表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
術後創感染	0		0		0		0		1	(<0.1)	1	(<0.1)
ヘルペス性直腸炎	0		0		0		0		1	(<0.1)	1	(<0.1)
前立腺感染	0		0		0		0		1	(<0.1)	1	(<0.1)
シュードモナス感染	0		0		0		1	(<0.1)	0		1	(<0.1)
肺結核	0		0		0		1	(<0.1)	0		1	(<0.1)
歯髄炎	0		0		0		0		5	(0.4)	6	(0.1)
腎盂腎炎	0		1	(0.8)	0		1	(<0.1)	2	(0.1)	3	(<0.1)
急性腎盂腎炎	1	(0.8)	1	(0.8)	0		3	(0.1)	1	(<0.1)	5	(0.1)
慢性腎盂腎炎	0		0		0		2	(<0.1)	0		2	(<0.1)
膿皮症	0		0		0		1	(<0.1)	0		1	(<0.1)
膿尿	0		0		0		1	(<0.1)	0		1	(<0.1)
Q熱	0		0		0		0		1	(<0.1)	1	(<0.1)
膿疱性皮疹	0		0		0		1	(<0.1)	1	(<0.1)	3	(<0.1)
気道感染	0		0		0		21	(0.7)	7	(0.5)	30	(0.6)
ウイルス性気道感染	0		0		0		6	(0.2)	3	(0.2)	10	(0.2)
鼻炎	0		0		1	(0.8)	9	(0.3)	3	(0.2)	12	(0.3)
陰嚢膿瘍	0		0		0		1	(<0.1)	0		1	(<0.1)
敗血症	1	(0.8)	0		0		2	(<0.1)	3	(0.2)	6	(0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
敗血症症候群	0		0		0		0		1	(<0.1)	1	(<0.1)
敗血症性ショック	1	(0.8)	0		0		1	(<0.1)	0		2	(<0.1)
副鼻腔炎	3	(2.5)	0		3	(2.4)	39	(1.4)	17	(1.2)	62	(1.3)
皮膚細菌感染	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
皮膚カンジダ	0		0		1	(0.8)	0		1	(<0.1)	1	(<0.1)
皮膚感染	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
軟部組織感染	0		0		0		0		0		2	(<0.1)
ブドウ球菌感染	0		0		0		0		3	(0.2)	3	(<0.1)
ブドウ球菌皮膚感染	0		0		0		0		1	(<0.1)	1	(<0.1)
縫合糸膿瘍	0		0		0		1	(<0.1)	0		1	(<0.1)
皮下組織膿瘍	0		0		0		5	(0.2)	2	(0.1)	7	(0.2)
股部白癬	0		0		0		1	(<0.1)	0		1	(<0.1)
白癬感染	0		1	(0.8)	0		2	(<0.1)	1	(<0.1)	3	(<0.1)
足部白癬	1	(0.8)	1	(0.8)	3	(2.4)	4	(0.1)	4	(0.3)	9	(0.2)
癜風	0		0		1	(0.8)	1	(<0.1)	1	(<0.1)	2	(<0.1)
扁桃炎	1	(0.8)	1	(0.8)	2	(1.6)	8	(0.3)	6	(0.4)	15	(0.3)
レンサ球菌性扁桃炎	0		0		0		1	(<0.1)	0		1	(<0.1)
歯膿瘍	1	(0.8)	0		0		9	(0.3)	3	(0.2)	15	(0.3)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
歯感染	0		0		0		2	(<0.1)	2	(0.1)	7	(0.2)
気管炎	0		0		0		5	(0.2)	1	(<0.1)	6	(0.1)
気管気管支炎	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
結核	0		0		1	(0.8)	0		1	(<0.1)	1	(<0.1)
上気道感染	4	(3.3)	5	(4.0)	5	(4.0)	118	(4.1)	76	(5.5)	219	(4.7)
細菌性上気道感染	0		0		0		1	(<0.1)	0		1	(<0.1)
尿路感染	3	(2.5)	2	(1.6)	1	(0.8)	101	(3.5)	66	(4.8)	186	(4.0)
尿路性敗血症	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
腟感染	0		0		0		3	(0.1)	0		3	(<0.1)
水痘	0		0		0		0		0		1	(<0.1)
ウイルス感染	0		0		1	(0.8)	1	(<0.1)	1	(<0.1)	3	(<0.1)
ウイルス性鼻炎	0		0		0		0		1	(<0.1)	2	(<0.1)
ウイルス性上気道感染	0		1	(0.8)	0		9	(0.3)	3	(0.2)	12	(0.3)
外陰部膿瘍	0		0		0		1	(<0.1)	0		1	(<0.1)
外陰部腟カンジダ症	0		1	(0.8)	1	(0.8)	2	(<0.1)	5	(0.4)	8	(0.2)
外陰腟真菌感染	0		0		0		5	(0.2)	3	(0.2)	8	(0.2)
外陰部腟炎	0		0		0		2	(<0.1)	0		2	(<0.1)
創傷感染	0		0		0		0		1	(<0.1)	1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
ブドウ球菌性創感染	0		0		0		0		1	(<0.1)	1	(<0.1)
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TOTAL EVENTS	70	(57.9)	70	(55.6)	73	(58.9)	717	(24.9)	434	(31.6)	1311	(28.3)
傷害、中毒および処置合併症												
偶発的過量投与	0		0		0		0		0		2	(<0.1)
麻酔による気道合併症	0		0		0		1	(<0.1)	0		1	(<0.1)
挫傷	0		1	(0.8)	0		5	(0.2)	1	(<0.1)	6	(0.1)
転倒	0		0		0		1	(<0.1)	0		1	(<0.1)
足骨折	0		0		0		0		1	(<0.1)	1	(<0.1)
靭帯捻挫	0		0		0		1	(<0.1)	0		1	(<0.1)
多発性外傷	0		0		0		0		1	(<0.1)	1	(<0.1)
処置後分泌物	0		0		0		0		1	(<0.1)	1	(<0.1)
処置後瘻孔	0		0		0		0		1	(<0.1)	1	(<0.1)
肋骨骨折	0		0		0		0		2	(0.1)	2	(<0.1)
サンバーン	0		0		0		1	(<0.1)	0		1	(<0.1)
熱傷	0		1	(0.8)	0		1	(<0.1)	1	(<0.1)	2	(<0.1)
胸椎骨折	0		0		0		0		1	(<0.1)	1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
歯牙破折	0		0		0		1	(<0.1)	0		1	(<0.1)
各種物質毒性	0		0		0		1	(<0.1)	0		1	(<0.1)
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TOTAL EVENTS	0		2	(1.6)	0		12	(0.4)	7	(0.5)	21	(0.5)
臨床検査												
アラニンアミノトランスフェラーゼ増加	5	(4.1)	5	(4.0)	5	(4.0)	105	(3.6)	47	(3.4)	165	(3.6)
アスパラギン酸アミノトランスフェラーゼ増加	4	(3.3)	4	(3.2)	3	(2.4)	81	(2.8)	32	(2.3)	128	(2.8)
アスペルギルス検査陽性	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
細菌検査	0		0		0		0		1	(<0.1)	1	(<0.1)
好塩基球数増加	0		0		0		0		0		1	(<0.1)
血中アルカリホスファターゼ増加	0		0		0		4	(0.1)	1	(<0.1)	5	(0.1)
血中β−D−グルカン増加	0		2	(1.6)	0		2	(<0.1)	0		2	(<0.1)
血中重炭酸塩減少	0		0		0		0		0		1	(<0.1)
血中ビリルビン増加	0		0		1	(0.8)	2	(<0.1)	1	(<0.1)	4	(<0.1)
血中カルシウム減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血中コレステロール増加	1	(0.8)	0		0		11	(0.4)	7	(0.5)	20	(0.4)
血中クレアチンホスホキナーゼ増加	3	(2.5)	10	(7.9)	14	(11.3)	111	(3.9)	100	(7.3)	239	(5.2)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL / ABT-494 ANY ABT-494 (N=4638) n (%)	
血中クレアチニン増加	1	(0.8)	0		1	(0.8)	19	(0.7)	14	(1.0)	35	(0.8)
血中葉酸減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血中ブドウ糖増加	0		0		0		1	(<0.1)	2	(0.1)	3	(<0.1)
血中免疫グロブリンG減少	0		0		2	(1.6)	0		2	(0.1)	2	(<0.1)
血中免疫グロブリンM減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血中副甲状腺ホルモン増加	0		0		0		1	(<0.1)	0		1	(<0.1)
血中リン減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血中カリウム減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血中カリウム増加	0		0		0		2	(<0.1)	0		2	(<0.1)
血圧上昇	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
血中ナトリウム減少	0		0		0		0		0		1	(<0.1)
血中トリグリセリド増加	1	(0.8)	1	(0.8)	0		12	(0.4)	2	(0.1)	16	(0.3)
血中尿素減少	0		0		0		0		0		1	(<0.1)
血中尿素増加	0		0		0		6	(0.2)	0		7	(0.2)
血中尿酸増加	0		0		0		1	(<0.1)	2	(0.1)	3	(<0.1)
体温上昇	0		0		0		0		1	(<0.1)	1	(<0.1)
癌胎児性抗原増加	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
CD8リンパ球減少	0		0		0		1	(<0.1)	0		1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
細胞マーカー増加	1	(0.8)	0		0		0		0		1	(<0.1)
尿中結晶陽性	0		0		0		1	(<0.1)	0		1	(<0.1)
サイトメガロウイルス検査陽性	0		0		2	(1.6)	0		2	(0.1)	2	(<0.1)
心電図QT延長	0		0		1	(0.8)	0		1	(<0.1)	1	(<0.1)
予備呼気量異常	0		0		0		1	(<0.1)	0		1	(<0.1)
γ－グルタミルトランスフェラーゼ増加	0		0		0		1	(<0.1)	0		1	(<0.1)
糸球体濾過率減少	0		0		0		1	(<0.1)	0		1	(<0.1)
尿中ブドウ糖	0		0		0		0		0		1	(<0.1)
尿中ブドウ糖陽性	0		0		0		0		1	(<0.1)	1	(<0.1)
握力低下	0		0		0		1	(<0.1)	0		1	(<0.1)
ヘマトクリット減少	0		0		0		0		1	(<0.1)	1	(<0.1)
ヘモグロビン減少	0		0		1	(0.8)	13	(0.5)	14	(1.0)	31	(0.7)
ヘモグロビン増加	0		0		0		1	(<0.1)	0		1	(<0.1)
肝酵素上昇	0		0		0		16	(0.6)	8	(0.6)	27	(0.6)
B型肝炎DNA測定陽性	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
B型肝炎DNA増加	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
B型肝炎表面抗原陽性	1	(0.8)	0		0		0		0		1	(<0.1)
高比重リポ蛋白減少	0		0		0		1	(<0.1)	0		1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
高比重リポ蛋白増加	1	(0.8)	0		1	(0.8)	2	(<0.1)	1	(<0.1)	4	(<0.1)
脂質異常	0		0		0		1	(<0.1)	0		1	(<0.1)
肝機能検査異常	0		1	(0.8)	0		2	(<0.1)	1	(<0.1)	3	(<0.1)
肝機能検査値上昇	4	(3.3)	4	(3.2)	4	(3.2)	19	(0.7)	8	(0.6)	32	(0.7)
低比重リポ蛋白減少	0		0		0		1	(<0.1)	0		1	(<0.1)
低比重リポ蛋白増加	0		1	(0.8)	0		4	(0.1)	5	(0.4)	9	(0.2)
リンパ球数減少	1	(0.8)	2	(1.6)	4	(3.2)	6	(0.2)	13	(0.9)	26	(0.6)
リンパ球数増加	1	(0.8)	0		0		1	(<0.1)	0		2	(<0.1)
単球数減少	0		0		0		1	(<0.1)	0		1	(<0.1)
単球数増加	0		0		0		0		1	(<0.1)	1	(<0.1)
結核菌群検査陽性	0		0		0		4	(0.1)	0		7	(0.2)
ナチュラルキラー細胞数	0		0		0		0		1	(<0.1)	1	(<0.1)
ナチュラルキラー細胞数減少	0		0		0		1	(<0.1)	0		1	(<0.1)
好中球数減少	4	(3.3)	1	(0.8)	2	(1.6)	11	(0.4)	15	(1.1)	35	(0.8)
好中球数増加	0		0		0		1	(<0.1)	2	(0.1)	3	(<0.1)
フィラデルフィア染色体陽性	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
血小板数減少	0		0		0		1	(<0.1)	0		1	(<0.1)
血小板数増加	0		0		0		2	(<0.1)	2	(0.1)	4	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL / ABT-494 ANY ABT-494 (N=4638) n (%)	
総蛋白増加	0		0		0		0		1	(<0.1)	1	(<0.1)
尿中蛋白陽性	0		1	(0.8)	0		1	(<0.1)	0		2	(<0.1)
プロテウス検査陽性	0		0		0		0		1	(<0.1)	1	(<0.1)
赤血球数減少	0		0		0		5	(0.2)	3	(0.2)	8	(0.2)
血沈亢進	0		0		0		1	(<0.1)	2	(0.1)	3	(<0.1)
子宮頚部スミア異常	0		0		0		0		1	(<0.1)	1	(<0.1)
ブドウ球菌検査陽性	0		0		0		0		1	(<0.1)	1	(<0.1)
Tリンパ球数減少	0		0		0		1	(<0.1)	0		1	(<0.1)
トランスアミナーゼ上昇	1	(0.8)	0		0		14	(0.5)	4	(0.3)	20	(0.4)
尿円柱	0		0		0		0		1	(<0.1)	1	(<0.1)
尿検査異常	0		0		0		0		1	(<0.1)	1	(<0.1)
尿中ケトン体陽性	0		0		0		0		0		1	(<0.1)
尿中白血球エステラーゼ	0		0		0		1	(<0.1)	0		1	(<0.1)
尿中白血球エステラーゼ陽性	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
尿中ウロビリノーゲン増加	0		0		0		0		0		1	(<0.1)
体重減少	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
体重増加	0		1	(0.8)	1	(0.8)	25	(0.9)	14	(1.0)	40	(0.9)
白血球数減少	3	(2.5)	0		3	(2.4)	7	(0.2)	9	(0.7)	24	(0.5)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
白血球数増加	0		0		0		0		1	(<0.1)	1	(<0.1)
尿中白血球	0		0		0		1	(<0.1)	0		1	(<0.1)
尿中白血球陽性	0		0		1	(0.8)	1	(<0.1)	3	(0.2)	4	(<0.1)
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TOTAL EVENTS	22	(18.2)	28	(22.2)	36	(29.0)	338	(11.7)	235	(17.1)	649	(14.0)
代謝および栄養障害												
異常体重増加	0		0		0		3	(0.1)	2	(0.1)	5	(0.1)
食欲障害	0		0		0		1	(<0.1)	0		1	(<0.1)
食欲減退	0		0		0		3	(0.1)	1	(<0.1)	5	(0.1)
糖尿病	1	(0.8)	0		0		1	(<0.1)	2	(0.1)	4	(<0.1)
コントロール不良の糖尿病	0		0		0		1	(<0.1)	0		1	(<0.1)
糖尿病性ケトアシドーシス	0		0		0		1	(<0.1)	0		1	(<0.1)
脂質異常症	6	(5.0)	7	(5.6)	4	(3.2)	25	(0.9)	12	(0.9)	46	(1.0)
体液貯留	0		0		0		2	(<0.1)	0		2	(<0.1)
高カルシウム血症	0		0		0		0		1	(<0.1)	2	(<0.1)
高コレステロール血症	2	(1.7)	2	(1.6)	1	(0.8)	29	(1.0)	24	(1.7)	68	(1.5)
高血糖	0		0		0		2	(<0.1)	1	(<0.1)	5	(0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
高カリウム血症	0		0		0		1	(<0.1)	0		1	(<0.1)
高脂血症	2	(1.7)	4	(3.2)	3	(2.4)	24	(0.8)	7	(0.5)	38	(0.8)
高リン酸塩血症	0		0		0		0		0		1	(<0.1)
高トリグリセリド血症	0		0		0		35	(1.2)	19	(1.4)	55	(1.2)
高尿酸血症	1	(0.8)	0		0		2	(<0.1)	0		3	(<0.1)
低アルブミン血症	1	(0.8)	0		0		0		0		1	(<0.1)
低カルシウム血症	0		0		0		1	(<0.1)	0		1	(<0.1)
低クロール血症	0		0		0		0		1	(<0.1)	1	(<0.1)
低コレステロール血症	0		0		0		1	(<0.1)	0		1	(<0.1)
低カリウム血症	1	(0.8)	1	(0.8)	0		1	(<0.1)	1	(<0.1)	3	(<0.1)
低脂血症	0		0		0		1	(<0.1)	0		1	(<0.1)
低マグネシウム血症	0		0		0		1	(<0.1)	0		1	(<0.1)
低ナトリウム血症	0		0		0		0		2	(0.1)	2	(<0.1)
低リン酸血症	0		0		0		5	(0.2)	1	(<0.1)	6	(0.1)
血液量減少症	0		0		0		1	(<0.1)	0		1	(<0.1)
食欲亢進	0		0		0		2	(<0.1)	0		2	(<0.1)
脂質代謝障害	0		0		0		0		1	(<0.1)	1	(<0.1)
栄養障害	1	(0.8)	0		0		0		0		1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
肥満	0		0		0		2	(<0.1)	0		2	(<0.1)
テタニー	0		0		0		0		1	(<0.1)	1	(<0.1)
2型糖尿病	0		0		0		0		1	(<0.1)	1	(<0.1)
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TOTAL EVENTS	13	(10.7)	13	(10.3)	8	(6.5)	131	(4.5)	72	(5.2)	240	(5.2)
筋骨格系および結合組織障害												
関節痛	0		1	(0.8)	0		7	(0.2)	3	(0.2)	11	(0.2)
関節炎	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
関節障害	0		0		0		1	(<0.1)	0		1	(<0.1)
背部痛	0		0		0		6	(0.2)	1	(<0.1)	7	(0.2)
滑液包炎	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
側腹部痛	0		0		0		0		1	(<0.1)	1	(<0.1)
出血性関節症	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
椎間板障害	1	(0.8)	0		0		0		0		1	(<0.1)
関節滲出液	0		0		0		1	(<0.1)	0		1	(<0.1)
筋肉疲労	0		0		0		0		1	(<0.1)	1	(<0.1)
筋痙縮	0		1	(0.8)	1	(0.8)	2	(<0.1)	5	(0.4)	7	(0.2)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ABT-494 ANY ABT-494 (N=4638) n (%)	
筋力低下	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
筋骨格系胸痛	0		0		0		2	(<0.1)	0		2	(<0.1)
筋骨格痛	1	(0.8)	0		0		1	(<0.1)	0		2	(<0.1)
筋骨格硬直	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
筋肉痛	0		0		0		6	(0.2)	3	(0.2)	11	(0.2)
頚部痛	0		0		0		1	(<0.1)	0		1	(<0.1)
変形性関節症	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
骨粗鬆症	0		1	(0.8)	0		2	(<0.1)	1	(<0.1)	3	(<0.1)
四肢痛	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
顎痛	0		0		0		0		1	(<0.1)	1	(<0.1)
関節周囲炎	0		1	(0.8)	0		1	(<0.1)	1	(<0.1)	2	(<0.1)
関節リウマチ	1	(0.8)	0		0		13	(0.5)	15	(1.1)	30	(0.6)
リウマトイド結節	0		0		0		0		1	(<0.1)	1	(<0.1)
滑膜炎	0		0		0		0		1	(<0.1)	1	(<0.1)
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TOTAL EVENTS	3	(2.5)	5	(4.0)	1	(0.8)	47	(1.6)	35	(2.5)	89	(1.9)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) 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）												
急性リンパ性白血病	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
胃腺癌	0		0		0		1	(<0.1)	0		1	(<0.1)
結腸腺癌	0		0		0		1	(<0.1)	0		1	(<0.1)
肛門癌	0		0		0		0		1	(<0.1)	1	(<0.1)
肛門性器疣贅	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
基底細胞癌	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
胃の良性新生物	1	(0.8)	0		0		0		0		1	(<0.1)
腎臓の良性新生物	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
膀胱癌	0		0		0		1	(<0.1)	0		1	(<0.1)
乳癌	0		0		0		0		1	(<0.1)	1	(<0.1)
子宮頚部癌第0期	0		0		1	(0.8)	0		1	(<0.1)	1	(<0.1)
軟骨腫	0		0		0		0		1	(<0.1)	1	(<0.1)
結腸癌	0		0		0		1	(<0.1)	0		1	(<0.1)
ホジキン病	0		0		1	(0.8)	0		1	(<0.1)	2	(<0.1)
浸潤性乳癌	0		0		0		0		0		1	(<0.1)
浸潤性乳管癌	0		0		0		1	(<0.1)	0		1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
遠隔転移を伴う肺腺癌	0	0	0	0	0	1 (<0.1)
肺腺癌第1期	0	0	0	0	0	1 (<0.1)
悪性黒色腫	0	0	0	0	1 (<0.1)	1 (<0.1)
表皮内悪性黒色腫	0	0	0	1 (<0.1)	0	1 (<0.1)
メラノサイト性母斑	0	0	0	1 (<0.1)	0	1 (<0.1)
非ホジキンリンパ腫	0	0	0	1 (<0.1)	0	1 (<0.1)
膵癌第4期	0	0	0	1 (<0.1)	0	1 (<0.1)
化膿性肉芽腫	0	0	0	1 (<0.1)	0	1 (<0.1)
直腸腺癌	0	1 (0.8)	0	1 (<0.1)	0	1 (<0.1)
遠隔転移を伴う直腸癌	0	0	0	0	1 (<0.1)	1 (<0.1)
腎癌第1期	0	0	0	1 (<0.1)	0	1 (<0.1)
皮膚乳頭腫	0	1 (0.8)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
皮膚有棘細胞癌	0	0	0	1 (<0.1)	0	1 (<0.1)
外陰部扁平上皮癌	0	0	0	1 (<0.1)	0	1 (<0.1)
精巣（純粋）セミノーマ	0	0	0	0	1 (<0.1)	1 (<0.1)
甲状腺B細胞性リンパ腫	0	0	0	0	0	1 (<0.1)
子宮癌	0	0	0	0	1 (<0.1)	1 (<0.1)
子宮平滑筋腫	0	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
TOTAL EVENTS	1	(0.8)	4	(3.2)	2	(1.6)	22	(0.8)	13	(0.9)	41	(0.9)
神経系障害												
異痛症	0		0		0		1	(<0.1)	0		1	(<0.1)
健忘	0		0		0		1	(<0.1)	0		1	(<0.1)
無嗅覚	0		0		0		1	(<0.1)	0		1	(<0.1)
平衡障害	0		0		0		0		1	(<0.1)	1	(<0.1)
灼熱感	0		0		0		1	(<0.1)	0		1	(<0.1)
手根管症候群	0		0		0		1	(<0.1)	0		1	(<0.1)
脳梗塞	1	(0.8)	0		0		0		0		1	(<0.1)
脳血管発作	0		0		0		0		1	(<0.1)	1	(<0.1)
糖尿病性ニューロパチー	0		0		0		0		1	(<0.1)	1	(<0.1)
浮動性めまい	0		2	(1.6)	0		14	(0.5)	8	(0.6)	23	(0.5)
体位性めまい	0		0		0		1	(<0.1)	0		1	(<0.1)
異常感覚	0		0		0		1	(<0.1)	0		1	(<0.1)
味覚異常	0		0		0		1	(<0.1)	0		1	(<0.1)
脳症	0		0		1	(0.8)	0		3	(0.2)	3	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
顔面麻痺	0		0		0		1	(<0.1)	0		1	(<0.1)
頭痛	1	(0.8)	3	(2.4)	4	(3.2)	38	(1.3)	24	(1.7)	69	(1.5)
知覚過敏	1	(0.8)	0		0		2	(<0.1)	2	(0.1)	5	(0.1)
感覚鈍麻	0		1	(0.8)	1	(0.8)	4	(0.1)	3	(0.2)	7	(0.2)
低酸素性虚血性脳症	0		0		0		1	(<0.1)	0		1	(<0.1)
ICU関連筋力低下	0		0		0		0		1	(<0.1)	1	(<0.1)
意識消失	0		0		0		1	(<0.1)	0		1	(<0.1)
腰仙部神経根障害	0		0		0		0		1	(<0.1)	1	(<0.1)
記憶障害	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
片頭痛	0		0		0		4	(0.1)	1	(<0.1)	5	(0.1)
視神経脊髄炎スペクトラム障害	0		0		0		0		1	(<0.1)	1	(<0.1)
末梢性ニューロパチー	0		0		0		1	(<0.1)	0		1	(<0.1)
神経毒性	0		0		0		1	(<0.1)	0		1	(<0.1)
錯感覚	0		0		0		2	(<0.1)	2	(0.1)	4	(<0.1)
腓骨神経麻痺	0		0		0		1	(<0.1)	0		1	(<0.1)
ヘルペス後神経痛	0		1	(0.8)	3	(2.4)	3	(0.1)	4	(0.3)	7	(0.2)
下肢静止不能症候群	0		0		0		0		1	(<0.1)	1	(<0.1)
坐骨神経痛	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
痙攣発作	0		0		0		1	(<0.1)	0		1	(<0.1)
感覚障害	1	(0.8)	0		0		0		0		1	(<0.1)
副鼻腔炎に伴う頭痛	0		0		0		0		2	(0.1)	2	(<0.1)
傾眠	0		0		0		3	(0.1)	0		4	(<0.1)
失神	0		0		0		1	(<0.1)	0		2	(<0.1)
緊張性頭痛	0		0		0		1	(<0.1)	0		1	(<0.1)
一過性全健忘	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
一過性脳虚血発作	1	(0.8)	0		0		2	(<0.1)	1	(<0.1)	4	(<0.1)
振戦	0		0		0		0		1	(<0.1)	1	(<0.1)
声帯不全麻痺	0		0		0		1	(<0.1)	0		1	(<0.1)
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TOTAL EVENTS	5	(4.1)	6	(4.8)	9	(7.3)	74	(2.6)	53	(3.9)	141	(3.0)
妊娠、産褥および周産期の状態												
自然流産	0		0		0		3	(0.1)	1	(<0.1)	4	(<0.1)
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TOTAL EVENTS	0		0		0		3	(0.1)	1	(<0.1)	4	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
精神障害									
感情不安定	0	0	0	0		1	(<0.1)	1	(<0.1)
不安	0	0	0	1	(<0.1)	2	(0.1)	3	(<0.1)
不安障害	0	0	0	0		1	(<0.1)	1	(<0.1)
錯乱状態	0	0	0	1	(<0.1)	0		1	(<0.1)
抑うつ気分	0	0	0	1	(<0.1)	1	(<0.1)	2	(<0.1)
うつ病	0	0	0	2	(<0.1)	2	(0.1)	5	(0.1)
不眠症	0	0	0	4	(0.1)	2	(0.1)	7	(0.2)
易刺激性	0	0	0	0		1	(<0.1)	1	(<0.1)
リビドー減退	0	0	0	1	(<0.1)	0		1	(<0.1)
気分動揺	0	0	0	1	(<0.1)	0		1	(<0.1)
パニック発作	0	0	0	0		0		1	(<0.1)
睡眠障害	0	0	0	0		1	(<0.1)	1	(<0.1)
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TOTAL EVENTS	0	0	0	10	(0.3)	9	(0.7)	22	(0.5)
腎および尿路障害									
急性腎障害	0	0	0	0		4	(0.3)	4	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
急性腎前性腎不全	0	0	0	1 (<0.1)	0	1 (<0.1)
慢性腎臓病	0	0	0	1 (<0.1)	0	1 (<0.1)
間質性膀胱炎	0	0	0	2 (<0.1)	0	2 (<0.1)
排尿困難	0	0	0	2 (<0.1)	3 (0.2)	5 (0.1)
糖尿	0	0	0	1 (<0.1)	0	1 (<0.1)
血尿	0	0	0	4 (0.1)	4 (0.3)	9 (0.2)
水腎症	0	1 (0.8)	0	1 (<0.1)	0	1 (<0.1)
白血球尿	0	0	0	8 (0.3)	0	8 (0.2)
腎結石症	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
頻尿	0	0	0	0	1 (<0.1)	1 (<0.1)
蛋白尿	0	0	0	7 (0.2)	0	8 (0.2)
腎嚢胞	1 (0.8)	0	0	0	1 (<0.1)	2 (<0.1)
腎不全	0	0	0	1 (<0.1)	0	1 (<0.1)
腎機能障害	1 (0.8)	0	0	0	0	1 (<0.1)
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TOTAL EVENTS	2 (1.7)	1 (0.8)	0	26 (0.9)	12 (0.9)	41 (0.9)

生殖系および乳房障害

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
腺筋症	0	0	0	1 (<0.1)	0	1 (<0.1)
亀頭包皮炎	0	0	1 (0.8)	0	1 (<0.1)	1 (<0.1)
良性前立腺肥大症	0	0	0	1 (<0.1)	0	1 (<0.1)
乳房腫瘤	0	0	0	0	1 (<0.1)	1 (<0.1)
乳房痛	0	0	0	0	1 (<0.1)	1 (<0.1)
子宮頚部上皮異形成	1 (0.8)	0	0	0	0	1 (<0.1)
子宮内膜増殖症	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
勃起不全	0	0	0	3 (0.1)	1 (<0.1)	4 (<0.1)
過長過多不規則月経	0	0	0	1 (<0.1)	0	1 (<0.1)
月経過多	0	0	0	2 (<0.1)	0	2 (<0.1)
月経障害	0	0	0	0	3 (0.2)	3 (<0.1)
希発月経	0	0	0	0	1 (<0.1)	1 (<0.1)
器質性勃起機能不全	0	0	0	1 (<0.1)	0	1 (<0.1)
卵巣嚢胞	0	0	0	1 (<0.1)	2 (0.1)	3 (<0.1)
前立腺炎	0	0	1 (0.8)	0	3 (0.2)	3 (<0.1)
陰部そう痒症	0	1 (0.8)	0	1 (<0.1)	0	1 (<0.1)
子宮頚部びらん	0	0	0	1 (<0.1)	0	1 (<0.1)
子宮出血	0	0	0	1 (<0.1)	0	1 (<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE / ABT-494 15 MG QD (N=126) n (%)	JAPANESE / ABT-494 30 MG QD (N=124) n (%)	OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
子宮ポリープ	0	0	0	1 (<0.1)	0	1 (<0.1)
腟出血	0	0	0	1 (<0.1)	0	1 (<0.1)
腟病変	0	0	0	0	1 (<0.1)	1 (<0.1)
女性外陰部潰瘍	0	0	0	0	0	1 (<0.1)
外陰腟そう痒症	0	0	0	0	1 (<0.1)	1 (<0.1)
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TOTAL EVENTS	1 (0.8)	1 (0.8)	2 (1.6)	13 (0.5)	14 (1.0)	29 (0.6)
呼吸器、胸郭および縦隔障害						
急性呼吸窮迫症候群	0	0	0	1 (<0.1)	0	2 (<0.1)
喘息	3 (2.5)	0	0	3 (0.1)	0	6 (0.1)
喘息クリーゼ	0	0	0	0	1 (<0.1)	1 (<0.1)
無気肺	0	0	0	0	2 (0.1)	2 (<0.1)
気管支拡張症	0	0	0	0	1 (<0.1)	1 (<0.1)
気管支痙攣	0	0	0	1 (<0.1)	0	1 (<0.1)
カタル	0	0	0	4 (0.1)	1 (<0.1)	5 (0.1)
慢性閉塞性肺疾患	0	0	0	2 (<0.1)	0	2 (<0.1)
咳嗽	1 (0.8)	2 (1.6)	4 (3.2)	32 (1.1)	22 (1.6)	60 (1.3)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
呼吸困難	0	0	0	7 (0.2)	3 (0.2)	10 (0.2)
労作性呼吸困難	0	0	0	0	1 (<0.1)	1 (<0.1)
鼻出血	0	0	0	1 (<0.1)	0	1 (<0.1)
喀血	0	0	0	1 (<0.1)	0	1 (<0.1)
間質性肺疾患	0	0	2 (1.6)	0	2 (0.1)	2 (<0.1)
肺浸潤	0	0	0	0	0	1 (<0.1)
鼻閉	0	0	0	1 (<0.1)	4 (0.3)	5 (0.1)
鼻潰瘍	0	0	0	0	1 (<0.1)	1 (<0.1)
口腔咽頭痛	1 (0.8)	0	0	10 (0.3)	7 (0.5)	19 (0.4)
咽頭紅斑	0	0	0	1 (<0.1)	0	1 (<0.1)
胸水	0	0	0	0	2 (0.1)	3 (<0.1)
胸膜線維症	0	0	0	1 (<0.1)	0	1 (<0.1)
胸膜炎	0	0	0	1 (<0.1)	0	1 (<0.1)
肺臓炎	0	0	0	0	1 (<0.1)	1 (<0.1)
気胸	0	0	1 (0.8)	0	2 (0.1)	2 (<0.1)
湿性咳嗽	0	0	0	6 (0.2)	1 (<0.1)	7 (0.2)
肺動脈性肺高血圧症	0	0	0	0	1 (<0.1)	1 (<0.1)
肺うっ血	0	0	0	1 (<0.1)	0	1 (<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE ABT-494 15 MG QD (N=126) n (%)		JAPANESE ABT-494 30 MG QD (N=124) n (%)		OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
肺塞栓症	0		0		0		3	(0.1)	1	(<0.1)	5	(0.1)
肺線維症	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
肺腫瘤	0		0		0		1	(<0.1)	0		1	(<0.1)
呼吸障害	0		0		0		1	(<0.1)	0		1	(<0.1)
呼吸不全	0		0		1	(0.8)	0		2	(0.1)	2	(<0.1)
気道うっ血	0		0		0		1	(<0.1)	3	(0.2)	4	(<0.1)
アレルギー性鼻炎	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
鼻漏	2	(1.7)	0		0		0		0		2	(<0.1)
副鼻腔うっ血	0		0		0		5	(0.2)	3	(0.2)	8	(0.2)
扁桃障害	0		0		0		1	(<0.1)	0		1	(<0.1)
上気道うっ血	0		0		0		1	(<0.1)	0		1	(<0.1)
上気道の炎症	0		1	(0.8)	3	(2.4)	1	(<0.1)	3	(0.2)	4	(<0.1)
喘鳴	0		0		0		2	(<0.1)	1	(<0.1)	3	(<0.1)
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TOTAL EVENTS	6	(5.0)	3	(2.4)	10	(8.1)	76	(2.6)	55	(4.0)	145	(3.1)
皮膚および皮下組織障害												
ざ瘡	0		1	(0.8)	1	(0.8)	7	(0.2)	7	(0.5)	15	(0.3)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE / ABT-494 7.5 MG QD (N=121) n (%)		JAPANESE / ABT-494 15 MG QD (N=126) n (%)		JAPANESE / ABT-494 30 MG QD (N=124) n (%)		OVERALL / ABT-494 6 MG BID /15 MG QD (N=2883) n (%)		OVERALL / ABT-494 12 MG BID /30 MG QD (N=1375) n (%)		OVERALL ANY ABT-494 (N=4638) n (%)	
光線角化症	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
脱毛症	0		0		0		14	(0.5)	11	(0.8)	26	(0.6)
水疱	0		0		0		1	(<0.1)	1	(<0.1)	2	(<0.1)
皮膚嚢腫	0		1	(0.8)	0		1	(<0.1)	0		1	(<0.1)
皮膚炎	0		0		0		4	(0.1)	1	(<0.1)	7	(0.2)
ざ瘡様皮膚炎	1	(0.8)	0		1	(0.8)	1	(<0.1)	2	(0.1)	4	(<0.1)
アレルギー性皮膚炎	0		1	(0.8)	0		2	(<0.1)	1	(<0.1)	3	(<0.1)
アトピー性皮膚炎	0		1	(0.8)	0		3	(0.1)	0		3	(<0.1)
接触皮膚炎	0		0		0		0		2	(0.1)	2	(<0.1)
疱疹状皮膚炎	0		0		0		1	(<0.1)	0		1	(<0.1)
びまん性脱毛症	0		0		0		0		1	(<0.1)	1	(<0.1)
薬疹	0		0		0		1	(<0.1)	0		1	(<0.1)
皮膚乾燥	0		1	(0.8)	0		1	(<0.1)	1	(<0.1)	2	(<0.1)
異汗性湿疹	0		0		0		0		2	(0.1)	2	(<0.1)
斑状出血	0		0		0		0		1	(<0.1)	1	(<0.1)
湿疹	2	(1.7)	1	(0.8)	2	(1.6)	6	(0.2)	3	(0.2)	11	(0.2)
紅斑	2	(1.7)	1	(0.8)	0		5	(0.2)	2	(0.1)	9	(0.2)
肉芽腫性酒さ	0		0		0		0		1	(<0.1)	1	(<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
汗腺炎	0	0	0	1 (<0.1)	0	1 (<0.1)
多汗症	0	0	0	1 (<0.1)	0	2 (<0.1)
間擦疹	0	0	0	0	1 (<0.1)	1 (<0.1)
斑	0	0	0	0	1 (<0.1)	1 (<0.1)
爪変色	0	0	0	1 (<0.1)	0	1 (<0.1)
爪痛	0	0	0	1 (<0.1)	0	1 (<0.1)
爪破損	1 (0.8)	0	1 (0.8)	0	2 (0.1)	3 (<0.1)
脂肪織炎	0	0	0	1 (<0.1)	0	1 (<0.1)
丘疹膿疱性酒さ	0	0	0	0	0	1 (<0.1)
点状出血	0	0	0	0	1 (<0.1)	1 (<0.1)
光線過敏性反応	0	0	0	1 (<0.1)	1 (<0.1)	3 (<0.1)
粃糠疹	0	0	0	1 (<0.1)	0	1 (<0.1)
そう痒症	0	0	1 (0.8)	6 (0.2)	4 (0.3)	12 (0.3)
乾癬	0	0	0	0	1 (<0.1)	1 (<0.1)
発疹	1 (0.8)	2 (1.6)	4 (3.2)	18 (0.6)	18 (1.3)	39 (0.8)
紅斑性皮疹	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
全身性皮疹	0	0	1 (0.8)	0	3 (0.2)	3 (<0.1)
斑状皮疹	0	0	0	1 (<0.1)	0	3 (<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
斑状丘疹状皮疹	0	0	0	2 (<0.1)	3 (0.2)	5 (0.1)
丘疹性皮疹	0	0	0	1 (<0.1)	3 (0.2)	4 (<0.1)
そう痒性皮疹	0	0	0	0	0	1 (<0.1)
リウマトイド好中球性皮膚症	0	0	0	1 (<0.1)	0	1 (<0.1)
鼻瘤	0	0	0	0	1 (<0.1)	1 (<0.1)
酒さ	0	0	0	6 (0.2)	5 (0.4)	11 (0.2)
脂漏性皮膚炎	0	1 (0.8)	0	1 (<0.1)	0	1 (<0.1)
皮膚障害	0	0	0	0	1 (<0.1)	1 (<0.1)
皮膚剥脱	0	0	0	1 (<0.1)	0	2 (<0.1)
皮膚病変	0	0	0	3 (0.1)	0	4 (<0.1)
皮膚腫瘤	0	0	0	1 (<0.1)	0	1 (<0.1)
皮膚潰瘍	0	2 (1.6)	0	3 (0.1)	3 (0.2)	6 (0.1)
蕁麻疹	0	0	0	1 (<0.1)	1 (<0.1)	3 (<0.1)
---	---	---	---	---	---	---
TOTAL EVENTS	6 (5.0)	10 (7.9)	8 (6.5)	92 (3.2)	77 (5.6)	190 (4.1)
血管障害						
深部静脈血栓症	0	1 (0.8)	0	2 (<0.1)	0	3 (<0.1)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	JAPANESE ABT-494 7.5 MG QD (N=121) n (%)	JAPANESE ABT-494 15 MG QD (N=126) n (%)	JAPANESE ABT-494 30 MG QD (N=124) n (%)	OVERALL ABT-494 6 MG BID /15 MG QD (N=2883) n (%)	OVERALL ABT-494 12 MG BID /30 MG QD (N=1375) n (%)	OVERALL ANY ABT-494 (N=4638) n (%)
本態性高血圧症	0	0	0	0	1 (<0.1)	1 (<0.1)
潮紅	0	0	0	1 (<0.1)	0	1 (<0.1)
血腫	0	0	0	0	0	1 (<0.1)
ほてり	0	0	0	2 (<0.1)	0	2 (<0.1)
高血圧	4 (3.3)	3 (2.4)	1 (0.8)	33 (1.1)	10 (0.7)	48 (1.0)
高血圧クリーゼ	0	0	0	1 (<0.1)	0	1 (<0.1)
低血圧	0	0	0	3 (0.1)	0	3 (<0.1)
虚血	0	0	0	0	1 (<0.1)	1 (<0.1)
骨盤静脈血栓症	0	0	0	1 (<0.1)	0	1 (<0.1)
末梢動脈血栓症	0	0	0	0	1 (<0.1)	1 (<0.1)
末梢静脈疾患	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
静脈炎	0	1 (0.8)	0	2 (<0.1)	0	2 (<0.1)
レイノー現象	0	0	0	1 (<0.1)	0	1 (<0.1)
血栓性静脈炎	0	0	0	2 (<0.1)	0	2 (<0.1)
表在性血栓性静脈炎	0	0	0	0	0	1 (<0.1)
---	---	---	---	---	---	---
TOTAL EVENTS	4 (3.3)	5 (4.0)	1 (0.8)	49 (1.7)	14 (1.0)	71 (1.5)

表 2.7.4.7-155. 更新時のウパダシチニブ併合解析の治験薬と関連ありの有害事象の器官別大分類別及び基本語別の発現割合（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）（続き）

	JAPANESE			OVERALL		
	ABT-494			ABT-494		
SYSTEM ORGAN CLASS MEDDRA 19.1 PREFERRED TERM	7.5 MG QD (N=121) n (%)	15 MG QD (N=126) n (%)	30 MG QD (N=124) n (%)	6 MG BID /15 MG QD (N=2883) n (%)	12 MG BID /30 MG QD (N=1375) n (%)	ANY ABT-494 (N=4638) n (%)

NOTE: ABT-494 6 MG BID/15 MG QD: SUBJECTS WHO STARTED ON UPADACITINIB 6 MG BID AND WHO SWITCHED FROM PLACEBO TO 6 MG BID IN PHASE 2 (CENSORED BY THE TIME OF FIRST DOSE TITRATION IN M13-538), AND SUBJECTS WHO RECEIVED UPADACITINIB 15 MG QD IN PHASE 3.
ABT-494 12 MG BID/30 MG QD: SUBJECTS WHO STARTED ON UPADACITINIB 12 MG BID IN PHASE 2 (UP TO THE SWITCH TO UPADACITINIB 6 MG BID IN PHASE 2 OLE), AND SUBJECTS WHO RECEIVED UPADACITINIB 30 MG QD IN PHASE 3.
ANY ABT-494: ALL SUBJECTS WHO RECEIVED AT LEAST ONE DOSE OF UPADACITINIB, INCLUDING DOSES OTHER THAN 6 MG BID/15 MG QD AND 12 MG BID/30 MG QD. DATA WAS NOT CENSORED WHEN SUBJECTS SWITCHED BETWEEN DIFFERENT UPADACITINIB DOSES.
TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS HAVING A REASONABLE POSSIBILITY OF BEING STUDY DRUG-RELATED.

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-ae-lt-j.sas

相互参照：Updated J-ISS additional analysis Table 1__1

表 2.7.4.7-156. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の重篤な感染症の発現率（被験者数換算）（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

	OVERALL / ABT-494 / 6 MG BID/15 MG QD (N=2883)	
MONTHS	**n/PYS (n/100PYS)**	**(95% CI)[A]**
0 - < 6	56/1327.5 (4.2)	(3.2, 5.5)
>= 6 - < 12	25/1074.2 (2.3)	(1.5, 3.4)
>= 12 - < 18	15/ 702.5 (2.1)	(1.2, 3.5)
>= 18	2/ 276.3 (0.7)	(0.1, 2.6)

NOTE: ABT-494 6 MG BID/15 MG QD: SUBJECTS WHO STARTED ON UPADACITINIB 6 MG BID AND WHO SWITCHED FROM PLACEBO TO 6 MG BID IN PHASE 2 (CENSORED BY THE TIME OF FIRST DOSE TITRATION IN M13-538), AND SUBJECTS WHO RECEIVED UPADACITINIB 15 MG QD IN PHASE 3.
TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-all-j.sas

相互参照：Updated J-ISS additional analysis Table 1　3.1

表 2.7.4.7-157. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の重篤な感染症の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

	ABT-494			
	7.5 MG QD (N=121)		15 MG QD (N=126)	
MONTHS	n/PYS (n/100PYS)	(95% CI)[A]	n/PYS (n/100PYS)	(95% CI)[A]
0 - < 6	4/ 58.5 (6.8)	(1.9, 17.5)	7/ 60.1 (11.6)	(4.7, 24.0)
>= 6 - < 12	1/ 55.2 (1.8)	(0.0, 10.1)	0/ 56.8	
>= 12 - < 18	2/ 48.7 (4.1)	(0.5, 14.8)	2/ 50.5 (4.0)	(0.5, 14.3)
>= 18	3/ 40.9 (7.3)	(1.5, 21.4)	1/ 40.2 (2.5)	(0.1, 13.9)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-lt-j.sas

相互参照：Updated J-ISS additional analysis Table 1__2.1

表 2.7.4.7-158. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の帯状疱疹の発現率（被験者数換算）（ウパダシチニブ併合解析集団, 日本申請用安全性併合解析）

	OVERALL		
	ABT-494		
	6 MG BID/15 MG QD (N=2883)		
MONTHS	n/PYS (n/100PYS)		(95% CI)[A]
0 - < 6	42/1325.3	(3.2)	(2.3, 4.3)
>= 6 - < 12	35/1064.0	(3.3)	(2.3, 4.6)
>= 12 - < 18	41/ 688.4	(6.0)	(4.3, 8.1)
>= 18	6/ 265.0	(2.3)	(0.8, 4.9)

NOTE: ABT-494 6 MG BID/15 MG QD: SUBJECTS WHO STARTED ON UPADACITINIB 6 MG BID AND WHO SWITCHED FROM PLACEBO TO 6 MG BID IN PHASE 2 (CENSORED BY THE TIME OF FIRST DOSE TITRATION IN M13-538), AND SUBJECTS WHO RECEIVED UPADACITINIB 15 MG QD IN PHASE 3.
TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-all-j.sas

相互参照：Updated J-ISS additional analysis Table 1　3.2

表 2.7.4.7-159. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の帯状疱疹の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

	ABT-494			
	7.5 MG QD (N=121)		15 MG QD (N=126)	
MONTHS	n/PYS (n/100PYS)	(95% CI)[A]	n/PYS (n/100PYS)	(95% CI)[A]
0 - < 6	5/ 57.8 (8.7)	(2.8, 20.2)	7/ 59.4 (11.8)	(4.7, 24.3)
>= 6 - < 12	3/ 52.6 (5.7)	(1.2, 16.7)	4/ 54.5 (7.3)	(2.0, 18.8)
>= 12 - < 18	6/ 45.5 (13.2)	(4.8, 28.7)	10/ 46.3 (21.6)	(10.4, 39.7)
>= 18	1/ 37.2 (2.7)	(0.1, 15.0)	3/ 34.1 (8.8)	(1.8, 25.7)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-lt-j.sas

相互参照：Updated J-ISS additional analysis Table 1__2.2

表 2.7.4.7-160. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の非黒色腫皮膚癌を除く悪性腫瘍の発現率（被験者数換算）（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

	OVERALL ABT-494 6 MG BID/15 MG QD (N=2883)	
MONTHS	**n/PYS (n/100PYS)**	**(95% CI)[A]**
0 - < 6	13/1333.3 (1.0)	(0.5, 1.7)
>= 6 - < 12	7/1086.8 (0.6)	(0.3, 1.3)
>= 12 - < 18	5/ 715.1 (0.7)	(0.2, 1.6)
>= 18	3/ 283.9 (1.1)	(0.2, 3.1)

NOTE: ABT-494 6 MG BID/15 MG QD: SUBJECTS WHO STARTED ON UPADACITINIB 6 MG BID AND WHO SWITCHED FROM PLACEBO TO 6 MG BID IN PHASE 2 (CENSORED BY THE TIME OF FIRST DOSE TITRATION IN M13-538), AND SUBJECTS WHO RECEIVED UPADACITINIB 15 MG QD IN PHASE 3.
TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-all-j.sas

相互参照：Updated J-ISS additional analysis Table 1　3.3

表 2.7.4.7-161. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の非黒色腫皮膚癌を除く悪性腫瘍の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

	ABT-494			
	7.5 MG QD (N=121)		15 MG QD (N=126)	
MONTHS	n/PYS (n/100PYS)	(95% CI)[A]	n/PYS (n/100PYS)	(95% CI)[A]
0 - < 6	0/ 58.6		1/ 60.4 (1.7)	(0.0, 9.2)
>= 6 - < 12	0/ 55.2		0/ 57.8	
>= 12 - < 18	1/ 49.3 (2.0)	(0.1, 11.3)	1/ 52.0 (1.9)	(0.0, 10.7)
>= 18	0/ 41.7		0/ 43.3	

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG AND NO MORE THAN 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY.
n/100PYS = NUMBER OF SUBJECTS WITH AT LEAST ONE EVENT PER 100 PATIENT-YEARS.
[A]: 95% CI ARE CALCULATED BASED ON THE EXACT METHOD FOR THE POISSON MEAN (GARWOOD, 1936).

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/iss-aesi-inc-6m-lt-j.sas

相互参照：Updated J-ISS additional analysis Table 1__2.3

表 2.7.4.7-162. 投与 60 週時データカットオフまでの治験継続中の被験者の概要（最大の解析対象集団，ウパダシチニブ群にランダム化された被験者）：M14-663 試験

	ABT-494		
STATUS	7.5 MG QD (N=49) n (%)	15 MG QD (N=49) n (%)	30 MG QD (N=50) n (%)
REMAINED IN STUDY THROUGH WEEK 60	44 (89.8)	43 (87.8)	32 (64.0)

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/m14663-wk60-status.sas

相互参照：Updated J-ISS additional analysis Table 2__1

表 2.7.4.7-163. 投与 48 週時データカットオフまでの治験継続中の被験者の概要（最大の解析対象集団，ウパダシチニブ群にランダム化された被験者）：M15-555 試験

	ABT-494 15 MG QD (N=217)		ABT-494 30 MG QD (N=215)	
STATUS	n	(%)	n	(%)
REMAINED IN STUDY THROUGH WEEK 48	172	(79.3)	188	(87.4)

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/m15555-wk48-status.sas

相互参照：Updated J-ISS additional analysis Table 2__3

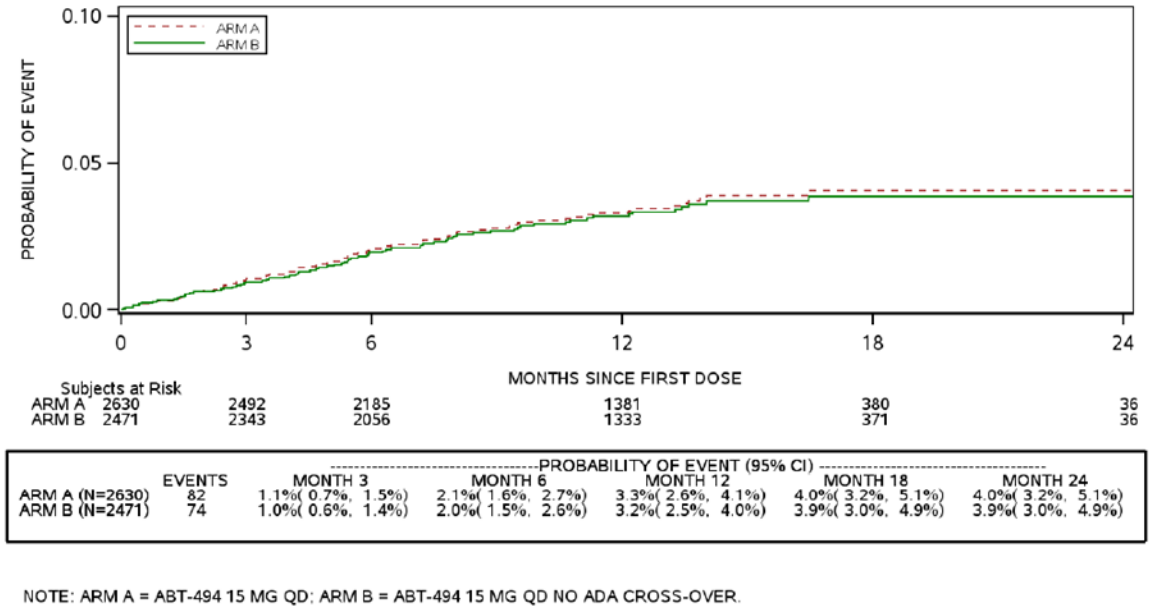
表 2.7.4.7-164. 投与 48 週時データカットオフまでの治験継続中の被験者の概要（最大の解析対象集団，ウパダシチニブ群にランダム化された被験者）：M13-545 試験

STATUS	ABT-494 7.5 MG QD (N=55) n (%)	ABT-494 15 MG QD (N=317) n (%)	ABT-494 30 MG QD (N=314) n (%)
REMAINED IN STUDY THROUGH WEEK 48	51 (92.7)	263 (83.0)	259 (82.5)

Program Source Code: /da/cs/data/d436/DEV/ABT-494/RA/SPEC_REQ/Japan_RMP_Brand/PROD/m13545-wk48-status.sas

相互参照：Updated J-ISS additional analysis Table 2__2

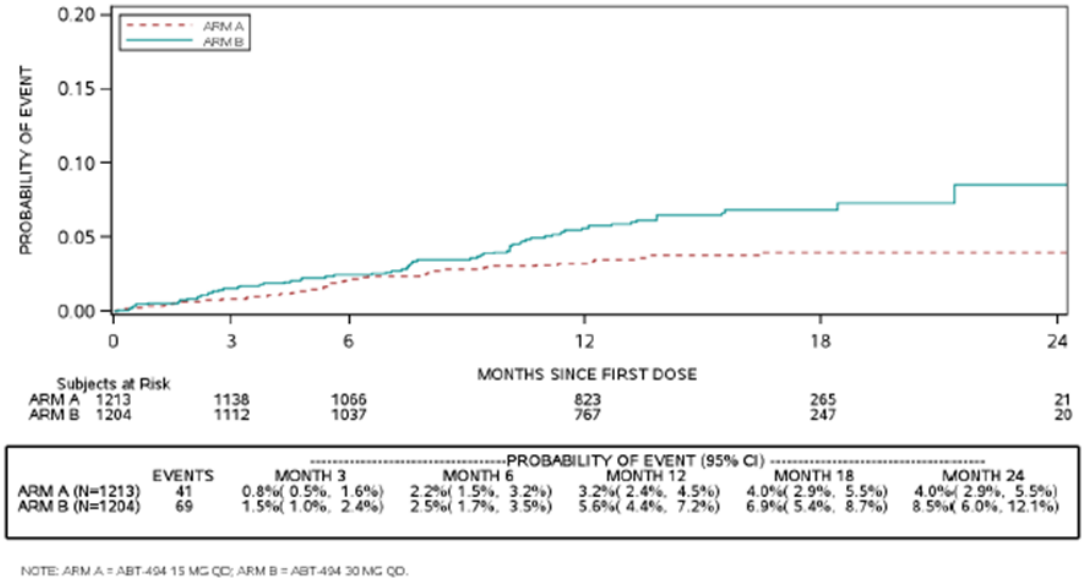
図 2.7.4.7-1. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の重篤な感染症の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



NOTE: ARM A = ABT-494 15 MG QD; ARM B = ABT-494 15 MG QD NO ADA CROSS-OVER.

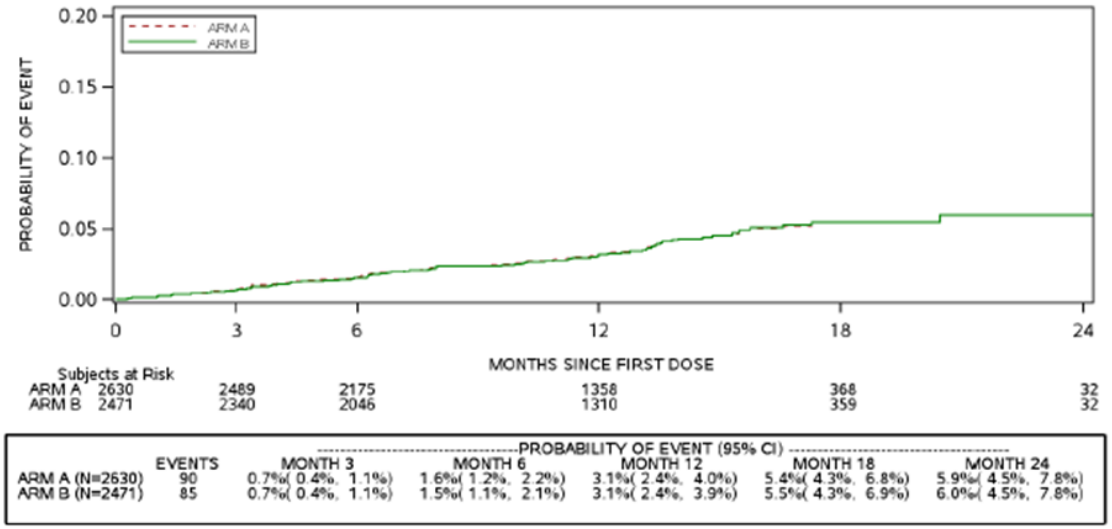
相互参照：ISS Figure 2.4__4.11.2.1

図 2.7.4.7-2. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の重篤な感染症の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



相互参照：ISS Figure 2.4__5.12.2.1

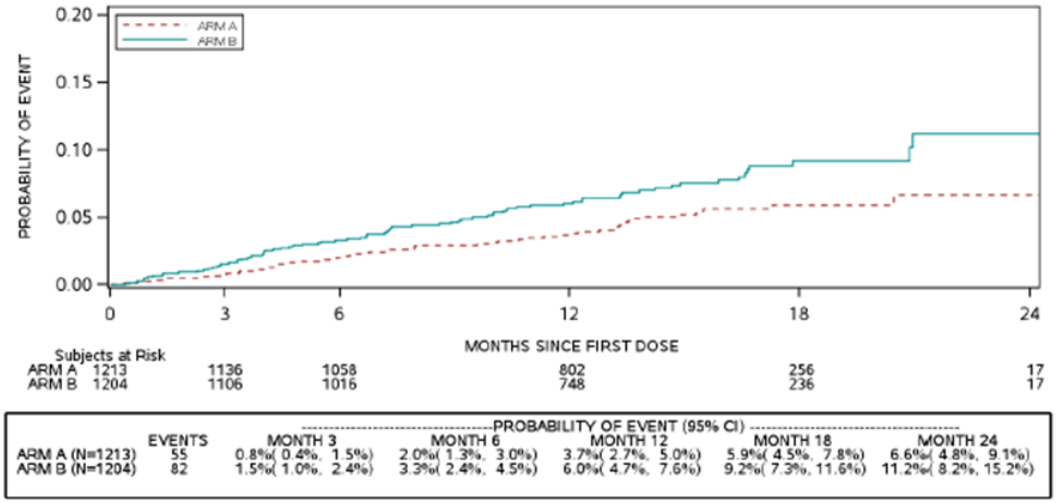
図 2.7.4.7-3. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の帯状疱疹の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



Note: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.

相互参照：ISS Figure 2.4__4.11.5.1

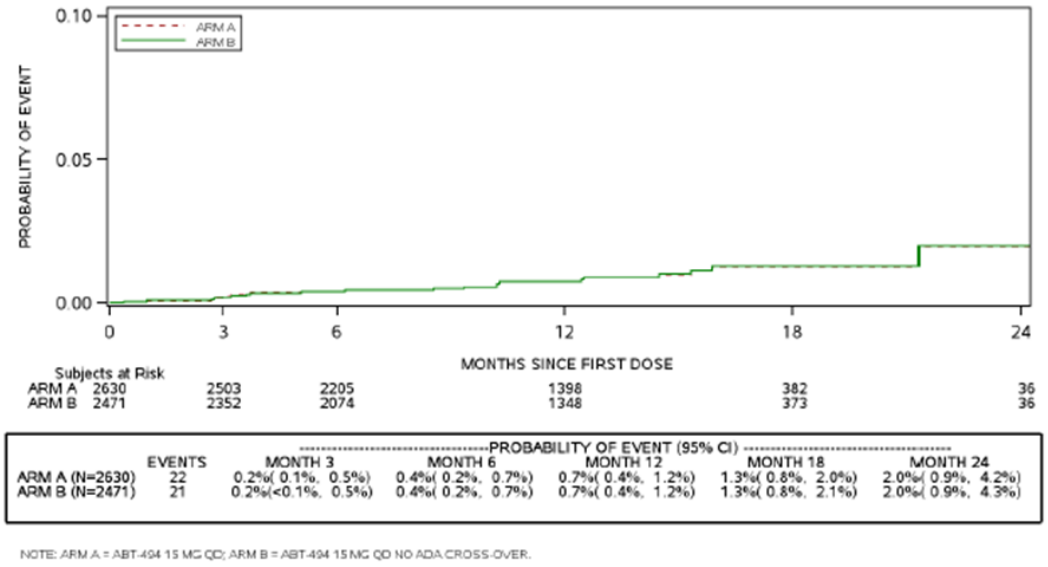
図 2.7.4.7-4. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の帯状疱疹の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



Note: Arm A = UPA 15 mg QD; Arm B = UPA 30 mg QD.

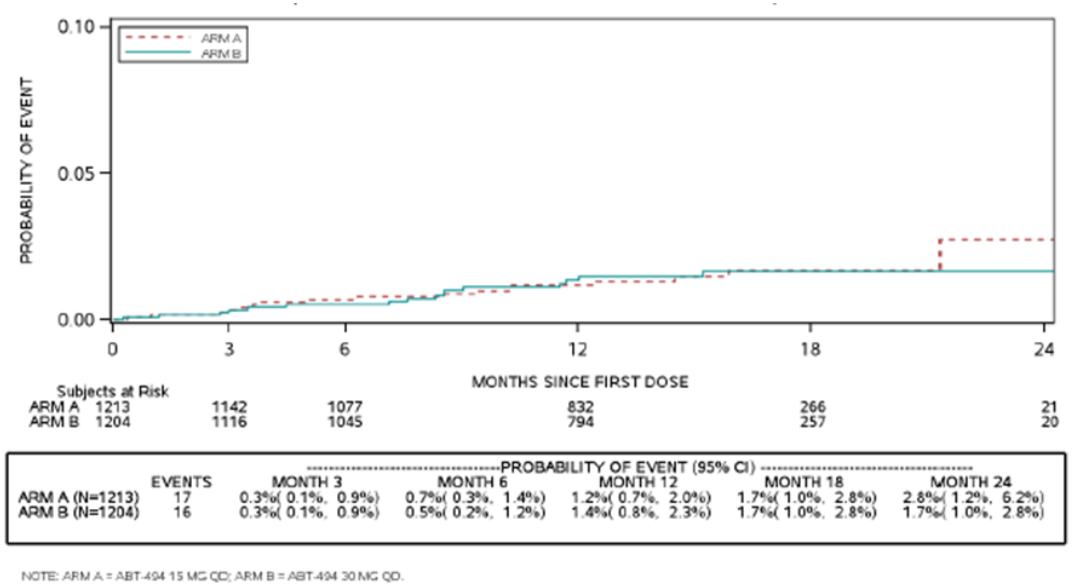
相互参照：ISS Figure 2.4__5.12.5.1

図 2.7.4.7-5. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の非黒色腫皮膚癌を除く悪性腫瘍の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



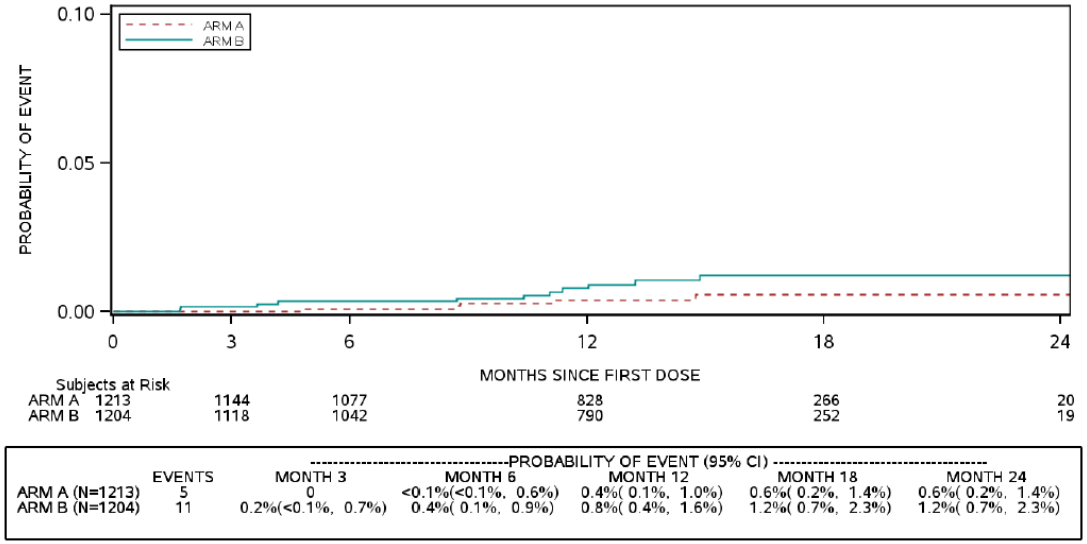
相互参照：ISS Figure 2.4__4.11.3.1

図 2.7.4.7-6. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の非黒色腫皮膚癌を除く悪性腫瘍の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



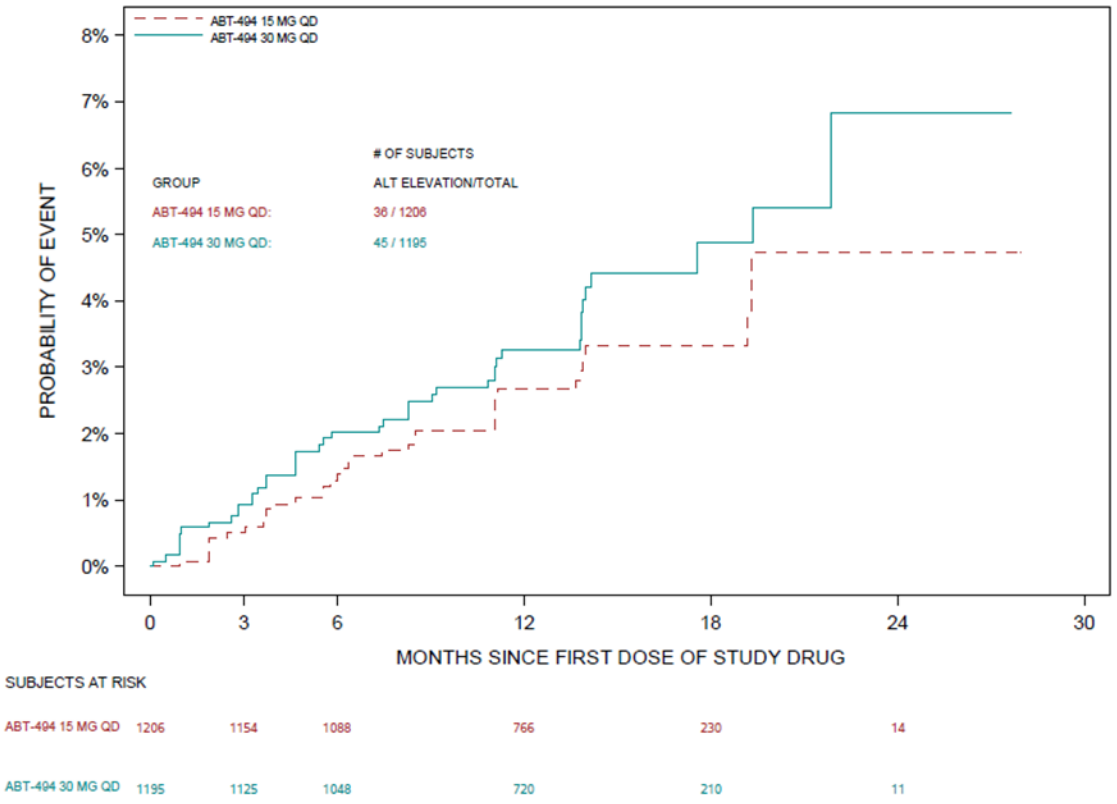
相互参照：ISS Figure 2.4__5.12.3.1

図 2.7.4.7-7. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の非黒色腫皮膚癌の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



相互参照：ISS Figure 2.4__5.12.4.1

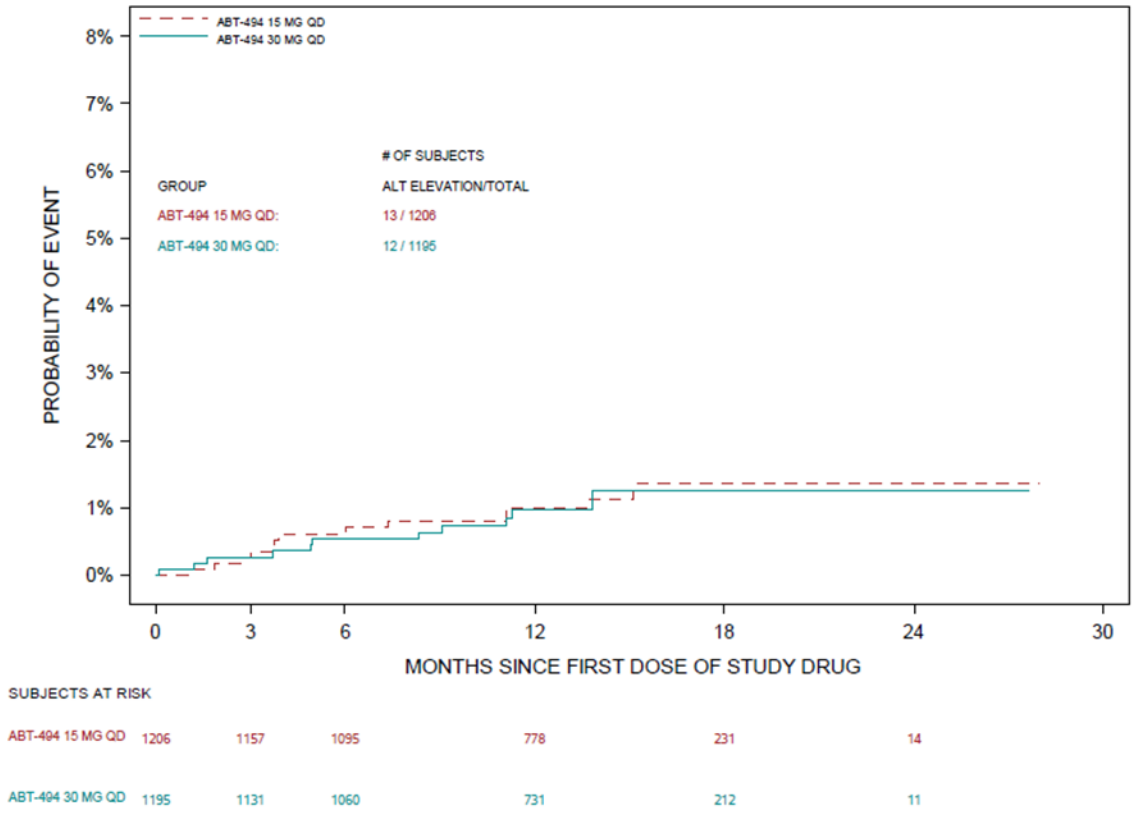
図 2.7.4.7-8. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の ALT が最初に基準値上限の 3 倍以上となるまでの時間の Kaplan-Meier 推定（米国・欧州申請用安全性併合解析）



Note: Censoring date is the date of the last available ALT result.

相互参照：ISS Figure 2.5__5.7.1

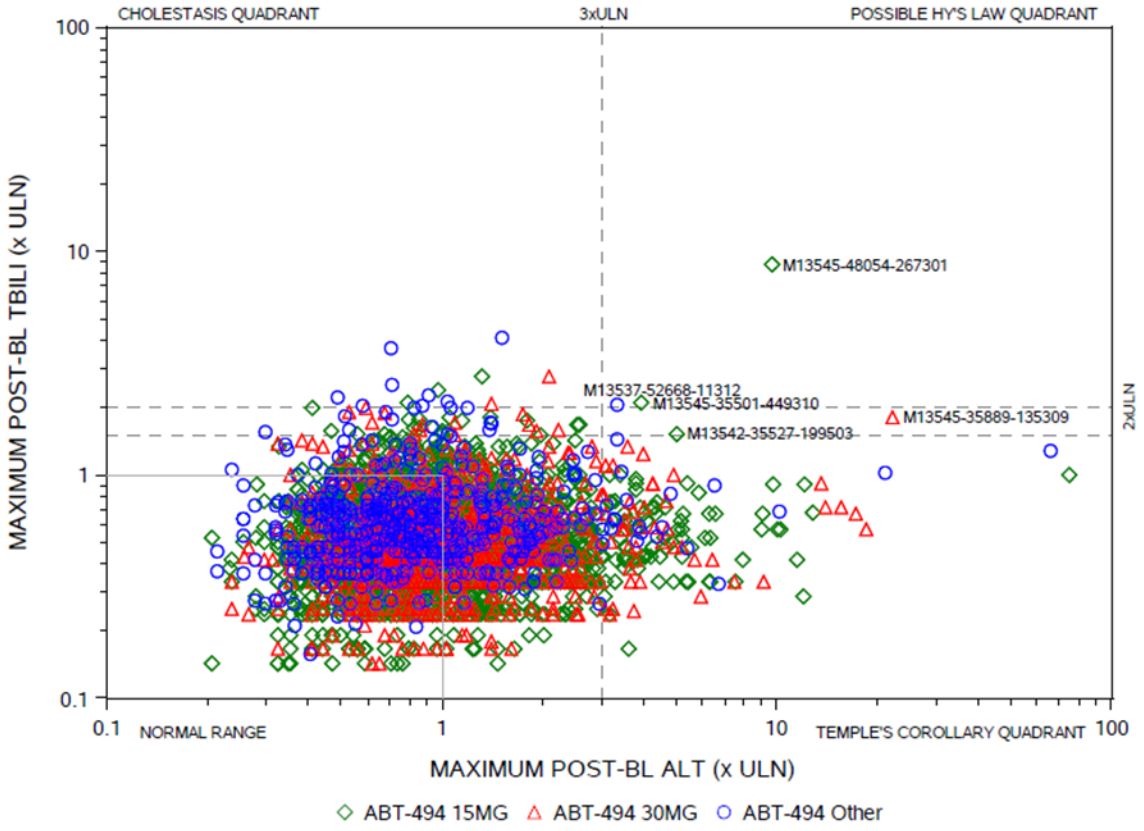
図 2.7.4.7-9. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の ALT が最初に基準値上限の 5 倍以上となるまでの時間の Kaplan-Meier 推定（米国・欧州申請用安全性併合解析）



Note: Censoring date is the date of the last available ALT result.

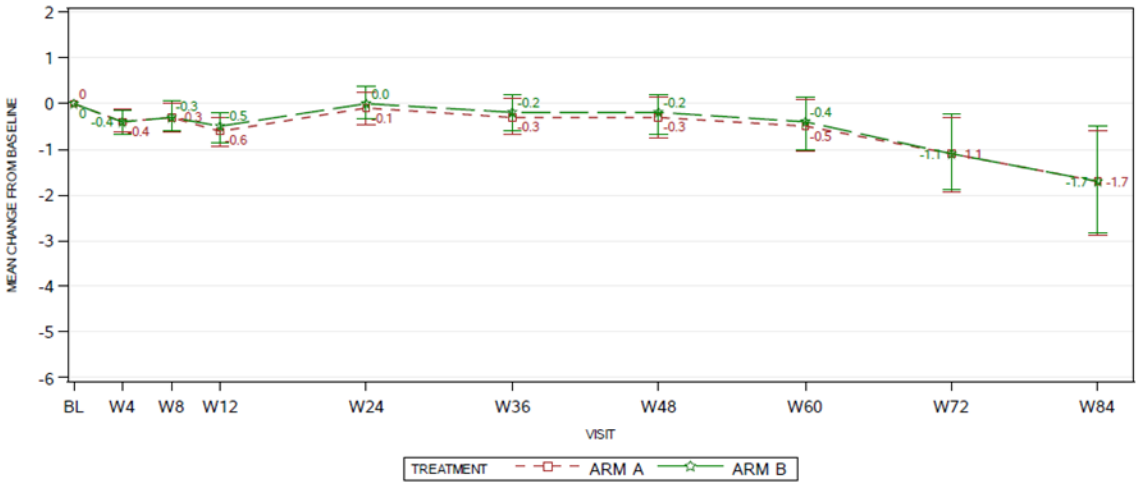
相互参照：ISS Figure 2.5__5.7.2

図 2.7.4.7-10. ウパダシチニブ併合解析集団（長期）の投与開始後の総ビリルビン最大値及び投与開始後の ALT 最大値の eDISH プロット（米国・欧州申請用安全性併合解析）



相互参照：ISS Figure 2.5__6.5.1

図 2.7.4.7-11. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）のヘモグロビン値のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



Notes: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.
Mean change from baseline over time by group with 95% CI.
Least Square (LS) means from analysis of covariance (ANCOVA) model adjusting for baseline are used.

相互参照：ISS Figure 2.5　4.5.1

図 2.7.4.7-12.　第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の好中球数のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



Notes: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.
Mean change from baseline over time by group with 95% CI.

LS means from ANCOVA model adjusting for baseline are used.

相互参照：ISS Figure 2.5__4.5.1

図 2.7.4.7-13. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）のリンパ球数のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



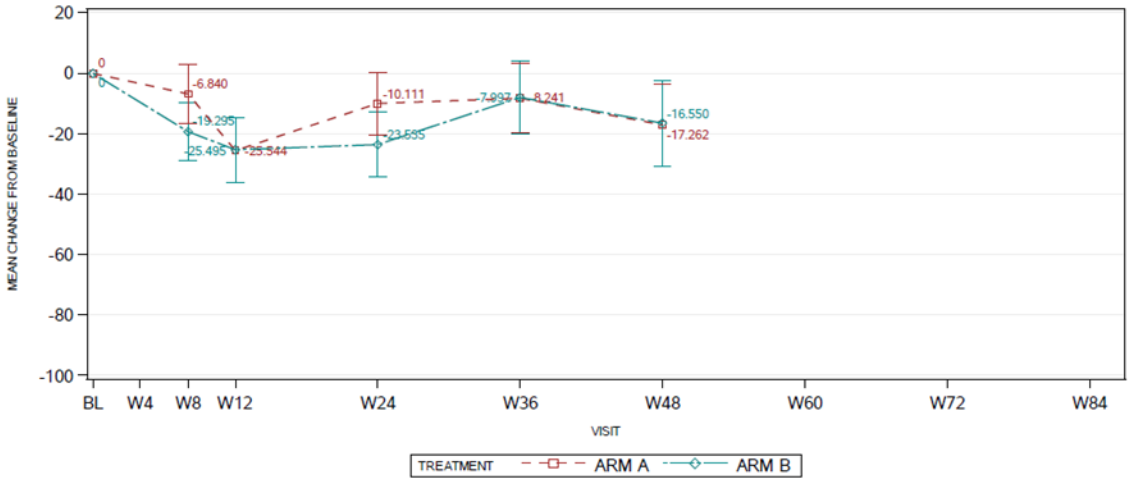
Notes: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.

Mean change from baseline over time by group with 95% CI.

LS means from ANCOVA model adjusting for baseline are used.

相互参照：ISS Figure 2.5__4.5.1

図 2.7.4.7-14. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-549 試験及び M13-542 試験）の NK 細胞数のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



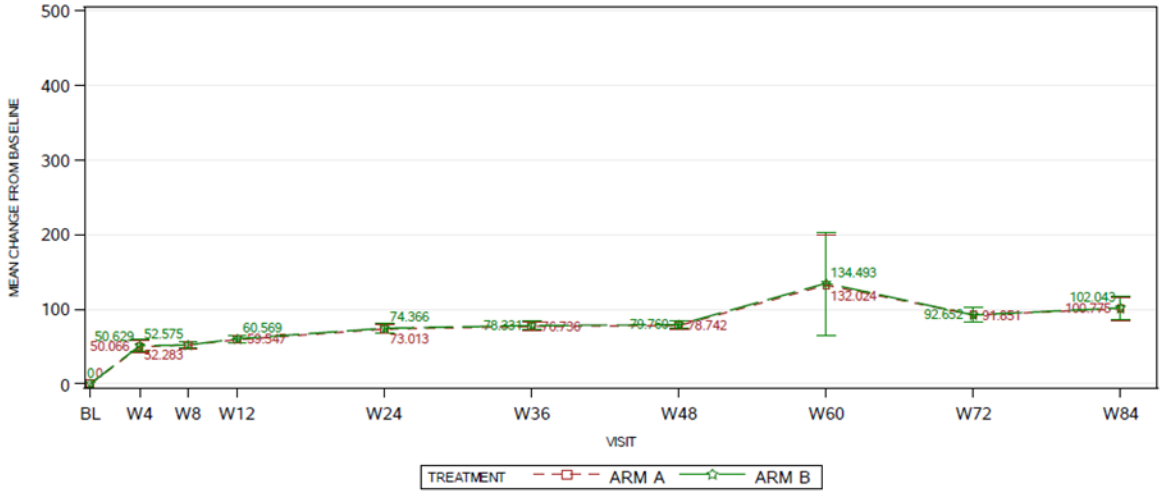
Notes: Arm A = UPA 15 mg QD; Arm B = UPA 30 mg QD.

Mean change from baseline over time by group with 95% CI.

LS means from ANCOVA model adjusting for baseline are used.

相互参照：ISS Figure 2.5__5.5.2

図 2.7.4.7-15. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）のクレアチンホスホキナーゼ値のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



SUBJECTS AT EACH VISIT

ARM A	2620	2571	2391	2522	2397	1996	1643	1087	582	279
ARM B	2461	2417	2255	2371	2249	1885	1572	1046	568	272

Notes: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.
Mean change from baseline over time by group with 95% CI.
LS means from ANCOVA model adjusting for baseline are used.

相互参照：ISS Figure 2.5　4.5.1

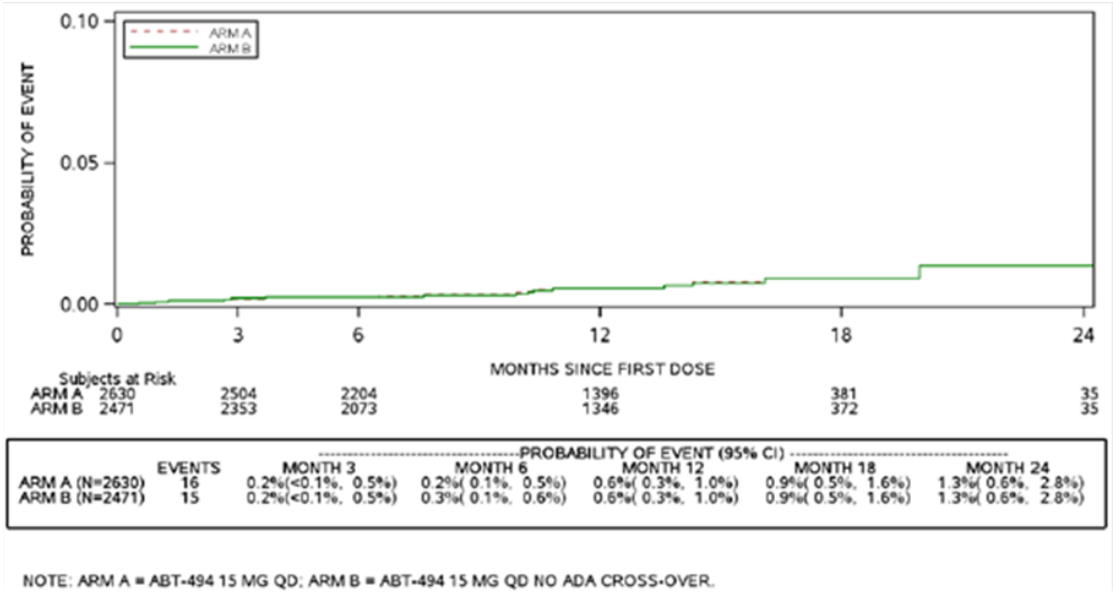
図 2.7.4.7-16.　第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）のクレアチニン値のベースラインからの平均変化量の経時的プロット（米国・欧州申請用安全性併合解析）



Notes: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.
Mean change from baseline over time by group with 95% CI.
LS means from ANCOVA model adjusting for baseline are used.

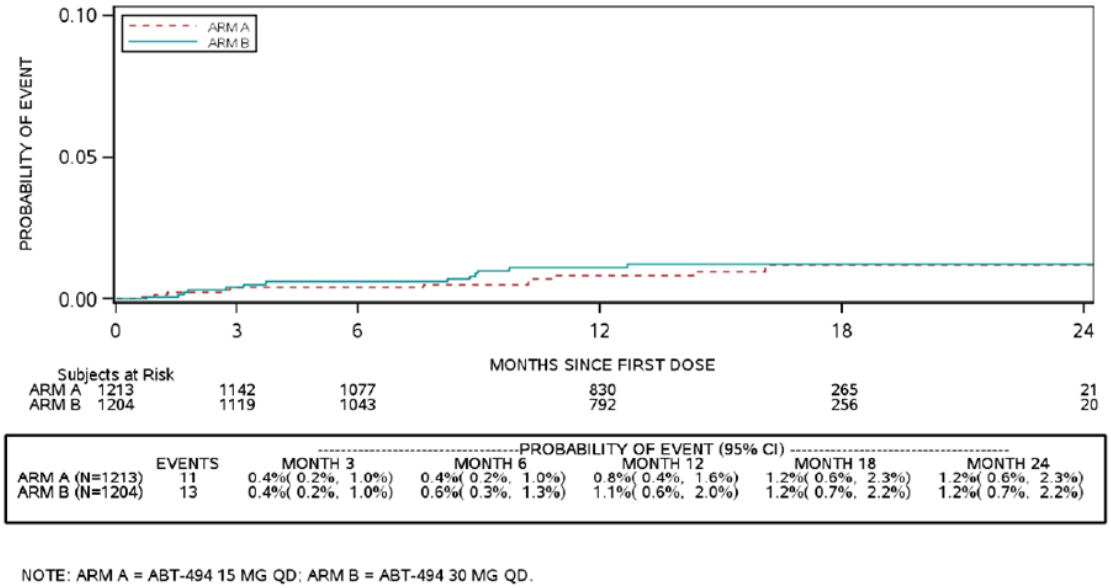
相互参照：ISS Figure 2.5__4.5.1

図 2.7.4.7-17. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の判定された主要心血管事象の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



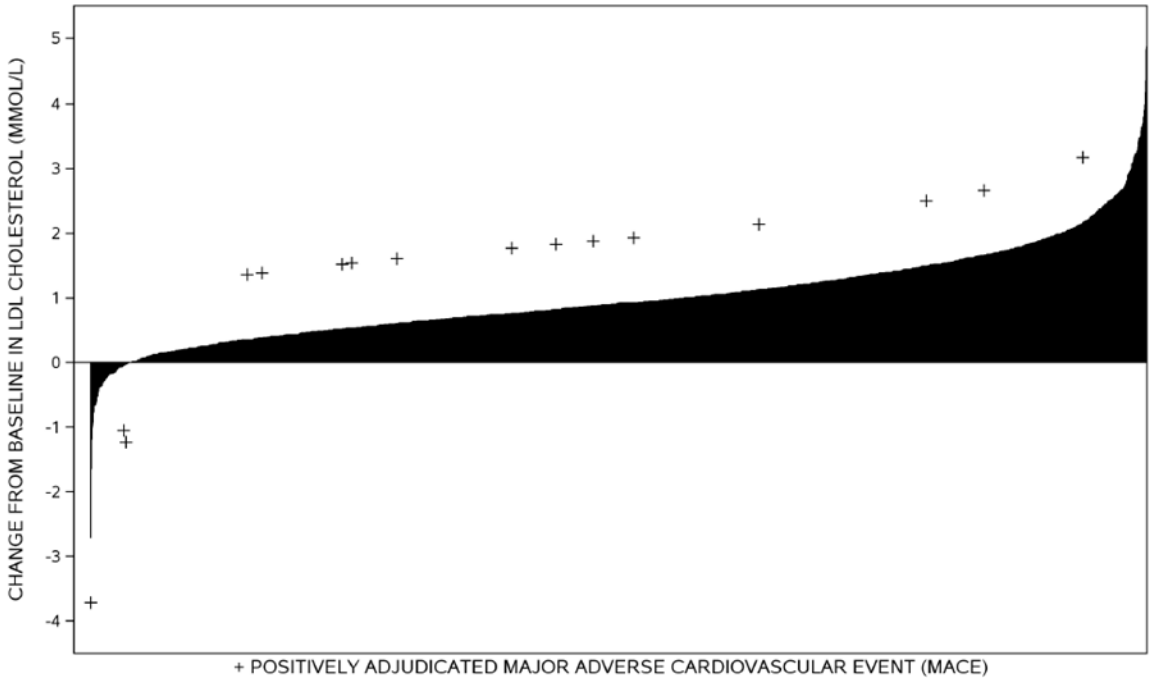
相互参照：ISS Figure 2.4__4.11.6.1

図 2.7.4.7-18. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の判定された主要心血管事象の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



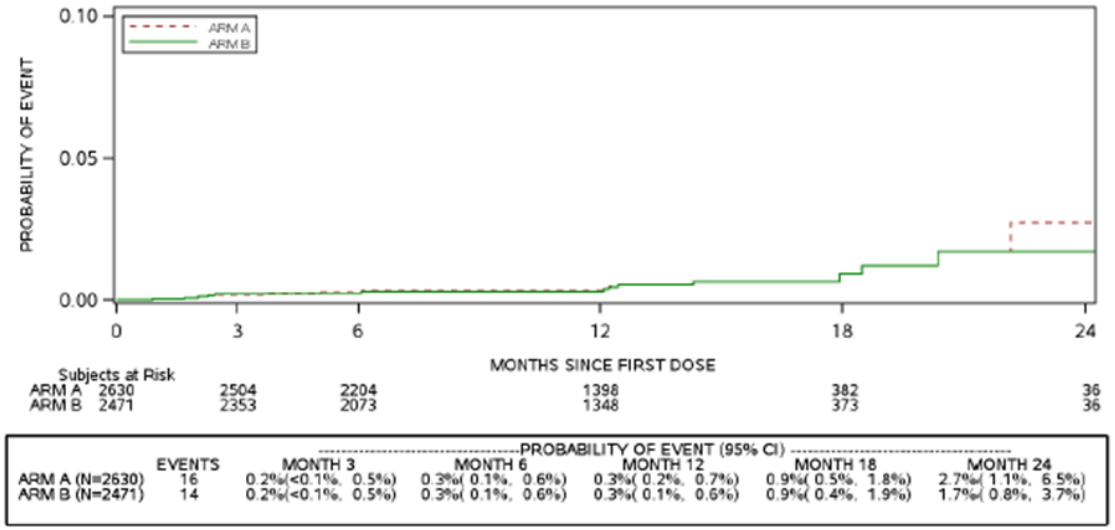
相互参照：ISS Figure 2.4__5.12.6.1

図 2.7.4.7-19. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の LDL-C のベースラインからの変化及び判定された主要心血管事象のウォーターフォールプロット（米国・欧州申請用安全性併合解析）



相互参照：ISS Figure 2.5　4.7

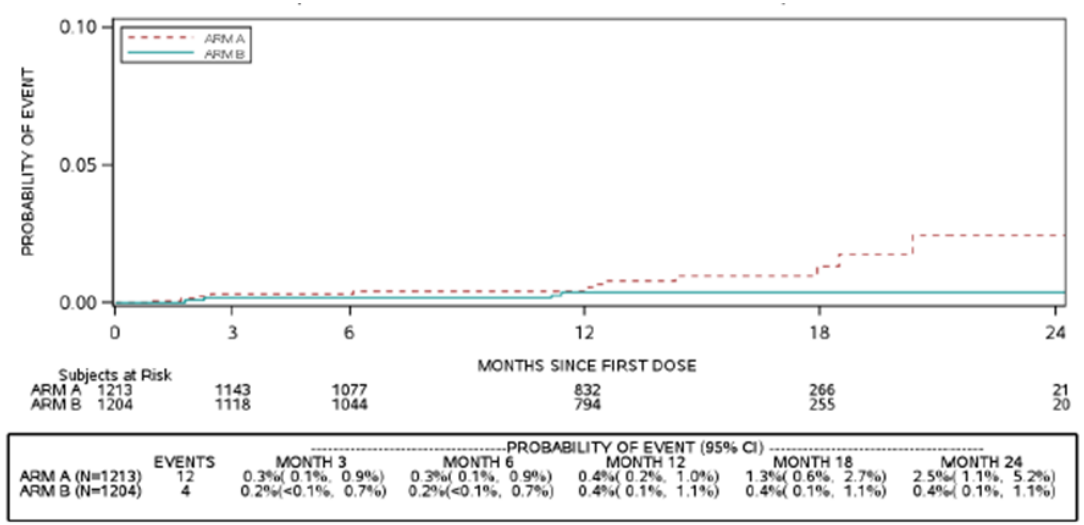
図 2.7.4.7-20. 第 III 相ウパダシチニブ 15 mg 併合解析集団（長期，第 III 相試験全 5 試験）の判定された静脈血栓塞栓症の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



Note: Arm A = UPA 15 mg QD; Arm B = UPA 15 mg QD no ADA crossover.

相互参照：ISS Figure 2.4__4.11.7.1

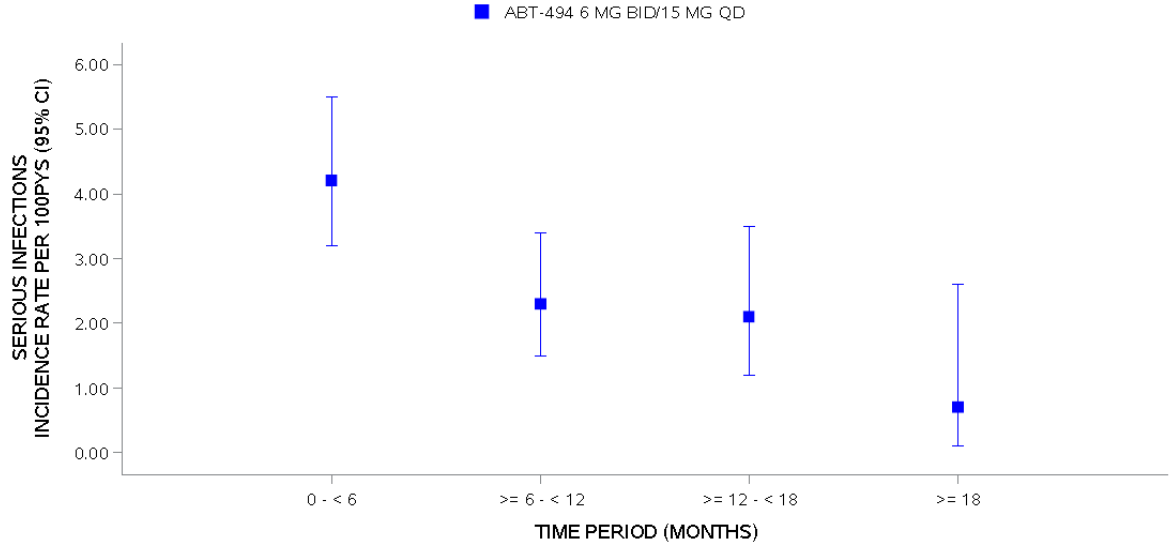
図 2.7.4.7-21. 第 III 相ウパダシチニブ 15 mg/30 mg 併合解析集団（長期，M13-545 試験，M13-549 試験，M15-555 試験，M13-542 試験）の判定された静脈血栓塞栓症の Kaplan-Meier 曲線（米国・欧州申請用安全性併合解析）



Note: Arm A = UPA 15 mg QD; Arm B = UPA 30 mg QD.

相互参照：ISS Figure 2.4__5.12.7.1

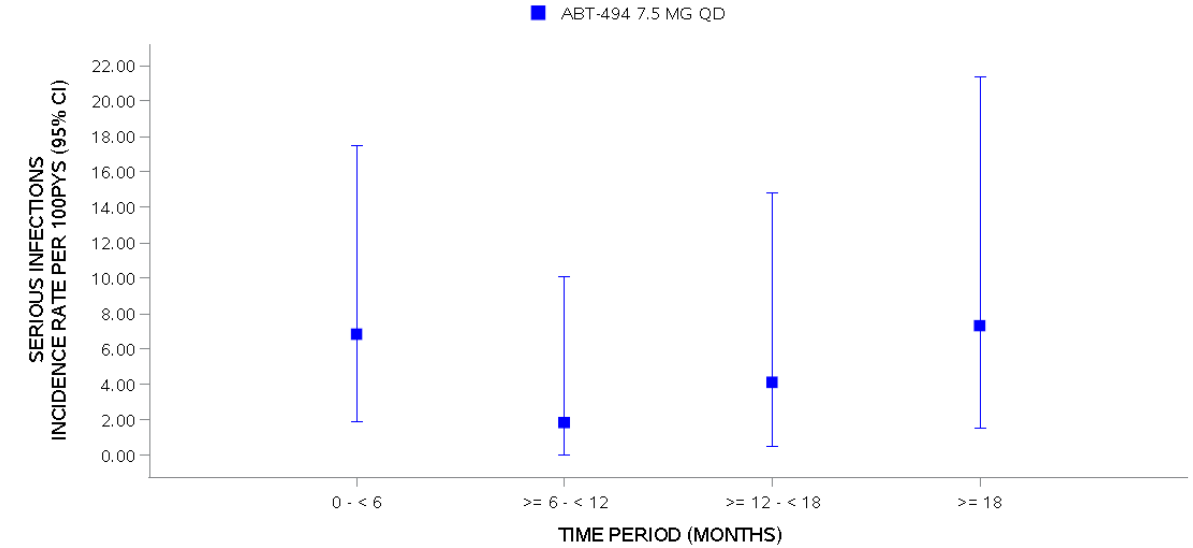
図 2.7.4.7-22. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の重篤な感染症の発現率（被験者数換算）（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）



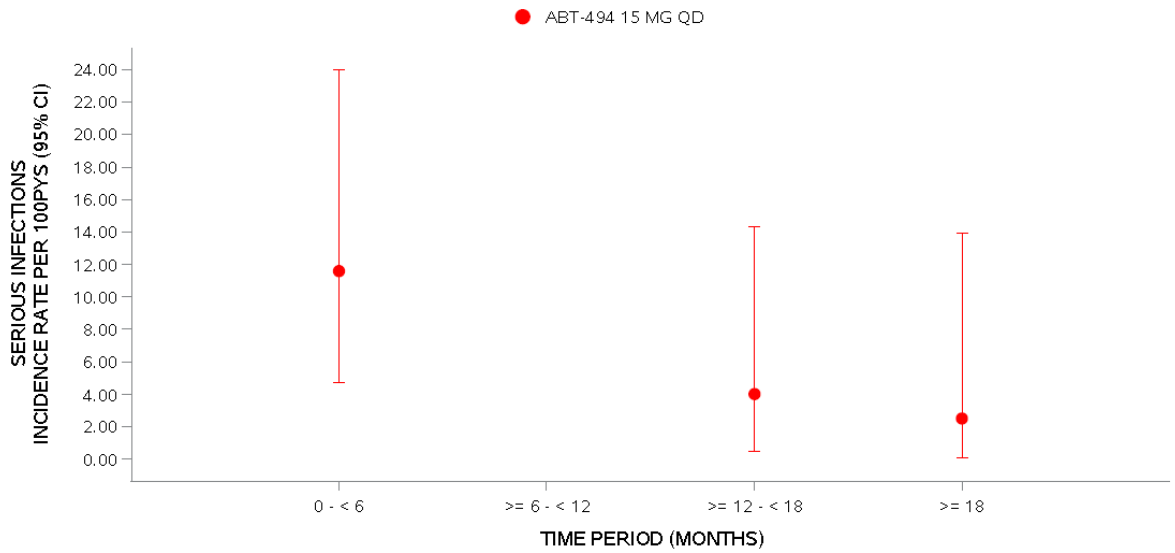
PATIENT YEARS	1327.5	1074.2	702.5	276.3
SUBJECTS WITH EVENTS	56	25	15	2
INCIDENCE RATE/100 PYS	4.2	2.3	2.1	0.7

相互参照：Updated J-ISS additional analysis Figure 1　3.1

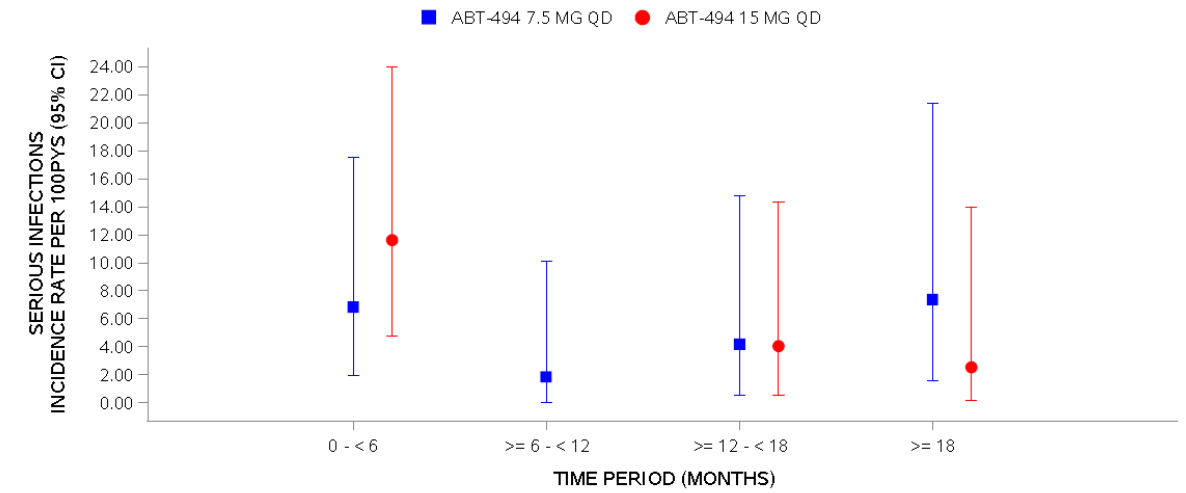
図 2.7.4.7-23. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の重篤な感染症の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）



PATIENT YEARS	58.5	55.2	48.7	40.9
SUBJECTS WITH EVENTS	4	1	2	3
INCIDENCE RATE/100 PYS	6.8	1.8	4.1	7.3



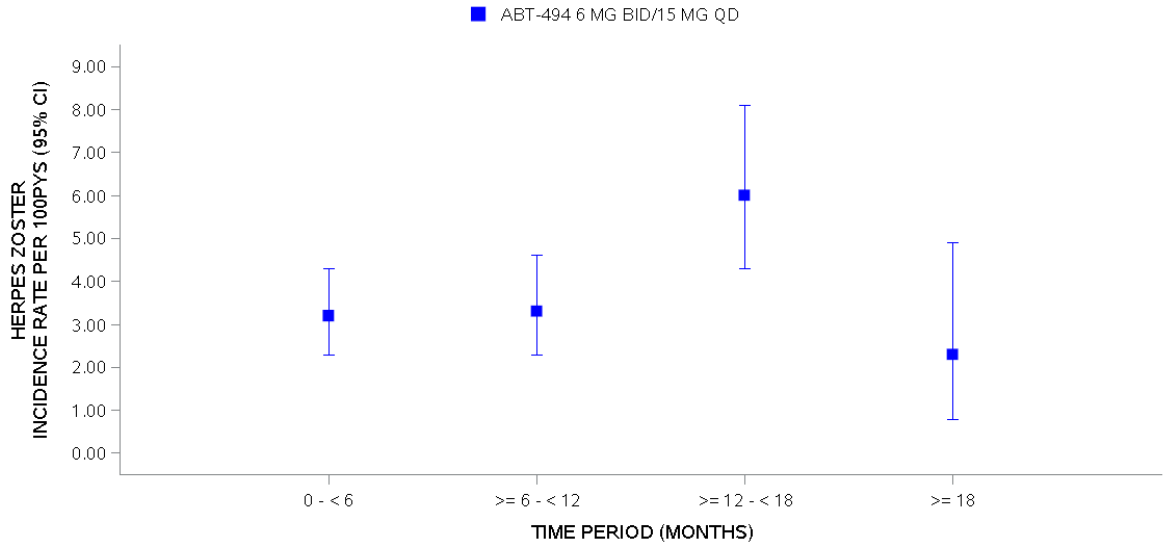
PATIENT YEARS	60.1	56.8	50.5	40.2
SUBJECTS WITH EVENTS	7	0	2	1
INCIDENCE RATE/100 PYS	11.6		4.0	2.5



ABT-494 7.5 MG QD				
PATIENT YEARS	58.5	55.2	48.7	40.9
SUBJECTS WITH EVENTS	4	1	2	3
INCIDENCE RATE/100 PYS	6.8	1.8	4.1	7.3
ABT-494 15 MG QD				
PATIENT YEARS	60.1	56.8	50.5	40.2
SUBJECTS WITH EVENTS	7	0	2	1
INCIDENCE RATE/100 PYS	11.6		4.0	2.5

相互参照：Updated J-ISS additional analysis Figure 1__2.1

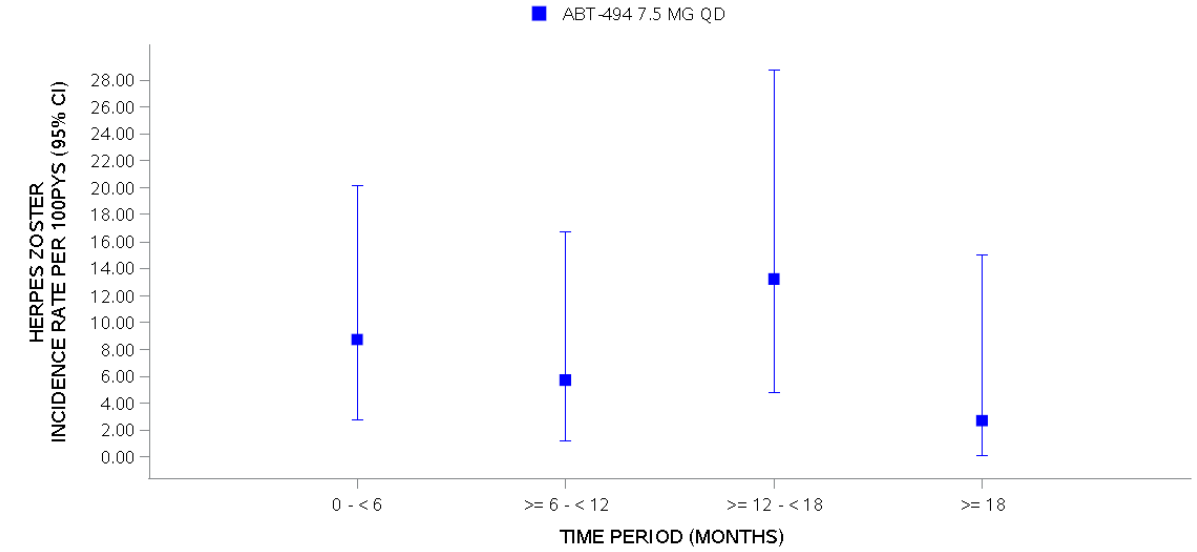
図 2.7.4.7-24. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の帯状疱疹の発現率（被験者数換算）（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）



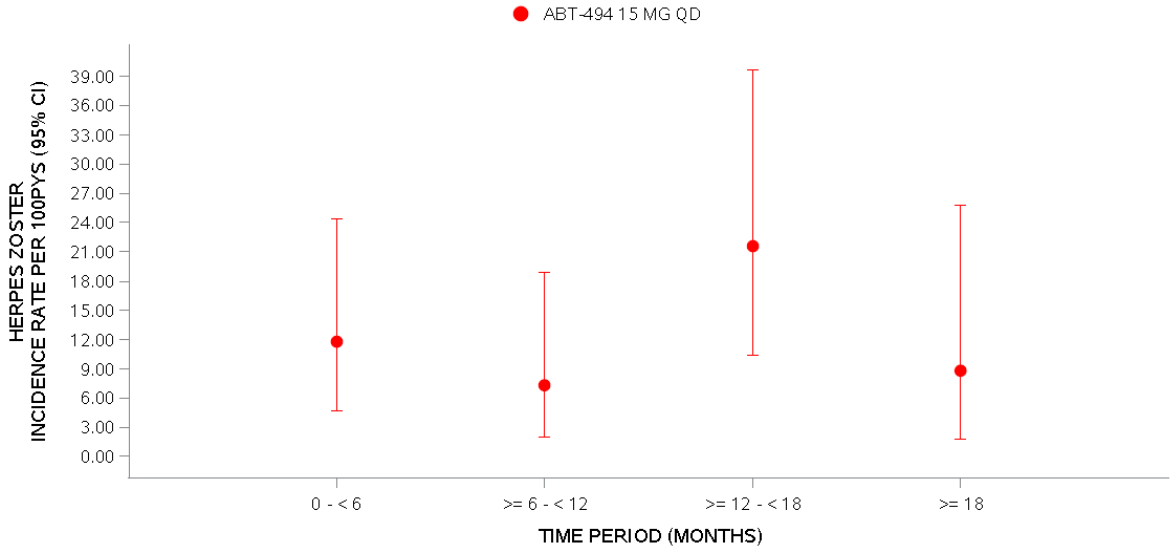
PATIENT YEARS	1325.3	1064.0	688.4	265.0
SUBJECTS WITH EVENTS	42	35	41	6
INCIDENCE RATE/100 PYS	3.2	3.3	6.0	2.3

相互参照：Updated J-ISS additional analysis Figure 1__3.2

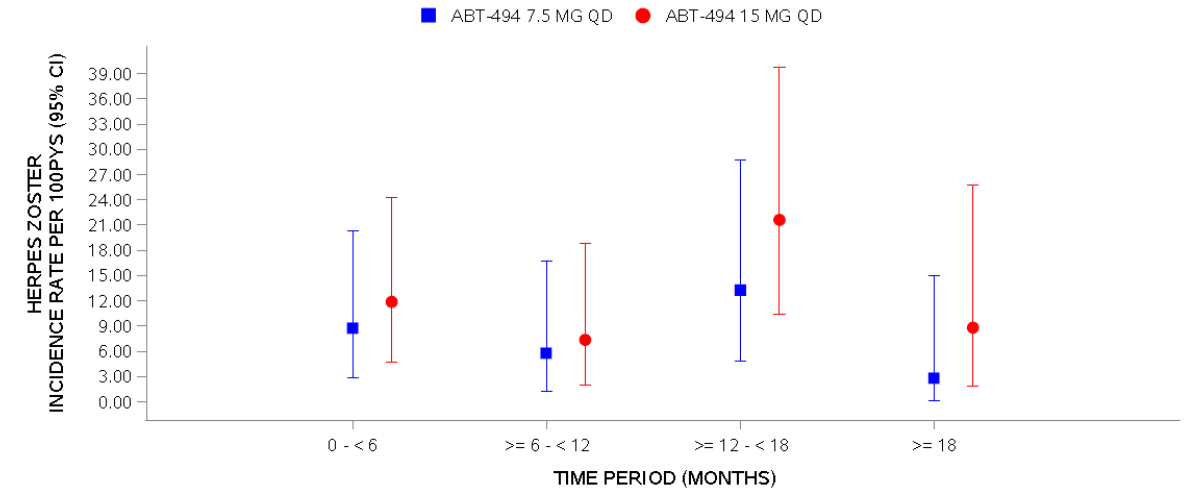
図 2.7.4.7-25. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の帯状疱疹の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）



PATIENT YEARS	57.8	52.6	45.5	37.2
SUBJECTS WITH EVENTS	5	3	6	1
INCIDENCE RATE/100 PYS	8.7	5.7	13.2	2.7



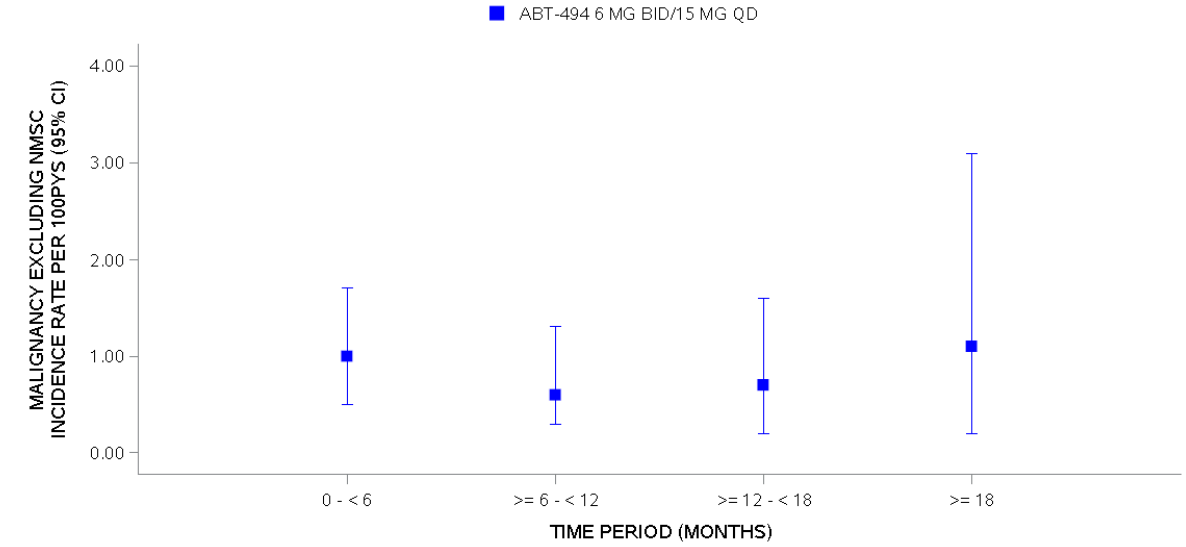
PATIENT YEARS	59.4	54.5	46.3	34.1
SUBJECTS WITH EVENTS	7	4	10	3
INCIDENCE RATE/100 PYS	11.8	7.3	21.6	8.8



ABT-494 7.5 MG QD				
PATIENT YEARS	57.8	52.6	45.5	37.2
SUBJECTS WITH EVENTS	5	3	6	1
INCIDENCE RATE/100 PYS	8.7	5.7	13.2	2.7
ABT-494 15 MG QD				
PATIENT YEARS	59.4	54.5	46.3	34.1
SUBJECTS WITH EVENTS	7	4	10	3
INCIDENCE RATE/100 PYS	11.8	7.3	21.6	8.8

相互参照：Updated J-ISS additional analysis Figure 1　2.2

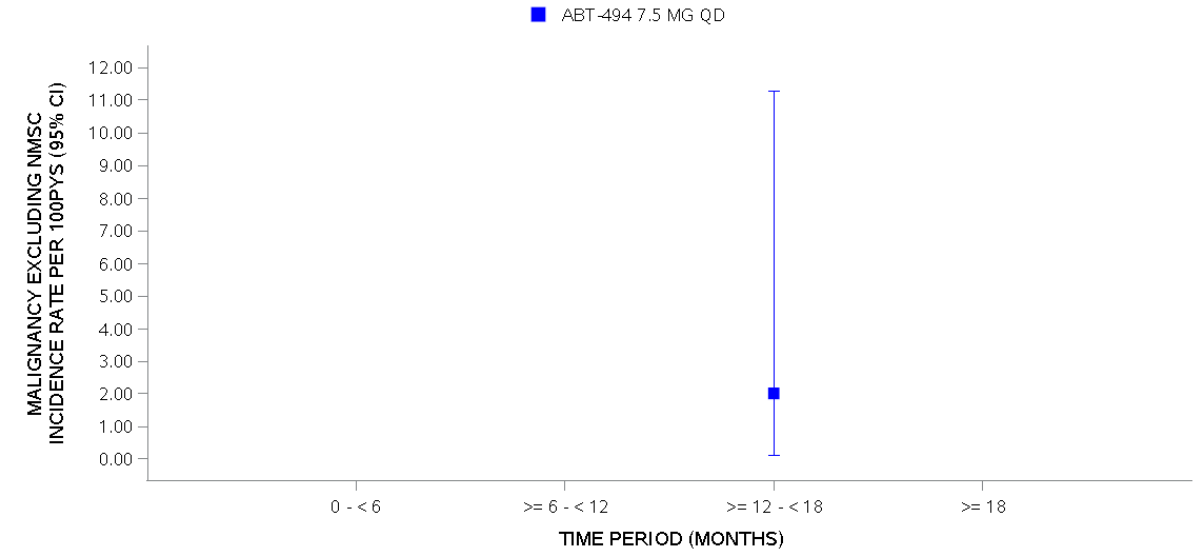
図 2.7.4.7-26. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の非黒色腫皮膚癌を除く悪性腫瘍の発現率（被験者数換算）（ウパダシチニブ併合解析集団，日本申請用安全性併合解析）

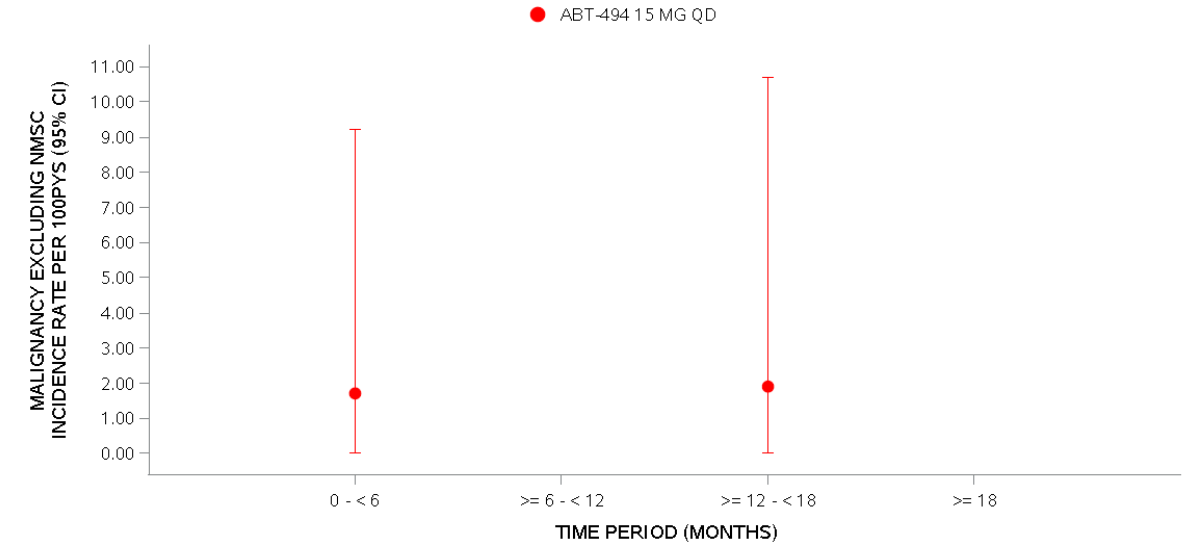


PATIENT YEARS	1333.3	1086.8	715.1	283.9
SUBJECTS WITH EVENTS	13	7	5	3
INCIDENCE RATE/100 PYS	1.0	0.6	0.7	1.1

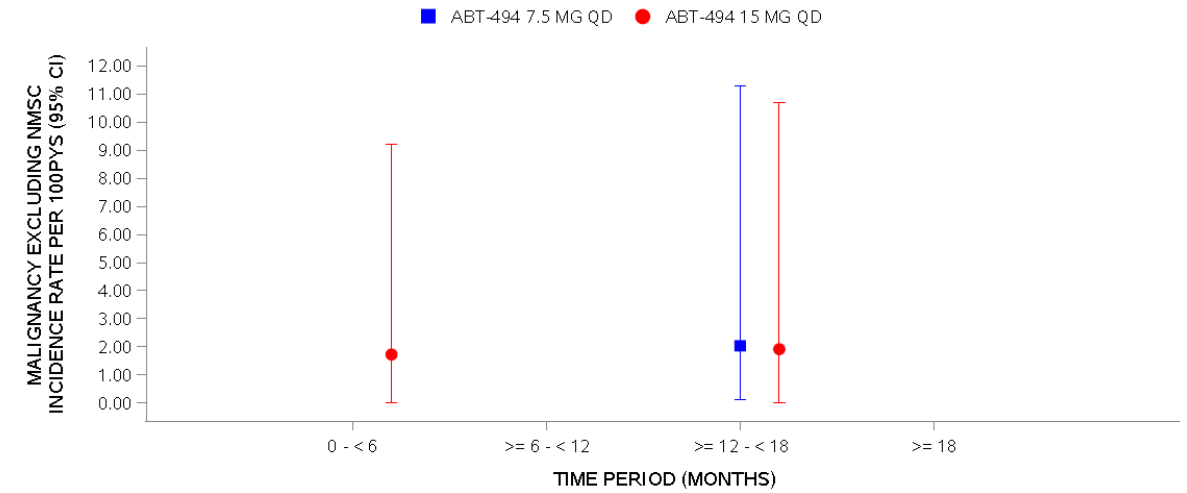
相互参照：Updated J-ISS additional analysis Figure 1__3.3

図 2.7.4.7-27. 更新時のウパダシチニブ併合解析の 100 人年あたりの発現時期別の非黒色腫皮膚癌を除く悪性腫瘍の発現率（被験者数換算）（日本人ウパダシチニブ併合解析集団，日本申請用安全性併合解析）





PATIENT YEARS	60.4	57.8	52.0	43.3
SUBJECTS WITH EVENTS	1	0	1	0
INCIDENCE RATE/100 PYS	1.7		1.9	



	0 - < 6	>= 6 - < 12	>= 12 - < 18	>= 18
ABT-494 7.5 MG QD				
PATIENT YEARS	58.6	55.2	49.3	41.7
SUBJECTS WITH EVENTS	0	0	1	0
INCIDENCE RATE/100 PYS			2.0	
ABT-494 15 MG QD				
PATIENT YEARS	60.4	57.8	52.0	43.3
SUBJECTS WITH EVENTS	1	0	1	0
INCIDENCE RATE/100 PYS	1.7		1.9	

相互参照：Updated J-ISS additional analysis Figure 1__2.3

2.7.4.7.1 Narrative Index

Narrative indices are provided below for events that are not included in a CSR provided with this submission or which were updated following data cutoff date for the CSR provided with this submission.

Study M13-538

Information regarding the following subject narratives was obtained from the data listings in the clinical database and may include additional information from the subject's safety file. Therefore, the narratives may contain additional information not available in the study tables.

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	15823		X	X	
[redacted]	12910			X	
[redacted]	18224		X		X
[redacted]	18224		X		X
[redacted]	18224			X	
[redacted]	18224			X	
[redacted]	22702		X	X	X
[redacted]	22702				X
[redacted]	22752		X	X	X
[redacted]	68603		X		X
[redacted]	68603		X	X	X
[redacted]	47441				X
[redacted]	47441				X
[redacted]	35483		X		
[redacted]	35483	X	X	X	
[redacted]	22735		X		
[redacted]	22735				X
[redacted]	22735				X
[redacted]	14000		X	X	
[redacted]	33746			X	X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	51322		X		X
[redacted]	51322		X		
[redacted]	15830				X
[redacted]	37106		X		
[redacted]	52852	X	X	X	

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	52852				X
[redacted]	22712		X		X
[redacted]	46124		X		
[redacted]	44153		X		X
[redacted]	34366		X		X
[redacted]	34366		X		X
[redacted]	19484				X
[redacted]	22818		X		X
[redacted]	52012			X	X
[redacted]	41430		X		X
[redacted]	22424		X	X	
[redacted]	19310		X	X	X
[redacted]	32485		X		X
[redacted]	51186		X		
[redacted]	53261		X	X	X
[redacted]	52007		X	X	
[redacted]	52007				X
[redacted]	52007		X		X
[redacted]	52007				X
[redacted]	52010		X		

[redacted]	47626	X	X	X
[redacted]	52011	X		X
[redacted]	52011	X	X	X
[redacted]	52011	X		
[redacted]	50380		X	
[redacted]	53512		X	
[redacted]	37375			X
[redacted]	37375	X	X	X
[redacted]	37375	X	X	X
[redacted]	37375			X
[redacted]	37375			X
[redacted]	39489			X
[redacted]	39489	X		

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	39489				X
[redacted]	39489			X	X
[redacted]	12949		X	X	
[redacted]	12949		X		X
[redacted]	12949			X	
[redacted]	53511				X
[redacted]	04559				X
[redacted]	14000		X		X
[redacted]	31782				X
[redacted]	31782		X		
[redacted]	48210		X		X
[redacted]	52667				X
[redacted]	52667				X
[redacted]	52668		X	X	X
[redacted]	48207				X
[redacted]	42499		X		
[redacted]	42499				X
[redacted]	51131		X		
[redacted]	39489		X		
[redacted]	39489		X	X	X

[redacted]	39489	X		
[redacted]	39489	X		X
[redacted]	39489	X		X
[redacted]	39489			X
[redacted]	39489			X
[redacted]	52677			X
[redacted]	52677	X	X	X
[redacted]	52679			X
[redacted]	52682	X		X
[redacted]	52682			X
[redacted]	52683		X	
[redacted]	52693			X
[redacted]	52693			X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	52689		X		
[redacted]	52690			X	
[redacted]	52690		X	X	
[redacted]	52690				X
[redacted]	79214		X	X	X
[redacted]	79214				X
[redacted]	79214				X
[redacted]	79214			X	
[redacted]	52692		X	X	X
[redacted]	52692		X		X
[redacted]	52692		X	X	X
[redacted]	52280			X	
[redacted]	52280				X
[redacted]	52280				X
[redacted]	47626		X		
[redacted]	52698		X	X	X
[redacted]	52697				X
[redacted]	36787			X	
[redacted]	74746				X
[redacted]	22818			X	

[redacted]	52704		X	
[redacted]	19484	X		X
[redacted]	46320		X	X
[redacted]	52714	X	X	
[redacted]	52714	X		X
[redacted]	52714		X	
[redacted]	52714	X		X
[redacted]	37335			X
[redacted]	52685			X
[redacted]	52687			X
[redacted]	52674	X		
[redacted]	52675			X
[redacted]	52675	X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest
[redacted]	52675				X
[redacted]	52675		X		
[redacted]	52675		X		X
[redacted]	51322			X	
[redacted]	51322		X	X	X
[redacted]	51322				X
[redacted]	37375	X	X	X	X
[redacted]	45642				X
[redacted]	45642	X	X	X	X
[redacted]	18220	X	X	X	X
[redacted]	18221		X		
[redacted]	34709		X	X	X
[redacted]	53602			X	X
[redacted]	14376				X
[redacted]	12942			X	X
[redacted]	47441				X
[redacted]	08586			X	X
[redacted]	04562		X		
[redacted]	18575				X
[redacted]	18596		X		

[redacted]	18596	X		
[redacted]	18596			X
[redacted]	18596	X	X	
[redacted]	32642	X	X	X
[redacted]	84608	X		

Study M13-545

Information regarding the following subject narratives was obtained from the data listings in the clinical database and may include additional information from the subject's safety file. Therefore, the narratives may contain additional information not available in the study tables. Subjects identified with an asterisk (*) in the table below had treatment-emergent adjudicated cardiovascular events.

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	05201				X		X
[redacted]	05201		X	X	X		X
[redacted]	36836		X				X
[redacted]	36836		X				X
[redacted]	36836		X		X		X
[redacted]	38374		X				X
[redacted]	38374		X		X	X	
[redacted]	38374				X		X
[redacted]	30394		X		X		X
[redacted]*	35889		X		X		X
[redacted]	48552				X		X
[redacted]	48552				X		X
[redacted]	91357			X			X
[redacted]	88048				X		X
[redacted]	88048		X		X		X
[redacted]	88048			X			X
[redacted]	91359				X	X	
[redacted]	91359				X		X
[redacted]	88192				X		X
[redacted]	88192				X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	48210				X		X
[redacted]	48210		X	X			X
[redacted]	48210		X	X	X	X	
[redacted]	52675				X		X
[redacted]	92070		X		X		X
[redacted]	92070				X		X
[redacted]	42498		X	X	X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	90956		X		X		X
[redacted]	90956		X	X		X	
[redacted]	41426		X		X		X
[redacted]	53796		X				X
[redacted]	91426		X				X
[redacted]	91426		X		X	X	
[redacted]	91426				X		X
[redacted]	92288				X		X
[redacted]	48054	X	X	X	X	X	
[redacted]	52677		X	X	X	X	
[redacted]	32497		X		X		X
[redacted]	52678		X		X		X
[redacted]	39363				X		X
[redacted]	51801		X				X
[redacted]*	51801	X	X	X	X		X
[redacted]	97757		X			X	
[redacted]	97757				X		X
[redacted]	52685				X	X	
[redacted]	51285	X	X	X	X		X
[redacted]	51285			X			X

[redacted]	37106	X	X	X		X
[redacted]	48160		X			X
[redacted]	53323	X			X	
[redacted]	53323	X	X		X	
[redacted]*	53323	X		X		X
[redacted]	53323		X			X
[redacted]	91481			X		X
[redacted]	50230		X			X
[redacted]	89261	X		X		X
[redacted]	90304			X		X
[redacted]	48385	X				X
[redacted]	52697	X				X
[redacted]	52697			X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	37936				X		X
[redacted]	41416				X		X
[redacted]	48414				X		X
[redacted]	46319				X		X
[redacted]	92249		X				X
[redacted]	90967			X	X		X
[redacted]	78353		X	X	X		X
[redacted]	38523		X				X
[redacted]	38523				X		X
[redacted]	22888		X		X		X
[redacted]	74746			X	X	X	
[redacted]	74746		X		X		X
[redacted]	36791		X		X	X	
[redacted]	51480		X		X	X	
[redacted]	52704				X		X
[redacted]	52704				X		X
[redacted]	51476			X			X
[redacted]	22356			X	X		X
[redacted]	91613			X			X
[redacted]	91613			X			X

[redacted]	90268			X			X	X	
[redacted]	90268						X		X
[redacted]	90268						X		X
[redacted]	49708						X		X
[redacted]	49708						X		X
[redacted]	49708						X		X
[redacted]	39376			X					X
[redacted]	39376						X		X
[redacted]	39376						X		X
[redacted]	39376	X		X		X	X		X
[redacted]	33524						X		X
[redacted]	19310						X		X
[redacted]	19310					X			X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	13588				X		X
[redacted]	13588				X		X
[redacted]	13588			X			X
[redacted]	13588				X		X
[redacted]	13588				X		X
[redacted]	37489		X		X		X
[redacted]	18596				X		X
[redacted]	22712			X			X
[redacted]	89867		X		X	X	
[redacted]	84608				X		X
[redacted]	84608				X		X
[redacted]	84608		X		X		X
[redacted]	84608		X		X	X	
[redacted]	53209				X		X
[redacted]	31297		X	X	X		X
[redacted]	31297		X				X
[redacted]	04559		X		X		X
[redacted]	04559		X		X		X
[redacted]	12949		X				X
[redacted]	48457				X		X

[redacted]	100435		X			X
[redacted]	100435			X	X	
[redacted]	39365	X	X	X		X
[redacted]	22719			X		X
[redacted]	49972	X		X		X
[redacted]	49972			X	X	
[redacted]	36770	X		X	X	
[redacted]	36772	X	X	X		X
[redacted]	36772	X				X
[redacted]	29349	X		X		X
[redacted]	29349			X		X
[redacted]	29349		X	X		X
[redacted]	38104	X				X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	38104				X		X
[redacted]	38270		X	X	X	X	
[redacted]	106985				X		X
[redacted]	38141				X		X
[redacted]	38141			X			X
[redacted]*	108116		X		X		X
[redacted]	108116				X		X
[redacted]	31856			X			X
[redacted]	38135				X		X
[redacted]	38242				X		X
[redacted]	38242		X		X		X
[redacted]	40132				X		X
[redacted]	40132				X		X
[redacted]	111639	X	X	X	X		X
[redacted]	111638				X		X
[redacted]	111939			X	X		X
[redacted]	111637				X		X
[redacted]	111637				X		X
[redacted]	50563				X		X
[redacted]	115129			X	X		X

[redacted]	25094				X		X
[redacted]	109902	X	X	X	X		
[redacted]	109903	X	X		X		
[redacted]	116750	X		X	X		
[redacted]	116750	X		X		X	
[redacted]	116750	X		X	X		
[redacted]	116750			X		X	
[redacted]	39015	X		X		X	
[redacted]	39015	X		X		X	
[redacted]	39015	X	X			X	
[redacted]	51228	X		X		X	
[redacted]	106471	X				X	
[redacted]	119048			X		X	

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	50700		X		X		X
[redacted]*	118146		X	X	X	X	
[redacted]	47918				X		X
[redacted]	118918			X	X	X	

Study M14-465

Information regarding the following subject narratives was obtained from the data listings in the clinical database and may include additional information from the subject's safety file. Therefore, the narratives may contain additional information not available in the study tables. Subjects identified with an asterisk (*) in the table below had treatment-emergent adjudicated cardiovascular events.

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	05201		X				X
[redacted]	53859				X		X
[redacted]	92173		X				X
[redacted]	92189		X				X
[redacted]	35483				X		X
[redacted]	19340		X		X		X
[redacted]	52674			X	X		X
[redacted]	48552		X		X		X
[redacted]	48552				X		X
[redacted]	48552				X		X
[redacted]	48552				X	X	
[redacted]	89997		X	X	X		X
[redacted]	91357				X		X
[redacted]	88048				X		X
[redacted]	88048		X	X	X		X
[redacted]	88048				X		X
[redacted]	91359				X		X
[redacted]	91359				X		X
[redacted]	91359				X		X
[redacted]	46468		X	X	X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	52665			X			X
[redacted]	52665				X		X
[redacted]	48209		X				X
[redacted]	48209		X		X	X	
[redacted]	48210				X		X
[redacted]	18619			X			X
[redacted]	40141				X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]*	100703	X	X		X		X
[redacted]	100703				X		X
[redacted]	100703				X		X
[redacted]	100703		X				X
[redacted]	100703				X		X
[redacted]	45854				X		X
[redacted]	45854				X		X
[redacted]	45854		X	X	X		X
[redacted]	46389		X	X	X		X
[redacted]	52675		X		X		X
[redacted]	52675				X		X
[redacted]	52675		X		X		X
[redacted]	103556		X	X	X		X
[redacted]	92241		X		X		X
[redacted]	92241			X			X
[redacted]	92241		X		X	X	
[redacted]	92070		X			X	
[redacted]	34421			X	X		X
[redacted]	91253				X		X
[redacted]	91253				X		X

[redacted]*	91253	X		X	X
[redacted]	91253	X	X		X
[redacted]	46124	X			X
[redacted]	46124	X			X
[redacted]	39104		X		X
[redacted]	42501		X		X
[redacted]	19361	X	X	X	X
[redacted]	91799			X	X
[redacted]	86857	X			X
[redacted]*	86857	X	X	X	X
[redacted]	51131			X	X
[redacted]	51131			X	X
[redacted]	107987		X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	107987		X				X
[redacted]	107987		X	X	X		X
[redacted]*	91426		X		X		X
[redacted]	91426		X				X
[redacted]	91491		X		X		X
[redacted]	39489	X	X	X			X
[redacted]	39489		X				X
[redacted]	27203		X		X		X
[redacted]	27203		X	X	X		X
[redacted]	76928		X		X		X
[redacted]	76928		X	X			X
[redacted]	76928		X		X		X
[redacted]	51135		X	X			X
[redacted]	52677		X				X
[redacted]	91474				X		X
[redacted]	97757		X		X		X
[redacted]	89995		X	X	X		X
[redacted]	52682		X		X		X
[redacted]	52683		X	X	X		X
[redacted]	82103			X			X

[redacted]	91477				X	X	X	
[redacted]	105586			X				X
[redacted]	105586				X			X
[redacted]	52685					X		X
[redacted]	52685					X		X
[redacted]	52685					X		X
[redacted]	52685					X		X
[redacted]	52685					X		X
[redacted]	52685					X		X
[redacted]*	52685	X		X		X	X	
[redacted]	52685			X	X	X		X
[redacted]	52685			X				X
[redacted]	52685					X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	52687		X	X	X		X
[redacted]	51285				X		X
[redacted]	51285		X		X	X	
[redacted]	51285		X	X	X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415				X		X
[redacted]	42415		X	X	X	X	
[redacted]	53117		X	X	X		X
[redacted]	53117				X		X
[redacted]	47626			X			X
[redacted]	41003		X		X		X
[redacted]	41003			X			X
[redacted]	53323				X		X
[redacted]	53323				X		X
[redacted]	53323				X		X

[redacted]	53323			X		X
[redacted]	49605	X		X		X
[redacted]	51322	X				X
[redacted]*	51322	X		X		X
[redacted]	42620	X	X	X		X
[redacted]	90304			X		X
[redacted]	90304			X		X
[redacted]	53803	X	X			X
[redacted]	37935	X				X
[redacted]	48386	X		X	X	
[redacted]	52697		X			X
[redacted]	52698			X		X
[redacted]	17885			X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	41416		X		X		X
[redacted]	41416		X				X
[redacted]	46319			X		X	
[redacted]	09968				X		X
[redacted]	78353		X				X
[redacted]	78353		X				X
[redacted]	78353				X		X
[redacted]	100161				X		X
[redacted]	22888				X		X
[redacted]	22888	X	X	X	X		X
[redacted]	36788	X	X	X	X		X
[redacted]	36789		X		X		X
[redacted]	36789				X		X
[redacted]*	74746		X	X	X		X
[redacted]	74746		X				X
[redacted]	74746				X		X
[redacted]	74746		X	X	X		X
[redacted]	36791	X	X	X	X		X
[redacted]	39313		X	X	X		X
[redacted]	39313		X				X

[redacted]	102544		X		X
[redacted]	91600	X			X
[redacted]	42851	X			X
[redacted]	39372	X		X	X
[redacted]	90268	X		X	X
[redacted]	90268			X	X
[redacted]	90269	X	X		X
[redacted]	90269			X	X
[redacted]	90269			X	X
[redacted]	49708	X		X	X
[redacted]	49708			X	X
[redacted]	49708			X	X
[redacted]	39376	X			X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	12910		X				X
[redacted]*	08586	X	X		X		X
[redacted]	53994			X			X
[redacted]	45918				X		X
[redacted]	86931		X				X
[redacted]	86931		X		X	X	
[redacted]	51792				X		X
[redacted]	51792		X		X		X
[redacted]*	51792	X	X	X	X		X
[redacted]	18596				X		X
[redacted]	18596				X		X
[redacted]*	15830		X	X	X		X
[redacted]	31240		X	X	X		X
[redacted]	31253		X	X			X
[redacted]	31253		X				X
[redacted]	18601		X				X
[redacted]	18601		X	X	X		X
[redacted]	100884			X			X
[redacted]	100884		X		X		X
[redacted]	22752			X			X

[redacted]	42936		X	X		X
[redacted]*	37329	X		X		X
[redacted]	88094			X		X
[redacted]	100889	X	X	X		X
[redacted]	19606	X		X		X
[redacted]*	84608	X		X		X
[redacted]	37375	X	X	X	X	
[redacted]	88312	X				X
[redacted]*	88312	X		X		X
[redacted]	91646		X	X		X
[redacted]	91646			X		X
[redacted]	36683	X				X
[redacted]	37519			X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	37519		X				X
[redacted]	86931				X		X
[redacted]	53615		X				X
[redacted]	107394		X				X
[redacted]	107394				X		X
[redacted]	110203		X		X		X
[redacted]	110678				X		X
[redacted]	101581				X		X
[redacted]	101581		X				X
[redacted]	101581		X		X		X
[redacted]	101581		X				X
[redacted]	101581				X		X
[redacted]	101581				X		X
[redacted]	100162		X		X		X
[redacted]	100888				X		X
[redacted]	100888				X		X
[redacted]	100888		X				X
[redacted]	100888				X		X
[redacted]	100888		X		X	X	
[redacted]	85208		X	X			X

[redacted]	49927	X		X	X
[redacted]	49927	X			X
[redacted]	49927			X	X
[redacted]	41351	X			X
[redacted]	89125	X			X
[redacted]	89125		X	X	X
[redacted]	89125	X			X
[redacted]	40132	X	X		X
[redacted]	40132			X	X
[redacted]	18317			X	X
[redacted]	247919			X	X
[redacted]	115593			X	X
[redacted]	112491	X		X	X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	112491				X	X	
[redacted]	93095			X	X		X
[redacted]	39570		X				X
[redacted]	46428		X				X
[redacted]	46428		X				X
[redacted]	54098		X	X	X	X	

Study M13-542

Information regarding the following subject narratives was obtained from the data listings in the clinical database and may include additional information from the subject's safety file. Therefore, the narratives may contain additional information not available in the study tables. Subjects identified with an asterisk (*) in the table below had treatment-emergent adjudicated cardiovascular events.

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	33515			X	X		X
[redacted]	35889		X				X
[redacted]	33746		X		X		X
[redacted]	107987				X		X
[redacted]	91418				X		X
[redacted]	32487		X				X
[redacted]	44932		X	X	X	X	
[redacted]	48641		X				X
[redacted]	91426			X			X
[redacted]	91426		X				X
[redacted]	91426				X		X
[redacted]*	47968		X				X
[redacted]	35486		X				X
[redacted]	39489		X				X
[redacted]	89994				X		X
[redacted]	52683				X		X
[redacted]	37106		X				X
[redacted]	52007				X		X
[redacted]	52007		X			X	
[redacted]	52007		X				X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	53323		X				X
[redacted]	79214		X				X
[redacted]	79214			X	X		X
[redacted]	91481				X		X
[redacted]*	91481		X				X
[redacted]	90959		X		X		X
[redacted]	42438		X				X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	51480			X			X
[redacted]	51480				X		X
[redacted]	35501		X				X
[redacted]*	19338		X	X	X	X	
[redacted]	22335				X		X
[redacted]	81695		X		X		X
[redacted]	48878				X		X
[redacted]	53261			X	X		X
[redacted]	37305				X		X
[redacted]	91095			X			X
[redacted]	15829		X	X	X		X
[redacted]	18220				X	X	
[redacted]	18220		X	X	X		X
[redacted]	18220			X	X		X
[redacted]	18220			X	X	X	
[redacted]	18221		X		X		X
[redacted]*	37489		X	X	X		X
[redacted]	86931		X		X		X
[redacted]	86931		X				X
[redacted]*	86931		X		X		X

[redacted]*	86931		X					X
[redacted]*	86931	X	X	X	X	X		
[redacted]	86931		X		X	X		
[redacted]	68603			X	X		X	
[redacted]	25089				X		X	
[redacted]	03590		X		X		X	
[redacted]	03590		X				X	
[redacted]*	03590		X		X	X		
[redacted]	18596		X				X	
[redacted]	18596				X		X	
[redacted]*	15830	X	X	X	X		X	
[redacted]	15830				X		X	
[redacted]	53617				X	X		

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]	90110			X			X
[redacted]	16636				X		X
[redacted]	31240				X		X
[redacted]	31240			X			X
[redacted]	40087				X		X
[redacted]	31267		X				X
[redacted]	04047			X	X		X
[redacted]*	04047		X	X	X		X
[redacted]	04047				X		X
[redacted]	89867		X	X	X		X
[redacted]	18272				X		X
[redacted]	18272		X		X		X
[redacted]*	84536	X	X	X	X		X
[redacted]	84536		X	X	X		X
[redacted]	84536		X				X
[redacted]*	84536		X	X	X	X	
[redacted]*	87844		X		X	X	
[redacted]	46078				X		X
[redacted]	31255		X				X
[redacted]	18609				X		X

[redacted]	18609	X		X	X	
[redacted]	91641	X		X		X
[redacted]	32137			X		X
[redacted]	32137	X		X	X	
[redacted]*	18612	X		X		X
[redacted]	32137	X	X	X	X	
[redacted]	46095	X		X		X
[redacted]	53209			X		X
[redacted]	12945			X		X
[redacted]	12945	X	X	X		X
[redacted]	12945	X				X
[redacted]	99828		X			X
[redacted]	53934			X		X

Subject Number	Investigator Number	Death	Serious Adverse Event	Adverse Event Leading to Discontinuation from Study	Event of Interest	Safety Update	New Narrative
[redacted]*	100162		X	X	X		X
[redacted]	37622		X		X	X	
[redacted]	53851		X				X
[redacted]*	100894			X			X
[redacted]	100163		X		X		X
[redacted]*	100985		X		X		X
[redacted]	100985		X		X		X
[redacted]	11402		X		X		X
[redacted]*	89125		X		X	X	
[redacted]*	89125		X		X	X	
[redacted]	89125		X				X
[redacted]	99413				X		X
[redacted]*	54046		X		X		X
[redacted]	109880				X		X