)/ [redacted]20[redacted] (767)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 RELATED PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted]20[redacted] (736)/ [redacted]20[redacted] (748)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (779)/ [redacted]20[redacted] (783)	神経系障害/ 一過性脳虚血発作/ LEFT-SIDED TRANSIENT ISCHEMIC ATTACK	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (540)/ [redacted]20[redacted] (541)	感染症および寄生虫症/ 肺炎/ RIGHT-SIDED PNEUMONIA (ETIOLOGY UNKNOWN)	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (43)/ [redacted]20[redacted] (51)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (62)/ [redacted]20[redacted] (69)	血液およびリンパ系障害/ 好中球減少症/ NEUTROPENIA	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (111)/ [redacted]20[redacted] (124)	感染症および寄生虫症/ 尿路感染/ URINARY INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (124)/ [redacted]20[redacted] (134)	感染症および寄生虫症/ COVID-19/ COVID - 19 INFECTION	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted]20[redacted] (135)/ [redacted]20[redacted] (135)	感染症および寄生虫症/ COVID-19/ COVID - 19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (497)/ [redacted] 20[redacted] (498)	腎および尿路障害/ 血尿/ HEMATURIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (257)/ [redacted] 20[redacted] (280)	感染症および寄生虫症/ ニューモシスチス・イロベチイ肺炎/ PNEUMOCYSTIS JIROVECI PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	-/ [redacted] 20[redacted] (476)	神経系障害/ 脳血管発作/ LEFT SIDE STROKE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	Yes	-/ [redacted] 20[redacted] (476)	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ PLUMONARY EMBOLISM	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	Yes	[redacted] 20[redacted] (428)/ [redacted] 20[redacted] (475)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 RELATED PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (476)/ [redacted] 20[redacted] (476)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 RELATED PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (476)/ [redacted] 20[redacted] (476)	神経系障害/ 脳血管発作/ LEFT SIDE STROKE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	Yes	[redacted] 20[redacted] (476)/ [redacted] 20[redacted] (476)	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ PLUMONARY EMBOLISM	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (461)/ [redacted] 20[redacted] (489)	感染症および寄生虫症/ 中枢神経系真菌性膿瘍/ ASPERGILLUS FUMIGATUS BRAIN ABSCESS	Yes/ 3/ NOT RELATED	DOSE REDUCED/ 2;3;5/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted] 20[redacted] (106)/ [redacted] 20[redacted] (112)	感染症および寄生虫症/ 肺炎/ BILATERAL PNEUMONIA (PATHOGEN UNIDENTIFIED)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (835)/ [redacted] 20[redacted] (843)	血液およびリンパ系障害/ 免疫性血小板減少症/ AUTOIMMUNE THROMBOCYTOPENIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (88)/ [redacted] 20[redacted] (89)	傷害、中毒および処置合併症/ 脊椎骨折/ SPINE FRACTURE	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted] 20[redacted] (95)/ [redacted] 20[redacted] (110)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (481)/ [redacted] 20[redacted] (491)	感染症および寄生虫症/ COVID-19/ SARS-COV-2 INFECTION	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 3/ FATAL
	Yes	[redacted] 20[redacted] (491)/ [redacted] 20[redacted] (491)	感染症および寄生虫症/ COVID-19/ SARS-COV-2 INFECTION	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 3/ FATAL
	Yes	[redacted] 20[redacted] (491)/ [redacted] 20[redacted] (491)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (10)/ [redacted]20[redacted] (17)	感染症および寄生虫症/ 敗血症性ショック/ SEPTIC SHOCK	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;3;4/ FATAL
	Yes	[redacted]20[redacted] (17)/ [redacted]20[redacted] (17)	感染症および寄生虫症/ 敗血症性ショック/ SEPTIC SHOCK	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3;4/ FATAL
[redacted]	Yes	[redacted]20[redacted] (98)/ [redacted]20[redacted] (108)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIAE-SARS-COV-2 ETHIOLOGY	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (243)/ [redacted]20[redacted] (261)	感染症および寄生虫症/ 髄膜炎/ CEREBROSPINAL MENINGITIS	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (689)/ [redacted]20[redacted] (694)	代謝および栄養障害/ 低ナトリウム血症/ HYPONATREMIA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (291)/ -	心臓障害/ 急性冠動脈症候群/ ACUTE CORONARY SYNDROME	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 1/ UNKNOWN
[redacted]	No	[redacted]20[redacted] (-18)/ [redacted]20[redacted] (-17)	血液およびリンパ系障害/ 貧血/ WORSENING OF ANEMIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (384)/ [redacted]20[redacted] (399)	感染症および寄生虫症/ 肺炎/ PNEUMONIA DEXTRA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (399)/ [redacted]20[redacted] (405)	感染症および寄生虫症/ 肺炎/ PNEUMONIA DEXTRA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (407)/ [redacted]20[redacted] (416)	感染症および寄生虫症/ 肺炎/ PNEUMONIA DEXTRA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	No	[redacted]20[redacted] (-31)/ [redacted]20[redacted] (-28)	傷害、中毒および処置合併症/ 頭部損傷/ HEAD INJURY	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (963)/ [redacted]20[redacted] (963)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (1052)/ [redacted]20[redacted] (1067)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (1075)/ [redacted]20[redacted] (1083)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (716)/ [redacted]20[redacted] (725)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺の良性新生物/ NON-CANCEROUS TUMOUR OF LEFT LUNG	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERING/RESOLVING

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted] 20[redacted] (-3)/ [redacted] 20[redacted] (1)	血液およびリンパ系障害/ 貧血/ ANEMIA GRADE 3	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;4/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (-36)/ [redacted] 20[redacted] (-13)	代謝および栄養障害/ 高カルシウム血症/ HIPERCALCEMIA	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (100)/ [redacted] 20[redacted] (106)	精神障害/ うつ病/ WORSENING DEPRESSION	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (807)/ [redacted] 20[redacted] (807)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (83)/ [redacted] 20[redacted] (85)	心臓障害/ 心房頻脈/ PAROXYSMAL ATRIAL TACHYCARDIA	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (766)/ [redacted] 20[redacted] (768)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted] 20[redacted] (769)/ [redacted] 20[redacted] (769)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (699)/ [redacted] 20[redacted] (707)	胃腸障害/ 腸炎/ ENTEROCOLITIS	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (491)/ [redacted]20[redacted] (496)	感染症および寄生虫症/ COVID-19/ COVID -19 INFECTION	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted]20[redacted] (497)/ [redacted]20[redacted] (497)	感染症および寄生虫症/ COVID-19/ COVID -19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (512)/ [redacted]20[redacted] (519)	臨床検査/ アラニンアミノトランスフェラーゼ増加/ INCREASED CONCENTRATION OF ALAT	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (512)/ [redacted]20[redacted] (519)	臨床検査/ アスパラギン酸アミノトランスフェラーゼ増加/ INCREASED CONCENTRATION OF ASPAT	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ NOT RECOVERED/NOT RESOLVED
	No	[redacted]20[redacted] (844)/ [redacted]20[redacted] (844)	感染症および寄生虫症/ 敗血症性ショック/ SEPTIC SHOCK	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (124)/ [redacted]20[redacted] (129)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺新生物/ TUMOUR OF LEFT LUNG (NO FURTHER INFORMATION)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (160)/ [redacted]20[redacted] (162)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 肺新生物/ TUMOUR OF LEFT LUNG (NO FURTHER INFORMATION)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (230)/ [redacted]20[redacted] (236)	胃腸障害/ 穿孔性胃潰瘍/ GASTRIC ULCER WITH PERFORATION	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (83)/ [redacted]20[redacted] (87)	肝胆道系障害/ 肝炎/ HEPATITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ FATAL
	No	[redacted]20[redacted] (98)/ [redacted]20[redacted] (98)	肝胆道系障害/ 肝不全/ LIVER FAILURE	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 2/ FATAL
	No	[redacted]20[redacted] (98)/ [redacted]20[redacted] (98)	肝胆道系障害/ 肝炎/ HEPATITIS	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (10)/ [redacted]20[redacted] (14)	血液およびリンパ系障害/ 溶血性貧血/ ANAEMIA HEMOLITICA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (350)/ [redacted]20[redacted] (354)	心臓障害/ 冠動脈疾患/ CORONARY HEART DISEASE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-24)/ [redacted]20[redacted] (-16)	感染症および寄生虫症/ 肺炎/ BILATERAL PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (41)/ [redacted]20[redacted] (42)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (140)/ [redacted]20[redacted] (147)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (174)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL
	No	[redacted]20[redacted] (174)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ カンジダ性肺炎/ CANDIDA TROPICANS PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL
	No	[redacted]20[redacted] (174)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL
	No	[redacted]20[redacted] (174)/ [redacted]20[redacted] (201)	代謝および栄養障害/ 悪液質/ CACHEXIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
	No	[redacted]20[redacted] (201)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL
	No	[redacted]20[redacted] (201)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ カンジダ性肺炎/ CANDIDA TROPICANS PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL
	No	[redacted]20[redacted] (201)/ [redacted]20[redacted] (201)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted]20[redacted] (201)/ [redacted]20[redacted] (201)	代謝および栄養障害/ 悪液質/ CACHEXIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
[redacted]	Yes	[redacted]20[redacted] (151)/ [redacted]20[redacted] (154)	胃腸障害/ 絞扼性臍ヘルニア/ STRANGULATED UMBILICAL HERNIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (572)/ [redacted]20[redacted] (584)	神経系障害/ 虚血性脳卒中/ ISCHEMIC STROKE	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (584)/ [redacted]20[redacted] (584)	神経系障害/ 虚血性脳卒中/ ISCHEMIC STROKE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (571)/ [redacted]20[redacted] (576)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (571)/ [redacted]20[redacted] (576)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-21)/ [redacted]20[redacted] (-19)	血液およびリンパ系障害/ 貧血/ WORSENING OF ANAEMIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (15)/ [redacted]20[redacted] (21)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted] 20[redacted] (15)/ [redacted] 20[redacted] (21)	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ ACUTE RESPIRATORY FAILURE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted] 20[redacted] (21)/ [redacted] 20[redacted] (21)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
[redacted]	No	[redacted] 20[redacted] (-2)/ [redacted] 20[redacted] (1)	血液およびリンパ系障害/ 貧血/ WORSENING ANEMIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (419)/ [redacted] 20[redacted] (427)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (427)/ [redacted] 20[redacted] (427)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (114)/ [redacted] 20[redacted] (155)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸腺癌/ ADENOCARCINOMA OF SIGMOID COLON	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted] 20[redacted] (156)/ [redacted] 20[redacted] (162)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸腺癌/ ADENOCARCINOMA OF SIGMOID COLON	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (237)/ [redacted]20[redacted] (237)	感染症および寄生虫症/ 敗血症性ショック/ SEPTIC SCHOCK	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (562)/ [redacted]20[redacted] (611)	精神障害/ うつ病/ DEPRESSION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (562)/ [redacted]20[redacted] (611)	精神障害/ 自殺行為/ SUCIDAL GESTURE WITHOUT INTEND TO DIE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (909)/ [redacted]20[redacted] (920)	感染症および寄生虫症/ COVID-19/ SARS-COV-2 INFECTION	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
	Yes	[redacted]20[redacted] (921)/ [redacted]20[redacted] (921)	感染症および寄生虫症/ COVID-19/ SARS-COV-2 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (606)/ [redacted]20[redacted] (606)	血管障害/ 大動脈瘤破裂/ REPTURED AORTIC ANEURYSM	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (864)/ [redacted]20[redacted] (872)	神経系障害/ 虚血性脳卒中/ ISCHEMIC STROKE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (519)/ [redacted]20[redacted] (526)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 子宮内膜腺癌/ ENDOMETRIAL ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (673)/ [redacted]20[redacted] (673)	心臓障害/ 急性心不全/ ACUTE HEART FAILURE OF UNKNOWN CAUSE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	No	[redacted]20[redacted] (859)/ [redacted]20[redacted] (859)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (270)/ [redacted]20[redacted] (305)	感染症および寄生虫症/ COVID-19/ SARS-COV-2 INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (569)/ [redacted]20[redacted] (576)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 INFECTION (PNEUMONIA)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (665)/ [redacted]20[redacted] (665)	一般・全身障害および投与部位の状態/ 死亡/ UNKNOWN CAUSE OF DEATH	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	No	[redacted]20[redacted] (194)/ [redacted]20[redacted] (194)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 4/ FATAL
	No	[redacted]20[redacted] (195)/ [redacted]20[redacted] (195)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 4/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (478)/ [redacted]20[redacted] (481)	血液およびリンパ系障害/ 貧血/ ANAEMIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 3;4;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (252)/ [redacted]20[redacted] (253)	血液およびリンパ系障害/ 血小板減少症/ THROMBOCYTOPENIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (273)/ [redacted]20[redacted] (274)	血液およびリンパ系障害/ 血小板減少症/ THROMBOCYTOPENIA	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;4;5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (318)/ [redacted]20[redacted] (330)	血液およびリンパ系障害/ 貧血/ ANAEMIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 4;5/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (318)/ [redacted]20[redacted] (330)	血液およびリンパ系障害/ 血小板減少症/ THROMBOCYTOPENIA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 4;5/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (325)/ [redacted]20[redacted] (330)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 脳新生物/ BRAIN TUMOR OF UNKNOWN ETIOLOGY, DIAGNOSIS UNKNOWN	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 5/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (327)/ [redacted]20[redacted] (329)	神経系障害/ 中枢神経系出血/ BLEEDING INTO THE CNS - NO FURTHER INFORMATION	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 5/ FATAL
	Yes	[redacted]20[redacted] (330)/ [redacted]20[redacted] (330)	神経系障害/ 中枢神経系出血/ BLEEDING INTO THE CNS - NO FURTHER INFORMATION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 5/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (99)/ [redacted] 20[redacted] (106)	神経系障害/ 失神/ SYNCOPE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (953)/ [redacted] 20[redacted] (959)	腎および尿路障害/ 急性腎障害/ ACUTE KIDNEY FAILURE LEFT	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (373)/ [redacted] 20[redacted] (373)	感染症および寄生虫症/ COVID-19肺炎/ SARS-COV-2 INFECTION (PNEUMONIA)	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (206)/ [redacted] 20[redacted] (227)	感染症および寄生虫症/ COVID-19肺炎/ SARS-COV2 PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (247)/ [redacted] 20[redacted] (261)	感染症および寄生虫症/ 肺炎/ PNEUMONIA (UNKNOWN ETIOLOGY)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (469)/ [redacted] 20[redacted] (469)	一般・全身障害および投与部位の状態/ 死亡/ DEATH OF UNKNOWN CAUSES	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (142)/ [redacted] 20[redacted] (148)	心臓障害/ 狭心症/ ANGINA PECTORIS	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (445)/ [redacted] 20[redacted] (446)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA DUE TO COVID 19	Yes/ 2/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (454)/ [redacted]20[redacted] (469)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA DUE TO COVID 19	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
	Yes	[redacted]20[redacted] (469)/ [redacted]20[redacted] (469)	感染症および寄生虫症/ COVID-19肺炎/ PNEUMONIA DUE TO COVID 19	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (75)/ [redacted]20[redacted] (82)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (173)/ [redacted]20[redacted] (181)	呼吸器、胸郭および縦隔障害/ 慢性閉塞性肺疾患/ WORSENING OF COPD	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (446)/ [redacted]20[redacted] (446)	感染症および寄生虫症/ COVID-19/ COVID 19 INFECTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (137)/ [redacted]20[redacted] (137)	血液およびリンパ系障害/ 低グロブリン血症/ HYPOGLOBULINEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (190)/ [redacted]20[redacted] (190)	血液およびリンパ系障害/ 低グロブリン血症/ HYPOGLOBULINEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (257)/ [redacted]20[redacted] (274)	血液およびリンパ系障害/ リンパ節症/ PROGRESIVE LYMPHODYNOPATHY	Yes/ 2/ NOT RELATED	DRUG WITHDRAWN/ 2;4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted]20[redacted] (453)/ [redacted]20[redacted] (461)	感染症および寄生虫症/ COVID-19/ COVID19	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2;3/ FATAL
	No	[redacted]20[redacted] (453)/ [redacted]20[redacted] (461)	神経系障害/ 虚血性脳卒中/ ISCHEMIC STROKE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ NOT RECOVERED/NOT RESOLVED
	No	[redacted]20[redacted] (461)/ [redacted]20[redacted] (461)	感染症および寄生虫症/ COVID-19/ COVID19	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (435)/ [redacted]20[redacted] (438)	胃腸障害/ 胃腸出血/ GASTROINTESTINAL BLEEDING	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (104)/ [redacted]20[redacted] (104)	血液およびリンパ系障害/ 低グロブリン血症/ HYPOGLOBULINEMIA	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (74)/ [redacted]20[redacted] (74)	血液およびリンパ系障害/ 低グロブリン血症/ HYPOGLOBULINEMIA	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (144)/ [redacted]20[redacted] (164)	感染症および寄生虫症/ シュードモナス性肺炎/ PNEUMONIA CAUSED BY PSEUDOMONAS LUTEOLA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
	Yes	[redacted]20[redacted] (155)/ [redacted]20[redacted] (164)	感染症および寄生虫症/ 細菌性下気道感染/ ACINETOBACTER BAUMANNII INFECTION OF THE LOWER RESPIRATORY TRACT	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
	Yes	[redacted]20[redacted] (155)/ [redacted]20[redacted] (164)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	Yes	[redacted]20[redacted] (165)/ [redacted]20[redacted] (165)	一般・全身障害および投与部位の状態/ 多臓器機能不全症候群/ MULTI ORGAN FAILURE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	Yes	[redacted]20[redacted] (165)/ [redacted]20[redacted] (165)	感染症および寄生虫症/ 細菌性下気道感染/ ACINETOBACTER BAUMANNII INFECTION OF THE LOWER RESPIRATORY TRACT	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
	Yes	[redacted]20[redacted] (165)/ [redacted]20[redacted] (165)	感染症および寄生虫症/ シュードモナス性肺炎/ PNEUMONIA CAUSED BY PSEUDOMONAS LUTEOLA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ FATAL
	Yes	[redacted]20[redacted] (165)/ [redacted]20[redacted] (165)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (22)/ [redacted] 20[redacted] (24)	腎および尿路障害/ 血尿/ HEMATURIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (78)/ [redacted] 20[redacted] (91)	腎および尿路障害/ 血尿/ HEMATURIA	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 3;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (95)/ [redacted] 20[redacted] (112)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (140)/ [redacted] 20[redacted] (146)	傷害、中毒および処置合併症/ 放射線性膀胱炎/ RADIATION CYSTITIS	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2;3;4/ RECOVERED/RESOLVED
	No	[redacted] 20[redacted] (197)/ [redacted] 20[redacted] (217)	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ COLITIS CAUSED BY CLOSTRIDIUM DIFFICILE	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 1/ NOT RECOVERED/NOT RESOLVED
	No	[redacted] 20[redacted] (252)/ [redacted] 20[redacted] (274)	胃腸障害/ 十二指腸炎/ DUODENITIS	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ NOT RECOVERED/NOT RESOLVED
	No	[redacted] 20[redacted] (252)/ [redacted] 20[redacted] (274)	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ ENTEROCOLITIS CAUSED BY CLOSTRIDIUM DIFFICILE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;3;4/ NOT RECOVERED/NOT RESOLVED
	No	[redacted] 20[redacted] (271)/ [redacted] 20[redacted] (273)	感染症および寄生虫症/ COVID-19/ COVID19	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;4/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	No	[redacted] 20[redacted] (271)/ [redacted] 20[redacted] (273)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	No	[redacted] 20[redacted] (273)/ [redacted] 20[redacted] (274)	感染症および寄生虫症/ COVID-19/ COVID19	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2;4/ FATAL
	No	[redacted] 20[redacted] (273)/ [redacted] 20[redacted] (274)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	No	[redacted] 20[redacted] (274)/ [redacted] 20[redacted] (274)	感染症および寄生虫症/ COVID-19/ COVID19	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2;4/ FATAL
	No	[redacted] 20[redacted] (274)/ [redacted] 20[redacted] (274)	呼吸器、胸郭および縦隔障害/ 呼吸不全/ RESPIRATORY FAILURE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (154)/ [redacted] 20[redacted] (167)	血液およびリンパ系障害/ リンパ節炎/ LYMPHADENITIS COLLI LEFT	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (753)/ [redacted] 20[redacted] (755)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 脂肪腫/ LIPOMA (LEFT LATERAL BACK)	Yes/ 3/ NOT RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted]20[redacted] (548)/ [redacted]20[redacted] (550)	神経系障害/ 末梢性感覚ニューロパチー/ SENSORY POLYNEUROPATHIE BOTH FEET, CALF RIGHT	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (49)/ [redacted]20[redacted] (68)	呼吸器、胸郭および縦隔障害/ 胸水/ PLEURAL EFFUSION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (59)/ [redacted]20[redacted] (68)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (544)/ [redacted]20[redacted] (548)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (544)/ [redacted]20[redacted] (548)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 4/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	No	[redacted]20[redacted] (-9)/ [redacted]20[redacted] (-8)	胃腸障害/ 腹痛/ ABDOMINAL PAIN	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (7)/ [redacted]20[redacted] (8)	血液およびリンパ系障害/ 貧血/ ANAEMIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (756)/ [redacted]20[redacted] (757)	心臓障害/ 心房細動/ ATRIAL FIBRILLATION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (778)/ [redacted]20[redacted] (778)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 遠隔転移を伴う皮膚有棘細胞癌/ RESIDUAL SQUAMOUS CELL CARCINOMA WITH PERINEURAL INVASION SCALP	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (683)/ [redacted]20[redacted] (683)	心臓障害/ うっ血性心筋症/ DILATED CARDIOMYOPATHY	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (925)/ [redacted]20[redacted] (929)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (939)/ [redacted]20[redacted] (944)	感染症および寄生虫症/ COVID-19肺炎/ COVID19 PNEUMONITIS	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (939)/ [redacted]20[redacted] (944)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 4/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (945)/ [redacted]20[redacted] (945)	感染症および寄生虫症/ COVID-19肺炎/ COVID19 PNEUMONITIS	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (945)/ [redacted]20[redacted] (945)	感染症および寄生虫症/ 細菌性肺炎/ BACTERIAL PNEUMONIA	Yes/ 5/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (570)/ [redacted]20[redacted] (571)	感染症および寄生虫症/ ウイルス性胃腸炎/ VIRAL GASTROENTERITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (612)/ [redacted]20[redacted] (614)	感染症および寄生虫症/ 爪囲炎/ INFECTED INGROWN R GREAT TOENAIL	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (647)/ [redacted]20[redacted] (649)	胃腸障害/ 下痢/ DIARRHEA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (694)/ [redacted]20[redacted] (698)	一般・全身障害および投与部位の状態/ 薬剤離脱症候群/ NON-NEUTROPENIC FEVERS DUE TO DRUG WITHDRAWAL	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-25)/ [redacted]20[redacted] (-17)	感染症および寄生虫症/ 上気道感染/ UPPER RESPIRATORY INFECTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (-25)/ [redacted]20[redacted] (-17)	腎および尿路障害/ 急性腎障害/ ACUTE KIDNEY INJURY	Yes/ 1/ NOT RELATED	NOT APPLICABLE/ 5/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (5)/ [redacted]20[redacted] (22)	心臓障害/ うっ血性心不全/ WORSENING OF CONGESTIVE CARDIAC FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (25)/ [redacted]20[redacted] (43)	感染症および寄生虫症/ 細菌性関節炎/ SEPTIC ARTHRITIS RIGHT ANKLE	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (255)/ [redacted]20[redacted] (302)	胃腸障害/ 腸間膜脂肪織炎/ MESENTERIC PANNICULITIS	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (518)/ [redacted]20[redacted] (520)	呼吸器、胸郭および縦隔障害/ 肺高血圧症/ PULMONARY HYPERTENSION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (648)/ [redacted]20[redacted] (659)	心臓障害/ うっ血性心不全/ WORSENING OF CONGESTIVE CARDIAC FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-7)/ [redacted]20[redacted] (-3)	感染症および寄生虫症/ 憩室炎/ ACUTE DIVERTICULITIS	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (222)/ [redacted]20[redacted] (247)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ SQUAMOUS CELL CARCINOMA R CHEEK	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (837)/ [redacted]20[redacted] (847)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (61)/ [redacted]20[redacted] (64)	心臓障害/ 心房細動/ ATRIAL FIBRILLATION	Yes/ 3/ RELATED	DRUG WITHDRAWN/ 2/ RECOVERED/RESOLVED WITH SEQUELAE

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (11)/ [redacted] 20[redacted] (21)	感染症および寄生虫症/ クリプトコッカス性肺炎/ CRYPTOCOCCAL PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (22)/ [redacted] 20[redacted] (63)	感染症および寄生虫症/ クリプトコッカス性肺炎/ CRYPTOCOCCAL PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (64)/ [redacted] 20[redacted] (64)	感染症および寄生虫症/ クリプトコッカス性肺炎/ CRYPTOCOCCAL PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (1015)/ [redacted] 20[redacted] (1079)	感染症および寄生虫症/ 細菌性関節炎/ SEPTIC ARTHRITIS (RIGHT SHOULDER)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (-14)/ [redacted] 20[redacted] (-13)	感染症および寄生虫症/ インフルエンザ/ INFLUENZA A INFECTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (155)/ [redacted] 20[redacted] (157)	肝胆道系障害/ 胆嚢炎/ CHOLECYSTISIS	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (161)/ [redacted] 20[redacted] (161)	胃腸障害/ 大腸炎/ COLITIS	Yes/ 3/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL
	Yes	[redacted] 20[redacted] (161)/ [redacted] 20[redacted] (161)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 4/ RELATED	NOT APPLICABLE/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (162)/ [redacted]20[redacted] (162)	胃腸障害/ 大腸炎/ COLITIS	Yes/ 5/ RELATED	NOT APPLICABLE/ 2;3;4/ FATAL
	Yes	[redacted]20[redacted] (162)/ [redacted]20[redacted] (162)	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes/ 5/ RELATED	NOT APPLICABLE/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (337)/ [redacted]20[redacted] (340)	心臓障害/ 心房粗動/ ATRIAL FLUTTER	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (161)/ [redacted]20[redacted] (169)	傷害、中毒および処置合併症/ 股関節部骨折/ LEFT HIP FRACTURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (1051)/ -	傷害、中毒および処置合併症/ 創離開/ WOUND DEHISCENCE LEFT FOOT	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (646)/ [redacted]20[redacted] (649)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;5/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (133)/ [redacted]20[redacted] (134)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (709)/ [redacted]20[redacted] (710)	神経系障害/ ヘルペス後神経痛/ POST-HERPETIC NEURALGIA	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (988)/ [redacted] 20[redacted] (989)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted] 20[redacted] (989)/ [redacted] 20[redacted] (989)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONITIS	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (172)/ [redacted] 20[redacted] (176)	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes/ 3/ NOT RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (685)/ [redacted] 20[redacted] (686)	感染症および寄生虫症/ インフルエンザ/ INFLUENZA A INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (691)/ [redacted] 20[redacted] (695)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (-72)/ [redacted] 20[redacted] (-62)	血液およびリンパ系障害/ 好中球減少症/ NEUTROPENIA	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (205)/ [redacted] 20[redacted] (213)	心臓障害/ 狭心症/ CHEST PAIN - CARDIAC	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (510)/ [redacted] 20[redacted] (513)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (525)/ [redacted]20[redacted] (527)	感染症および寄生虫症/ 感染/ INFECTION - UNKNOWN LOCATION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (272)/ [redacted]20[redacted] (273)	筋骨格系および結合組織障害/ ピロリン酸カルシウム結晶性軟骨石灰化症/ PSUEDO-GOUT RIGHT KNEE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (149)/ [redacted]20[redacted] (154)	呼吸器、胸郭および縦隔障害/ 喀血/ HAEMOPTYSIS	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (206)/ [redacted]20[redacted] (213)	一般・全身障害および投与部位の状態/ 倦怠感/ MALAISE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
	Yes	[redacted]20[redacted] (206)/ [redacted]20[redacted] (213)	肝胆道系障害/ 黄疸/ UNSPECIFIED JAUNDICE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
	Yes	[redacted]20[redacted] (206)/ [redacted]20[redacted] (213)	筋骨格系および結合組織障害/ 運動性低下/ DECREASED MOBILITY	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (65)/ [redacted]20[redacted] (65)	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 1/ FATAL
[redacted]	No	[redacted]20[redacted] (-7)/ [redacted]20[redacted] (-6)	一般・全身障害および投与部位の状態/ 発熱/ LOW GRADE FEVER	Yes/ 1/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (-3)/ [redacted]20[redacted] (1)	代謝および栄養障害/ 脱水/ DEHYDRATION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (120)/ [redacted]20[redacted] (147)	血液およびリンパ系障害/ リンパ節症/ NEW PALPABLE LYMPHADENOPATHY	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	No	[redacted]20[redacted] (148)/ [redacted]20[redacted] (148)	血液およびリンパ系障害/ リンパ節症/ NEW PALPABLE LYMPHADENOPATHY	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
[redacted]	Yes	[redacted]20[redacted] (295)/ [redacted]20[redacted] (305)	感染症および寄生虫症/ レジオネラ菌性肺炎/ LEGIONELLA PNEUMONIA	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (325)/ [redacted]20[redacted] (379)	感染症および寄生虫症/ 乳様突起炎/ MASTOIDITIS/OTITIS EXTERNA DUE TO ASPERGILLUS FUMIGATUS	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;3/ RECOVERING/RESOLVING
	Yes	[redacted]20[redacted] (331)/ [redacted]20[redacted] (378)	感染症および寄生虫症/ レジオネラ菌性肺炎/ LEGIONELLA PNEUMONIA	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (333)/ [redacted]20[redacted] (378)	感染症および寄生虫症/ ニューモシスチス・イロベチイ肺炎/ PNEUMOCYSTIS JIROVECI PNEUMONIA	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (791)/ [redacted]20[redacted] (792)	感染症および寄生虫症/ ニューモシスチス・イロベチイ 肺炎/ PNEUMOCYSTITIS JIROVECII PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (805)/ [redacted]20[redacted] (813)	感染症および寄生虫症/ 下気道感染/ LOWER RESPIRATORY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (94)/ [redacted]20[redacted] (104)	感染症および寄生虫症/ 肺炎/ BILATERAL LOWER LOBE COMMUNITY ACQUIRED PNEUMONIA	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 2;4/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-23)/ [redacted]20[redacted] (-10)	感染症および寄生虫症/ レジオネラ菌性肺炎/ LEGIONELLA PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (638)/ [redacted]20[redacted] (651)	感染症および寄生虫症/ 肺炎/ COMMUNITY ACQUIRED PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-1)/ [redacted]20[redacted] (3)	代謝および栄養障害/ 高カルシウム血症/ HYPERCALCAEMIA	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (372)/ [redacted]20[redacted] (394)	代謝および栄養障害/ 高カルシウム血症/ HYPERCALCAEMIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (395)/ [redacted]20[redacted] (395)	代謝および栄養障害/ 高カルシウム血症/ HYPERCALCAEMIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (307)/ [redacted]20[redacted] (330)	感染症および寄生虫症/ アシネトバクター性菌血症/ BACTERAEMIA - ACINETOBACTER BAUMANII BACTARAEMIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (307)/ [redacted]20[redacted] (330)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (353)/ [redacted]20[redacted] (356)	心臓障害/ うっ血性心不全/ CONGESTIVE HEART FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (353)/ [redacted]20[redacted] (373)	感染症および寄生虫症/ 蜂巣炎/ RE-INFECTION LEFT LEG CELLULITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (403)/ [redacted]20[redacted] (434)	心臓障害/ うっ血性心不全/ CONGESTIVE HEART FAILURE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (408)/ [redacted]20[redacted] (409)	感染症および寄生虫症/ 外耳炎/ LEFT ACUTE OTITIS EXTERNA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (408)/ [redacted]20[redacted] (439)	感染症および寄生虫症/ 下気道感染/ LOWER RESPIRATORY TRACT INFECTION	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (681)/ [redacted]20[redacted] (690)	代謝および栄養障害/ 高血糖/ HYPERGLYCEMIA	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (32)/ [redacted]20[redacted] (43)	感染症および寄生虫症/ 肺炎/ PULMONARY INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (262)/ [redacted]20[redacted] (267)	感染症および寄生虫症/ 肺炎/ COMMUNITY-ACQUIRED PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (89)/ [redacted]20[redacted] (91)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (92)/ [redacted]20[redacted] (117)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (278)/ [redacted]20[redacted] (281)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (281)/ [redacted]20[redacted] (291)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (291)/ [redacted]20[redacted] (326)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (111)/ [redacted]20[redacted] (170)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (129)/ [redacted]20[redacted] (472)	感染症および寄生虫症/ 感染/ INFECTION OF UNKNOWN CAUSE	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (472)/ [redacted]20[redacted] (472)	一般・全身障害および投与部位の状態/ 死亡/ DEATH UNEXPLAINED	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (254)/ [redacted]20[redacted] (372)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ RELATED	DOSE REDUCED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (510)/ [redacted]20[redacted] (533)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (1023)/ [redacted]20[redacted] (1030)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (2)/ [redacted]20[redacted] (6)	感染症および寄生虫症/ 大腸感染/ COLON INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (6)/ [redacted]20[redacted] (13)	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (13)/ [redacted]20[redacted] (21)	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (659)/ [redacted]20[redacted] (687)	眼障害/ 白内障/ EARLY CATARACT	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	No	[redacted]20[redacted] (-16)/ [redacted]20[redacted] (-3)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (28)/ [redacted]20[redacted] (30)	臨床検査/ 血中クレアチニン増加/ CREATININE INCREASED	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (92)/ [redacted]20[redacted] (153)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (106)/ [redacted]20[redacted] (231)	感染症および寄生虫症/ B型肝炎/ HEPATITIS B HEPATITIS VIRAL	Yes/ 3/ RELATED	DOSE NOT CHANGED/ 2/ NOT RECOVERED/NOT RESOLVED
	No	[redacted]20[redacted] (153)/ [redacted]20[redacted] (231)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (231)/ [redacted]20[redacted] (231)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 5/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (76)/ [redacted]20[redacted] (104)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (104)/ [redacted]20[redacted] (109)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (109)/ [redacted]20[redacted] (118)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (252)/ [redacted]20[redacted] (260)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (260)/ [redacted]20[redacted] (273)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 2/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (639)/ [redacted]20[redacted] (642)	胃腸障害/ 便秘/ CONSTIPATION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (639)/ [redacted]20[redacted] (642)	胃腸障害/ 胃腸障害/ GASTROINTESTINAL DISORDERS-NO FURTHER INFORMATION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (646)/ [redacted]20[redacted] (650)	胃腸障害/ 胃炎/ GASTRITIS	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (364)/ [redacted] 20[redacted] (368)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (425)/ [redacted] 20[redacted] (429)	感染症および寄生虫症/ 尿路感染/ URINARY TRACT INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (425)/ [redacted] 20[redacted] (429)	代謝および栄養障害/ 水中毒/ WATER POISONING	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (1017)/ [redacted] 20[redacted] (1032)	耳および迷路障害/ 耳鳴/ THE RIGHT EAR TINNITUS	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;3;5/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted] 20[redacted] (1017)/ [redacted] 20[redacted] (1072)	血管障害/ 高血圧/ INTERMITTENT HYPERTENSION	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted] 20[redacted] (361)/ [redacted] 20[redacted] (376)	感染症および寄生虫症/ 感染/ AN INFECTION WITH AN UNDEFINED LESION(UNKNOWN ETIOLOGY)	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (376)/ [redacted] 20[redacted] (399)	感染症および寄生虫症/ 感染/ AN INFECTION WITH AN UNDEFINED LESION(UNKNOWN ETIOLOGY)	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (399)/ [redacted]20[redacted] (399)	感染症および寄生虫症/ 感染/ AN INFECTION WITH AN UNDEFINED LESION(UNKNOWN ETIOLOGY)	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (3)/ [redacted]20[redacted] (5)	臨床検査/ 血小板数減少/ DECREASED PLATELET COUNT	Yes/ 4/ RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (5)/ [redacted]20[redacted] (12)	臨床検査/ 血小板数減少/ DECREASED PLATELET COUNT	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (31)/ [redacted]20[redacted] (36)	臨床検査/ 血小板数減少/ DECREASED PLATELET COUNT	Yes/ 1/ RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (29)/ [redacted]20[redacted] (32)	血液およびリンパ系障害/ 貧血/ ANEMIA	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (35)/ [redacted]20[redacted] (39)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (202)/ [redacted]20[redacted] (353)	感染症および寄生虫症/ 肺結核/ LUNG INFECTION(TUBERCULOSIS)	Yes/ 3/ RELATED	DOSE REDUCED;DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ UNKNOWN

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (328)/ [redacted] 20[redacted] (328)	傷害、中毒および処置合併症/ 転倒/ FALL	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (328)/ [redacted] 20[redacted] (347)	傷害、中毒および処置合併症/ 大腿骨骨折/ RIGHT INTERTROCHANTERIC COMMINUTED FRACTURE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (456)/ [redacted] 20[redacted] (457)	臨床検査/ 検査結果偽陽性/ PSEUDOTHROMBOCYTOPENIA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (457)/ [redacted] 20[redacted] (458)	臨床検査/ 検査結果偽陽性/ PSEUDOTHROMBOCYTOPENIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (458)/ [redacted] 20[redacted] (461)	臨床検査/ 検査結果偽陽性/ PSEUDOTHROMBOCYTOPENIA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (17)/ [redacted] 20[redacted] (30)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 4/ RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (30)/ [redacted] 20[redacted] (56)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (182)/ [redacted] 20[redacted] (187)	感染症および寄生虫症/ 上気道感染/ UPPER RESPIRATORY TRACT INFECTION	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (197)/ -	感染症および寄生虫症/ 気管支肺アスペルギルス症/ PNEUMONIA ASPERGILLUS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ UNKNOWN

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted] 20[redacted] (-25)/ [redacted] 20[redacted] (-19)	感染症および寄生虫症/ 皮膚感染/ SKIN SOFT-TISSUE INFECTION(LEFT NECK)	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (42)/ [redacted] 20[redacted] (78)	感染症および寄生虫症/ 帯状疱疹/ SIMPLE HERPES ZOSTER(WORSENING)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (958)/ [redacted] 20[redacted] (961)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸直腸腺癌/ COLORECTAL ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (64)/ [redacted] 20[redacted] (77)	感染症および寄生虫症/ 肛門膿瘍/ PERIANAL ABSCESS	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (88)/ [redacted] 20[redacted] (152)	感染症および寄生虫症/ 肺炎/ PULMONARY INFECTION	Yes/ 3/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted] 20[redacted] (152)/ [redacted] 20[redacted] (152)	感染症および寄生虫症/ 肺炎/ PULMONARY INFECTION	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (364)/ [redacted] 20[redacted] (428)	神経系障害/ 脳梗塞/ CEREBRAL INFARCTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (90)/ [redacted]20[redacted] (93)	神経系障害/ 脳梗塞/ CEREBRAL INFARCTION	Yes/ 3/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (93)/ [redacted]20[redacted] (93)	神経系障害/ 脳梗塞/ CEREBRAL INFARCTION	Yes/ 5/ RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (505)/ [redacted]20[redacted] (507)	胃腸障害/ 大腸ポリープ/ COLON POLYPS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (858)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 胃腺癌/ GASTRIC ADENOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (599)/ [redacted]20[redacted] (613)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ SQUAMOUS CELL SKIN CANCER(LEFT FACIAL)	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (343)/ [redacted]20[redacted] (347)	胃腸障害/ 鼠径ヘルニア/ LEFT INGUINAL HERNIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (468)/ [redacted]20[redacted] (771)	感染症および寄生虫症/ スポロトリコーシス/ SPOROTRICHOSIS	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (402)/ [redacted]20[redacted] (439)	感染症および寄生虫症/ 帯状疱疹/ HERPES ZOSTER	Yes/ 2/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (439)/ [redacted]20[redacted] (468)	感染症および寄生虫症/ 帯状疱疹/ HERPES ZOSTER	Yes/ 1/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE
[redacted]	Yes	[redacted]20[redacted] (3)/ [redacted]20[redacted] (4)	代謝および栄養障害/ 食欲減退/ POOR APPETITE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (3)/ [redacted]20[redacted] (4)	神経系障害/ 構語障害/ SLURRED SPEECH	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (3)/ [redacted]20[redacted] (4)	精神障害/ 譫妄/ DELIRIUM	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (5)/ [redacted]20[redacted] (15)	代謝および栄養障害/ 食欲減退/ POOR APPETITE	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (5)/ [redacted]20[redacted] (15)	神経系障害/ 構語障害/ SLURRED SPEECH	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (5)/ [redacted]20[redacted] (15)	精神障害/ 譫妄/ DELIRIUM	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 1/ NOT RECOVERED/NOT RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (15)/ [redacted]20[redacted] (15)	一般・全身障害および投与部位の状態/ 死亡/ UNEXPLAINED DEATH	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (1012)/ [redacted]20[redacted] (1043)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 腎盂および尿管移行上皮癌/ LOW-GRADE INVASIVE PAPILLARY UROTHELIAL CARCINOMA(LEFT KIDNEY AND URETER)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (233)/ [redacted]20[redacted] (235)	感染症および寄生虫症/ 上気道感染/ ACUTE UPPER RESPIRATORY TRACT INFECTION	Yes/ 2/ RELATED	DOSE NOT CHANGED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (126)/ [redacted]20[redacted] (196)	呼吸器、胸郭および縦隔障害/ 呼吸困難/ DYSPNEA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	No	[redacted]20[redacted] (196)/ [redacted]20[redacted] (196)	呼吸器、胸郭および縦隔障害/ 呼吸困難/ DYSPNEA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (8)/ [redacted]20[redacted] (9)	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (9)/ [redacted]20[redacted] (12)	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 2;4/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (17)/ [redacted]20[redacted] (22)	感染症および寄生虫症/ 上気道感染/ UPPER RESPIRATORY INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (33)/ [redacted]20[redacted] (34)	感染症および寄生虫症/ エプスタイン・バーウイルス感染/ EB VIRUS INFECTION	Yes/ 1/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERING/RESOLVING
	Yes	[redacted]20[redacted] (34)/ [redacted]20[redacted] (38)	感染症および寄生虫症/ エプスタイン・バーウイルス感染/ EB VIRUS INFECTION	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 2/ RECOVERING/RESOLVING
	Yes	[redacted]20[redacted] (146)/ [redacted]20[redacted] (148)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 口腔血管腫/ LEFT MAXILLARY GINGIVAL TUMOR (HEMANGIOMA TYPE)	Yes/ 3/ NOT RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (-7)/ [redacted]20[redacted] (-2)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (6)/ [redacted]20[redacted] (16)	一般・全身障害および投与部位の状態/ 発熱/ FEVER	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (188)/ [redacted]20[redacted] (189)	臨床検査/ 白血球数減少/ LOW WHITE BLOOD CELL COUNT	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (189)/ [redacted]20[redacted] (190)	臨床検査/ 白血球数減少/ LOW WHITE BLOOD CELL COUNT	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (190)/ [redacted]20[redacted] (191)	臨床検査/ 白血球数減少/ LOW WHITE BLOOD CELL COUNT	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (191)/ [redacted]20[redacted] (192)	臨床検査/ 白血球数減少/ LOW WHITE BLOOD CELL COUNT	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (192)/ [redacted]20[redacted] (193)	臨床検査/ 白血球数減少/ LOW WHITE BLOOD CELL COUNT	Yes/ 1/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (404)/ [redacted]20[redacted] (410)	生殖系および乳房障害/ 外陰嚢胞/ LEFT VULVAR CYST AGGRAVATION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (860)/ -	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 胃腺癌/ GASTRIC ADNOCARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ NOT RECOVERED/NOT RESOLVED
[redacted]	Yes	[redacted]20[redacted] (18)/ [redacted]20[redacted] (19)	感染症および寄生虫症/ 気管支炎/ BRONCHIAL INFECTION(UNKNOWN REASON)	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (528)/ [redacted]20[redacted] (528)	一般・全身障害および投与部位の状態/ 疲労/ SIGNIFICANT FATIGUE	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
	No	[redacted]20[redacted] (528)/ [redacted]20[redacted] (528)	一般・全身障害および投与部位の状態/ 疼痛/ GENERAL ACHING	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (30)/ [redacted]20[redacted] (42)	感染症および寄生虫症/ 肺炎/ LUNG INFECTION	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (688)/ [redacted]20[redacted] (738)	血管障害/ 末梢動脈閉塞性疾患/ EXACERBATION OF ARTERIOSCLEROSIS OBLITERANS IN BOTH LOWER EXTREMITIES	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted]20[redacted] (43)/ [redacted]20[redacted] (50)	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (59)/ [redacted]20[redacted] (64)	感染症および寄生虫症/ 軟部組織感染/ POST TRAUMATIC SOFT TISSUE INFECTION	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (375)/ [redacted]20[redacted] (383)	感染症および寄生虫症/ 蜂巣炎/ LEG CELLULITIS	Yes/ 3/ NOT RELATED	DOSE NOT CHANGED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (600)/ [redacted]20[redacted] (600)	傷害、中毒および処置合併症/ 転倒/ FALLING	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 1/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted]20[redacted] (600)/ [redacted]20[redacted] (618)	傷害、中毒および処置合併症/ 頭蓋脳損傷/ BRAIN TRAUMA	Yes/ 4/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted] 20[redacted] (600)/ [redacted] 20[redacted] (618)	神経系障害/ 脳出血/ CEREBRAL HEMORRHAGE	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (618)/ [redacted] 20[redacted] (618)	傷害、中毒および処置合併症/ 頭蓋脳損傷/ BRAIN TRAUMA	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (618)/ [redacted] 20[redacted] (618)	神経系障害/ 脳出血/ CEREBRAL HEMORRHAGE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (382)/ [redacted] 20[redacted] (388)	心臓障害/ 心室細動/ VENTRICULAR FIBRILATION	Yes/ 4/ RELATED	NOT APPLICABLE/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (382)/ [redacted] 20[redacted] (388)	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ ACUTE RESPIRATORY FAILURE	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 2;3;4/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (383)/ [redacted] 20[redacted] (421)	一般・全身障害および投与部位の状態/ カテーテル留置部位血腫/ HEMATOMA AT THE SITE OF ARTERY CANNULATION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (125)/ [redacted] 20[redacted] (134)	感染症および寄生虫症/ 感染性腱鞘炎/ ABSCESS AND PURULENT TENDOVAGINITIS (3RD FINGER OF THE RIGHT HAND)	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (468)/ [redacted]20[redacted] (475)	感染症および寄生虫症/ COVID-19肺炎/ BILATERAL COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;3/ RECOVERED/RESOLVED
[redacted]	No	[redacted]20[redacted] (145)/ [redacted]20[redacted] (148)	呼吸器、胸郭および縦隔障害/ 肺障害/ NON-INFECTIOUS LUNG LESION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	No	[redacted]20[redacted] (823)/ [redacted]20[redacted] (823)	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ ACUTE RESPIRATORY FAILURE	Yes/ 5/ NOT RELATED	DOSE NOT CHANGED/ 1/ FATAL
[redacted]	Yes	[redacted]20[redacted] (125)/ [redacted]20[redacted] (127)	一般・全身障害および投与部位の状態/ 発熱/ FEBRILE CONDITION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (44)/ [redacted]20[redacted] (49)	血液およびリンパ系障害/ 発熱性好中球減少症/ FEBRILIE NEUTROPENIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (80)/ [redacted]20[redacted] (89)	感染症および寄生虫症/ 肺炎/ TERMINAL BILATERAL PNEUMONIA UKNKNOWN ETIOLOGY	Yes/ 4/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (89)/ [redacted]20[redacted] (89)	感染症および寄生虫症/ 肺炎/ TERMINAL BILATERAL PNEUMONIA UKNKNOWN ETIOLOGY	Yes/ 5/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (82)/ [redacted] 20[redacted] (88)	感染症および寄生虫症/ 肺炎/ TERMINAL BILATERAL PNEUMONIA	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted] 20[redacted] (82)/ [redacted] 20[redacted] (88)	感染症および寄生虫症/ 尿路性敗血症/ UROSEPSIS	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ NOT RECOVERED/NOT RESOLVED
	Yes	[redacted] 20[redacted] (88)/ [redacted] 20[redacted] (88)	感染症および寄生虫症/ 肺炎/ TERMINAL BILATERAL PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (553)/ [redacted] 20[redacted] (561)	肝胆道系障害/ 急性胆嚢炎/ RECURRENT ACUTE CHOLECYSTITIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (562)/ [redacted] 20[redacted] (578)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (572)/ [redacted] 20[redacted] (593)	感染症および寄生虫症/ 細菌性敗血症/ BACTERIAL SEPSIS	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (572)/ [redacted] 20[redacted] (593)	感染症および寄生虫症/ 肺炎/ IN BILATERAL PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted] 20[redacted] (593)/ [redacted] 20[redacted] (593)	感染症および寄生虫症/ 細菌性敗血症/ BACTERIAL SEPSIS	Yes/ 5/ NOT RELATED	DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
	Yes	[redacted]20[redacted] (593)/ [redacted]20[redacted] (593)	感染症および寄生虫症/ 肺炎/ IN BILATERAL PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
[redacted]	Yes	[redacted]20[redacted] (351)/ [redacted]20[redacted] (370)	感染症および寄生虫症/ 血腫感染/ INFECTED HEMATOMA OF THE LEFT HAMSTRING	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (556)/ [redacted]20[redacted] (561)	感染症および寄生虫症/ COVID-19肺炎/ COVID19 - PNEUMONIA	Yes/ 3/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted]20[redacted] (562)/ [redacted]20[redacted] (562)	感染症および寄生虫症/ COVID-19肺炎/ COVID19 - PNEUMONIA	Yes/ 5/ RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	No	[redacted]20[redacted] (-31)/ [redacted]20[redacted] (-30)	神経系障害/ 失神/ VASOVAGAL SYNCOPE	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (845)/ [redacted]20[redacted] (858)	感染症および寄生虫症/ COVID-19/ COVID-19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (917)/ [redacted]20[redacted] (934)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (603)/ [redacted] 20[redacted] (606)	胃腸障害/ 鼠径ヘルニア/ INGUINAL HERNIA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (780)/ [redacted] 20[redacted] (799)	腎および尿路障害/ 急性腎障害/ PRERENAL ACUTE RENAL FAILURE	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
	Yes	[redacted] 20[redacted] (800)/ [redacted] 20[redacted] (800)	腎および尿路障害/ 急性腎障害/ PRERENAL ACUTE RENAL FAILURE	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (613)/ [redacted] 20[redacted] (624)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (259)/ [redacted] 20[redacted] (259)	感染症および寄生虫症/ 心内膜炎/ INFECTIOUS ENDOCARDITIS	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (54)/ [redacted] 20[redacted] (60)	臨床検査/ 血中ビリルビン増加/ BLOOD BILIRUBIN INCREASED,	Yes/ 4/ RELATED	DRUG WITHDRAWN/ 1/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (61)/ [redacted] 20[redacted] (103)	臨床検査/ 血中ビリルビン増加/ BLOOD BILIRUBIN INCREASED,	Yes/ 3/ RELATED	DRUG WITHDRAWN/ 1/ RECOVERED/RESOLVED

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (65)/ [redacted] 20[redacted] (79)	心臓障害/ 心不全/ HEART FAILURE	Yes/ 4/ RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (73)/ [redacted] 20[redacted] (81)	血液およびリンパ系障害/ 好中球減少症/ NEUTROPENIA	Yes/ 4/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (459)/ [redacted] 20[redacted] (461)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
[redacted]	No	[redacted] 20[redacted] (465)/ [redacted] 20[redacted] (465)	血液およびリンパ系障害/ リンパ節症/ INCREASED LYMPHADENOPATHY (SIGNIFICANT IN THE RIGHT AXILLA)	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL
[redacted]	Yes	[redacted] 20[redacted] (416)/ [redacted] 20[redacted] (461)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL
	Yes	[redacted] 20[redacted] (462)/ [redacted] 20[redacted] (462)	感染症および寄生虫症/ COVID-19肺炎/ COVID-19 PNEUMONIA	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (179)/ [redacted] 20[redacted] (192)	感染症および寄生虫症/ 肺炎/ PNEUMONIA- UNKNOWN ETIOLOGY	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (814)/ [redacted] 20[redacted] (825)	心臓障害/ 上室性頻脈/ SUPRAVENTRICULAR TACHYCARDIA	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (170)/ [redacted] 20[redacted] (181)	感染症および寄生虫症/ COVID-19/ COVID-19 INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 1/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (925)/ [redacted] 20[redacted] (945)	感染症および寄生虫症/ 脳炎/ ASEPTIC MENINGO-ENCEPHALITIS	Yes/ 3/ NOT RELATED	DOSE REDUCED;DRUG INTERRUPTED/ 2/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted] 20[redacted] (599)/ [redacted] 20[redacted] (607)	感染症および寄生虫症/ COVID-19肺炎/ BILATERAL PNEUMONIA, COVID-19	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (547)/ [redacted] 20[redacted] (553)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 皮膚有棘細胞癌/ SPINOCELLULAR CARCINOMA	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED WITH SEQUELAE

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (304)/ [redacted]20[redacted] (359)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱移行上皮癌/ PAPILLAR UROTHELIAL CARCINOMA HIGH GRADE NON-INVASIVE, LOCALISED IN BLADDER	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (695)/ [redacted]20[redacted] (704)	傷害、中毒および処置合併症/ 処置後合併症/ NECROSIS IN URINAL BLADDER AFTER CARCINOMA RESECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
	Yes	[redacted]20[redacted] (837)/ [redacted]20[redacted] (847)	感染症および寄生虫症/ 尿路感染/ URINARY INFECTION	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2/ RECOVERING/RESOLVING
	No	[redacted]20[redacted] (903)/ [redacted]20[redacted] (911)	傷害、中毒および処置合併症/ 処置後合併症/ NECROSIS IN URINAL BLADDER AFTER CARCINOMA RESECTION	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 2;3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted]20[redacted] (453)/ [redacted]20[redacted] (458)	感染症および寄生虫症/ 肺炎/ BILATERAL PNEUMONIA (UNKNOWN ETIOLOGY)	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL
	Yes	[redacted]20[redacted] (459)/ [redacted]20[redacted] (459)	感染症および寄生虫症/ 肺炎/ BILATERAL PNEUMONIA (UNKNOWN ETIOLOGY)	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	No	[redacted] 20[redacted] (-9)/ [redacted] 20[redacted] (1)	感染症および寄生虫症/ 尿路感染/ URINARY INFECTION	Yes/ 2/ NOT RELATED	NOT APPLICABLE/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (327)/ [redacted] 20[redacted] (329)	神経系障害/ 一過性脳虚血発作/ TRANSIENT ISCHEMIC ATTACK	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 1/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (1040)/ [redacted] 20[redacted] (1045)	心臓障害/ 心房細動/ ATRIAL FIBRILATION - WORSENING	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (211)/ [redacted] 20[redacted] (232)	感染症および寄生虫症/ 肺炎/ PNEUMONIA ON LEFT SIDE UNKNOWN ETIOLOGY	Yes/ 3/ RELATED	DRUG INTERRUPTED/ 2/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (863)/ [redacted] 20[redacted] (876)	感染症および寄生虫症/ クレブシエラ菌性肺炎/ PNEUMONIA - ETIOLOGY KLEBSIELLA PNEUMONIE	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 2;3/ RECOVERED/RESOLVED
	Yes	[redacted] 20[redacted] (1094)/ [redacted] 20[redacted] (1103)	先天性、家族性および遺伝性障害/ 気管支原性嚢胞/ BRONCHOGENIC CYST WORSENING	Yes/ 2/ NOT RELATED	DOSE NOT CHANGED/ 3/ RECOVERED/RESOLVED
[redacted]	No	[redacted] 20[redacted] (747)/ [redacted] 20[redacted] (771)	代謝および栄養障害/ 食欲減退/ ANOREXIA	Yes/ 5/ NOT RELATED	NOT APPLICABLE/ 1/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted] 20[redacted] (474)/ [redacted] 20[redacted] (479)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 膀胱移行上皮癌/ PAPILLARY UROTHELIAL NEOPLASM OF LOW MALIGNANT POTENTIAL (BLADDER) START AS MICROSCOPIC HEMATURIA	Yes/ 2/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED
[redacted]	Yes	[redacted] 20[redacted] (518)/ [redacted] 20[redacted] (661)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸腺癌/ INTESTINAL TYPE ADENOCARCINOMA OF COLON WITH METASTASIS OF LIVER	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (661)/ [redacted] 20[redacted] (695)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸腺癌/ INTESTINAL TYPE ADENOCARCINOMA OF COLON WITH METASTASIS OF LIVER	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL
	Yes	[redacted] 20[redacted] (696)/ [redacted] 20[redacted] (696)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸腺癌/ INTESTINAL TYPE ADENOCARCINOMA OF COLON WITH METASTASIS OF LIVER	Yes/ 5/ NOT RELATED	DRUG WITHDRAWN/ 2;3/ FATAL

Patient ID	Treatment Emergent	AE Start Date (Study Day)/ AE Stop Date (Study Day)	System Organ Class/ Preferred Term/ AE Term	Serious/ CTCAE Grade/ Relationship	Study Drug Action Taken/ Other Action[a]/ Event Outcome
[redacted]	Yes	[redacted]20[redacted] (236)/ [redacted]20[redacted] (239)	感染症および寄生虫症/ COVID-19肺炎/ COVID 19 BILATERAL PNEUMONIA, CONFIRMED,	Yes/ 3/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED WITH SEQUELAE
	Yes	[redacted]20[redacted] (240)/ [redacted]20[redacted] (305)	感染症および寄生虫症/ COVID-19肺炎/ COVID 19 BILATERAL PNEUMONIA, CONFIRMED,	Yes/ 4/ NOT RELATED	DRUG WITHDRAWN;DRUG INTERRUPTED/ 2;3;4/ RECOVERED/RESOLVED WITH SEQUELAE
	No	[redacted]20[redacted] (306)/ [redacted]20[redacted] (390)	感染症および寄生虫症/ 急性COVID-19後症候群/ CHRONIC RESPIRATORY INSUFICIENCY POST-COVID	Yes/ 3/ NOT RELATED	NOT APPLICABLE/ 1/ RECOVERING/RESOLVING
[redacted]	Yes	[redacted]20[redacted] (606)/ [redacted]20[redacted] (610)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 基底細胞癌/ SKIN BASALIOMA ON THE RIGHT LEG	Yes/ 3/ NOT RELATED	DRUG INTERRUPTED/ 3/ RECOVERED/RESOLVED

Source: Listing 16.2.7.2 in BGB-3111-305 clinical study report (data cutoff date of 08 August 2022). Data cutoff: 08AUG2022. Data extraction: [redacted]20[redacted].

[a] Other action taken: 1 = none, 2 = concomitant medication, 3 = concomitant procedure or surgery, 4 = blood products transfusion, 5 = other.

表 58： 治療下で発現した有害事象：器官別大分類別及び基本語別（BGB-3111-205 試験、安全性解析対象集団）

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
Patients with at least 1 TEAE	91 (100.0)
血液およびリンパ系障害	38 (41.8)
貧血	32 (35.2)
血小板減少症	12 (13.2)
好中球減少症	4 (4.4)
好酸球増加症	1 (1.1)
リンパ節痛	1 (1.1)
心臓障害	16 (17.6)
洞性徐脈	3 (3.3)
第一度房室ブロック	2 (2.2)
右脚ブロック	2 (2.2)
動悸	2 (2.2)
心室性不整脈	2 (2.2)
心室性期外収縮	2 (2.2)
急性冠動脈症候群	1 (1.1)
上室性不整脈	1 (1.1)
心房細動	1 (1.1)
心不全	1 (1.1)
心肺不全	1 (1.1)
心筋虚血	1 (1.1)
上室性期外収縮	1 (1.1)
移動性ペースメーカー	1 (1.1)
耳および迷路障害	5 (5.5)
回転性めまい	2 (2.2)
耳痛	1 (1.1)
聴力低下	1 (1.1)
中耳の炎症	1 (1.1)
内分泌障害	2 (2.2)
甲状腺腫	1 (1.1)
甲状腺腫瘤	1 (1.1)
眼障害	9 (9.9)
結膜充血	2 (2.2)
ドライアイ	2 (2.2)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
流涙増加	2 (2.2)
眼そう痒症	1 (1.1)
緑内障	1 (1.1)
涙器出血	1 (1.1)
黄斑症	1 (1.1)
胃腸障害	58 (63.7)
下痢	20 (22.0)
便秘	9 (9.9)
上腹部痛	8 (8.8)
歯痛	8 (8.8)
嘔吐	8 (8.8)
腹部膨満	7 (7.7)
胃炎	5 (5.5)
消化不良	4 (4.4)
歯周病	4 (4.4)
腹痛	3 (3.3)
胃食道逆流性疾患	3 (3.3)
口腔内潰瘍形成	3 (3.3)
悪心	3 (3.3)
腹部不快感	2 (2.2)
慢性胃炎	2 (2.2)
鼓腸	2 (2.2)
胃腸出血	2 (2.2)
歯肉腫脹	2 (2.2)
臍径ヘルニア	2 (2.2)
異常便	1 (1.1)
肛門潰瘍	1 (1.1)
十二指腸潰瘍	1 (1.1)
小腸炎	1 (1.1)
変色便	1 (1.1)
歯肉出血	1 (1.1)
歯肉痛	1 (1.1)
血便排泄	1 (1.1)
痔核	1 (1.1)
腸閉塞	1 (1.1)
腸管ポリープ	1 (1.1)
口腔内出血	1 (1.1)
肛門周囲痛	1 (1.1)
直腸炎	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
吐き戻し	1 (1.1)
上部消化管出血	1 (1.1)
一般・全身障害および投与部位の状態	26 (28.6)
発熱	12 (13.2)
インフルエンザ様疾患	5 (5.5)
疲労	3 (3.3)
末梢性浮腫	3 (3.3)
無力症	1 (1.1)
胸部不快感	1 (1.1)
多臓器機能不全症候群	1 (1.1)
疼痛	1 (1.1)
肝胆道系障害	14 (15.4)
高ビリルビン血症	6 (6.6)
肝機能異常	4 (4.4)
胆嚢炎	1 (1.1)
慢性胆嚢炎	1 (1.1)
胆石症	1 (1.1)
肝不全	1 (1.1)
肝損傷	1 (1.1)
免疫系障害	2 (2.2)
節足動物咬傷アレルギー	1 (1.1)
造影剤アレルギー	1 (1.1)
感染症および寄生虫症	81 (89.0)
上気道感染	51 (56.0)
肺炎	34 (37.4)
尿路感染	17 (18.7)
皮膚感染	11 (12.1)
咽頭炎	9 (9.9)
気管支炎	8 (8.8)
胃腸炎	7 (7.7)
帯状疱疹	7 (7.7)
歯肉炎	5 (5.5)
爪囲炎	5 (5.5)
歯周炎	5 (5.5)
副鼻腔炎	5 (5.5)
無症候性細菌尿	4 (4.4)
口腔ヘルペス	4 (4.4)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
B 型肝炎	3 (3.3)
B 型肝炎再活性化	3 (3.3)
膿疱性皮疹	3 (3.3)
扁桃炎	3 (3.3)
肛門直腸感染	2 (2.2)
結膜炎	2 (2.2)
感染性腸炎	2 (2.2)
インフルエンザ	2 (2.2)
腹部感染	1 (1.1)
虫垂炎	1 (1.1)
細菌性膣症	1 (1.1)
細菌性気管支炎	1 (1.1)
クリプトコッカス症	1 (1.1)
感染性皮膚炎	1 (1.1)
眼感染	1 (1.1)
毛包炎	1 (1.1)
ウイルス性胃腸炎	1 (1.1)
ウイルス性肝炎	1 (1.1)
ヘルペス性皮膚炎	1 (1.1)
単純ヘルペス	1 (1.1)
ヘルペスウイルス感染	1 (1.1)
感染	1 (1.1)
感染性胸水	1 (1.1)
喉頭炎	1 (1.1)
口唇感染	1 (1.1)
下気道感染	1 (1.1)
リンパ節感染	1 (1.1)
リンパ管炎	1 (1.1)
上咽頭炎	1 (1.1)
口腔感染	1 (1.1)
中耳炎	1 (1.1)
耳下腺炎	1 (1.1)
咽頭膿瘍	1 (1.1)
真菌性肺炎	1 (1.1)
歯髄炎	1 (1.1)
鼻炎	1 (1.1)
軟部組織感染	1 (1.1)
脾感染	1 (1.1)
足部白癬	1 (1.1)
気管炎	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
ウイルス感染	1 (1.1)
傷害、中毒および処置合併症	12 (13.2)
靭帯捻挫	3 (3.3)
四肢損傷	2 (2.2)
節足動物咬傷	1 (1.1)
脳ヘルニア	1 (1.1)
挫傷	1 (1.1)
手骨折	1 (1.1)
人工関節周囲骨折	1 (1.1)
肋骨骨折	1 (1.1)
創合併症	1 (1.1)
臨床検査	83 (91.2)
好中球数減少	70 (76.9)
血小板数減少	39 (42.9)
二酸化炭素増加	23 (25.3)
白血球数減少	23 (25.3)
アラニンアミノトランスフェラーゼ増加	16 (17.6)
尿中ウロビリノーゲン増加	15 (16.5)
アスパラギン酸アミノトランスフェラーゼ増加	14 (15.4)
血中ビリルビン増加	14 (15.4)
尿中血陽性	11 (12.1)
心電図 QT 延長	8 (8.8)
γーグルタミルトランスフェラーゼ増加	8 (8.8)
低比重リポ蛋白減少	8 (8.8)
リンパ球数減少	8 (8.8)
好中球百分率減少	8 (8.8)
尿中赤血球陽性	8 (8.8)
血中アルカリホスファターゼ増加	7 (7.7)
細菌検査陽性	6 (6.6)
血中クレアチニン増加	6 (6.6)
血中フィブリノゲン減少	6 (6.6)
高比重リポ蛋白減少	6 (6.6)
体重減少	6 (6.6)
血中乳酸脱水素酵素増加	5 (5.5)
血中ブドウ糖増加	4 (4.4)
グロブリン減少	4 (4.4)
ヘモグロビン減少	4 (4.4)
高比重リポ蛋白増加	4 (4.4)
尿中白血球陽性	4 (4.4)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
血中免疫グロブリン A 減少	3 (3.3)
二酸化炭素減少	3 (3.3)
尿中白血球エステラーゼ陽性	3 (3.3)
白血球数増加	3 (3.3)
活性化部分トロンボプラスチン時間延長	2 (2.2)
α ヒドロキシ酪酸脱水素酵素増加	2 (2.2)
血中免疫グロブリン G 減少	2 (2.2)
血中免疫グロブリン M 減少	2 (2.2)
血圧上昇	2 (2.2)
血中トリグリセリド増加	2 (2.2)
B 型肝炎 DNA 増加	2 (2.2)
リポ蛋白（a）増加	2 (2.2)
低比重リポ蛋白増加	2 (2.2)
好中球数増加	2 (2.2)
尿中亜硝酸塩陽性	2 (2.2)
尿比重増加	2 (2.2)
アポリポ蛋白増加	1 (1.1)
アスパラギン酸アミノトランスフェラーゼ減少	1 (1.1)
抱合ビリルビン増加	1 (1.1)
血中アルブミン減少	1 (1.1)
血中コレステロール減少	1 (1.1)
血中コレステロール増加	1 (1.1)
血中マグネシウム減少	1 (1.1)
血中尿素増加	1 (1.1)
血中尿酸増加	1 (1.1)
好酸球数増加	1 (1.1)
フィブリン D ダイマー増加	1 (1.1)
ヘモグロビン増加	1 (1.1)
心拍数増加	1 (1.1)
軽鎖分析値減少	1 (1.1)
リポ蛋白増加	1 (1.1)
リンパ球百分率減少	1 (1.1)
酸素飽和度低下	1 (1.1)
血小板凝集低下	1 (1.1)
尿中蛋白陽性	1 (1.1)
総胆汁酸増加	1 (1.1)
尿中ケトン体陽性	1 (1.1)
尿量減少	1 (1.1)
体重増加	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
代謝および栄養障害	58 (63.7)
低カリウム血症	28 (30.8)
高血糖	26 (28.6)
高尿酸血症	18 (19.8)
低カルシウム血症	13 (14.3)
低アルブミン血症	12 (13.2)
低ナトリウム血症	10 (11.0)
高トリグリセリド血症	7 (7.7)
高コレステロール血症	5 (5.5)
高カルシウム血症	4 (4.4)
低リン酸血症	4 (4.4)
食欲減退	2 (2.2)
高カリウム血症	2 (2.2)
高マグネシウム血症	2 (2.2)
高ナトリウム血症	2 (2.2)
低クロール血症	2 (2.2)
低マグネシウム血症	2 (2.2)
電解質失調	1 (1.1)
耐糖能障害	1 (1.1)
高クロール血症	1 (1.1)
高脂血症	1 (1.1)
高リン酸塩血症	1 (1.1)
低 HDL コレステロール血症	1 (1.1)
低コレステロール血症	1 (1.1)
低血糖	1 (1.1)
低蛋白血症	1 (1.1)
低尿酸血症	1 (1.1)
低亜鉛血症	1 (1.1)
鉄欠乏	1 (1.1)
筋骨格系および結合組織障害	12 (13.2)
背部痛	3 (3.3)
椎間板突出	2 (2.2)
変形性関節症	2 (2.2)
四肢痛	2 (2.2)
滑膜炎	2 (2.2)
関節痛	1 (1.1)
骨痛	1 (1.1)
筋肉疲労	1 (1.1)
筋骨格痛	1 (1.1)
骨関節障害	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
腱鞘炎	1 (1.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5 (5.5)
胃腺癌	2 (2.2)
乳癌	1 (1.1)
結腸癌	1 (1.1)
直腸癌	1 (1.1)
神経系障害	25 (27.5)
頭痛	8 (8.8)
浮動性めまい	7 (7.7)
ヘルペス後神経痛	2 (2.2)
頚動脈硬化症	1 (1.1)
脳梗塞	1 (1.1)
脳虚血	1 (1.1)
脳血管不全	1 (1.1)
間代	1 (1.1)
てんかん	1 (1.1)
顔面麻痺	1 (1.1)
頭蓋内出血	1 (1.1)
感覚鈍麻	1 (1.1)
ラクナ梗塞	1 (1.1)
末梢性運動ニューロパチー	1 (1.1)
睡眠の質低下	1 (1.1)
坐骨神経痛	1 (1.1)
傾眠	1 (1.1)
精神障害	4 (4.4)
不眠症	2 (2.2)
不安	1 (1.1)
幻覚	1 (1.1)
腎および尿路障害	46 (50.5)
血尿	39 (42.9)
蛋白尿	14 (15.4)
白血球尿	2 (2.2)
頻尿	2 (2.2)
尿管結石症	2 (2.2)
尿道痛	2 (2.2)
アルブミン尿	1 (1.1)
尿路結石	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
水腎症	1 (1.1)
腎不全	1 (1.1)
尿閉	1 (1.1)
生殖系および乳房障害	7 (7.7)
良性前立腺肥大症	3 (3.3)
後天性陰嚢水瘤	1 (1.1)
萎縮性外陰腟炎	1 (1.1)
性器浮腫	1 (1.1)
腟出血	1 (1.1)
呼吸器、胸郭および縦隔障害	46 (50.5)
咳嗽	23 (25.3)
口腔咽頭痛	6 (6.6)
鼻出血	5 (5.5)
鼻閉塞	4 (4.4)
扁桃肥大	4 (4.4)
鼻閉	2 (2.2)
口腔咽頭不快感	2 (2.2)
咽頭紅斑	2 (2.2)
咽頭出血	2 (2.2)
鼻漏	2 (2.2)
喘息	1 (1.1)
気管支拡張症	1 (1.1)
慢性気管支炎	1 (1.1)
肺気腫	1 (1.1)
低酸素症	1 (1.1)
喉頭の炎症	1 (1.1)
鼻腔腫瘤	1 (1.1)
鼻茸	1 (1.1)
胸膜炎	1 (1.1)
肺臓炎	1 (1.1)
湿性咳嗽	1 (1.1)
肺腫瘤	1 (1.1)
呼吸不全	1 (1.1)
気道出血	1 (1.1)
アレルギー性鼻炎	1 (1.1)
皮膚および皮下組織障害	52 (57.1)
紫斑	31 (34.1)
発疹	15 (16.5)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
皮下出血	7 (7.7)
斑状丘疹状皮疹	5 (5.5)
アレルギー性皮膚炎	3 (3.3)
斑状出血	3 (3.3)
そう痒症	3 (3.3)
皮膚出血	3 (3.3)
紅斑	2 (2.2)
寝汗	2 (2.2)
皮膚嚢腫	1 (1.1)
皮膚炎	1 (1.1)
ざ瘡様皮膚炎	1 (1.1)
湿疹	1 (1.1)
点状出血	1 (1.1)
毛細血管拡張症	1 (1.1)
蕁麻疹	1 (1.1)
丘疹状蕁麻疹	1 (1.1)
血管障害	10 (11.0)
高血圧	9 (9.9)
末梢動脈閉塞性疾患	1 (1.1)
末梢動脈閉塞	1 (1.1)

Source: Table 14.3.1.2.2.1 in BGB-3111-205 clinical study report. Data cutoff: 11SEP2020; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
TEAE = treatment-emergent adverse event.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
MedDRA Version: 23.0

表 59： 投与に関連のある有害事象：器官別大分類別及び基本語別（BGB-3111-205 試験、安全性解析対象集団）

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
Patients with at least 1 treatment-related TEAE	90 (98.9)
血液およびリンパ系障害	33 (36.3)
貧血	25 (27.5)
血小板減少症	11 (12.1)
好中球減少症	3 (3.3)
好酸球増加症	1 (1.1)
リンパ節痛	1 (1.1)
心臓障害	11 (12.1)
右脚ブロック	2 (2.2)
洞性徐脈	2 (2.2)
心室性不整脈	2 (2.2)
心室性期外収縮	2 (2.2)
急性冠動脈症候群	1 (1.1)
上室性不整脈	1 (1.1)
心房細動	1 (1.1)
上室性期外収縮	1 (1.1)
移動性ペースメーカー	1 (1.1)
耳および迷路障害	3 (3.3)
聴力低下	1 (1.1)
中耳の炎症	1 (1.1)
回転性めまい	1 (1.1)
眼障害	5 (5.5)
ドライアイ	2 (2.2)
結膜充血	1 (1.1)
眼そう痒症	1 (1.1)
流涙増加	1 (1.1)
胃腸障害	28 (30.8)
下痢	7 (7.7)
便秘	4 (4.4)
腹部膨満	3 (3.3)
歯周病	3 (3.3)
上腹部痛	2 (2.2)
慢性胃炎	2 (2.2)
胃炎	2 (2.2)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
胃食道逆流性疾患	2 (2.2)
歯痛	2 (2.2)
腹痛	1 (1.1)
異常便	1 (1.1)
十二指腸潰瘍	1 (1.1)
消化不良	1 (1.1)
変色便	1 (1.1)
胃腸出血	1 (1.1)
歯肉出血	1 (1.1)
歯肉痛	1 (1.1)
歯肉腫脹	1 (1.1)
腸閉塞	1 (1.1)
口腔内出血	1 (1.1)
口腔内潰瘍形成	1 (1.1)
悪心	1 (1.1)
上部消化管出血	1 (1.1)
一般・全身障害および投与部位の状態	13 (14.3)
発熱	8 (8.8)
疲労	2 (2.2)
無力症	1 (1.1)
インフルエンザ様疾患	1 (1.1)
末梢性浮腫	1 (1.1)
肝胆道系障害	10 (11.0)
高ビリルビン血症	6 (6.6)
肝機能異常	3 (3.3)
肝損傷	1 (1.1)
免疫系障害	2 (2.2)
節足動物咬傷アレルギー	1 (1.1)
造影剤アレルギー	1 (1.1)
感染症および寄生虫症	52 (57.1)
肺炎	25 (27.5)
上気道感染	24 (26.4)
尿路感染	8 (8.8)
咽頭炎	5 (5.5)
副鼻腔炎	5 (5.5)
皮膚感染	5 (5.5)
気管支炎	3 (3.3)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
B 型肝炎	3 (3.3)
B 型肝炎再活性化	3 (3.3)
帯状疱疹	3 (3.3)
歯周炎	3 (3.3)
膿疱性皮疹	3 (3.3)
肛門直腸感染	2 (2.2)
歯肉炎	2 (2.2)
口腔ヘルペス	2 (2.2)
虫垂炎	1 (1.1)
細菌性膣症	1 (1.1)
結膜炎	1 (1.1)
感染性皮膚炎	1 (1.1)
感染性腸炎	1 (1.1)
胃腸炎	1 (1.1)
ウイルス性肝炎	1 (1.1)
感染	1 (1.1)
喉頭炎	1 (1.1)
リンパ節感染	1 (1.1)
鼻炎	1 (1.1)
軟部組織感染	1 (1.1)
気管炎	1 (1.1)
傷害、中毒および処置合併症	1 (1.1)
挫傷	1 (1.1)
臨床検査	80 (87.9)
好中球数減少	69 (75.8)
血小板数減少	37 (40.7)
二酸化炭素増加	22 (24.2)
白血球数減少	21 (23.1)
尿中ウロビリノーゲン増加	13 (14.3)
アラニンアミノトランスフェラーゼ増加	12 (13.2)
アスパラギン酸アミノトランスフェラーゼ増加	11 (12.1)
血中ビリルビン増加	11 (12.1)
尿中血陽性	10 (11.0)
心電図 QT 延長	8 (8.8)
γーグルタミルトランスフェラーゼ増加	8 (8.8)
好中球百分率減少	8 (8.8)
尿中赤血球陽性	8 (8.8)
細菌検査陽性	6 (6.6)
血中アルカリホスファターゼ増加	6 (6.6)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
血中フィブリノゲン減少	6 (6.6)
リンパ球数減少	6 (6.6)
血中クレアチニン増加	5 (5.5)
低比重リポ蛋白減少	5 (5.5)
血中ブドウ糖増加	4 (4.4)
ヘモグロビン減少	4 (4.4)
血中乳酸脱水素酵素増加	3 (3.3)
グロブリン減少	3 (3.3)
高比重リポ蛋白減少	3 (3.3)
尿中白血球エステラーゼ陽性	3 (3.3)
体重減少	3 (3.3)
白血球数増加	3 (3.3)
尿中白血球陽性	3 (3.3)
αヒドロキシ酪酸脱水素酵素増加	2 (2.2)
血中免疫グロブリン A 減少	2 (2.2)
B 型肝炎 DNA 増加	2 (2.2)
高比重リポ蛋白増加	2 (2.2)
リポ蛋白（a）増加	2 (2.2)
尿中亜硝酸塩陽性	2 (2.2)
活性化部分トロンボプラスチン時間延長	1 (1.1)
アポリポ蛋白増加	1 (1.1)
アスパラギン酸アミノトランスフェラーゼ減少	1 (1.1)
抱合ビリルビン増加	1 (1.1)
血中アルブミン減少	1 (1.1)
血中コレステロール増加	1 (1.1)
血中免疫グロブリン G 減少	1 (1.1)
血中マグネシウム減少	1 (1.1)
血中尿素増加	1 (1.1)
血中尿酸増加	1 (1.1)
二酸化炭素減少	1 (1.1)
好酸球数増加	1 (1.1)
軽鎖分析値減少	1 (1.1)
リポ蛋白増加	1 (1.1)
低比重リポ蛋白増加	1 (1.1)
リンパ球百分率減少	1 (1.1)
好中球数増加	1 (1.1)
血小板凝集低下	1 (1.1)
尿中蛋白陽性	1 (1.1)
尿比重増加	1 (1.1)
尿中ケトン体陽性	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
体重増加	1 (1.1)
代謝および栄養障害	36 (39.6)
高尿酸血症	13 (14.3)
低カリウム血症	11 (12.1)
高血糖	10 (11.0)
低カルシウム血症	7 (7.7)
低アルブミン血症	5 (5.5)
高コレステロール血症	4 (4.4)
高トリグリセリド血症	4 (4.4)
低ナトリウム血症	4 (4.4)
低リン酸血症	3 (3.3)
低マグネシウム血症	2 (2.2)
高カリウム血症	1 (1.1)
高マグネシウム血症	1 (1.1)
低クロール血症	1 (1.1)
低コレステロール血症	1 (1.1)
低蛋白血症	1 (1.1)
低尿酸血症	1 (1.1)
低亜鉛血症	1 (1.1)
鉄欠乏	1 (1.1)
筋骨格系および結合組織障害	4 (4.4)
四肢痛	2 (2.2)
背部痛	1 (1.1)
椎間板突出	1 (1.1)
筋肉疲労	1 (1.1)
滑膜炎	1 (1.1)
腱鞘炎	1 (1.1)
神経系障害	9 (9.9)
浮動性めまい	4 (4.4)
頭痛	3 (3.3)
脳虚血	1 (1.1)
頭蓋内出血	1 (1.1)
末梢性運動ニューロパチー	1 (1.1)
睡眠の質低下	1 (1.1)
ヘルペス後神経痛	1 (1.1)
坐骨神経痛	1 (1.1)
精神障害	2 (2.2)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
不眠症	2 (2.2)
腎および尿路障害	39 (42.9)
血尿	35 (38.5)
蛋白尿	10 (11.0)
白血球尿	2 (2.2)
アルブミン尿	1 (1.1)
頻尿	1 (1.1)
尿道痛	1 (1.1)
生殖系および乳房障害	1 (1.1)
良性前立腺肥大症	1 (1.1)
呼吸器、胸郭および縦隔障害	16 (17.6)
咳嗽	6 (6.6)
鼻出血	4 (4.4)
咽頭出血	2 (2.2)
喘息	1 (1.1)
慢性気管支炎	1 (1.1)
低酸素症	1 (1.1)
喉頭の炎症	1 (1.1)
鼻腔腫瘤	1 (1.1)
胸膜炎	1 (1.1)
鼻漏	1 (1.1)
皮膚および皮下組織障害	49 (53.8)
紫斑	31 (34.1)
発疹	8 (8.8)
皮下出血	7 (7.7)
斑状出血	3 (3.3)
そう痒症	3 (3.3)
皮膚出血	3 (3.3)
紅斑	2 (2.2)
斑状丘疹状皮疹	2 (2.2)
皮膚炎	1 (1.1)
ざ瘡様皮膚炎	1 (1.1)
アレルギー性皮膚炎	1 (1.1)
寝汗	1 (1.1)
点状出血	1 (1.1)
毛細血管拡張症	1 (1.1)
丘疹状蕁麻疹	1 (1.1)

System Organ Class Preferred Term	Zanubrutinib (N = 91) n (%)
血管障害	4 (4.4)
高血圧	3 (3.3)
末梢動脈閉塞性疾患	1 (1.1)
末梢動脈閉塞	1 (1.1)

Source: Table 14.3.1.2.2.2 in BGB-3111-205 clinical study report. Data cutoff: 11SEP2020; Data extraction: [redacted]20[redacted]; Data Source: ADSL, ADAE
TEAE = treatment-emergent adverse event.
Patients with multiple events for a given Preferred Term and System Organ Class are counted only once for each Preferred Term and System Organ Class, respectively.
Treatment-related TEAEs include those events considered by the investigator to be related, probably and possibly related, or with missing assessment of the causal relationship.
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表 60： その他の重篤な有害事象の一覧（BGB-3111-205 試験、安全性解析対象集団）

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 気管支炎/ [BRONCHIAL INFECTION] (7)	[redacted] 20[redacted] (184)/ 20[redacted] (192) [9]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	呼吸器、胸郭および縦隔障害/ 気管支拡張症/ [BRONCHIECTASIS] (8)	[redacted] 20[redacted] (184)/ 20[redacted] (192) [9]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
Patient: [redacted] (SLL)									
[redacted] 20[redacted] / 160 mg BID	神経系障害/ 脳血管不全/ [INSUFFICIENT BLOOD SUPPLY FROM CEREBRAL ARTERIES] (28)	[redacted] 20[redacted] (948)/ 20[redacted] (953) [6]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION (POSITIVE FOR MYCOPLASMA PNEUMONIAE, A LITTLE INFLAMMATION OF THE LEFT LUNG)] (5)	[redacted] 20[redacted] (4)/ 20[redacted] (14) [11]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Unlikely Related	Not Recovered/Not Resolved		3
	感染症および寄生虫症/ 感染性腸炎/ [INTESTINAL INFECTION (DIARRHEA)] (7)	[redacted] 20[redacted] (6)/ 20[redacted] (9) [4]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Related	Recovered/Resolved		2
	心臓障害/ 心不全/ [HEART FAILURE] (24)	[redacted] 20[redacted] (14)/ 20[redacted] (23) [10]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Unlikely Related	Not Recovered/Not Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION (POSITIVE FOR MYCOPLASMA PNEUMONIAE, A LITTLE INFLAMMATION OF THE LEFT LUNG)] (28)	[redacted] (14)/ [redacted] (23) [10]	Grade 4: Life-threatening or Disabling	Yes	Drug Interrupted	Unlikely Related	Not Recovered/Not Resolved		3
	呼吸器、胸郭および縦隔障害/ 呼吸不全/ [RESPIRATORY FAILURE] (29)	[redacted] (14)/ [redacted] (23) [10]	Grade 4: Life-threatening or Disabling	Yes	Dose Not Changed	Unlikely Related	Not Recovered/Not Resolved		3
Patient: [redacted] (CLL)									
[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (22)	[redacted] (632)/ [redacted] (638) [7]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION (PNEUMONIA)] (9)	[redacted] (33)/ [redacted] (45) [13]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (SLL)									
[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION (PNEUMONIA)] (7)	[redacted] (61)/ [redacted] (352) [292]	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn /Drug Interrupted	Possibly Related	Recovered/Resolved		2
	感染症および寄生虫症/ 感染性皮膚炎/ [INFECTED RASH] (8)	[redacted] (65)/ [redacted] (290) [226]	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn /Drug Interrupted	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted]/ 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 直腸癌/ [RECTAL CANCER] (55)	[redacted] 20[redacted] (1135)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Drug Withdrawn	Unlikely Related	Not Recovered/Not Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ B 型肝炎/ [HEPATITIS B VIRUS INFECTION] (24)	[redacted] 20[redacted] (194)/ [redacted] 20[redacted] (306) [113]	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn /Drug Interrupted	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 胃腺癌/ [MIDDLE - POORLY DIFFERENTIATED ADENOCARCINOMA OF GASTRIC ANTRUM MUCOSA] (42)	[redacted] 20[redacted] (680)/ [redacted] 20[redacted] (700) [21]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Unlikely Related	Recovered/Resolved With Sequelae		1
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (64)	[redacted] 20[redacted] (996)/ [redacted] 20[redacted] (1005) [10]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肛門直腸感染/ [ANORECTAL INFECTION] (27)	[redacted] 20[redacted] (396)/ [redacted] 20[redacted] (412) [17]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
	胃腸障害/ 腸管ポリープ/ [INTESTINAL POLYPS] (58)	[redacted] 20[redacted] (737)/ [redacted] 20[redacted] (739) [3]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (37)	[redacted] 20[redacted] (387)/ [redacted] 20[redacted] (408) [22]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Dose Not Changed	Possibly Related	Recovered/Resolved		2
	感染症および寄生虫症/ B 型肝炎/ [HEPATITIS B VIRUS INFECTION] (54)	[redacted] 20[redacted] (619)/ [redacted] 20[redacted] (653) [35]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Drug Withdrawn	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (39)	[redacted] 20[redacted] (861)/ [redacted] 20[redacted] (872) [12]	Grade 2: Moderate	Yes	Dose Not Changed	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ B 型肝炎/ [VIRAL HEPATITIS B] (45)	[redacted] 20[redacted] (691)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		1
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (8)	[redacted] 20[redacted] (101)/ [redacted] 20[redacted] (108) [8]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Not Related	Recovered/Resolved		1
	神経系障害/ ヘルペス後神経痛/ [NEURALGIA (AFTER SHINGLES)] (14)	[redacted] 20[redacted] (177)/ [redacted] 20[redacted] (184) [8]	Grade 2: Moderate	Yes	Dose Not Changed	Unlikely Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (2)	[redacted] 20[redacted] (8)/ [redacted] 20[redacted] (29) [22]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovering/Resolving		2
	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (4)	[redacted] 20[redacted] (30)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Not Recovered/Not Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
	胃腸障害/ 腸閉塞/ [INCOMPLETE INTESTINAL OBSTRUCTION] (9)	[redacted] 20[redacted] (38)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Not Recovered/Not Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (20)	[redacted] 20[redacted] (728)/ [redacted] 20[redacted] (754) [27]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	神経系障害/ 頭蓋内出血/ [INTRACRANIAL HEMORRHAGE] (9)	[redacted] 20[redacted] (369)/ [redacted] 20[redacted] (424) [56]	Grade 2: Moderate	Yes	Drug Interrupted /Drug Withdrawn	Possibly Related	Recovered/Resolved With Sequelae		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (1)	[redacted] 20[redacted] (1)/ [redacted] 20[redacted] (14) [14]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Not Related	Recovering/Resolving		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (2)	[redacted] 20[redacted] (14)/ [redacted] 20[redacted] (20) [7]	Grade 2: Moderate	Yes	Drug Interrupted	Not Related	Recovered/Resolved With Sequelae		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (3)	[redacted] 20[redacted] (28)/ [redacted] 20[redacted] (42) [15]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (6)	[redacted] 20[redacted] (42)/ [redacted] 20[redacted] (97) [56]	Grade 2: Moderate	Yes	Drug Withdrawn	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 虫垂炎/ [APPENDICITIS] (20)	[redacted] 20[redacted] (697)/ [redacted] 20[redacted] (711) [15]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
	臨床検査/ 好中球数減少/ [BLOOD NEUTROPHIL COUNT DECREASED] (26)	[redacted] 20[redacted] (783)/ [redacted] 20[redacted] (796) [14]	Grade 4: Life-threatening or Disabling	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (27)	[redacted] 20[redacted] (783)/ [redacted] 20[redacted] (838) [56]	Grade 2: Moderate	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 胃腸炎/ [ACUTE GASTROENTERITIS] (4)	[redacted] 20[redacted] (40)/	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Unknown		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (22)	[redacted] 20[redacted] (231)/ [redacted] 20[redacted] (235) [5]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Dose Reduced	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	筋骨格系および結合組織障害/ 骨関節障害/ [OSTEOARTHROPATHY] (7)	[redacted] 20[redacted] (297)/ [redacted] 20[redacted] (318) [22]	Grade 2: Moderate	Yes	Drug Interrupted	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (16)	[redacted] 20[redacted] (527)/ [redacted] 20[redacted] (536) [10]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted] / 160 mg BID	生殖系および乳房障害/ 良性前立腺肥大症/ [PROSTATIC HYPERPLASIA WORSENING] (13)	[redacted] 20[redacted] (897)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 皮膚感染/ [SKIN INFECTION] (4)	[redacted] 20[redacted] (63)/ 20[redacted] (68) [6]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (2)	[redacted] 20[redacted] (100)/ 20[redacted] (113) [14]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	血液およびリンパ系障害/ 貧血/ [ANEMIA] (38)	[redacted] 20[redacted] (309)/ 20[redacted] (394) [86]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Recovering/Resolving		2
	血液およびリンパ系障害/ 貧血/ [ANEMIA] (48)	[redacted] 20[redacted] (394)/ 20[redacted] (441) [48]	Grade 1: Mild	Yes	Dose Not Changed	Possibly Related	Not Recovered/Not Resolved		2
	感染症および寄生虫症/ 皮膚感染/ [SKIN INFECTION] (54)	[redacted] 20[redacted] (430)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Drug Withdrawn	Possibly Related	Not Recovered/Not Resolved		2
	血液およびリンパ系障害/ 貧血/ [ANEMIA] (55)	[redacted] 20[redacted] (441)/ 20[redacted] (452) [12]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Recovering/Resolving		2
	血液およびリンパ系障害/ 貧血/ [ANEMIA] (65)	[redacted] 20[redacted] (452)/ 20[redacted] (454) [3]	Grade 2: Moderate	Yes	Dose Not Changed	Possibly Related	Not Recovered/Not Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
	血液およびリンパ系障害/ 貧血/ [ANEMIA] (68)	[redacted] 20[redacted] (454)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Possibly Related	Not Recovered/Not Resolved		2
	臨床検査/ 血小板数減少/ [PLATELET COUNT DECREASED] (83)	[redacted] 20[redacted] (469)/ ONGOING	Grade 4: Life-threatening or Disabling	Yes	Not Applicable	Unlikely Related	Not Recovered/Not Resolved		3
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	肝胆道系障害/ 胆嚢炎/ [CHOLECYSTITIS] (12)	[redacted] 20[redacted] (240)/ 20[redacted] (246) [7]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (SLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION] (4)	[redacted] 20[redacted] (168)/ 20[redacted] (174) [7]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	内分泌障害/ 甲状腺腫/ [NODULAR GOITER] (6)	[redacted] 20[redacted] (963)/ 20[redacted] (977) [15]	Grade 2: Moderate	Yes	Drug Interrupted	Not Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	皮膚および皮下組織障害/ 斑状丘疹状皮疹/ [RASH MACULO-PAPULAR (RUPTURE)] (12)	[redacted] 20[redacted] (285)/ 20[redacted] (293) [9]	Grade 1: Mild	Yes	Dose Not Changed	Unlikely Related	Recovering/Resolving		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	胃腸障害/ 痔核/ [INTERNAL AND EXTERNAL MIXED HEMORRHOIDS] (19)	[redacted] 20[redacted] (478)/ 20[redacted] (510) [33]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	腎および尿路障害/ 尿管結石症/ [UPPER URETERAL CALCULI WITH HYDRONEPHROSIS] (30)	[redacted] 20[redacted] (603)/ 20[redacted] (605) [3]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
	腎および尿路障害/ 水腎症/ [UPPER URETERAL CALCULI WITH HYDRONEPHROSIS] (31)	[redacted] 20[redacted] (603)/ 20[redacted] (605) [3]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	感染症および寄生虫症/ 気管支炎/ [ACUTE BRONCHITIS] (16)	[redacted] 20[redacted] (390)/ 20[redacted] (406) [17]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
	感染症および寄生虫症/ 気管支炎/ [ACUTE BRONCHITIS] (17)	[redacted] 20[redacted] (478)/ 20[redacted] (499) [22]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovering/Resolving		2
	感染症および寄生虫症/ 胃腸炎/ [ACUTE GASTROENTERITIS] (25)	[redacted] 20[redacted] (845)/ 20[redacted] (881) [37]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 乳癌/ [MAMMARY CANCER] (11)	[redacted] 20[redacted] (222)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn	Not Related	Not Recovered/Not Resolved		1
Patient: [redacted] (CLL)									
[redacted] 20[redacted] / 160 mg BID	心臓障害/ 心筋虚血/ [MYOCARDIAL ISCHEMIA] (7)	[redacted] 20[redacted] (60)/ 20[redacted] (73) [14]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted]/ 160 mg BID	傷害、中毒および処置合併症/ 手骨折/ [RIGHT HAND FIRST METACARPAL BASE COMMINUTED FRACTURE] (4)	[redacted] 20[redacted] (46)/ [redacted] 20[redacted] (226) [181]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (18)	[redacted] 20[redacted] (1141)/ [redacted] 20[redacted] (1168) [28]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (4)	[redacted] 20[redacted] (11)/ [redacted] 20[redacted] (29) [19]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (15)	[redacted] 20[redacted] (192)/ [redacted] 20[redacted] (199) [8]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	神経系障害/ 頭痛/ [HEADACHE] (25)	[redacted] 20[redacted] (752)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Drug Withdrawn	Unlikely Related	Not Recovered/Not Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	神経系障害/ 頭痛/ [HEADACHE] (18)	[redacted] 20[redacted] (272)/ [redacted] 20[redacted] (366) [95]	Grade 2: Moderate	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	傷害、中毒および処置合併症/ 人工関節周囲骨折/ [PERIPROSTHETIC FRACTURE OF LEFT FEMUR] (52)	[redacted] 20[redacted] (818)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Not Related	Not Recovered/Not Resolved		2
	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (59)	[redacted] 20[redacted] (1013)/ [redacted] 20[redacted] (1032) [20]	Grade 2: Moderate	Yes	Dose Not Changed	Possibly Related	Recovered/Resolved		2

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ クリプトコッカス症/ [CRYPTOCOCCUS INFECTION IN PARAPHARYNGEAL AND NASOPHARYNX] (36)	[redacted] 20[redacted] (905)/ [redacted] 20[redacted] (942) [38]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted /Dose Reduced	Not Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 結腸癌/ [COLON CANCER] (17)	[redacted] 20[redacted] (57)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn /Drug Interrupted	Not Related	Not Recovered/Not Resolved		2
	感染症および寄生虫症/ 真菌性肺炎/ [FUNGAL PNEUMONIA] (22)	[redacted] 20[redacted] (60)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Not Recovered/Not Resolved		1
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (9)	[redacted] 20[redacted] (621)/ [redacted] 20[redacted] (625) [5]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 肺炎/ [LUNG INFECTION] (14)	[redacted] 20[redacted] (957)/ [redacted] 20[redacted] (969) [13]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺炎/ [PNEUMONIA] (20)	[redacted] 20[redacted] (674)/ [redacted] 20[redacted] (679) [6]	Grade 2: Moderate	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION WORSEN] (3)	[redacted] 20[redacted] (7)/ 20[redacted] (16) [10]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 上気道感染/ [UPPER RESPIRATORY INFECTION] (11)	[redacted] 20[redacted] (37)/ 20[redacted] (50) [14]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
	感染症および寄生虫症/ 脾感染/ [SPLENIC INFECTION] (15)	[redacted] 20[redacted] (85)/ 20[redacted] (111) [27]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Not Related	Recovered/Resolved With Sequelae		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 感染性胸水/ [PULMONARY EMPYEMA] (9)	[redacted] 20[redacted] (190)/ 20[redacted] (211) [22]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Not Related	Recovered/Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 気管支炎/ [BRONCHITIS] (14)	[redacted] 20[redacted] (367)/ 20[redacted] (372) [6]	Grade 3: Severe or Medically Significant	Yes	Drug Interrupted	Possibly Related	Recovered/Resolved		2
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 胃腺癌/ [STOMACH SIGNET-RING CELL CARCINOMA] (22)	[redacted] 20[redacted] (704)/ ONGOING	Grade 3: Severe or Medically Significant	Yes	Drug Withdrawn /Drug Interrupted	Unlikely Related	Not Recovered/Not Resolved		2
Patient: [redacted] (CLL)									
[redacted] 20[redacted]/ 160 mg BID	感染症および寄生虫症/ 肺炎/ [PULMONARY INFECTION OF LEFT LOWER LUNG] (15)	[redacted] 20[redacted] (309)/ 20[redacted] (344) [36]	Grade 3: Severe or Medically Significant	Yes	Dose Not Changed	Unlikely Related	Recovered/Resolved		2

Source: Listing 16.2.7.3 in BGB-3111-205 clinical study report. Data cutoff: 11SEP2020; Data extraction: [redacted] 20[redacted]; Data Source: ADAE, EC

Treatment Start Date/ Prescribed Dose	System Organ Class/ AE Preferred Term/ [AE Term]	AE Start Date (Study Day)/ AE End Date (Study Day) [Duration (Days)]	AE Toxicity Grade	SAE?	Action Taken	AE Relationship	AE Outcome	AE Assoc.[a]	AE Resulted In [b]

[a] AE Association: 1 - Persistent or significant disability or incapacity, 2 - Congenital anomaly or birth defect
[b] AE Resulted In: 1- Important medical event, 2 - Hospitalization, 3 - Life Threatening, 4 - Death.