表 8-21 投与中止に至った有害事象の一覧 - AK1820-301試験のCohort AおよびCohort A/B併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
Cohort A								
ISA (28)	[redacted]#	Male/ 8[redacted]/ Asian	感染症および寄生虫症/ 肺炎球菌感染	29 (1)/ 30 (2)	Yes/ Severe/ 4	Not Related	Fatal	Drug Withdrawn
ISA (1)	[redacted]#	Male/ 6[redacted]/ Asian	皮膚および皮下組織障害/ 冷汗	2 (1)/ 3 (2)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn
			呼吸器、胸郭および縦隔障害/ 呼吸困難	2 (1)/ 6 (5)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn
			耳および迷路障害/ 耳管開放	2 (1)/ Ongoing (Ongoing)	No/ Moderate	Not Related	Recovering/ Resolving	Drug Withdrawn
			神経系障害/ 感覚鈍麻	2 (1)/ 8 (7)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn
			呼吸器、胸郭および縦隔障害/ 口腔咽頭不快感	2 (1)/ 6 (5)	No/ Moderate	Related	Recovered/ Resolved	Drug Withdrawn
ISA (68)	[redacted]#	Male/ 7[redacted]/ Asian	代謝および栄養障害/ 低ナトリウム血症	69 (1)/ 84 (16)	Yes/ Severe/ 4	Related	Recovered/ Resolved	Drug Withdrawn

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 23.1

Program Name: l_ae_discon_2.sas
Program Run: 23JUN21:18:07:52

表 8-21 投与中止に至った有害事象の一覧 - AK1820-301試験のCohort AおよびCohort A/B併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
Cohort A								
ISA (1)	[redacted]#	Male/ 7[redacted]/ Asian	一般・全身障害および投与部位の状態/ 注射部位蕁麻疹	1 (0)/ 2 (1)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn
ISA (55)	[redacted]#	Male/ 5[redacted]/ Asian	感染症および寄生虫症/ 感染性胸水	27 (-28)/ Ongoing (Ongoing)	Yes/ Severe/ 4	Not Related	Recovering/ Resolving	Drug Withdrawn
ISA (4)	[redacted]#	Male/ 8[redacted]/ Asian	代謝および栄養障害/ 高カリウム血症	3 (-1)/ 31 (27)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn
			腎および尿路障害/ 腎機能障害	3 (-1)/ Ongoing (Ongoing)	No/ Mild	Related	Recovering/ Resolving	Drug Withdrawn
ISA (24)	[redacted]#	Male/ 7[redacted]/ Asian	胃腸障害/ 悪心	14 (-10)/ 42 (18)	No/ Moderate	Related	Recovered/ Resolved	Drug Withdrawn
ISA (62)	[redacted]#	Female/ 5[redacted]/ Asian	臨床検査/ 肝機能検査値上昇	48 (-14)/ Ongoing (Ongoing)	No/ Mild	Related	Not Recovered/ Not Resolved	Drug Withdrawn
ISA (43)	[redacted]#	Male/ 7[redacted]/ Asian	肝胆道系障害/ 肝機能異常	43 (0)/ Ongoing (Ongoing)	No/ Mild	Related	Not Recovered/ Not Resolved	Drug Withdrawn

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 23.1

Program Name: l_ae_discon_2.sas
Program Run: 23JUN21:18:07:52

表 8-21 投与中止に至った有害事象の一覧 - AK1820-301試験のCohort AおよびCohort A/B併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
Cohort A								
ISA (46)	[redacted]#	Male/ 7[redacted]/ Asian	肝胆道系障害/ 肝機能異常	38 (-8)/ Ongoing (Ongoing)	No/ Mild	Related	Recovering/ Resolving	Drug Withdrawn
VRC (3)	[redacted]#	Male/ 6[redacted]/ Asian	神経系障害/ 多発ニューロパチー	2 (-1)/ Ongoing (Ongoing)	No/ Mild	Related	Recovering/ Resolving	Drug Withdrawn
VRC (15)	[redacted]#	Male/ 8[redacted]/ Asian	眼障害/ 視力障害	1 (-14)/ 29 (14)	No/ Moderate	Related	Recovered/ Resolved	Drug Withdrawn
VRC (24)	[redacted]#	Male/ 8[redacted]/ Asian	肝胆道系障害/ 肝機能異常	7 (-17)/ 56 (32)	No/ Moderate	Related	Recovered/ Resolved	Drug Withdrawn
VRC (12)	[redacted]#	Male/ 7[redacted]/ Asian	筋骨格系および結合組織障害/ 横紋筋融解症	5 (-7)/ Ongoing (Ongoing)	Yes/ Moderate/ 4	Related	Recovering/ Resolving	Drug Withdrawn
			肝胆道系障害/ 薬物性肝障害	13 (1)/ Ongoing (Ongoing)	Yes/ Moderate/ 4	Related	Recovering/ Resolving	Drug Withdrawn
Cohort A/B併合（Cohort Aで表示ずみの被験者を除く）								
ISA (13)	[redacted]#	Female/ 8[redacted]/ Asian	臨床検査/ 心電図異常	14 (1)/ 21 (8)	No/ Mild	Related	Recovered/ Resolved	Drug Withdrawn

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 23.1

Program Name: l_ae_discon_2.sas
Program Run: 23JUN21:18:07:52

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (10)	[redacted]#	Male/ 5[redacted]/ White	心臓障害/ 心停止	11 (1)/ 11 (1)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
			血管障害/ 低血圧	11 (1)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
			腎および尿路障害/ 急性腎不全	11 (1)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			呼吸器、胸郭および縦隔障害/ 呼吸不全	11 (1)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
			感染症および寄生虫症/ 敗血症性ショック	11 (1)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (7)	[redacted]#	Female/ 4[redacted]/ White	精神障害/ 錯乱状態	4 (-3)/ 10 (3)	No/ Moderate	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (73)	[redacted]#	Male/ 4[redacted]/ White	傷害、中毒および処置合併症/ 過量投与	74 (1)/ 74 (1)	No/ Moderate	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (19)	[redacted]#	Female/ 4[redacted]/ White	神経系障害/ てんかん	20 (1)/ 20 (1)	Yes/ Severe/ 2	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (4)	[redacted]#	Female/ 3[redacted]/ White	呼吸器、胸郭および縦隔障害/ 急性呼吸不全	4 (0)/ 5 (1)	Yes/ Severe/ 1	Remotely Related	Fatal	Drug Withdrawn/ No
ISA (3)	[redacted]#	Female/ 5[redacted]/ White	臨床検査/ 血中ビリルビン増加	3 (0)/ Ongoing (Ongoing)	No/ Moderate	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (33)	[redacted]#	Male/ 2[redacted]/ White	呼吸器、胸郭および縦隔障害/ 呼吸窮迫	30 (-3)/ 41 (8)	Yes/ Severe/ 1	Remotely Related	Fatal	Drug Withdrawn/ Yes
ISA (34)	[redacted]#	Male/ 4[redacted]/ White	神経系障害/ てんかん	35 (1)/ 48 (14)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (17)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ 血中ナトリウム減少	16 (-1)/ 23 (6)	Yes/ Moderate/ 4	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
			精神障害/ 錯乱状態	16 (-1)/ 21 (4)	No/ Severe	Unrelated	Recovered/ Resolved With Sequelae	Drug Withdrawn/ No
ISA (19)	[redacted]#	Female/ 6[redacted]/ White	神経系障害/ 脳症	19 (0)/ 58 (39)	Yes/ Severe/ 3	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (6)	[redacted]#	Male/ 6[redacted]/ White	感染症および寄生虫症/ 気管支肺アスペルギルス症	6 (0)/ 9 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
ISA (12)	[redacted]#	Female/ 7[redacted]/ White	感染症および寄生虫症/ アスペルギルス症	12 (0)/ 25 (13)	No/ Moderate	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (26)	[redacted]#	Female/ 5[redacted]/ White	胃腸障害/ 小腸閉塞	26 (0)/ 35 (9)	Yes/ Severe/ 6	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No
			胃腸障害/ 嘔吐	26 (0)/ 34 (8)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (6)	[redacted]#	Male/ 7[redacted]/ White	心臓障害/ 上室性頻脈	6 (0)/ 8 (2)	Yes/ Severe/ 2	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (3)	[redacted]#	Male/ 6[redacted]/ White	感染症および寄生虫症/ 心内膜炎	3 (0)/ 17 (14)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
ISA (7)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ トランスアミナーゼ上昇	4 (-3)/ Ongoing (Ongoing)	No/ Severe	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (5)	[redacted]#	Female/ 7[redacted]/ White	呼吸器、胸郭および縦隔障害/ 呼吸困難	5 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Possibly Related	Recovering/Resolving	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (54)	[redacted]#	Male/ 3[redacted]/ White	心臓障害/ 心肺停止	54 (0)/ 54 (0)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
ISA (12)	[redacted]#	Male/ 2[redacted]/ White	全身障害および投与局所様態/ 悪寒	12 (0)/ 12 (0)	Yes/ Severe/ 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
ISA (5)	[redacted]#	Male/ 6[redacted]/ White	腎および尿路障害/ 腎不全	1 (-4)/ Ongoing (Ongoing)	Yes/ Severe/ 4	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (57)	[redacted]#	Female/ 4[redacted]/ Asian	眼障害/ 視神経症	56 (-1)/ Ongoing (Ongoing)	Yes/ Severe/ 3	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (35)	[redacted]#	Female/ 6[redacted]/ Asian	血液およびリンパ系障害/ 汎血球減少症	32 (-3)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (2)	[redacted]#	Male/ 5[redacted]/ Asian	感染症および寄生虫症/ 敗血症	2 (0)/ 2 (0)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (51)	[redacted]#	Female/ 4[redacted]/ Asian	呼吸器、胸郭および縦隔障害/ 呼吸不全	49 (-2)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (12)	[redacted]#	Female/ 5[redacted]/ Asian	感染症および寄生虫症/ 肺炎	11 (-1)/ Ongoing (Ongoing)	No/ Moderate	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (16)	[redacted]#	Female/ 5[redacted]/ Asian	神経系障害/ 痙攣	16 (0)/ 16 (0)	No/ Severe	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			感染症および寄生虫症/ 真菌感染	16 (0)/ 26 (10)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ Yes
ISA (33)	[redacted]#	Female/ 2[redacted]/ Asian	心臓障害/ うっ血性心筋症	32 (-1)/ 164 (131)	Yes/ Severe/ 1	Remotely Related	Fatal	Drug Withdrawn/ Yes
ISA (6)	[redacted]#	Female/ 4[redacted]/ Asian	感染症および寄生虫症/ 敗血症性ショック	3 (-3)/ 6 (0)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (20)	[redacted]#	Male/ 3[redacted]/ Asian	神経系障害/ 痙攣	20 (0)/ 20 (0)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
			呼吸器、胸郭および縦隔障害/ 呼吸困難	20 (0)/ Ongoing (Ongoing)	No/ Severe	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (13)	[redacted]#	Male/ 2[redacted]/ Asian	感染症および寄生虫症/ 気管支肺炎	8 (-5)/ Ongoing (Ongoing)	Yes/ Moderate/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (8)	[redacted]#	Male/ 6[redacted]/ White	腎および尿路障害/ 腎不全	4 (-4)/ 28 (20)	Yes/ Severe/ 4	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
ISA (2)	[redacted]#	Female/ 4[redacted]/ White	皮膚および皮下組織障害/ アレルギー性皮膚炎	2 (0)/ 31 (29)	No/ Moderate	Probably Related	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (56)	[redacted]#	Male/ 6[redacted]/ White	胃腸障害/ 嚥下障害	18 (-38)/ Ongoing (Ongoing)	No/ Moderate	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (12)	[redacted]#	Male/ 5[redacted]/ White	皮膚および皮下組織障害/ 皮膚炎	5 (-7)/ 20 (8)	Yes/ Moderate/ 6	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			皮膚および皮下組織障害/ 皮膚炎	5 (-7)/ 20 (8)	Yes/ Severe/ 6	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			筋骨格系および結合組織障害/ 筋炎	5 (-7)/ 20 (8)	Yes/ Severe/ 6	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			筋骨格系および結合組織障害/ 筋炎	5 (-7)/ 20 (8)	Yes/ Severe/ 6	Remotely Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			臨床検査/ 血中ビリルビン増加	9 (-3)/ Ongoing (Ongoing)	No/ Moderate	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (9)	[redacted]#	Female/ 4[redacted]/ White	感染症および寄生虫症/ 感染	7 (-2)/ 19 (10)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
ISA (4)	[redacted]#	Male/ 5[redacted]/ White	肝胆道系障害/ 急性肝炎	5 (1)/ 6 (2)	Yes/ Severe/ 1	Remotely Related	Fatal	Drug Withdrawn/ No
ISA (24)	[redacted]#	Female/ 7[redacted]/ White	感染症および寄生虫症/ 真菌感染	12 (-12)/ 37 (13)	Yes/ Severe/ 1	Probably Related	Fatal	Drug Withdrawn/ Yes
VRC (9)	[redacted]#	Male/ 6[redacted]/ White	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）/ 再発急性骨髄性白血病	6 (-3)/ 14 (5)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
VRC (7)	[redacted]#	Male/ 6[redacted]/ White	皮膚および皮下組織障害/ 発疹	6 (-1)/ 7 (0)	Yes/ Severe/ 4	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (5)	[redacted]#	Male/ 6[redacted]/ White	精神障害/ 幻視	5 (0)/ 7 (2)	Yes/ Moderate/ 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (18)	[redacted]#	Male/ 5[redacted]/ White	肝胆道系障害/ 肝不全	18 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 1	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (2)	[redacted]#	Male/ 7[redacted]/ White	精神障害/ 錯乱状態	3 (1)/ 4 (2)	Yes/ Moderate / 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
			精神障害/ 幻視	3 (1)/ 4 (2)	Yes/ Moderate / 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (10)	[redacted]#	Male/ 7[redacted]/ White	臨床検査/ 肝機能検査異常	8 (-2)/ 43 (33)	No/ Moderate	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (10)	[redacted]#	Male/ 4[redacted]/ White	感染症および寄生虫症/ 髄膜炎	10 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			胃腸障害/ 悪心	10 (0)/ 11 (1)	No/ Mild	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
			胃腸障害/ 嘔吐	10 (0)/ 11 (1)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No

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SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (13)	[redacted]#	Male/ 6[redacted]/ White	心臓障害/ 心室性頻脈	13 (0)/ 13 (0)	Yes/ Severe/ 4	Probably Related	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (42)	[redacted]#	Male/ 2[redacted]/ White	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	38 (-4)/ 44 (2)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
VRC (6)	[redacted]#	Male/ 7[redacted]/ White	精神障害/ 幻視	3 (-3)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			精神障害/ 錯乱状態	5 (-1)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
VRC (22)	[redacted]#	Male/ 4[redacted]/ White	血液およびリンパ系障害/ 汎血球減少症	20 (-2)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
VRC (20)	[redacted]#	Male/ 4[redacted]/ White	腎および尿路障害/ 急性腎不全	11 (-9)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No

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SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (22)	[redacted]#	Female/ 6[redacted]/ White	臨床検査/ 血中アルカリホスファターゼ増加	14 (-8)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Probably Related	Recovering/Resolving	Drug Withdrawn/ No
VRC (39)	[redacted]#	Male/ 6[redacted]/ White	感染症および寄生虫症/ シュードモナス性敗血症	37 (-2)/ 40 (1)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (7)	[redacted]#	Male/ 3[redacted]/ White	肝胆道系障害/ 肝不全	7 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
VRC (44)	[redacted]#	Female/ 3[redacted]/ White	感染症および寄生虫症/ ムコール症	44 (0)/ Ongoing (Ongoing)	No/ Moderate	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
VRC (3)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ 肝機能検査異常	2 (-1)/ 25 (22)	Yes/ Severe/ 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (63)	[redacted]#	Female/ 6[redacted]/ White	腎および尿路障害/ 腎不全	63 (0)/ Ongoing (Ongoing)	No/ Severe	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

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SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
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Program Name: l_ae_discon_1.sas
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表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (32)	[redacted]#	Male/ 6[redacted]/ White	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) / 慢性リンパ性白血病	36 (4)/ 58 (26)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
VRC (14)	[redacted]#	Male/ 7[redacted]/ White	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	11 (-3)/ 16 (2)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
			感染症および寄生虫症/ 細菌性敗血症	11 (-3)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
VRC (13)	[redacted]#	Male/ 5[redacted]/ White	感染症および寄生虫症/ アスペルギルス症	8 (-5)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
VRC (58)	[redacted]#	Male/ 6[redacted]/ White	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	58 (0)/ 61 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
			感染症および寄生虫症/ 細菌性敗血症	58 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

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*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
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Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (8)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ アラニン・アミノトランスフェラーゼ増加	7 (-1)/ Ongoing (Ongoing)	No/ Moderate	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			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	7 (-1)/ Ongoing (Ongoing)	No/ Moderate	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			肝胆道系障害/ 肝炎	7 (-1)/ Ongoing (Ongoing)	No/ Mild	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			肝胆道系障害/ 高ビリルビン血症	7 (-1)/ 35 (27)	No/ Severe	Probably Related	Recovered/ Resolved With Sequelae	Drug Withdrawn/ No
VRC (3)	[redacted]#	Female/ 5[redacted]	心臓障害/ 心肺停止	4 (1)/ 4 (1)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ Yes
VRC (13)	[redacted]#	Female/ 3[redacted]/ White	臨床検査/ 肝酵素上昇	13 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No

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表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (1)	[redacted]#	Male/ 4[redacted]/ White	全身障害および投与局所様態/ 悪寒	1 (0)/ 1 (0)	Yes/ Severe/ 2	Probably Related	Recovered/ Resolved	Drug Withdrawn/ Yes
			神経系障害/ 振戦	1 (0)/ 1 (0)	Yes/ Severe/ 2	Probably Related	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (9)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ 心電図ＱＴ延長	2 (-7)/ 13 (4)	Yes/ Severe/ 2	Probably Related	Recovered/ Resolved With Sequelae	Drug Withdrawn/ No
VRC (11)	[redacted]#	Female/ 6[redacted]/ White	感染症および寄生虫症/ 全身性カンジダ	9 (-2)/ 16 (5)	No/ Severe	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (18)	[redacted]#	Female/ 4[redacted]/ White	感染症および寄生虫症/ ブドウ球菌感染	17 (-1)/ 26 (8)	No/ Severe	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (51)	[redacted]#	Male/ 2[redacted]/ White	血液およびリンパ系障害/ 微小血管症性溶血性貧血	51 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 4	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

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Program Name: l_ae_discon_1.sas
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表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (25)	[redacted]#	Male/ 7[redacted]/ White	皮膚および皮下組織障害/ 発疹	25 (0)/ 62 (37)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (4)	[redacted]#	Male/ 4[redacted]/ White	精神障害/ 幻覚	4 (0)/ 7 (3)	Yes/ Severe/ 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (3)	[redacted]#	Male/ 5[redacted]/ White	皮膚および皮下組織障害/ 薬疹	2 (-1)/ 14 (11)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (35)	[redacted]#	Male/ 8[redacted]/ White	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	37 (2)/ 38 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
VRC (38)	[redacted]#	Female/ 6[redacted]/ White	胃腸障害/ 悪心	2 (-36)/ 49 (11)	No/ Mild	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (17)	[redacted]#	Female/ 5[redacted]/ White	神経系障害/ くも膜下出血	17 (0)/ 18 (1)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ No

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Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (6)	[redacted]#	Female/ 6[redacted]/ White	眼障害/ 眼瞼浮腫	4 (-2)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			皮膚および皮下組織障害/ 発疹	4 (-2)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
VRC (42)	[redacted]#	Male/ 5[redacted]/ White	感染症および寄生虫症/ 真菌感染	42 (0)/ 44 (2)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (13)	[redacted]#	Female/ 5[redacted]/ White	肝胆道系障害/ 肝機能異常	6 (-7)/ Ongoing (Ongoing)	No/ Moderate	Remotely Related	Recovering/Resolving	Drug Withdrawn/ No
VRC (27)	[redacted]#	Male/ 6[redacted]/ Asian	肝胆道系障害/ 高ビリルビン血症	17 (-10)/ Ongoing (Ongoing)	No/ Severe	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			肝胆道系障害/ 高トランスアミナーゼ血症	17 (-10)/ Ongoing (Ongoing)	No/ Severe	Probably Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

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Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (2)	[redacted]#	Male/ 5[redacted]/ Asian	心臓障害/ 心停止	3 (1)/ 3 (1)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ No
VRC (61)	[redacted]#	Male/ 7[redacted]/ Asian	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	63 (2)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
VRC (1)	[redacted]#	Male/ 4[redacted]/ Asian	感染症および寄生虫症/ 肺感染	1 (0)/ Ongoing (Ongoing)	No/ Moderate	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
VRC (7)	[redacted]#	Male/ 5[redacted]/ Asian	精神障害/ 不快気分	7 (0)/ 8 (1)	No/ Mild	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (27)	[redacted]#	Male/ 6[redacted]/ Asian	胃腸障害/ 嘔吐	26 (-1)/ 28 (1)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No

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Program Name: l_ae_discon_1.sas
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表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (8)	[redacted]#	Male/ 4[redacted]/ Asian	感染症および寄生虫症/ 肺炎	9 (1)/ 11 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
			感染症および寄生虫症/ 敗血症	9 (1)/ 11 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (5)	[redacted]#	Female/ 3[redacted]/ Asian	皮膚および皮下組織障害/ 発疹	5 (0)/ 6 (1)	No/ Mild	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No
			免疫系障害/ 急性肝移植片対宿主病	8 (3)/ 40 (35)	No/ Moderate	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
			感染症および寄生虫症/ 肺感染	18 (13)/ 41 (36)	No/ Moderate	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (5)	[redacted]#	Male/ 3[redacted]/ Asian	呼吸器、胸郭および縦隔障害/ 呼吸不全	5 (0)/ 9 (4)	Yes/ Severe/ 1	Remotely Related	Fatal	Drug Withdrawn/ Yes

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PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (5)	[redacted]#	Male/ 3[redacted]/ White	感染症および寄生虫症/ 敗血症	5 (0)/ 6 (1)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (5)	[redacted]#	Male/ 3[redacted]/ Asian	呼吸器、胸郭および縦隔障害/ 呼吸不全	2 (-3)/ 6 (1)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (81)	[redacted]#	Male/ 6[redacted]/ White	神経系障害/ 大発作痙攣	81 (0)/ 81 (0)	Yes/ Severe/ 4	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
VRC (14)	[redacted]#	Male/ 2[redacted]/ Asian	感染症および寄生虫症/ 敗血症	14 (0)/ 14 (0)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (14)	[redacted]#	Male/ 5[redacted]/ Asian	呼吸器、胸郭および縦隔障害/ 呼吸窮迫	10 (-4)/ 23 (9)	Yes/ Severe/ 6	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (63)	[redacted]#	Female/ 2[redacted]/ White	感染症および寄生虫症/ 細菌性敗血症	62 (-1)/ 75 (12)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
			代謝および栄養障害/ 代謝性アシドーシス	62 (-1)/ 75 (12)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No
			腎および尿路障害/ 急性腎不全	62 (-1)/ 75 (12)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No
VRC (45)	[redacted]#	Male/ 7[redacted]/ White	精神障害/ 抑うつ気分	43 (-2)/ 47 (2)	Yes/ Severe/ 6	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
VRC (22)	[redacted]#	Female/ 6[redacted]/ White	神経系障害/ 昏迷	17 (-5)/ 25 (3)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
VRC (25)	[redacted]#	Female/ 4[redacted]/ White	呼吸器、胸郭および縦隔障害/ 呼吸不全	22 (-3)/ 32 (7)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
9766-CL-0104試験								
VRC (7)	[redacted]#	Male/ 5[redacted]/ White	呼吸器、胸郭および縦隔障害/ 呼吸不全	6 (-1)/ 11 (4)	Yes/ Severe/ 6	Possibly Related	Recovered/ Resolved With Sequelae	Drug Withdrawn/ Yes
VRC (24)	[redacted]#	Female/ 5[redacted]/ White	肝胆道系障害/ 肝病変	22 (-2)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
			血液およびリンパ系障害/ 脾臓病変	22 (-2)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ No
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (44)	[redacted]#	Female/ 8[redacted]/ Black or African American	神経系障害/ 脳血管発作	45 (1)/ 48 (4)	Yes/ Severe/ 4	Unrelated	Recovered/ Resolved With Sequelae	Drug Withdrawn/ No
ISA (509)	[redacted]#	Male/ 6[redacted]/ White	感染症および寄生虫症/ 大腸菌性菌血症	509 (0)/ Ongoing (Ongoing)	Yes/ Moderate / 2	Unrelated	Recovering/Resolving	Drug Withdrawn/ Yes
ISA (394)	[redacted]#	Male/ 5[redacted]/ White	感染症および寄生虫症/ アスペルギルス症	394 (0)/ Ongoing (Ongoing)	Yes/ Moderate / 6	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (19)	[redacted]#	Female/ 2[redacted]/ White	神経系障害/ 卒中の出血性変化	5 (-14)/ 71 (52)	Yes/ Severe/ 2	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (33)	[redacted]#	Female/ 5[redacted]/ White	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）/ 再発急性骨髄性白血病	17 (-16)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ No
ISA (26)	[redacted]#	Female/ 5[redacted]/ White	感染症および寄生虫症/ 脳膿瘍	22 (-4)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Unrelated	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (33)	[redacted]#	Male/ 5[redacted]/ Black or African American	臨床検査/ アラニン・アミノトランスフェラーゼ増加	28 (-5)/ 35 (2)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
			臨床検査/ 血中アルカリホスファターゼ増加	28 (-5)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Recovering/Resolving	Drug Withdrawn/ No
			臨床検査/ 血中乳酸脱水素酵素増加	28 (-5)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Recovering/Resolving	Drug Withdrawn/ No
			臨床検査/ γ－グルタミルトランスフェラーゼ増加	28 (-5)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Recovering/Resolving	Drug Withdrawn/ No
ISA (50)	[redacted]#	Male/ 6[redacted]/ White	臨床検査/ 肝酵素上昇	50 (0)/ 78 (28)	No/ Moderate	Possibly Related	Recovered/ Resolved	Drug Withdrawn/ No
ISA (87)	[redacted]#	Male/ 7[redacted]/ White	感染症および寄生虫症/ アスペルギルス症	81 (-6)/ 100 (13)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (18)	[redacted]#	Male/ 2[redacted]/ White	肝胆道系障害/ 急性肝不全	18 (0)/ Ongoing (Ongoing)	Yes/ Severe/ 2	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (10)	[redacted]#	Male/ 4[redacted]/ White	感染症および寄生虫症/ 敗血症性ショック	10 (0)/ 10 (0)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
ISA (119)	[redacted]#	Male/ 7[redacted]/ White	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）/ 白血病再発	120 (1)/ 123 (4)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ Yes
ISA (86)	[redacted]#	Male/ 5[redacted]/ White	胃腸障害/ 悪心	86 (0)/ 100 (14)	No/ Severe	Unrelated	Recovered/ Resolved	Drug Withdrawn/ Yes
ISA (12)	[redacted]#	Female/ 2[redacted]/ White	胃腸障害/ 嘔吐	3 (-9)/ Ongoing (Ongoing)	No/ Moderate	Possibly Related	Recovering/Resolving	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (73)	[redacted]#	Male/ 5[redacted]/ White	精神障害/ 錯乱状態	70 (-3)/ 77 (4)	Yes/ Moderate/ 4	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
			精神障害/ 幻覚	70 (-3)/ 77 (4)	Yes/ Moderate/ 4	Probably Related	Recovered/ Resolved	Drug Withdrawn/ No
			腎および尿路障害/ 急性腎不全	74 (1)/ Ongoing (Ongoing)	Yes/ Severe/ 6	Possibly Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes
ISA (4)	[redacted]#	Male/ 1[redacted]/ Asian	腎および尿路障害/ 急性腎不全	3 (-1)/ 20 (16)	Yes/ Severe/ 6	Unrelated	Recovered/ Resolved	Drug Withdrawn/ No
ISA (19)	[redacted]#	Male/ 2[redacted]/ White	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）/ 悪性新生物進行	19 (0)/ 19 (0)	Yes/ Severe/ 1	Unrelated	Fatal	Drug Withdrawn/ No
ISA (229)	[redacted]#	Male/ 5[redacted]/ White	感染症および寄生虫症/ 真菌感染	227 (-2)/ Ongoing (Ongoing)	Yes/ Severe/ 4	Remotely Related	Not Recovered/ Not Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-22 投与中止に至った有害事象の一覧 - 9766-CL-0104試験および海外第III相試験併合

Treatment Group (Duration)	Subject ID	Sex/ Age/ Race	SOC/ PT	Onset Day*/ End Day*	Serious/ Severity/ SAE Code	Relationship	Outcome	Action Taken/ Treatment Required
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）								
ISA (6)	[redacted]#	Female/ 6[redacted]/ White	感染症および寄生虫症/ 敗血症性ショック	7 (1)/ 8 (2)	Yes/ Severe/ 1	Possibly Related	Fatal	Drug Withdrawn/ Yes

ISA: Isavuconazole, VRC: Voriconazole
#: Subject prematurely discontinued treatment.
E: Estimated from missing or partial date.
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class
PT: Preferred Term
&: Sponsor defined SAE.
SAE Codes: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
MedDRA ver 12.1

Program Name: l_ae_discon_1.sas
Program Run: 25JUN21:10:11:22

表 8-23 死亡に至った肝機能異常・肝炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_hepa_death_2.sas
Program Run: 16JUN21:13:27:47

表 8-24 重篤な肝機能異常・肝炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 60)	Voriconazole (N = 30)	Isavuconazole (N = 73)
Overall	0	1 (3.3%)	0
薬物性肝障害	0	1 (3.3%)	0

Program Name: t_ae_hepa_ser_2.sas
Program Run: 16JUN21:13:27:52

表 8-25 投与中止に至った肝機能異常・肝炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 60)	Voriconazole (N = 30)	Isavuconazole (N = 73)
Overall	3 (5.0%)	2 (6.7%)	3 (4.1%)
肝機能異常	2 (3.3%)	1 (3.3%)	2 (2.7%)
肝機能検査値上昇	1 (1.7%)	0	1 (1.4%)
薬物性肝障害	0	1 (3.3%)	0

Program Name: t_ae_hepa_discon_2.sas
Program Run: 16JUN21:13:27:56

表 8-26 死亡に至った肝機能異常・肝炎に関連する有害事象 －9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	1 (0.4%)	0	1 (0.2%)
急性肝炎	1 (0.4%)	0	1 (0.2%)

Program Name: t_ae_hepa_death_1.sas
Program Run: 31MAY21:18:48:33

表 8-27 重篤な肝機能異常・肝炎に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	3 (1.2%)	9 (3.5%)	5 (1.2%)
肝機能検査異常	1 (0.4%)	1 (0.4%)	1 (0.2%)
肝炎	1 (0.4%)	0	1 (0.2%)
急性肝炎	1 (0.4%)	0	1 (0.2%)
肝不全	0	2 (0.8%)	0
肝機能異常	0	2 (0.8%)	0
高ビリルビン血症	0	2 (0.8%)	0
急性肝移植片対宿主病	0	1 (0.4%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.4%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.4%)	0
血中ビリルビン増加	0	1 (0.4%)	0
肝酵素上昇	0	1 (0.4%)	0
急性肝不全	0	0	1 (0.2%)
肝障害	0	0	1 (0.2%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_hepa_ser_1.sas
Program Run: 31MAY21:18:48:38

表 8-28 投与中止に至った肝機能異常・肝炎に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	4 (1.6%)	10 (3.9%)	7 (1.7%)
血中ビリルビン増加	2 (0.8%)	0	2 (0.5%)
急性肝炎	1 (0.4%)	0	1 (0.2%)
トランスアミナーゼ上昇	1 (0.4%)	0	1 (0.2%)
肝不全	0	2 (0.8%)	0
高ビリルビン血症	0	2 (0.8%)	0
肝機能検査異常	0	2 (0.8%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.4%)	1 (0.2%)
肝酵素上昇	0	1 (0.4%)	1 (0.2%)
急性肝移植片対宿主病	0	1 (0.4%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.4%)	0
肝機能異常	0	1 (0.4%)	0
肝病変	0	1 (0.4%)	0
肝炎	0	1 (0.4%)	0
高トランスアミナーゼ血症	0	1 (0.4%)	0
急性肝不全	0	0	1 (0.2%)
γ－グルタミルトランスフェラーゼ増加	0	0	1 (0.2%)

Program Name: t_ae_hepa_discon_1.sas
Program Run: 31MAY21:18:48:43

表 8-29 死亡に至ったアナフィラキシーに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_anaphy_death_2.sas
Program Run: 16JUN21:13:28:00

表 8-30 重篤なアナフィラキシーに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_anaphy_ser_2.sas
Program Run: 16JUN21:13:28:05

表 8-31 投与中止に至ったアナフィラキシーに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_anaphy_discon_2.sas
Program Run: 16JUN21:13:28:09

表 8-32 死亡に至ったアナフィラキシーに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_anaphy_death_1.sas
Program Run: 31MAY21:18:49:01

表 8-33 重篤なアナフィラキシーに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	1 (0.4%)	3 (1.2%)	1 (0.2%)
アナフィラキシーショック	1 (0.4%)	0	1 (0.2%)
アナフィラキシー反応	0	2 (0.8%)	0
ショック	0	1 (0.4%)	0

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_anaphy_ser_1.sas
Program Run: 31MAY21:18:49:06

表 8-34 投与中止に至ったアナフィラキシーに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_anaphy_discon_1.sas
Program Run: 31MAY21:18:49:11

表 8-35 死亡に至った重度皮膚障害に関連する有害事象 - AK1820-301試験のCohort Aおよび Cohort A/B併合

No data

Program Name: t_ae_skin_death_2.sas
Program Run: 16JUN21:13:28:16

表 8-36 重篤な重度皮膚障害に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_skin_ser_2.sas
Program Run: 16JUN21:13:28:21

表 8-37 投与中止に至った重度皮膚障害に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_skin_discon_2.sas
Program Run: 16JUN21:13:28:25

表 8-38 死亡に至った重度皮膚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_skin_death_1.sas
Program Run: 31MAY21:18:49:29

表 8-39 重篤な重度皮膚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_skin_ser_1.sas
Program Run: 31MAY21:18:49:34

表 8-40 投与中止に至った重度皮膚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_skin_discon_1.sas
Program Run: 31MAY21:18:49:40

表 8-41 死亡に至った注入部位／注射部位反応に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

No data

Program Name: t_ae_inject_death_2.sas
Program Run: 16JUN21:13:28:31

表 8-42 重篤な注入部位／注射部位反応に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

No data

Program Name: t_ae_inject_ser_2.sas
Program Run: 16JUN21:13:28:38

表 8-43 投与中止に至った注入部位／注射部位反応に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 8)	Voriconazole (N = 2)	Isavuconazole (N = 9)
Overall	1 (12.5%)	0	1 (11.1%)
注射部位蕁麻疹	1 (12.5%)	0	1 (11.1%)

Program Name: t_ae_inject_discon_2.sas
Program Run: 16JUN21:13:28:45

表 8-44 死亡に至った注入部位／注射部位反応に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

No data

Program Name: t_ae_inject_death_1.sas
Program Run: 31MAY21:18:49:59

表 8-45 重篤な注入部位／注射部位反応に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 357)
Overall	1 (0.4%)	0	1 (0.3%)
注入部位感染	1 (0.4%)	0	1 (0.3%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_inject_ser_1.sas
Program Run: 31MAY21:18:50:05

表 8-46 投与中止に至った注入部位／注射部位反応に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

No data

Program Name: t_ae_inject_discon_1.sas
Program Run: 31MAY21:18:50:10

表 8-47 死亡に至ったIRRに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 8)	Voriconazole (N = 2)	Isavuconazole (N = 9)
Overall	0	0	1 (11.1%)
急性心筋梗塞	0	0	1 (11.1%)

Program Name: t_ae_irr_death_2.sas
Program Run: 16JUN21:13:28:51

表 8-48 重篤なIRRに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 8)	Voriconazole (N = 2)	Isavuconazole (N = 9)
Overall	0	0	1 (11.1%)
急性心筋梗塞	0	0	1 (11.1%)

Program Name: t_ae_irr_ser_2.sas
Program Run: 16JUN21:13:28:55

表 8-49 投与中止に至ったIRRに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合の静脈内投与例

No data

Program Name: t_ae_irr_discon_2.sas
Program Run: 16JUN21:13:28:59

表 8-50 死亡に至ったIRRに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 357)
Overall	5 (1.9%)	5 (1.9%)	7 (2.0%)
呼吸不全	3 (1.2%)	4 (1.5%)	4 (1.1%)
急性呼吸不全	2 (0.8%)	0	3 (0.8%)
急性心筋梗塞	0	1 (0.4%)	0

Program Name: t_ae_irr_death_1.sas
Program Run: 31MAY21:18:50:27

表 8-51 重篤なIRRに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 357)
Overall	26 (10.1%)	18 (6.9%)	34 (9.5%)
呼吸不全	10 (3.9%)	9 (3.5%)	14 (3.9%)
急性呼吸不全	4 (1.6%)	3 (1.2%)	7 (2.0%)
呼吸窮迫	3 (1.2%)	2 (0.8%)	3 (0.8%)
呼吸困難	3 (1.2%)	0	3 (0.8%)
痙攣	2 (0.8%)	1 (0.4%)	3 (0.8%)
悪寒	1 (0.4%)	1 (0.4%)	1 (0.3%)
低酸素症	1 (0.4%)	1 (0.4%)	1 (0.3%)
アナフィラキシーショック	1 (0.4%)	0	1 (0.3%)
てんかん	1 (0.4%)	0	1 (0.3%)
過敏症	1 (0.4%)	0	1 (0.3%)
低血圧	1 (0.4%)	0	1 (0.3%)
急性心筋梗塞	0	1 (0.4%)	1 (0.3%)
発熱	0	1 (0.4%)	0

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_irr_ser_1.sas
Program Run: 31MAY21:18:50:31

表 8-52 投与中止に至ったIRRに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合の静脈内投与例

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 357)
Overall	8 (3.1%)	6 (2.3%)	8 (2.2%)
呼吸不全	2 (0.8%)	4 (1.5%)	2 (0.6%)
痙攣	2 (0.8%)	0	2 (0.6%)
呼吸困難	2 (0.8%)	0	2 (0.6%)
悪寒	1 (0.4%)	1 (0.4%)	1 (0.3%)
急性呼吸不全	1 (0.4%)	0	1 (0.3%)
てんかん	1 (0.4%)	0	1 (0.3%)
低血圧	1 (0.4%)	0	1 (0.3%)
呼吸窮迫	0	1 (0.4%)	0

Program Name: t_ae_irr_discon_1.sas
Program Run: 31MAY21:18:50:36

表 8-53 死亡に至ったトルサード ド ポアントに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_torsades_death_2.sas
Program Run: 16JUN21:13:29:04

表 8-54 重篤なトルサード ド ポアントに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_torsades_ser_2.sas
Program Run: 16JUN21:13:29:08

表 8-55 投与中止に至ったトルサード ド ポアントに関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_torsades_discon_2.sas
Program Run: 16JUN21:13:29:13

表 8-56 死亡に至ったトルサード ド ポアントに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	2 (0.8%)	5 (1.9%)	4 (1.0%)
心停止	1 (0.4%)	3 (1.2%)	1 (0.2%)
心肺停止	1 (0.4%)	1 (0.4%)	3 (0.7%)
心突然死	0	1 (0.4%)	0

Program Name: t_ae_torsades_death_1.sas
Program Run: 31MAY21:18:50:54

表 8-57 重篤なトルサード ド ポアントに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	3 (1.2%)	11 (4.2%)	5 (1.2%)
心肺停止	2 (0.8%)	2 (0.8%)	4 (1.0%)
心停止	1 (0.4%)	5 (1.9%)	1 (0.2%)
心室性頻脈	0	2 (0.8%)	0
心電図ＱＴ延長	0	1 (0.4%)	0
心突然死	0	1 (0.4%)	0

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_torsades_ser_1.sas
Program Run: 31MAY21:18:50:59

表 8-58 投与中止に至ったトルサード ド ポアントに関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	2 (0.8%)	4 (1.5%)	2 (0.5%)
心停止	1 (0.4%)	1 (0.4%)	1 (0.2%)
心肺停止	1 (0.4%)	1 (0.4%)	1 (0.2%)
心電図ＱＴ延長	0	1 (0.4%)	0
心室性頻脈	0	1 (0.4%)	0

Program Name: t_ae_torsades_discon_1.sas
Program Run: 31MAY21:18:51:03

表 8-59 失神 (Syncope) または意識消失 (LOC) を発現した被験者 - 9766-CL-0104試験

Patient No./ Treatment Duration (days)	Treatment Group	Relationship Investigator	Serious	Age (years), Race, Sex	TEAE/ Intensity	Onset and End Day/ Resolution
[redacted]/ 76	Isavuconazole	Unrelated	N	6[redacted], White, Male	失神/ Moderate	22/22 Resolved
[redacted]/ 81	Isavuconazole	Unrelated	N	2[redacted], White, Male	失神/ Mild	39/39 Resolved
[redacted]/ 17	Isavuconazole	Unrelated	N	6[redacted], White, Male	意識消失/ Severe	18/30 Resolved With Sequelae
[redacted]/ 84	Isavuconazole	Unrelated	N	4[redacted], White, Female	失神/ Severe	29/39 Resolved
[redacted]/ 84	Isavuconazole	Unrelated	N	6[redacted], White, Male	失神/ Mild	108/108 Resolved
[redacted]/ 9	Isavuconazole	Unrelated	N	8[redacted], White, Male	意識消失/ Moderate	9/Ongoing Not Resolved
[redacted]/ 3	Isavuconazole	Unrelated	N	6[redacted], White, Male	意識消失/ Severe	17/Ongoing Not Resolved
[redacted]/ 61	Isavuconazole	Remotely Related	N	6[redacted], White, Male	失神/ Mild	27/27 Resolved
[redacted]/ 84	Isavuconazole	Unrelated	N	4[redacted], Asian, Male	失神/ Mild	43/43 Resolved
[redacted]/ 85	Isavuconazole	Unrelated	N	6[redacted], White, Male	失神/ Mild	87/87 Resolved
[redacted]/ 22	Voriconazole	Unrelated	N	6[redacted], White, Female	失神/ Moderate	47/47 Resolved
[redacted]/ 84	Voriconazole	Unrelated	N	5[redacted], White, Male	失神/ Severe	91/91 Resolved

LOC: loss of consciousness
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: l_ae_loc_1.sas
Program Run: 23JUN21:09:51:53

表 8-60 死亡に至った急性膵炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_panc_death_2.sas
Program Run: 16JUN21:13:29:17

表 8-61 重篤な急性膵炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_panc_ser_2.sas
Program Run: 16JUN21:13:29:22

表 8-62 投与中止に至った急性膵炎に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_panc_discon_2.sas
Program Run: 16JUN21:13:29:26

表 8-63 死亡に至った急性膵炎に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_panc_death_1.sas
Program Run: 31MAY21:18:51:25

表 8-64 重篤な急性膵炎に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	0	0	1 (0.2%)
膵炎	0	0	1 (0.2%)
再発性膵炎	0	0	1 (0.2%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_panc_ser_1.sas
Program Run: 31MAY21:18:51:31

表 8-65 投与中止に至った急性膵炎に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_panc_discon_1.sas
Program Run: 31MAY21:18:51:35

表 8-66 死亡に至った精神神経症状に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_psy_death_2.sas
Program Run: 16JUN21:13:29:31

表 8-67 重篤な精神神経症状に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_psy_ser_2.sas
Program Run: 16JUN21:13:29:35

表 8-68 投与中止に至った精神神経症状に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_psy_discon_2.sas
Program Run: 16JUN21:13:29:41

表 8-69 死亡に至った精神神経症状に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_psy_death_1.sas
Program Run: 31MAY21:18:51:54

表 8-70 重篤な精神神経症状に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	1 (0.4%)	3 (1.2%)	3 (0.7%)
うつ病	1 (0.4%)	0	1 (0.2%)
幻視	0	2 (0.8%)	0
錯乱状態	0	1 (0.4%)	1 (0.2%)
幻覚	0	1 (0.4%)	1 (0.2%)
異常行動	0	0	1 (0.2%)
攻撃性	0	0	1 (0.2%)
激越	0	0	1 (0.2%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_psy_ser_1.sas
Program Run: 31MAY21:18:51:59

表 8-71 投与中止に至った精神神経症状に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	2 (0.8%)	5 (1.9%)	3 (0.7%)
錯乱状態	2 (0.8%)	2 (0.8%)	3 (0.7%)
幻視	0	3 (1.2%)	0
幻覚	0	1 (0.4%)	1 (0.2%)
不快気分	0	1 (0.4%)	0

Program Name: t_ae_psy_discon_1.sas
Program Run: 31MAY21:18:52:04

表 8-72 死亡に至った視覚障害に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_ocular_death_2.sas
Program Run: 16JUN21:13:29:47

表 8-73 重篤な視覚障害に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_ocular_ser_2.sas
Program Run: 16JUN21:13:29:52

表 8-74 投与中止に至った視覚障害に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A		Cohort A/B併合
Preferred Term	Isavuconazole (N = 60)	Voriconazole (N = 30)	Isavuconazole (N = 73)
Overall	0	1 (3.3%)	0
視力障害	0	1 (3.3%)	0

Program Name: t_ae_ocular_discon_2.sas
Program Run: 16JUN21:13:29:57

表 8-75 追跡調査期の抗真菌薬の併用割合（追跡調査期の視覚障害発現有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

	Cohort A				Cohort A/B併合	
	Isavuconazole		Voriconazole		Isavuconazole	
	追跡調査期に視覚障害あり (N = 7)	追跡調査期に視覚障害なし (N = 53)	追跡調査期に視覚障害あり (N = 0)	追跡調査期に視覚障害なし (N = 30)	追跡調査期に視覚障害あり (N = 8)	追跡調査期に視覚障害なし (N = 65)
AMPHOTERICIN B	0	2 (3.8%)	0	0	0	2 (3.1%)
FLUCONAZOLE	0	0	0	0	0	6 (9.2%)
ITRACONAZOLE	0	8 (15.1%)	0	0	0	8 (12.3%)
MICAFUNGIN SODIUM	0	2 (3.8%)	0	1 (3.3%)	0	2 (3.1%)
POSACONAZOLE	0	1 (1.9%)	0	0	0	1 (1.5%)
VORICONAZOLE	7 (100.0%)	11 (20.8%)	0	5 (16.7%)	8 (100.0%)	12 (18.5%)

・追跡調査期に視覚障害を発現した被験者の場合、治験薬投与終了翌日から発現までの期間内に抗真菌薬を併用した被験者を集計。追跡調査期に複数回視覚障害を発現した場合、治験薬投与終了翌日からいずれかの発現までの期間内に抗真菌薬を併用した被験者を集計

・追跡調査期に視覚障害を発現しなかった被験者の場合、治験薬投与終了翌日から治験薬投与終了35日後までの期間内に抗真菌薬を併用した被験者を集計

Program Name: t_followup_dose_2.sas
Program Run: 18JUN21:10:29:37

表 8-76 追跡調査期に発現した視覚障害一覧 - AK1820-301試験のCohort AおよびCohort A/B併合

投与群	被験者番号	追跡調査期に発現した視覚障害	治験薬投与終了翌日から視覚障害発現までの抗真菌薬の使用有無（使用した抗真菌薬）
Cohort A			
ISAVUCONAZOLE	[redacted]	羞明	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	羞明	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	羞明	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	複視	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
Cohort A/B併合（Cohort Aで表示ずみの被験者を除く）			
ISAVUCONAZOLE	[redacted]	色覚異常	あり (VORICONAZOLE)
		羞明	あり (VORICONAZOLE)
		霧視	あり (VORICONAZOLE)

MedDRA ver 23.1

Program Name: l_followup_eye_2.sas
Program Run: 23JUN21:12:28:59

表 8-77 死亡に至った視覚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_ocular_death_1.sas
Program Run: 31MAY21:18:52:36

表 8-78 重篤な視覚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	2 (0.8%)	0	2 (0.5%)
片側失明	1 (0.4%)	0	1 (0.2%)
視神経症	1 (0.4%)	0	1 (0.2%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_ocular_ser_1.sas
Program Run: 31MAY21:18:52:42

表 8-79 投与中止に至った視覚障害に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	1 (0.4%)	0	1 (0.2%)
視神経症	1 (0.4%)	0	1 (0.2%)

Program Name: t_ae_ocular_discon_1.sas
Program Run: 31MAY21:18:52:47

表 8-80 追跡調査期の抗真菌薬の併用割合（追跡調査期の視覚障害発現有無別）- 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Isavuconazole		Voriconazole		Isavuconazole	
	追跡調査期に視覚障害あり (N = 6)	追跡調査期に視覚障害なし (N = 251)	追跡調査期に視覚障害あり (N = 8)	追跡調査期に視覚障害なし (N = 251)	追跡調査期に視覚障害あり (N = 7)	追跡調査期に視覚障害なし (N = 396)
AMPHOTERICIN B	3 (50.0%)	35 (13.9%)	1 (12.5%)	19 (7.6%)	4 (57.1%)	46 (11.6%)
ANIDULAFUNGIN	0	5 (2.0%)	0	0	0	5 (1.3%)
CASPOFUNGIN	0	20 (8.0%)	1 (12.5%)	15 (6.0%)	1 (14.3%)	21 (5.3%)
FLUCONAZOLE	1 (16.7%)	11 (4.4%)	1 (12.5%)	12 (4.8%)	1 (14.3%)	15 (3.8%)
ITRACONAZOLE	0	9 (3.6%)	0	14 (5.6%)	0	17 (4.3%)
MICAFUNGIN	0	2 (0.8%)	0	1 (0.4%)	0	5 (1.3%)
NYSTATIN	0	3 (1.2%)	0	0	0	5 (1.3%)
POSACONAZOLE	0	13 (5.2%)	0	11 (4.4%)	0	21 (5.3%)
VORICONAZOLE	3 (50.0%)	58 (23.1%)	3 (37.5%)	41 (16.3%)	3 (42.9%)	71 (17.9%)

・追跡調査期に視覚障害を発現した被験者の場合、治験薬投与終了翌日から発現までの期間内に抗真菌薬を併用した被験者を集計。追跡調査期に複数回視覚障害を発現した場合、治験薬投与終了翌日からいずれかの発現までの期間内に抗真菌薬を併用した被験者を集計

・追跡調査期に視覚障害を発現しなかった被験者の場合、治験薬投与終了翌日から治験薬投与終了28日後までの期間内に抗真菌薬を併用した被験者を集計

Program Name: t_followup_dose_1.sas
Program Run: 16JUN21:11:56:07

表 8-81 追跡調査期に発現した視覚障害一覧 - 9766-CL-0104試験および海外第III相試験併合

投与群	被験者番号	追跡調査期に発現した視覚障害	治験薬投与終了翌日から視覚障害発現までの抗真菌薬の使用有無（使用した抗真菌薬）
9766-CL-0104試験			
ISAVUCONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	眼球浮腫	あり (AMPHOTERICIN B)
ISAVUCONAZOLE	[redacted]	色盲	あり (AMPHOTERICIN B,VORICONAZOLE)
ISAVUCONAZOLE	[redacted]	眼球浮腫	あり (FLUCONAZOLE)
ISAVUCONAZOLE	[redacted]	眼筋麻痺	あり (AMPHOTERICIN B)
ISAVUCONAZOLE	[redacted]	視力低下	あり (VORICONAZOLE)
VORICONAZOLE	[redacted]	視力障害	あり (FLUCONAZOLE)
VORICONAZOLE	[redacted]	霧視	あり (CASPOFUNGIN)
VORICONAZOLE	[redacted]	視力低下	なし
VORICONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
VORICONAZOLE	[redacted]	差明	あり (AMPHOTERICIN B,VORICONAZOLE)
VORICONAZOLE	[redacted]	差明	なし
VORICONAZOLE	[redacted]	視力低下	なし
VORICONAZOLE	[redacted]	視力障害	あり (VORICONAZOLE)
海外第III相試験併合（9766-CL-0104試験で表示ずみの被験者を除く）			
ISAVUCONAZOLE	[redacted]	眼痛	あり (AMPHOTERICIN B,CASPOFUNGIN)

MedDRA ver 12.1

Program Name: l_followup_eye_1.sas
Program Run: 25JUN21:10:11:22

表 8-82 死亡に至った皮膚または子宮の悪性腫瘍に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_skin_ut_death_2.sas
Program Run: 16JUN21:13:30:10

表 8-83 重篤な皮膚または子宮の悪性腫瘍に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_skin_ut_ser_2.sas
Program Run: 16JUN21:13:30:16

表 8-84 投与中止に至った皮膚または子宮の悪性腫瘍に関連する有害事象 - AK1820-301試験のCohort AおよびCohort A/B併合

No data

Program Name: t_ae_skin_ut_discon_2.sas
Program Run: 16JUN21:13:30:21

表 8-85 死亡に至った皮膚または子宮の悪性腫瘍に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_skin_ut_death_1.sas
Program Run: 09JUN21:10:31:27

表 8-86 重篤な皮膚または子宮の悪性腫瘍に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験		海外第III相試験併合
Preferred Term	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
Overall	1 (0.4%)	0	1 (0.2%)
子宮内膜癌	1 (0.4%)	0	1 (0.2%)

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_skin_ut_ser_1.sas
Program Run: 09JUN21:10:31:27

表 8-87 投与中止に至った皮膚または子宮の悪性腫瘍に関連する有害事象 - 9766-CL-0104試験および海外第III相試験併合

No data

Program Name: t_ae_skin_ut_discon_1.sas
Program Run: 09JUN21:10:31:27

表 8-88 単回投与例における人口統計学的特性およびその他の特性 - 海外第I相試験併合（単回投与）

Parameter Category/Statistic	Single Dose 40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total (N = 279)
Age (years)							
n	6	6	38	6	120	103	279
Mean (SD)	34.8 (6.97)	37.0 (8.00)	46.3 (10.64)	33.8 (7.25)	40.8 (18.68)	35.3 (9.33)	39.2 (14.62)
Median	34.5	38.5	48.5	35.5	34.0	36.0	37.0
Min - Max	27 - 45	28 - 45	23 - 64	23 - 43	18 - 85	20 - 54	18 - 85
Age Category 1							
<= 45	6 (100.0%)	6 (100.0%)	15 (39.5%)	6 (100.0%)	75 (62.5%)	90 (87.4%)	198 (71.0%)
> 45 to <= 65	0	0	23 (60.5%)	0	23 (19.2%)	13 (12.6%)	59 (21.1%)
> 65	0	0	0	0	22 (18.3%)	0	22 (7.9%)
Age Category 2							
<= 65	6 (100.0%)	6 (100.0%)	38 (100.0%)	6 (100.0%)	98 (81.7%)	103 (100.0%)	257 (92.1%)
> 65 to <= 75	0	0	0	0	19 (15.8%)	0	19 (6.8%)
> 75	0	0	0	0	3 (2.5%)	0	3 (1.1%)
Gender							
Male	6 (100.0%)	6 (100.0%)	27 (71.1%)	6 (100.0%)	73 (60.8%)	103 (100.0%)	221 (79.2%)
Female	0	0	11 (28.9%)	0	47 (39.2%)	0	58 (20.8%)

*:North America includes Canada and United State of America. W Europe/Aust/N Zealand: countries in Western Europe, Australia, New Zealand. Other includes any other countries not listed above.
BMI : body mass index

Program Name: t_demo_sad_3.sas
Program Run: 04JUN21:17:21:31

表 8-88 単回投与例における人口統計学的特性およびその他の特性 - 海外第I相試験併合（単回投与）

Parameter Category/Statistic	Single Dose 40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total (N = 279)
Race							
White	6 (100.0%)	6 (100.0%)	38 (100.0%)	6 (100.0%)	65 (54.2%)	100 (97.1%)	221 (79.2%)
Black or African American	0	0	0	0	21 (17.5%)	3 (2.9%)	24 (8.6%)
Asian	0	0	0	0	26 (21.7%)	0	26 (9.3%)
Other	0	0	0	0	8 (6.7%)	0	8 (2.9%)
Ethnic Origin							
Hispanic or Latino	0	0	0	0	20 (19.6%)	0	20 (19.6%)
Not Hispanic or Latino	0	0	0	0	82 (80.4%)	0	82 (80.4%)
Missing	6	6	38	6	18	103	177
BMI Category (kg/m^2)							
< 25	2 (33.3%)	3 (50.0%)	12 (31.6%)	5 (83.3%)	55 (45.8%)	49 (47.6%)	126 (45.2%)
>= 25 to < 30	4 (66.7%)	3 (50.0%)	17 (44.7%)	1 (16.7%)	48 (40.0%)	50 (48.5%)	123 (44.1%)
>= 30	0	0	9 (23.7%)	0	17 (14.2%)	4 (3.9%)	30 (10.8%)
Geographic Region*							
North America	0	0	0	0	102 (85.0%)	0	102 (36.6%)
W Europe/Aust/N Zealand	6 (100.0%)	6 (100.0%)	6 (15.8%)	6 (100.0%)	6 (5.0%)	103 (100.0%)	133 (47.7%)
Other Regions	0	0	32 (84.2%)	0	12 (10.0%)	0	44 (15.8%)

*:North America includes Canada and United State of America. W Europe/Aust/N Zealand: countries in Western Europe, Australia, New Zealand. Other includes any other countries not listed above.
BMI : body mass index

Program Name: t_demo_sad_3.sas
Program Run: 04JUN21:17:21:31

表 8-89 発現割合が5%以上の有害事象 - 海外第I相試験併合

MedDRA v12.1	海外第I相試験併合
Preferred Term	Isavuconazole (N = 1049)
Overall	563 (53.7%)
頭痛	185 (17.6%)
悪心	90 (8.6%)
浮動性めまい	77 (7.3%)
下痢	76 (7.2%)

Program Name: t_ae_sum_freq_5_3.sas
Program Run: 31MAY21:18:53:05

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
Overall	3 (50.0%)	0	11 (28.9%)	1 (16.7%)	47 (39.2%)	61 (59.2%)	123 (44.1%)	4 (28.6%)	12 (33.3%)
神経系障害	2 (33.3%)	0	1 (2.6%)	1 (16.7%)	15 (12.5%)	37 (35.9%)	56 (20.1%)	1 (7.1%)	9 (25.0%)
頭痛	2 (33.3%)	0	0	1 (16.7%)	8 (6.7%)	30 (29.1%)	41 (14.7%)	1 (7.1%)	5 (13.9%)
浮動性めまい	0	0	0	0	5 (4.2%)	9 (8.7%)	14 (5.0%)	0	5 (13.9%)
傾眠	0	0	0	0	0	3 (2.9%)	3 (1.1%)	0	0
灼熱感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
脳炎	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
ギラン・バレー症候群	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
知覚過敏	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
感覚鈍麻	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
神経炎	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
錯感覚	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
失神寸前の状態	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
坐骨神経痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
胃腸障害	0	0	3 (7.9%)	1 (16.7%)	11 (9.2%)	27 (26.2%)	42 (15.1%)	2 (14.3%)	4 (11.1%)
下痢	0	0	1 (2.6%)	0	4 (3.3%)	8 (7.8%)	13 (4.7%)	1 (7.1%)	2 (5.6%)
悪心	0	0	0	0	2 (1.7%)	10 (9.7%)	12 (4.3%)	0	1 (2.8%)
腹痛	0	0	0	0	2 (1.7%)	5 (4.9%)	7 (2.5%)	1 (7.1%)	0
嘔吐	0	0	0	0	0	5 (4.9%)	5 (1.8%)	1 (7.1%)	0
上腹部痛	0	0	1 (2.6%)	1 (16.7%)	0	1 (1.0%)	3 (1.1%)	0	0
便秘	0	0	0	0	2 (1.7%)	1 (1.0%)	3 (1.1%)	0	0
口内乾燥	0	0	0	0	0	3 (2.9%)	3 (1.1%)	0	1 (2.8%)
鼓腸	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
口の感覚鈍麻	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	1 (2.8%)
腹部不快感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
下腹部痛	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
消化不良	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
排便回数増加	0	0	0	1 (16.7%)	0	0	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
舌痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
血便排泄	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
レッチング	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
全身障害および投与局所様態	0	0	0	0	17 (14.2%)	12 (11.7%)	29 (10.4%)	0	7 (19.4%)
疲労	0	0	0	0	1 (0.8%)	5 (4.9%)	6 (2.2%)	0	1 (2.8%)
熱感	0	0	0	0	0	5 (4.9%)	5 (1.8%)	0	5 (13.9%)
注入部位発疹	0	0	0	0	4 (3.3%)	0	4 (1.4%)	0	0
注入部位血管外漏出	0	0	0	0	2 (1.7%)	0	2 (0.7%)	0	0
注入部位反応	0	0	0	0	2 (1.7%)	0	2 (0.7%)	0	0
注入部位蕁麻疹	0	0	0	0	2 (1.7%)	0	2 (0.7%)	0	0
無力症	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	1 (2.8%)
胸部不快感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
顔面浮腫	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
冷感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
インフルエンザ様疾患	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位知覚消失	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位出血	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位刺激感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位静脈炎	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位腫脹	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位熱感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
圧痛	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
感染症および寄生虫症	0	0	1 (2.6%)	0	3 (2.5%)	11 (10.7%)	15 (5.4%)	1 (7.1%)	2 (5.6%)
鼻咽頭炎	0	0	0	0	1 (0.8%)	10 (9.7%)	11 (3.9%)	0	2 (5.6%)
インフルエンザ	0	0	1 (2.6%)	0	1 (0.8%)	0	2 (0.7%)	0	0
爪囲炎	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
鼻炎	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
扁桃炎	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
外陰腟真菌感染	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
口腔ヘルペス	0	0	0	0	0	0	0	1 (7.1%)	0
筋骨格系および結合組織障害	0	0	1 (2.6%)	0	4 (3.3%)	8 (7.8%)	13 (4.7%)	0	0
背部痛	0	0	1 (2.6%)	0	2 (1.7%)	1 (1.0%)	4 (1.4%)	0	0
筋肉痛	0	0	0	0	0	3 (2.9%)	3 (1.1%)	0	0
関節痛	0	0	0	0	1 (0.8%)	1 (1.0%)	2 (0.7%)	0	0
筋骨格痛	0	0	0	0	1 (0.8%)	1 (1.0%)	2 (0.7%)	0	0
筋痙縮	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
筋硬化症	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
頚部痛	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
四肢痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
呼吸器、胸郭および縦隔障害	1 (16.7%)	0	1 (2.6%)	0	2 (1.7%)	9 (8.7%)	13 (4.7%)	0	0
口腔咽頭痛	0	0	1 (2.6%)	0	1 (0.8%)	5 (4.9%)	7 (2.5%)	0	0
咳嗽	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
鼻閉	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
鼻出血	1 (16.7%)	0	0	0	0	0	1 (0.4%)	0	0
鼻漏	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
くしゃみ	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
皮膚および皮下組織障害	0	0	0	0	5 (4.2%)	6 (5.8%)	11 (3.9%)	0	1 (2.8%)
紅斑	0	0	0	0	1 (0.8%)	5 (4.9%)	6 (2.2%)	0	0
そう痒症	0	0	0	0	4 (3.3%)	0	4 (1.4%)	0	0
接触性皮膚炎	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
皮膚乾燥	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
湿疹	0	0	0	0	0	0	0	0	1 (2.8%)
臨床検査	0	0	6 (15.8%)	0	4 (3.3%)	0	10 (3.6%)	0	0
血圧上昇	0	0	4 (10.5%)	0	0	0	4 (1.4%)	0	0
アラニン・アミノトランスフェラーゼ増加	0	0	1 (2.6%)	0	1 (0.8%)	0	2 (0.7%)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (2.6%)	0	1 (0.8%)	0	2 (0.7%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
体温上昇	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0
抱合ビリルビン増加	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
血中ビリルビン増加	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
Ｃ－反応性蛋白増加	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
肝酵素上昇	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
好中球数減少	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
白血球数減少	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
眼障害	0	0	1 (2.6%)	0	0	3 (2.9%)	4 (1.4%)	0	0
結膜炎	0	0	1 (2.6%)	0	0	1 (1.0%)	2 (0.7%)	0	0
眼刺激	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
眼部腫脹	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
血液およびリンパ系障害	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0
好中球減少症	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0
傷害、中毒および処置合併症	0	0	0	0	2 (1.7%)	0	2 (0.7%)	1 (7.1%)	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
皮膚裂傷	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
熱傷	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
挫傷	0	0	0	0	0	0	0	1 (7.1%)	0
外科および内科処置	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
デンタルケア	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
抜歯	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
血管障害	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
静脈痛	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
心臓障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
心血管不全	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
耳および迷路障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
耳鳴	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
代謝および栄養障害	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
食欲減退	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-90 単回投与における有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
精神障害	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
精神緩慢	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
生殖系および乳房障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
性器灼熱感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_sum_sad_3.sas
Program Run: 31MAY21:18:53:11

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
Overall	5 (83.3%)	3 (50.0%)	6 (100.0%)	127 (72.6%)	26 (63.4%)	260 (48.3%)	34 (87.2%)	440 (57.1%)	69 (53.9%)	165 (28.9%)	5 (4.1%)
神経系障害	2 (33.3%)	1 (16.7%)	2 (33.3%)	77 (44.0%)	7 (17.1%)	137 (25.5%)	22 (56.4%)	244 (31.7%)	44 (34.4%)	61 (10.7%)	1 (0.8%)
頭痛	2 (33.3%)	0	2 (33.3%)	59 (33.7%)	4 (9.8%)	65 (12.1%)	14 (35.9%)	144 (18.7%)	30 (23.4%)	29 (5.1%)	0
浮動性めまい	0	1 (16.7%)	0	17 (9.7%)	2 (4.9%)	36 (6.7%)	7 (17.9%)	63 (8.2%)	13 (10.2%)	16 (2.8%)	1 (0.8%)
傾眠	0	0	0	10 (5.7%)	3 (7.3%)	33 (6.1%)	3 (7.7%)	48 (6.2%)	8 (6.3%)	11 (1.9%)	0
錯感覚	0	0	0	1 (0.6%)	0	12 (2.2%)	6 (15.4%)	19 (2.5%)	5 (3.9%)	3 (0.5%)	0
味覚異常	0	0	0	1 (0.6%)	0	6 (1.1%)	4 (10.3%)	11 (1.4%)	1 (0.8%)	0	0
感覚鈍麻	0	0	0	1 (0.6%)	0	4 (0.7%)	1 (2.6%)	6 (0.8%)	0	2 (0.4%)	0
注意力障害	0	0	0	1 (0.6%)	0	0	4 (10.3%)	5 (0.6%)	1 (0.8%)	0	0
緊張性頭痛	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	1 (0.2%)	0
振戦	0	0	0	0	0	3 (0.6%)	1 (2.6%)	4 (0.5%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
平衡障害	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
灼熱感	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	1 (0.2%)	0
体位性めまい	0	0	0	1 (0.6%)	1 (2.4%)	0	0	2 (0.3%)	1 (0.8%)	1 (0.2%)	0
片頭痛	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	0	0
嗅覚錯誤	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	1 (0.2%)	0
失神寸前の状態	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	3 (0.5%)	0
異常感覚	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
顔面神経麻痺	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
嗜眠	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
記憶障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
不随意性筋収縮	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	1 (0.8%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
神経圧迫	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
末梢性感覚ニューロパチー	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
睡眠の質低下	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
副鼻腔炎に伴う頭痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
意識変容状態	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
構語障害	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
運動機能障害	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
胃腸障害	1 (16.7%)	1 (16.7%)	1 (16.7%)	65 (37.1%)	11 (26.8%)	111 (20.6%)	22 (56.4%)	207 (26.9%)	21 (16.4%)	51 (8.9%)	3 (2.5%)
悪心	0	0	0	22 (12.6%)	3 (7.3%)	43 (8.0%)	10 (25.6%)	78 (10.1%)	6 (4.7%)	15 (2.6%)	3 (2.5%)
下痢	1 (16.7%)	0	0	26 (14.9%)	2 (4.9%)	32 (5.9%)	3 (7.7%)	63 (8.2%)	1 (0.8%)	20 (3.5%)	0
腹痛	0	1 (16.7%)	0	13 (7.4%)	2 (4.9%)	8 (1.5%)	2 (5.1%)	26 (3.4%)	8 (6.3%)	8 (1.4%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
嘔吐	0	0	0	6 (3.4%)	1 (2.4%)	10 (1.9%)	3 (7.7%)	20 (2.6%)	0	9 (1.6%)	0
口内乾燥	0	0	0	5 (2.9%)	0	8 (1.5%)	5 (12.8%)	18 (2.3%)	1 (0.8%)	0	0
便秘	0	0	0	5 (2.9%)	1 (2.4%)	9 (1.7%)	1 (2.6%)	15 (1.9%)	1 (0.8%)	4 (0.7%)	0
消化不良	0	0	0	3 (1.7%)	1 (2.4%)	9 (1.7%)	0	13 (1.7%)	3 (2.3%)	1 (0.2%)	0
上腹部痛	0	0	0	3 (1.7%)	0	7 (1.3%)	1 (2.6%)	11 (1.4%)	1 (0.8%)	1 (0.2%)	0
腹部不快感	0	0	0	2 (1.1%)	2 (4.9%)	6 (1.1%)	0	10 (1.3%)	0	1 (0.2%)	0
口唇乾燥	0	0	0	1 (0.6%)	0	6 (1.1%)	2 (5.1%)	9 (1.2%)	0	0	0
鼓腸	0	0	0	4 (2.3%)	0	4 (0.7%)	0	8 (1.0%)	1 (0.8%)	2 (0.4%)	0
口の感覚鈍麻	0	0	0	0	0	3 (0.6%)	4 (10.3%)	7 (0.9%)	0	0	0
口の錯感覚	0	0	0	0	0	5 (0.9%)	2 (5.1%)	7 (0.9%)	0	0	0
下腹部痛	0	0	0	0	0	4 (0.7%)	1 (2.6%)	5 (0.6%)	1 (0.8%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
腹部膨満	0	0	0	2 (1.1%)	0	2 (0.4%)	0	4 (0.5%)	2 (1.6%)	1 (0.2%)	0
胃食道逆流性疾患	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	1 (0.2%)	0
歯肉出血	0	0	0	0	0	3 (0.6%)	1 (2.6%)	4 (0.5%)	0	0	0
歯肉炎	0	0	1 (16.7%)	3 (1.7%)	0	0	0	4 (0.5%)	0	0	0
口腔内潰瘍形成	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	1 (0.2%)	0
歯痛	0	0	0	3 (1.7%)	0	0	0	3 (0.4%)	1 (0.8%)	2 (0.4%)	0
変色便	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
排便回数増加	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	0	0
胃腸音異常	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
アフタ性口内炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
呼気臭	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
口唇症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
嚥下障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
胃炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血便排泄	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0
メレナ	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
口腔そう痒症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
肛門周囲痛	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
舌水疱形成	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
舌苔	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
舌変色	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
口唇のひび割れ	0	0	0	0	0	0	0	0	0	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
口唇炎	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
舌炎	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
痔核	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
全身障害および投与局所様態	2 (33.3%)	1 (16.7%)	3 (50.0%)	47 (26.9%)	14 (34.1%)	63 (11.7%)	8 (20.5%)	132 (17.1%)	25 (19.5%)	25 (4.4%)	0
疲労	1 (16.7%)	0	1 (16.7%)	22 (12.6%)	1 (2.4%)	8 (1.5%)	2 (5.1%)	35 (4.5%)	5 (3.9%)	9 (1.6%)	0
熱感	0	0	0	5 (2.9%)	1 (2.4%)	26 (4.8%)	0	32 (4.2%)	0	4 (0.7%)	0
カテーテル留置部位疼痛	0	0	0	6 (3.4%)	5 (12.2%)	0	0	11 (1.4%)	5 (3.9%)	1 (0.2%)	0
血管穿刺部位疼痛	0	0	0	0	2 (4.9%)	5 (0.9%)	2 (5.1%)	9 (1.2%)	1 (0.8%)	2 (0.4%)	0
カテーテル留置部位血腫	0	0	0	2 (1.1%)	5 (12.2%)	0	0	7 (0.9%)	3 (2.3%)	0	0
無力症	0	0	0	2 (1.1%)	0	4 (0.7%)	0	6 (0.8%)	3 (2.3%)	1 (0.2%)	0
胸痛	0	0	0	3 (1.7%)	0	2 (0.4%)	1 (2.6%)	6 (0.8%)	3 (2.3%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
カテーテル留置部位関連反応	0	0	0	4 (2.3%)	1 (2.4%)	0	0	5 (0.6%)	5 (3.9%)	0	0
非心臓性胸痛	0	0	0	0	0	3 (0.6%)	1 (2.6%)	4 (0.5%)	0	0	0
血管穿刺部位血腫	0	0	0	2 (1.1%)	0	2 (0.4%)	0	4 (0.5%)	2 (1.6%)	0	0
血管穿刺部位反応	1 (16.7%)	1 (16.7%)	0	0	0	2 (0.4%)	0	4 (0.5%)	0	0	0
カテーテル留置部位炎症	0	0	0	1 (0.6%)	2 (4.9%)	0	0	3 (0.4%)	1 (0.8%)	1 (0.2%)	0
胸部不快感	0	0	0	1 (0.6%)	0	1 (0.2%)	1 (2.6%)	3 (0.4%)	0	0	0
冷感	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	1 (0.8%)	0	0
酩酊感	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0
インフルエンザ様疾患	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	2 (1.6%)	1 (0.2%)	0
口渇	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	0	0
カテーテル留置部位静脈炎	0	0	0	2 (1.1%)	2 (4.9%)	0	0	2 (0.3%)	0	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
悪寒	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	1 (0.2%)	0
注入部位静脈炎	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
注入部位反応	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
易刺激性	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	3 (0.5%)	0
穿刺部位疼痛	0	0	2 (33.3%)	0	0	0	0	2 (0.3%)	0	0	0
静脈穿刺部位血栓	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
乾燥症	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	0	0
宿酔	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
注入部位発疹	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
倦怠感	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	2 (0.4%)	0
末梢性浮腫	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
恥骨上痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
ゆったり感	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
注入部位紅斑	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
注入部位血腫	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
注入部位疼痛	0	0	0	0	0	0	0	0	3 (2.3%)	0	0
穿刺部位硬結	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
軟部組織の炎症	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
血管穿刺部位出血	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
呼吸器、胸郭および縦隔障害	1 (16.7%)	0	0	25 (14.3%)	1 (2.4%)	31 (5.8%)	1 (2.6%)	59 (7.7%)	2 (1.6%)	8 (1.4%)	0
口腔咽頭痛	0	0	0	16 (9.1%)	0	6 (1.1%)	0	22 (2.9%)	2 (1.6%)	2 (0.4%)	0
咳嗽	1 (16.7%)	0	0	4 (2.3%)	0	3 (0.6%)	0	8 (1.0%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
咽喉乾燥	0	0	0	1 (0.6%)	0	5 (0.9%)	0	6 (0.8%)	0	0	0
鼻出血	0	0	0	0	0	6 (1.1%)	0	6 (0.8%)	0	1 (0.2%)	0
鼻閉	0	0	0	0	0	6 (1.1%)	0	6 (0.8%)	0	0	0
鼻漏	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	1 (0.2%)	0
咽喉刺激感	0	0	0	2 (1.1%)	0	2 (0.4%)	0	4 (0.5%)	0	1 (0.2%)	0
呼吸困難	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	0	0
しゃっくり	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	1 (0.2%)	0
咽喉絞扼感	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
発声障害	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	0	1 (0.2%)	0
鼻乾燥	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
鼻粘膜障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
咽頭感覚鈍麻	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
副鼻腔うっ血	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
くしゃみ	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
呼吸時疼痛	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
感染症および寄生虫症	4 (66.7%)	1 (16.7%)	4 (66.7%)	20 (11.4%)	1 (2.4%)	19 (3.5%)	0	49 (6.4%)	10 (7.8%)	17 (3.0%)	0
鼻咽頭炎	3 (50.0%)	1 (16.7%)	2 (33.3%)	9 (5.1%)	1 (2.4%)	6 (1.1%)	0	22 (2.9%)	5 (3.9%)	1 (0.2%)	0
上気道感染	0	0	0	7 (4.0%)	0	4 (0.7%)	0	11 (1.4%)	0	5 (0.9%)	0
鼻炎	1 (16.7%)	1 (16.7%)	2 (33.3%)	3 (1.7%)	0	2 (0.4%)	0	9 (1.2%)	2 (1.6%)	1 (0.2%)	0
口腔ヘルペス	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	1 (0.8%)	0	0
胃腸炎	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	0	0
咽頭炎	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
副鼻腔炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
ウイルス性上気道感染	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
外陰部腟カンジダ症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
医療機器関連感染	0	0	0	0	0	0	0	0	0	6 (1.1%)	0
帯状疱疹	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
麦粒腫	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
膿疱性皮疹	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
足部白癬	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
腟感染	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
ウイルス感染	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
血管障害	1 (16.7%)	0	0	9 (5.1%)	1 (2.4%)	18 (3.3%)	21 (53.8%)	49 (6.4%)	5 (3.9%)	6 (1.1%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
ほてり	0	0	0	2 (1.1%)	1 (2.4%)	11 (2.0%)	20 (51.3%)	33 (4.3%)	5 (3.9%)	3 (0.5%)	0
潮紅	0	0	0	6 (3.4%)	0	5 (0.9%)	1 (2.6%)	12 (1.6%)	0	2 (0.4%)	0
起立性低血圧	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0
血腫	1 (16.7%)	0	0	0	0	0	0	1 (0.1%)	0	0	0
蒼白	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
静脈炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血管拡張	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
皮膚および皮下組織障害	0	0	0	14 (8.0%)	4 (9.8%)	27 (5.0%)	2 (5.1%)	46 (6.0%)	6 (4.7%)	7 (1.2%)	0
皮膚乾燥	0	0	0	0	0	7 (1.3%)	0	7 (0.9%)	0	2 (0.4%)	0
接触性皮膚炎	0	0	0	0	1 (2.4%)	4 (0.7%)	0	5 (0.6%)	1 (0.8%)	1 (0.2%)	0
紅斑	0	0	0	1 (0.6%)	0	4 (0.7%)	0	5 (0.6%)	0	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
発疹	0	0	0	2 (1.1%)	0	3 (0.6%)	0	5 (0.6%)	0	1 (0.2%)	0
ざ瘡	0	0	0	2 (1.1%)	0	2 (0.4%)	0	4 (0.5%)	1 (0.8%)	0	0
そう痒症	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
丘疹	0	0	0	2 (1.1%)	0	2 (0.4%)	0	4 (0.5%)	0	0	0
脱毛症	0	0	0	1 (0.6%)	1 (2.4%)	1 (0.2%)	0	3 (0.4%)	3 (2.3%)	0	0
多汗症	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	1 (0.2%)	0
皮膚刺激	0	0	0	1 (0.6%)	2 (4.9%)	0	0	2 (0.3%)	1 (0.8%)	0	0
斑状出血	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
毛質異常	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
爪の障害	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
全身性そう痒症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
紅斑性皮疹	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
斑状皮疹	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
そう痒性皮疹	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	1 (0.2%)	0
皮膚障害	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
皮膚剥脱	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
皮膚病変	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
皮膚異常臭	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
冷汗	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
筋骨格系および結合組織障害	2 (33.3%)	0	0	16 (9.1%)	1 (2.4%)	19 (3.5%)	7 (17.9%)	45 (5.8%)	9 (7.0%)	12 (2.1%)	1 (0.8%)
筋肉痛	0	0	0	5 (2.9%)	1 (2.4%)	5 (0.9%)	1 (2.6%)	12 (1.6%)	2 (1.6%)	3 (0.5%)	0
四肢痛	1 (16.7%)	0	0	2 (1.1%)	0	2 (0.4%)	1 (2.6%)	6 (0.8%)	2 (1.6%)	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
関節痛	0	0	0	2 (1.1%)	0	1 (0.2%)	2 (5.1%)	5 (0.6%)	0	1 (0.2%)	0
背部痛	1 (16.7%)	0	0	3 (1.7%)	0	0	1 (2.6%)	5 (0.6%)	4 (3.1%)	1 (0.2%)	0
筋骨格痛	0	0	0	0	0	5 (0.9%)	0	5 (0.6%)	1 (0.8%)	0	1 (0.8%)
筋痙縮	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	2 (0.4%)	0
筋攣縮	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	0	0
筋骨格硬直	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
頚部痛	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	1 (0.2%)	0
重感	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
側腹部痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0
筋力低下	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
筋骨格系胸痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
滑液嚢腫	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
筋肉内出血	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
筋緊張	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
筋骨格不快感	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
筋炎	0	0	0	0	0	0	0	0	0	2 (0.4%)	0
精神障害	0	0	0	8 (4.6%)	3 (7.3%)	9 (1.7%)	9 (23.1%)	28 (3.6%)	7 (5.5%)	6 (1.1%)	1 (0.8%)
不安	0	0	0	0	0	2 (0.4%)	5 (12.8%)	7 (0.9%)	2 (1.6%)	1 (0.2%)	1 (0.8%)
不眠症	0	0	0	1 (0.6%)	1 (2.4%)	2 (0.4%)	2 (5.1%)	6 (0.8%)	1 (0.8%)	1 (0.2%)	0
多幸気分	0	0	0	1 (0.6%)	0	2 (0.4%)	2 (5.1%)	5 (0.6%)	1 (0.8%)	2 (0.4%)	0
落ち着きのなさ	0	0	0	1 (0.6%)	0	0	2 (5.1%)	3 (0.4%)	0	0	0
異常な夢	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
錯乱状態	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
悪夢	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	3 (2.3%)	0	0
激越	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	1 (0.8%)	0	0
怒り	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
妄想	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	0	0	0
気分変調性障害	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
神経過敏	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
恐怖症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
睡眠障害	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
緊張	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
歯ぎしり	0	0	0	0	0	0	0	0	0	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
リビドー減退	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
傷害、中毒および処置合併症	0	0	0	7 (4.0%)	4 (9.8%)	9 (1.7%)	3 (7.7%)	23 (3.0%)	7 (5.5%)	4 (0.7%)	0
医療機器使用部位反応	0	0	0	2 (1.1%)	1 (2.4%)	3 (0.6%)	1 (2.6%)	7 (0.9%)	4 (3.1%)	0	0
創傷	0	0	0	2 (1.1%)	1 (2.4%)	1 (0.2%)	0	4 (0.5%)	0	0	0
挫傷	0	0	0	2 (1.1%)	1 (2.4%)	0	0	3 (0.4%)	0	0	0
中毒	0	0	0	0	0	1 (0.2%)	2 (5.1%)	3 (0.4%)	0	0	0
節足動物咬傷	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	2 (1.6%)	0	0
足骨折	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
上腕骨骨折	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
損傷	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
関節損傷	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
引っかき傷	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0
皮膚裂傷	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	1 (0.8%)	1 (0.2%)	0
処置によるめまい	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
処置による悪心	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
眼障害	0	0	0	8 (4.6%)	0	8 (1.5%)	5 (12.8%)	21 (2.7%)	6 (4.7%)	3 (0.5%)	0
眼乾燥	0	0	0	1 (0.6%)	0	2 (0.4%)	1 (2.6%)	4 (0.5%)	0	1 (0.2%)	0
羞明	0	0	0	0	0	1 (0.2%)	3 (7.7%)	4 (0.5%)	0	2 (0.4%)	0
眼瞼痙攣	0	0	0	1 (0.6%)	0	1 (0.2%)	1 (2.6%)	3 (0.4%)	0	0	0
眼刺激	0	0	0	3 (1.7%)	0	0	0	3 (0.4%)	0	0	0
霧視	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	1 (0.8%)	1 (0.2%)	0
眼痛	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
視力障害	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	2 (1.6%)	0	0
結膜充血	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
結膜炎	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	1 (0.8%)	0	0
アレルギー性結膜炎	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
複視	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
眼充血	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
臨床検査	0	0	0	2 (1.1%)	0	18 (3.3%)	1 (2.6%)	21 (2.7%)	0	6 (1.1%)	0
アラニン・アミノトランスフェラーゼ増加	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	2 (0.4%)	0
血中クレアチニン増加	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	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	3 (0.6%)	0	3 (0.4%)	0	2 (0.4%)	0
血中トリグリセリド増加	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
尿中赤血球陽性	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
アラニン・アミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
アスパラギン酸アミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血中クレアチンホスホキナーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
心電図異常T波	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
γ－グルタミルトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
ヘマトクリット減少	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0
ヘモグロビン減少	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0
肝酵素上昇	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
リパーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
肝機能検査異常	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	1 (0.2%)	0
白血球数減少	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
尿中白血球陽性	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血中コレステロール増加	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
血圧上昇	0	0	0	0	0	0	0	0	0	2 (0.4%)	0
心拍数増加	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
代謝および栄養障害	0	0	0	5 (2.9%)	0	9 (1.7%)	4 (10.3%)	18 (2.3%)	3 (2.3%)	4 (0.7%)	0
食欲減退	0	0	0	3 (1.7%)	0	8 (1.5%)	2 (5.1%)	13 (1.7%)	1 (0.8%)	4 (0.7%)	0
多飲症	0	0	0	1 (0.6%)	0	1 (0.2%)	2 (5.1%)	4 (0.5%)	1 (0.8%)	0	0
異常体重減少	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
脱水	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
腎および尿路障害	0	0	0	4 (2.3%)	0	6 (1.1%)	2 (5.1%)	12 (1.6%)	1 (0.8%)	8 (1.4%)	0
頻尿	0	0	0	1 (0.6%)	0	3 (0.6%)	1 (2.6%)	5 (0.6%)	1 (0.8%)	1 (0.2%)	0
尿意切迫	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	0	0
着色尿	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	7 (1.2%)	0
排尿困難	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
多尿	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
腎臓痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
耳および迷路障害	0	0	0	1 (0.6%)	0	8 (1.5%)	0	9 (1.2%)	0	1 (0.2%)	0
回転性めまい	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
耳痛	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
聴覚過敏	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
耳鳴	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
耳垢栓塞	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
心臓障害	0	0	0	0	0	3 (0.6%)	5 (12.8%)	8 (1.0%)	2 (1.6%)	0	0
動悸	0	0	0	0	0	3 (0.6%)	4 (10.3%)	7 (0.9%)	2 (1.6%)	0	0
頻脈	0	0	0	0	0	0	2 (5.1%)	2 (0.3%)	0	0	0
免疫系障害	0	0	0	3 (1.7%)	0	1 (0.2%)	0	4 (0.5%)	0	0	0
節足動物咬傷アレルギー	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	0	0	0
節足動物刺傷アレルギー	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
生殖系および乳房障害	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	3 (2.3%)	2 (0.4%)	0
生殖器痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
腟出血	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
外陰腟不快感	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
外陰腟そう痒症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
月経困難症	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
過少月経	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
不規則月経	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
不正子宮出血	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
腟分泌物	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
血液およびリンパ系障害	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
好酸球増加症	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	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	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-91 反復投与における有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
皮膚乳頭腫	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
外科および内科処置	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
抜歯	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
内分泌障害	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
早発初経	0	0	0	0	0	0	0	0	0	1 (0.2%)	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_sum_mad_3.sas
Program Run: 31MAY21:18:53:18

表 8-92 発現割合が2%以上の副作用 - 海外第I相試験併合

MedDRA v12.1	海外第I相試験併合
Preferred Term	Isavuconazole (N = 1049)
Overall	464 (44.2%)
頭痛	169 (16.1%)
悪心	82 (7.8%)
下痢	67 (6.4%)
浮動性めまい	66 (6.3%)
熱感	35 (3.3%)
疲労	34 (3.2%)
ほてり	33 (3.1%)
傾眠	28 (2.7%)
腹痛	26 (2.5%)
嘔吐	25 (2.4%)

Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_freq_2_3.sas
Program Run: 02JUN21:14:51:30

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
Overall	3 (50.0%)	0	10 (26.3%)	1 (16.7%)	27 (22.5%)	52 (50.5%)	93 (33.3%)	2 (14.3%)	11 (30.6%)
神経系障害	2 (33.3%)	0	0	1 (16.7%)	9 (7.5%)	36 (35.0%)	48 (17.2%)	0	9 (25.0%)
頭痛	2 (33.3%)	0	0	1 (16.7%)	6 (5.0%)	30 (29.1%)	39 (14.0%)	0	5 (13.9%)
浮動性めまい	0	0	0	0	3 (2.5%)	8 (7.8%)	11 (3.9%)	0	5 (13.9%)
傾眠	0	0	0	0	0	3 (2.9%)	3 (1.1%)	0	0
灼熱感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
知覚過敏	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
感覚鈍麻	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
坐骨神経痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
胃腸障害	0	0	3 (7.9%)	1 (16.7%)	4 (3.3%)	26 (25.2%)	34 (12.2%)	1 (7.1%)	4 (11.1%)
下痢	0	0	1 (2.6%)	0	2 (1.7%)	8 (7.8%)	11 (3.9%)	1 (7.1%)	2 (5.6%)
悪心	0	0	0	0	1 (0.8%)	10 (9.7%)	11 (3.9%)	0	1 (2.8%)
腹痛	0	0	0	0	1 (0.8%)	4 (3.9%)	5 (1.8%)	0	0
嘔吐	0	0	0	0	0	5 (4.9%)	5 (1.8%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
上腹部痛	0	0	1 (2.6%)	1 (16.7%)	0	1 (1.0%)	3 (1.1%)	0	0
口内乾燥	0	0	0	0	0	3 (2.9%)	3 (1.1%)	0	1 (2.8%)
鼓腸	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
口の感覚鈍麻	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	1 (2.8%)
下腹部痛	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
便秘	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
消化不良	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
排便回数増加	0	0	0	1 (16.7%)	0	0	1 (0.4%)	0	0
舌痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
レッチング	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
全身障害および投与局所様態	0	0	0	0	14 (11.7%)	12 (11.7%)	26 (9.3%)	0	7 (19.4%)
疲労	0	0	0	0	1 (0.8%)	5 (4.9%)	6 (2.2%)	0	1 (2.8%)
熱感	0	0	0	0	0	5 (4.9%)	5 (1.8%)	0	5 (13.9%)
注入部位発疹	0	0	0	0	4 (3.3%)	0	4 (1.4%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
注入部位反応	0	0	0	0	2 (1.7%)	0	2 (0.7%)	0	0
注入部位蕁麻疹	0	0	0	0	2 (1.7%)	0	2 (0.7%)	0	0
無力症	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	1 (2.8%)
胸部不快感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
顔面浮腫	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
冷感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
注入部位知覚消失	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位刺激感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位腫脹	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
注入部位熱感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
圧痛	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
臨床検査	0	0	6 (15.8%)	0	4 (3.3%)	0	10 (3.6%)	0	0
血圧上昇	0	0	4 (10.5%)	0	0	0	4 (1.4%)	0	0
体温上昇	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
アラニン・アミノトランスフェラーゼ増加	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	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	1 (0.8%)	0	1 (0.4%)	0	0
抱合ビリルビン増加	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
血中ビリルビン増加	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
肝酵素上昇	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
好中球数減少	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
白血球数減少	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
皮膚および皮下組織障害	0	0	0	0	3 (2.5%)	6 (5.8%)	9 (3.2%)	0	0
紅斑	0	0	0	0	1 (0.8%)	5 (4.9%)	6 (2.2%)	0	0
そう痒症	0	0	0	0	3 (2.5%)	0	3 (1.1%)	0	0
皮膚乾燥	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
呼吸器、胸郭および縦隔障害	1 (16.7%)	0	1 (2.6%)	0	0	2 (1.9%)	4 (1.4%)	0	0
口腔咽頭痛	0	0	1 (2.6%)	0	0	2 (1.9%)	3 (1.1%)	0	0
鼻出血	1 (16.7%)	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
感染症および寄生虫症	0	0	1 (2.6%)	0	1 (0.8%)	1 (1.0%)	3 (1.1%)	1 (7.1%)	0
インフルエンザ	0	0	1 (2.6%)	0	0	0	1 (0.4%)	0	0
鼻咽頭炎	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
鼻炎	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
外陰腟真菌感染	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
口腔ヘルペス	0	0	0	0	0	0	0	1 (7.1%)	0
血液およびリンパ系障害	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0
好中球減少症	0	0	2 (5.3%)	0	0	0	2 (0.7%)	0	0
眼障害	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
眼刺激	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
眼部腫脹	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
筋骨格系および結合組織障害	0	0	0	0	0	2 (1.9%)	2 (0.7%)	0	0
背部痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
筋骨格痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-93 単回投与における副作用 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
筋硬化症	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
心臓障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
心血管不全	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
耳および迷路障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
耳鳴	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
精神障害	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
精神緩慢	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
生殖系および乳房障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
性器灼熱感	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
血管障害	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0
静脈痛	0	0	0	0	0	1 (1.0%)	1 (0.4%)	0	0

ISA: isavuconazole
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_sad_3.sas
Program Run: 02JUN21:14:51:34

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
Overall	3 (50.0%)	2 (33.3%)	4 (66.7%)	112 (64.0%)	19 (46.3%)	212 (39.4%)	34 (87.2%)	371 (48.2%)	53 (41.4%)	37 (6.5%)	0
神経系障害	2 (33.3%)	1 (16.7%)	2 (33.3%)	66 (37.7%)	5 (12.2%)	109 (20.3%)	22 (56.4%)	205 (26.6%)	37 (28.9%)	15 (2.6%)	0
頭痛	2 (33.3%)	0	2 (33.3%)	55 (31.4%)	4 (9.8%)	55 (10.2%)	14 (35.9%)	130 (16.9%)	28 (21.9%)	10 (1.8%)	0
浮動性めまい	0	1 (16.7%)	0	14 (8.0%)	1 (2.4%)	32 (5.9%)	7 (17.9%)	55 (7.1%)	11 (8.6%)	2 (0.4%)	0
傾眠	0	0	0	5 (2.9%)	0	18 (3.3%)	2 (5.1%)	25 (3.2%)	4 (3.1%)	1 (0.2%)	0
錯感覚	0	0	0	0	0	12 (2.2%)	5 (12.8%)	17 (2.2%)	3 (2.3%)	0	0
味覚異常	0	0	0	0	0	6 (1.1%)	4 (10.3%)	10 (1.3%)	1 (0.8%)	0	0
注意力障害	0	0	0	1 (0.6%)	0	0	4 (10.3%)	5 (0.6%)	1 (0.8%)	0	0
感覚鈍麻	0	0	0	0	0	4 (0.7%)	1 (2.6%)	5 (0.6%)	0	1 (0.2%)	0
振戦	0	0	0	0	0	3 (0.6%)	1 (2.6%)	4 (0.5%)	0	0	0
緊張性頭痛	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
平衡障害	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
灼熱感	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	1 (0.2%)	0
体位性めまい	0	0	0	1 (0.6%)	1 (2.4%)	0	0	2 (0.3%)	1 (0.8%)	1 (0.2%)	0
嗅覚錯誤	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	0	0
異常感覚	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
嗜眠	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
記憶障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
片頭痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	1 (0.8%)	0	0
不随意性筋収縮	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	1 (0.8%)	0	0
神経圧迫	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
末梢性感覚ニューロパチー	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
睡眠の質低下	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
構語障害	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
運動機能障害	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
胃腸障害	1 (16.7%)	1 (16.7%)	1 (16.7%)	61 (34.9%)	11 (26.8%)	100 (18.6%)	22 (56.4%)	192 (24.9%)	18 (14.1%)	8 (1.4%)	0
悪心	0	0	0	22 (12.6%)	3 (7.3%)	36 (6.7%)	10 (25.6%)	71 (9.2%)	5 (3.9%)	2 (0.4%)	0
下痢	1 (16.7%)	0	0	26 (14.9%)	2 (4.9%)	25 (4.6%)	3 (7.7%)	56 (7.3%)	1 (0.8%)	1 (0.2%)	0
腹痛	0	1 (16.7%)	0	12 (6.9%)	2 (4.9%)	5 (0.9%)	1 (2.6%)	21 (2.7%)	6 (4.7%)	1 (0.2%)	0
嘔吐	0	0	0	6 (3.4%)	1 (2.4%)	10 (1.9%)	3 (7.7%)	20 (2.6%)	0	1 (0.2%)	0
口内乾燥	0	0	0	4 (2.3%)	0	8 (1.5%)	5 (12.8%)	17 (2.2%)	1 (0.8%)	0	0
便秘	0	0	0	5 (2.9%)	1 (2.4%)	8 (1.5%)	1 (2.6%)	14 (1.8%)	1 (0.8%)	1 (0.2%)	0
消化不良	0	0	0	3 (1.7%)	1 (2.4%)	9 (1.7%)	0	13 (1.7%)	3 (2.3%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
上腹部痛	0	0	0	3 (1.7%)	0	7 (1.3%)	1 (2.6%)	11 (1.4%)	0	0	0
腹部不快感	0	0	0	2 (1.1%)	2 (4.9%)	5 (0.9%)	0	9 (1.2%)	0	0	0
口の感覚鈍麻	0	0	0	0	0	3 (0.6%)	4 (10.3%)	7 (0.9%)	0	0	0
口の錯感覚	0	0	0	0	0	5 (0.9%)	2 (5.1%)	7 (0.9%)	0	0	0
鼓腸	0	0	0	4 (2.3%)	0	2 (0.4%)	0	6 (0.8%)	1 (0.8%)	1 (0.2%)	0
口唇乾燥	0	0	0	1 (0.6%)	0	2 (0.4%)	2 (5.1%)	5 (0.6%)	0	0	0
下腹部痛	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
胃食道逆流性疾患	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	0	0
歯肉炎	0	0	1 (16.7%)	3 (1.7%)	0	0	0	4 (0.5%)	0	0	0
腹部膨満	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	2 (1.6%)	0	0
歯肉出血	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
口腔内潰瘍形成	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	0	0
変色便	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
排便回数増加	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	1 (0.8%)	0	0
胃腸音異常	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
アフタ性口内炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
呼気臭	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
胃炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血便排泄	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
メレナ	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
口腔そう痒症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
肛門周囲痛	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0

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Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
舌水疱形成	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
舌苔	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
舌変色	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
口唇のひび割れ	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
口唇炎	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
全身障害および投与局所様態	1 (16.7%)	0	1 (16.7%)	30 (17.1%)	2 (4.9%)	48 (8.9%)	6 (15.4%)	88 (11.4%)	14 (10.9%)	9 (1.6%)	0
熱感	0	0	0	4 (2.3%)	1 (2.4%)	25 (4.6%)	0	30 (3.9%)	0	3 (0.5%)	0
疲労	1 (16.7%)	0	1 (16.7%)	17 (9.7%)	1 (2.4%)	6 (1.1%)	2 (5.1%)	28 (3.6%)	5 (3.9%)	5 (0.9%)	0
無力症	0	0	0	2 (1.1%)	0	4 (0.7%)	0	6 (0.8%)	3 (2.3%)	0	0
胸痛	0	0	0	3 (1.7%)	0	2 (0.4%)	1 (2.6%)	6 (0.8%)	2 (1.6%)	0	0
胸部不快感	0	0	0	1 (0.6%)	0	1 (0.2%)	1 (2.6%)	3 (0.4%)	0	0	0

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Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
酩酊感	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0
非心臓性胸痛	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	0	0
口渇	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	0	0
悪寒	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
インフルエンザ様疾患	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	1 (0.8%)	0	0
注入部位静脈炎	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
注入部位反応	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
易刺激性	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	1 (0.2%)	0
乾燥症	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	0	0
冷感	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
宿酔	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

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Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
注入部位発疹	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
倦怠感	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	2 (0.4%)	0
注入部位紅斑	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
注入部位血腫	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
注入部位疼痛	0	0	0	0	0	0	0	0	3 (2.3%)	0	0
血管障害	0	0	0	9 (5.1%)	1 (2.4%)	17 (3.2%)	21 (53.8%)	47 (6.1%)	5 (3.9%)	1 (0.2%)	0
ほてり	0	0	0	2 (1.1%)	1 (2.4%)	11 (2.0%)	20 (51.3%)	33 (4.3%)	5 (3.9%)	0	0
潮紅	0	0	0	6 (3.4%)	0	5 (0.9%)	1 (2.6%)	12 (1.6%)	0	0	0
起立性低血圧	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0
蒼白	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
血管拡張	0	0	0	0	0	0	0	0	0	1 (0.2%)	0

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Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
呼吸器、胸郭および縦隔障害	0	0	0	18 (10.3%)	0	18 (3.3%)	1 (2.6%)	37 (4.8%)	1 (0.8%)	3 (0.5%)	0
口腔咽頭痛	0	0	0	11 (6.3%)	0	2 (0.4%)	0	13 (1.7%)	1 (0.8%)	2 (0.4%)	0
咽喉乾燥	0	0	0	1 (0.6%)	0	4 (0.7%)	0	5 (0.6%)	0	0	0
鼻閉	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
鼻出血	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0
咽喉刺激感	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	0	1 (0.2%)	0
咳嗽	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
呼吸困難	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	0	0
しゃっくり	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0
鼻漏	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0
咽喉絞扼感	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0

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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
鼻乾燥	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
鼻粘膜障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
咽頭感覚鈍麻	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
筋骨格系および結合組織障害	1 (16.7%)	0	0	10 (5.7%)	1 (2.4%)	11 (2.0%)	4 (10.3%)	27 (3.5%)	3 (2.3%)	1 (0.2%)	0
筋肉痛	0	0	0	4 (2.3%)	1 (2.4%)	4 (0.7%)	0	9 (1.2%)	1 (0.8%)	0	0
背部痛	0	0	0	2 (1.1%)	0	0	1 (2.6%)	3 (0.4%)	1 (0.8%)	1 (0.2%)	0
筋痙縮	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	0	0
筋骨格痛	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0
四肢痛	1 (16.7%)	0	0	1 (0.6%)	0	0	1 (2.6%)	3 (0.4%)	0	0	0
関節痛	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	0	0
重感	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0

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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
側腹部痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
筋力低下	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
筋骨格系胸痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
筋肉内出血	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
筋緊張	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
筋攣縮	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
皮膚および皮下組織障害	0	0	0	8 (4.6%)	2 (4.9%)	14 (2.6%)	1 (2.6%)	25 (3.2%)	4 (3.1%)	2 (0.4%)	0
皮膚乾燥	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	2 (0.4%)	0
そう痒症	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
発疹	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	0	0
脱毛症	0	0	0	1 (0.6%)	1 (2.4%)	1 (0.2%)	0	3 (0.4%)	3 (2.3%)	0	0

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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
ざ瘡	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	1 (0.8%)	0	0
紅斑	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	1 (0.2%)	0
毛質異常	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
多汗症	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
爪の障害	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
全身性そう痒症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
紅斑性皮疹	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
斑状皮疹	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
丘疹	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
皮膚刺激	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	0	0	0
皮膚病変	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
皮膚異常臭	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
精神障害	0	0	0	6 (3.4%)	2 (4.9%)	6 (1.1%)	8 (20.5%)	21 (2.7%)	6 (4.7%)	0	0
不安	0	0	0	0	0	1 (0.2%)	3 (7.7%)	4 (0.5%)	2 (1.6%)	0	0
多幸気分	0	0	0	1 (0.6%)	0	1 (0.2%)	2 (5.1%)	4 (0.5%)	1 (0.8%)	0	0
落ち着きのなさ	0	0	0	1 (0.6%)	0	0	2 (5.1%)	3 (0.4%)	0	0	0
錯乱状態	0	0	0	2 (1.1%)	0	0	0	2 (0.3%)	0	0	0
不眠症	0	0	0	1 (0.6%)	0	0	1 (2.6%)	2 (0.3%)	0	0	0
悪夢	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	3 (2.3%)	0	0
異常な夢	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
激越	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	1 (0.8%)	0	0
怒り	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0

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Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
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表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
妄想	0	0	0	0	1 (2.4%)	0	0	1 (0.1%)	0	0	0
気分変調性障害	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
神経過敏	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
恐怖症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
緊張	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
眼障害	0	0	0	6 (3.4%)	0	8 (1.5%)	5 (12.8%)	19 (2.5%)	4 (3.1%)	1 (0.2%)	0
羞明	0	0	0	0	0	1 (0.2%)	3 (7.7%)	4 (0.5%)	0	1 (0.2%)	0
眼瞼痙攣	0	0	0	1 (0.6%)	0	1 (0.2%)	1 (2.6%)	3 (0.4%)	0	0	0
眼乾燥	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	0	0
眼刺激	0	0	0	3 (1.7%)	0	0	0	3 (0.4%)	0	0	0
霧視	0	0	0	2 (1.1%)	0	1 (0.2%)	0	3 (0.4%)	1 (0.8%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
眼痛	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
結膜充血	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
視力障害	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	2 (1.6%)	0	0
複視	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
臨床検査	0	0	0	2 (1.1%)	0	16 (3.0%)	1 (2.6%)	19 (2.5%)	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	0	0	1 (0.6%)	0	3 (0.6%)	0	4 (0.5%)	0	0	0
血中クレアチニン増加	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	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	3 (0.6%)	0	3 (0.4%)	0	0	0
血中トリグリセリド増加	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
尿中赤血球陽性	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
アラニン・アミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
アスパラギン酸アミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血中クレアチンホスホキナーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
γ－グルタミルトランスフェラーゼ異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
ヘマトクリット減少	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
ヘモグロビン減少	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
肝酵素上昇	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
リパーゼ増加	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
肝機能検査異常	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
尿中白血球陽性	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
感染症および寄生虫症	0	0	1 (16.7%)	5 (2.9%)	1 (2.4%)	9 (1.7%)	0	16 (2.1%)	2 (1.6%)	2 (0.4%)	0
上気道感染	0	0	0	4 (2.3%)	0	2 (0.4%)	0	6 (0.8%)	0	0	0
鼻咽頭炎	0	0	0	1 (0.6%)	1 (2.4%)	3 (0.6%)	0	5 (0.6%)	0	1 (0.2%)	0
鼻炎	0	0	1 (16.7%)	0	0	2 (0.4%)	0	3 (0.4%)	0	0	0
口腔ヘルペス	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	1 (0.8%)	0	0
咽頭炎	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
胃腸炎	0	0	0	0	0	0	0	0	1 (0.8%)	0	0
膿疱性皮疹	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
代謝および栄養障害	0	0	0	4 (2.3%)	0	7 (1.3%)	4 (10.3%)	15 (1.9%)	2 (1.6%)	1 (0.2%)	0
食欲減退	0	0	0	2 (1.1%)	0	6 (1.1%)	2 (5.1%)	10 (1.3%)	1 (0.8%)	1 (0.2%)	0
多飲症	0	0	0	1 (0.6%)	0	1 (0.2%)	2 (5.1%)	4 (0.5%)	1 (0.8%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
異常体重減少	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
耳および迷路障害	0	0	0	1 (0.6%)	0	8 (1.5%)	0	9 (1.2%)	0	0	0
回転性めまい	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	0	0
耳痛	0	0	0	1 (0.6%)	0	1 (0.2%)	0	2 (0.3%)	0	0	0
聴覚過敏	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
耳鳴	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
腎および尿路障害	0	0	0	2 (1.1%)	0	6 (1.1%)	1 (2.6%)	9 (1.2%)	1 (0.8%)	0	0
頻尿	0	0	0	0	0	3 (0.6%)	1 (2.6%)	4 (0.5%)	1 (0.8%)	0	0
尿意切迫	0	0	0	1 (0.6%)	0	2 (0.4%)	0	3 (0.4%)	0	0	0
多尿	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
腎臓痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-94 反復投与における副作用 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
心臓障害	0	0	0	0	0	3 (0.6%)	5 (12.8%)	8 (1.0%)	2 (1.6%)	0	0
動悸	0	0	0	0	0	3 (0.6%)	4 (10.3%)	7 (0.9%)	2 (1.6%)	0	0
頻脈	0	0	0	0	0	0	2 (5.1%)	2 (0.3%)	0	0	0
傷害、中毒および処置合併症	0	0	0	1 (0.6%)	0	1 (0.2%)	2 (5.1%)	4 (0.5%)	0	0	0
中毒	0	0	0	0	0	1 (0.2%)	2 (5.1%)	3 (0.4%)	0	0	0
挫傷	0	0	0	1 (0.6%)	0	0	0	1 (0.1%)	0	0	0
血液およびリンパ系障害	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
好酸球増加症	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
生殖系および乳房障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	1 (0.8%)	0	0
生殖器痛	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
腟分泌物	0	0	0	0	0	0	0	0	1 (0.8%)	0	0

ISA: isavuconazole; Moxi: moxifloxacin
Study drug-related adverse events include those reported as remotely, possibly or probably related to study drug by the investigator and those with a missing relationship.

Program Name: t_ae_side_mad_3.sas
Program Run: 02JUN21:14:51:38

表 8-95 重篤な有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/年齢/国籍	SOC/PT	発現日*/終了日*	重篤性/程度/SAE番号	因果関係	転帰	治験薬の処置/治療の要否
MD (BAP00213)	ISA 100 mg	[redacted]	Male/3[redacted]/Other	臨床検査/アラニン・アミノトランスフェラーゼ増加	36 (-35)/183 (112)	Yes/Severe	Possible	Recovered/Resolved	Dose Not Changed/No
SD (BAP00777)	ISA 100 mg	[redacted]	Female/6[redacted]/White	神経系障害/ギラン・バレー症候群	18 (17)/M (M)	Yes/Severe	Not Related	Recovering/Resolving	Dose Not Changed/Yes
				神経系障害/脳炎	27 (26)/43 (42)	Yes/Severe	Not Related	Recovered/Resolved	Dose Not Changed/Yes
MD (9766-CL-0031)	ISA 200 mg	[redacted]	Female/6[redacted]/White	胃腸障害/胃炎	29 (13)/54 (38)	Yes/Mild/4	Probable	Recovered/Resolved	Dose Not Changed/Yes
				胃腸障害/胃食道逆流性疾患	29 (13)/32 (16)	Yes/Severe/4	Probable	Recovered/Resolved	Dose Not Changed/Yes
MD (9766-CL-0042)	ISA 200 mg	[redacted]#	Female/3[redacted]/White	神経系障害/感覚鈍麻	7 (-1)/8 (0)	Yes/Mild/6	Probable	Recovered/Resolved	Drug Withdrawn/No
				胃腸障害/口の感覚鈍麻	7 (-1)/9 (1)	Yes/Mild/6	Probable	Recovered/Resolved	Drug Withdrawn/No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
A TEAE with a missing seriousness was considered a serious TEAE.
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment; M: Missing or partial date

Program Name: l_ae_ser_3.sas
Program Run: 23JUN21:11:21:13

表 8-96 単回投与における投与中止に至った有害事象 - 海外第I相試験併合（単回投与）

MedDRA v12.1	Single Dose								
System Organ Class Preferred Term	40 mg (N = 6)	80 mg (N = 6)	100 mg (N = 38)	160 mg (N = 6)	200 mg (N = 120)	400 mg (N = 103)	Total ISA (N = 279)	Placebo (N = 14)	Substrate (N = 36)
Overall	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
全身障害および投与局所様態	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0
胸部不快感	0	0	0	0	1 (0.8%)	0	1 (0.4%)	0	0

ISA: isavuconazole

Program Name: t_ae_discon_sad_3.sas
Program Run: 31MAY21:18:53:43

表 8-97 反復投与における投与中止に至った有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
Overall	1 (16.7%)	0	0	0	0	11 (2.0%)	7 (17.9%)	19 (2.5%)	0	8 (1.4%)	0
胃腸障害	1 (16.7%)	0	0	0	0	5 (0.9%)	2 (5.1%)	8 (1.0%)	0	1 (0.2%)	0
下痢	1 (16.7%)	0	0	0	0	1 (0.2%)	1 (2.6%)	3 (0.4%)	0	0	0
嘔吐	0	0	0	0	0	2 (0.4%)	1 (2.6%)	3 (0.4%)	0	0	0
悪心	0	0	0	0	0	0	2 (5.1%)	2 (0.3%)	0	0	0
口の感覚鈍麻	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
口の錯感覚	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
口腔内潰瘍形成	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
神経系障害	1 (16.7%)	0	0	0	0	3 (0.6%)	4 (10.3%)	8 (1.0%)	0	0	0
頭痛	1 (16.7%)	0	0	0	0	1 (0.2%)	3 (7.7%)	5 (0.6%)	0	0	0
浮動性めまい	0	0	0	0	0	1 (0.2%)	2 (5.1%)	3 (0.4%)	0	0	0
注意力障害	0	0	0	0	0	0	2 (5.1%)	2 (0.3%)	0	0	0
感覚鈍麻	0	0	0	0	0	2 (0.4%)	0	2 (0.3%)	0	0	0
平衡障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_discon_mad_3.sas
Program Run: 31MAY21:18:53:46

表 8-97 反復投与における投与中止に至った有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
灼熱感	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
味覚異常	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
記憶障害	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
錯感覚	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
精神障害	0	0	0	0	0	2 (0.4%)	4 (10.3%)	6 (0.8%)	0	0	0
不安	0	0	0	0	0	1 (0.2%)	3 (7.7%)	4 (0.5%)	0	0	0
不眠症	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
悪夢	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
恐怖症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
落ち着きのなさ	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
全身障害および投与局所様態	0	0	0	0	0	3 (0.6%)	2 (5.1%)	5 (0.6%)	0	0	0
非心臓性胸痛	0	0	0	0	0	1 (0.2%)	1 (2.6%)	2 (0.3%)	0	0	0
酩酊感	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0
熱感	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_discon_mad_3.sas
Program Run: 31MAY21:18:53:46

表 8-97 反復投与における投与中止に至った有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
血管穿刺部位疼痛	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
臨床検査	0	0	0	0	0	4 (0.7%)	0	4 (0.5%)	0	5 (0.9%)	0
血中クレアチニン増加	0	0	0	0	0	3 (0.6%)	0	3 (0.4%)	0	0	0
心電図異常Ｔ波	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	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	0	0	0	2 (0.4%)	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	0	0	0	2 (0.4%)	0
血中コレステロール増加	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
血圧上昇	0	0	0	0	0	0	0	0	0	2 (0.4%)	0
ヘマトクリット減少	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
ヘモグロビン減少	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
心拍数増加	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
血管障害	0	0	0	0	0	1 (0.2%)	3 (7.7%)	4 (0.5%)	0	0	0
ほてり	0	0	0	0	0	0	3 (7.7%)	3 (0.4%)	0	0	0
潮紅	0	0	0	0	0	1 (0.2%)	0	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_discon_mad_3.sas
Program Run: 31MAY21:18:53:46

表 8-97 反復投与における投与中止に至った有害事象 - 海外第I相試験併合（反復投与）

MedDRA v12.1	Multiple Dose										
System Organ Class Preferred Term	40 mg (N = 6)	50 mg (N = 6)	80 mg (N = 6)	100 mg (N = 175)	150 mg (N = 41)	200 mg (N = 538)	600 mg (N = 39)	Total ISA (N = 770)	Placebo (N = 128)	Substrate (N = 570)	Moxi (N = 122)
心臓障害	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
動悸	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
感染症および寄生虫症	1 (16.7%)	0	0	0	0	0	0	1 (0.1%)	0	2 (0.4%)	0
鼻咽頭炎	1 (16.7%)	0	0	0	0	0	0	1 (0.1%)	0	0	0
腟感染	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
ウイルス感染	0	0	0	0	0	0	0	0	0	1 (0.2%)	0
傷害、中毒および処置合併症	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0
中毒	0	0	0	0	0	0	1 (2.6%)	1 (0.1%)	0	0	0

ISA: isavuconazole; Moxi: moxifloxacin

Program Name: t_ae_discon_mad_3.sas
Program Run: 31MAY21:18:53:46

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者 番号	性別/ 年齢/ 国籍	SOC/ PT	発現日*/ 終了日*	重篤性/ 程度/ SAE番号	因果 関係	転帰	治験薬の 処置/ 治療の 要否
MD (BAP00140)	ISA 40 mg	[redacted]#	Male/ 3[redacted]/ White	胃腸障害/ 下痢	9 (-1)/ 10 (0)	No/ Moderate	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/ 頭痛	9 (-1)/ 14 (4)	No/ Moderate	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				感染症および寄生虫症/ 鼻咽頭炎	9 (-1)/ 14 (4)	No/ Moderate	Not Related	Recovered/ Resolved	Drug Withdrawn/ No
SD (9766-CL-0018)	ISA 200 mg	[redacted]#	Female/ 2[redacted]/ Other	全身障害および投与局所様態/ 胸部不快感	1 (0)/ 1 (0)	No/ Moderate	Probable	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/年齢/国籍	SOC/PT	発現日*/終了日*	重篤性/程度/SAE番号	因果関係	転帰	治験薬の処置/治療の要否
MD (9766-CL-0021)	ISA 200 mg	[redacted]#	Male/4[redacted]/White	全身障害および投与局所様態/熱感	20 (-5)/33 (8)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/灼熱感	23 (-2)/50 (25)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				胃腸障害/口の錯感覚	23 (-2)/23 (-2)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				血管障害/潮紅	24 (-1)/33 (8)	No/Mild	Probable	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/頭痛	24 (-1)/28 (3)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/Yes
				神経系障害/錯感覚	25 (0)/27 (2)	No/Mild	Probable	Recovered/Resolved	Drug Withdrawn/No
MD (9766-CL-0022)	ISA 200 mg	[redacted]#	Male/4[redacted]/White	臨床検査/血中クレアチニン増加	14 (0)/34 (20)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
MD (9766-CL-0022)	ISA 200 mg	[redacted]#	Male/4[redacted]/Black or African American	臨床検査/血中クレアチニン増加	14 (0)/28 (14)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
MD (9766-CL-0023)	ISA 200 mg	[redacted]#	Male/4[redacted]/White	臨床検査/血中クレアチニン増加	8 (0)/18 (10)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者 番号	性別/ 年齢/ 国籍	SOC/ PT	発現日*/ 終了日*	重篤性/ 程度/ SAE番号	因果 関係	転帰	治験薬の 処置/ 治療の 要否
MD (9766-CL-0024)	ISA 200 mg	[redacted]#	Male/ 3[redacted]/ White	胃腸障害/ 下痢	7 (0)/ 10 (3)	No/ Moderate	Probable	Recovered/ Resolved	Drug Withdrawn/ Yes
MD (9766-CL-0035)	ISA 200 mg	[redacted]#	Male/ 3[redacted]/ White	精神障害/ 悪夢	3 (0)/ 3 (0)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
MD (9766-CL-0035)	ISA 200 mg	[redacted]#	Female/ 2[redacted]/ Asian	胃腸障害/ 嘔吐	2 (0)/ 2 (0)	No/ Moderate	Probable	Recovered/ Resolved	Drug Withdrawn/ No
MD (9766-CL-0042)	ISA 200 mg	[redacted]#	Female/ 3[redacted]/ White	神経系障害/ 感覚鈍麻	7 (-1)/ 8 (0)	Yes/ Mild/ 6	Probable	Recovered/ Resolved	Drug Withdrawn/ No
				胃腸障害/ 口の感覚鈍麻	7 (-1)/ 9 (1)	Yes/ Mild/ 6	Probable	Recovered/ Resolved	Drug Withdrawn/ No
MD (9766-CL-0051)	ISA 200 mg	[redacted]#	Female/ 3[redacted]/ White	胃腸障害/ 嘔吐	4 (-1)/ 5 (0)	No/ Mild	Probable	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者 番号	性別/ 年齢/ 国籍	SOC/ PT	発現日*/ 終了日*	重篤性/ 程度/ SAE番号	因果 関係	転帰	治験薬の 処置/ 治療の 要否
MD (9766-CL-0053)	ISA 200 mg	[redacted] #	Male/ 5[redacted]/ White	精神障害/ 不眠症	12 (-1)/ 14 (1)	No/ Mild	Not Related	Recovered/ Resolved	Drug Withdrawn/ No
				精神障害/ 不安	13 (0)/ 13 (0)	No/ Mild	Not Related	Recovered/ Resolved	Drug Withdrawn/ No
				臨床検査/ 心電図異常T波	13 (0)/ 15 (2)	No/ Mild	Not Related	Recovered/ Resolved	Drug Withdrawn/ No
				全身障害および投与局所様態/ 非心臓性胸痛	13 (0)/ 13 (0)	No/ Mild	Not Related	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/年齢/国籍	SOC/PT	発現日*/終了日*	重篤性/程度/SAE番号	因果関係	転帰	治験薬の処置/治療の要否
MD (9766-CL-0053)	ISA 200 mg	[redacted]#	Male/4[redacted]/Asian	神経系障害/感覚鈍麻	7 (-6)/22 (9)	No/Mild	Probable	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/味覚異常	9 (-4)/21 (8)	No/Moderate	Probable	Recovered/Resolved	Drug Withdrawn/No
				全身障害および投与局所様態/酩酊感	9 (-4)/17 (4)	No/Mild	Probable	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/記憶障害	9 (-4)/17 (4)	No/Mild	Probable	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/平衡障害	13 (0)/17 (4)	No/Moderate	Probable	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/浮動性めまい	13 (0)/17 (4)	No/Moderate	Probable	Recovered/Resolved	Drug Withdrawn/No
MD (9766-CL-0017)	ISA 600 mg	[redacted]#	Male/2[redacted]/Asian	精神障害/落ち着きのなさ	9 (0)/10 (1)	No/Moderate	Possible	Recovered/Resolved	Drug Withdrawn/No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/年齢/国籍	SOC/PT	発現日*/終了日*	重篤性/程度/SAE番号	因果関係	転帰	治験薬の処置/治療の要否
MD (9766-CL-0017)	ISA 600 mg	[redacted]	# Male/3[redacted]/White	胃腸障害/悪心	1 (-4)/5 (0)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				血管障害/ほてり	2 (-3)/5 (0)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				精神障害/不安	4 (-1)/6 (1)	No/Mild	Not Related	Recovered/Resolved	Drug Withdrawn/No
				胃腸障害/下痢	5 (0)/6 (1)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/浮動性めまい	5 (0)/6 (1)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No
				神経系障害/頭痛	5 (0)/5 (0)	No/Mild	Possible	Recovered/Resolved	Drug Withdrawn/No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/年齢/国籍	SOC/PT	発現日*/終了日*	重篤性/程度/SAE番号	因果関係	転帰	治験薬の処置/治療の要否
MD (9766-CL-0017)	ISA 600 mg	[redacted]	# Female/ 3[redacted]/ White	心臓障害/動悸	5 (-1)/ 7 (1)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				精神障害/不安	6 (0)/ 7 (1)	No/ Mild	Not Related	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/注意力障害	6 (0)/ 7 (1)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/頭痛	6 (0)/ 7 (1)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ Yes
MD (9766-CL-0017)	ISA 600 mg	[redacted]	# Male/ 2[redacted]/ White	精神障害/不安	3 (-2)/ 6 (1)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/注意力障害	3 (-2)/ 7 (2)	No/ Moderate	Probable	Recovered/ Resolved	Drug Withdrawn/ No
				傷害、中毒および処置合併症/中毒	3 (-2)/ 13 (8)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				血管障害/ほてり	5 (0)/ 8 (3)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				精神障害/恐怖症	6 (1)/ 6 (1)	No/ Moderate	Possible	Recovered/ Resolved	Drug Withdrawn/ No

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-98 投与中止に至った有害事象の一覧 - 海外第I相試験併合

単回/反復の別 (試験)	ISA 用量群	被験者番号	性別/ 年齢/ 国籍	SOC/ PT	発現日*/ 終了日*	重篤性/ 程度/ SAE番号	因果関係	転帰	治験薬の処置/ 治療の要否
MD (9766-CL-0017)	ISA 600 mg	[redacted]#	Male/ 2[redacted]/ Asian	血管障害/ ほてり	3 (-8)/ 16 (5)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/ 浮動性めまい	7 (-4)/ 13 (2)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				神経系障害/ 頭痛	8 (-3)/ 13 (2)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				胃腸障害/ 悪心	10 (-1)/ 12 (1)	No/ Mild	Possible	Recovered/ Resolved	Drug Withdrawn/ No
				胃腸障害/ 嘔吐	11 (0)/ 11 (0)	No/ Moderate	Possible	Recovered/ Resolved	Drug Withdrawn/ No
MD (9766-CL-0017)	ISA 600 mg	[redacted]#	Female/ 4[redacted]/ White	全身障害および投与局所様態/ 非心臓性胸痛	6 (0)/ 23 (17)	No/ Moderate	Possible	Recovered/ Resolved	Drug Withdrawn/ Yes
MD (9766-CL-0017)	ISA 600 mg	[redacted]#	Female/ 2[redacted]/ White	全身障害および投与局所様態/ 血管穿刺部位疼痛	4 (-1)/ 10 (5)	No/ Moderate	Not Related	Recovered/ Resolved	Drug Withdrawn/ Yes

ISA: Isavuconazole, SD: Single Dose, MD: Multiple Dose
*: Study day calculated relative to first dose date of study medication. Days relative to last dose are included in parentheses.
SOC: System Organ Class; PT: Preferred Term
MedDRA ver 12.1
SAE番号: 1=Death; 2=Life Threatening; 3=Permanent Disability; 4=Hospitalization; 5=Congenital Anomaly; 6=Important Medical Event
#: Subject prematurely discontinued treatment.

Program Name: l_ae_discon_3.sas
Program Run: 23JUN21:11:21:13

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Basophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	0.039	0.0333	0.00	0.030	0.17	-	-	-	-	-	-
Day 3	60	0.027	0.0205	0.00	0.029	0.10	60	-0.012	0.0322	-0.17	-0.001	0.03
Day 7	58	0.033	0.0252	0.00	0.030	0.14	58	-0.006	0.0297	-0.11	0.000	0.06
Day 14	57	0.039	0.0329	0.00	0.030	0.20	57	-0.002	0.0303	-0.11	0.000	0.13
Day 28	53	0.030	0.0238	0.00	0.028	0.12	53	-0.010	0.0334	-0.12	-0.005	0.12
Day 42	51	0.026	0.0189	0.00	0.020	0.08	51	-0.016	0.0351	-0.11	-0.010	0.08
EOT	60	0.025	0.0238	0.00	0.020	0.12	60	-0.014	0.0253	-0.11	-0.010	0.04
FU	55	0.037	0.0389	0.00	0.030	0.25	55	-0.003	0.0300	-0.11	-0.001	0.08
Voriconazole (N = 30)												
Baseline	30	0.045	0.0368	0.00	0.036	0.17	-	-	-	-	-	-
Day 3	29	0.037	0.0298	0.00	0.030	0.10	29	-0.009	0.0345	-0.11	0.000	0.04
Day 7	29	0.044	0.0311	0.00	0.040	0.10	29	-0.002	0.0311	-0.08	0.000	0.04
Day 14	27	0.048	0.0310	0.00	0.040	0.12	27	-0.001	0.0375	-0.11	0.000	0.06
Day 28	27	0.035	0.0255	0.00	0.030	0.11	27	-0.010	0.0347	-0.11	-0.003	0.05
Day 42	25	0.040	0.0331	0.00	0.030	0.17	25	-0.006	0.0455	-0.13	0.000	0.11
EOT	30	0.031	0.0261	0.00	0.030	0.09	30	-0.013	0.0354	-0.11	0.000	0.03
FU	30	0.034	0.0292	0.00	0.030	0.13	30	-0.011	0.0494	-0.17	-0.002	0.13
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	0.040	0.0343	0.00	0.030	0.17	-	-	-	-	-	-
Day 3	73	0.028	0.0233	0.00	0.028	0.11	73	-0.012	0.0317	-0.17	-0.004	0.06
Day 7	71	0.043	0.0947	0.00	0.030	0.80	71	0.002	0.0914	-0.11	0.000	0.72
Day 14	69	0.037	0.0318	0.00	0.030	0.20	69	-0.005	0.0328	-0.11	0.000	0.13
Day 28	64	0.029	0.0227	0.00	0.027	0.12	64	-0.010	0.0329	-0.12	-0.004	0.12
Day 42	61	0.025	0.0184	0.00	0.020	0.08	61	-0.017	0.0344	-0.11	-0.010	0.08
EOT	73	0.026	0.0236	0.00	0.020	0.12	73	-0.014	0.0271	-0.11	-0.010	0.04
FU	66	0.034	0.0367	0.00	0.026	0.25	66	-0.006	0.0313	-0.11	-0.001	0.08

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Eosinophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	0.212	0.2135	0.00	0.160	1.31	-	-	-	-	-	-
Day 3	60	0.187	0.1984	0.00	0.141	1.13	60	-0.024	0.0987	-0.34	-0.018	0.27
Day 7	58	0.188	0.2353	0.00	0.130	1.58	58	-0.027	0.1354	-0.50	-0.030	0.36
Day 14	57	0.176	0.1630	0.00	0.120	0.84	57	-0.042	0.1551	-0.54	-0.019	0.33
Day 28	53	0.198	0.2902	0.00	0.120	1.69	53	-0.027	0.2454	-0.50	-0.041	1.32
Day 42	51	0.155	0.1996	0.00	0.100	1.13	51	-0.077	0.1750	-0.55	-0.076	0.76
EOT	60	0.122	0.1318	0.00	0.096	0.86	60	-0.090	0.1623	-0.67	-0.062	0.26
FU	55	0.138	0.1007	0.00	0.110	0.60	55	-0.087	0.1626	-0.71	-0.057	0.22
Voriconazole (N = 30)												
Baseline	30	0.312	0.2521	0.00	0.263	1.02	-	-	-	-	-	-
Day 3	29	0.364	0.3883	0.00	0.240	1.66	29	0.042	0.2500	-0.35	-0.021	0.76
Day 7	29	0.467	0.9151	0.00	0.272	5.07	29	0.144	0.7628	-0.24	0.015	4.05
Day 14	27	0.378	0.5615	0.02	0.232	2.98	27	0.036	0.3997	-0.24	-0.049	1.96
Day 28	27	0.413	0.8572	0.00	0.247	4.56	27	0.085	0.7026	-0.29	-0.014	3.54
Day 42	25	0.501	1.3100	0.00	0.260	6.73	25	0.171	1.1619	-0.25	-0.020	5.71
EOT	30	0.287	0.3983	0.00	0.210	2.17	30	-0.025	0.2584	-0.32	-0.034	1.15
FU	30	0.350	0.5604	0.00	0.197	3.10	30	0.037	0.4237	-0.30	-0.038	2.08
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	0.205	0.2022	0.00	0.161	1.31	-	-	-	-	-	-
Day 3	73	0.181	0.1947	0.00	0.130	1.13	73	-0.024	0.1111	-0.34	-0.020	0.37
Day 7	71	0.179	0.2191	0.00	0.120	1.58	71	-0.028	0.1263	-0.50	-0.025	0.36
Day 14	69	0.167	0.1594	0.00	0.110	0.84	69	-0.040	0.1467	-0.54	-0.019	0.33
Day 28	64	0.184	0.2695	0.00	0.114	1.69	64	-0.028	0.2248	-0.50	-0.041	1.32
Day 42	61	0.160	0.2161	0.00	0.100	1.13	61	-0.058	0.1958	-0.55	-0.060	0.78
EOT	73	0.124	0.1326	0.00	0.090	0.86	73	-0.081	0.1556	-0.67	-0.060	0.26
FU	66	0.140	0.1181	0.00	0.105	0.60	66	-0.072	0.1668	-0.71	-0.053	0.39

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Erythrocytes (10^12/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	4.25	0.690	2.7	4.25	6.2	-	-	-	-	-	-
Day 3	60	4.30	0.746	2.7	4.29	6.0	60	0.05	0.270	-0.5	0.04	1.0
Day 7	58	4.35	0.755	2.6	4.35	5.8	58	0.11	0.310	-0.8	0.15	0.7
Day 14	57	4.32	0.716	2.6	4.25	6.3	57	0.06	0.245	-0.5	0.03	0.9
Day 28	53	4.27	0.693	2.6	4.27	5.9	53	-0.03	0.250	-0.5	-0.03	0.5
Day 42	51	4.36	0.631	3.0	4.29	6.2	51	-0.01	0.301	-0.7	0.00	0.7
EOT	60	4.10	0.710	2.6	4.14	6.0	60	-0.15	0.389	-0.9	-0.19	1.1
FU	55	4.07	0.615	2.5	4.05	5.9	55	-0.27	0.401	-1.1	-0.34	0.6
Voriconazole (N = 30)												
Baseline	30	4.00	0.673	2.2	4.11	5.1	-	-	-	-	-	-
Day 3	30	3.99	0.677	2.3	4.12	5.3	30	-0.02	0.232	-0.6	0.03	0.4
Day 7	30	4.00	0.667	2.5	4.09	5.2	30	-0.01	0.243	-0.7	0.05	0.3
Day 14	28	4.05	0.530	3.0	4.11	5.2	28	0.01	0.316	-0.8	0.05	0.6
Day 28	27	4.10	0.517	3.0	4.24	5.0	27	0.04	0.333	-0.6	0.05	0.9
Day 42	25	4.09	0.490	3.0	4.17	4.9	25	0.04	0.377	-0.9	0.07	0.9
EOT	30	4.02	0.619	2.5	4.18	4.9	30	0.02	0.468	-1.5	0.06	0.9
FU	30	4.09	0.580	3.0	4.16	5.0	30	0.09	0.524	-1.2	0.13	1.6
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	4.19	0.702	2.7	4.15	6.2	-	-	-	-	-	-
Day 3	73	4.22	0.757	2.7	4.19	6.0	73	0.04	0.254	-0.5	0.01	1.0
Day 7	71	4.27	0.771	2.6	4.30	5.8	71	0.09	0.300	-0.8	0.12	0.7
Day 14	69	4.26	0.738	2.4	4.25	6.3	69	0.06	0.267	-0.8	0.03	0.9
Day 28	64	4.24	0.701	2.6	4.24	5.9	64	0.00	0.272	-0.5	-0.01	1.0
Day 42	61	4.29	0.677	2.5	4.25	6.2	61	-0.02	0.313	-0.7	0.00	0.7
EOT	73	4.05	0.724	2.6	4.07	6.0	73	-0.14	0.375	-0.9	-0.17	1.1
FU	66	4.03	0.677	2.3	4.03	5.9	66	-0.25	0.412	-1.1	-0.31	0.6

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Hemoglobin (g/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	125.7	18.76	85	123.0	162	-	-	-	-	-	-
Day 3	60	127.2	20.58	83	128.0	169	60	1.6	7.91	-17	1.0	26
Day 7	58	128.9	21.48	78	128.0	169	58	3.0	9.30	-30	4.0	18
Day 14	57	128.7	20.11	81	126.0	170	57	2.4	7.26	-14	2.0	24
Day 28	53	128.3	18.29	86	129.0	164	53	1.1	6.80	-15	1.0	15
Day 42	51	131.6	17.43	86	132.0	166	51	2.6	9.02	-17	4.0	23
EOT	60	127.0	18.25	79	128.5	168	60	1.3	11.22	-19	0.0	28
FU	55	127.6	16.21	89	127.0	158	55	0.0	11.32	-25	-1.0	31
Voriconazole (N = 30)												
Baseline	30	117.2	20.16	67	119.5	158	-	-	-	-	-	-
Day 3	30	117.1	21.12	74	120.0	163	30	0.0	7.06	-21	1.0	13
Day 7	30	117.2	20.97	76	121.5	164	30	0.0	7.42	-21	1.0	11
Day 14	28	118.6	17.69	93	119.0	165	28	0.5	8.93	-25	0.5	18
Day 28	27	119.6	17.13	89	124.0	154	27	0.6	9.87	-21	2.0	24
Day 42	25	119.5	17.29	88	122.0	151	25	1.1	11.19	-21	1.0	28
EOT	30	118.3	21.32	75	121.0	151	30	1.2	13.45	-23	-0.5	28
FU	30	121.2	20.74	75	119.5	148	30	4.0	15.69	-23	3.0	53
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	124.9	18.83	85	123.0	162	-	-	-	-	-	-
Day 3	73	126.1	20.66	83	126.0	169	73	1.2	7.58	-17	1.0	26
Day 7	71	127.6	21.60	78	128.0	169	71	2.5	9.16	-30	3.0	18
Day 14	69	128.0	20.39	78	126.0	170	69	2.3	7.85	-23	2.0	24
Day 28	64	128.3	18.37	86	129.5	164	64	1.7	7.47	-15	1.0	24
Day 42	61	130.4	18.70	82	131.0	166	61	2.2	9.70	-19	3.0	25
EOT	73	126.0	19.18	79	125.0	168	73	1.0	10.94	-20	0.0	28
FU	66	126.8	18.22	75	127.0	174	66	-0.2	11.88	-26	-1.0	31

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Leukocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	6.86	2.340	0.0	6.60	12.0	-	-	-	-	-	-
Day 3	60	6.66	2.344	0.0	6.40	11.8	60	-0.21	1.320	-4.6	0.06	3.5
Day 7	58	6.39	2.148	0.1	6.10	11.6	58	-0.50	1.480	-4.1	-0.33	3.8
Day 14	57	6.44	2.106	0.1	6.30	12.6	57	-0.54	1.460	-3.8	-0.50	3.5
Day 28	53	6.51	2.705	0.5	6.40	18.9	53	-0.62	2.254	-4.8	-0.70	9.8
Day 42	51	6.45	1.848	2.0	6.28	10.8	51	-0.75	1.426	-4.6	-0.60	2.2
EOT	60	6.44	2.608	0.0	6.40	18.9	60	-0.43	2.173	-4.9	-0.65	9.8
FU	55	6.55	2.612	0.6	6.20	19.0	55	-0.55	2.152	-4.4	-0.80	9.9
Voriconazole (N = 30)												
Baseline	30	6.28	2.407	0.1	6.42	11.3	-	-	-	-	-	-
Day 3	29	6.87	2.258	2.0	6.90	12.6	29	0.38	1.065	-1.4	0.50	2.6
Day 7	29	7.12	3.141	4.0	6.10	18.6	29	0.63	3.722	-1.8	-0.21	18.4
Day 14	27	7.25	2.532	3.9	7.70	12.9	27	0.45	1.488	-1.6	0.40	5.2
Day 28	27	6.22	1.617	4.1	6.18	9.3	27	-0.28	1.439	-2.2	-0.60	4.7
Day 42	25	6.72	2.425	3.6	6.73	13.7	25	0.22	2.509	-2.8	-0.60	8.9
EOT	30	6.65	3.038	3.3	5.78	18.6	30	0.37	3.992	-2.6	-0.45	18.4
FU	30	6.04	2.342	1.9	5.43	12.5	30	-0.24	1.984	-3.0	-0.70	6.3
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	6.91	2.396	0.0	6.60	13.9	-	-	-	-	-	-
Day 3	73	6.61	2.313	0.0	6.40	11.8	73	-0.29	1.331	-4.6	0.00	3.5
Day 7	71	6.32	2.029	0.1	6.10	11.6	71	-0.61	1.656	-7.2	-0.34	3.8
Day 14	69	6.47	2.046	0.1	6.30	12.6	69	-0.52	1.457	-3.8	-0.50	3.5
Day 28	64	6.38	2.592	0.5	6.40	18.9	64	-0.62	2.069	-4.8	-0.75	9.8
Day 42	61	6.21	1.847	2.0	6.00	10.8	61	-0.86	1.424	-4.6	-0.80	2.2
EOT	73	6.30	2.521	0.0	6.22	18.9	73	-0.61	2.082	-4.9	-0.80	9.8
FU	66	6.44	2.717	0.6	6.18	19.0	66	-0.55	2.185	-4.9	-0.80	9.9

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Lymphocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	1.417	0.7622	0.00	1.243	3.82	-	-	-	-	-	-
Day 3	60	1.585	0.9801	0.03	1.412	6.33	60	0.168	0.5899	-1.43	0.064	2.50
Day 7	58	1.529	0.8676	0.04	1.480	5.49	58	0.100	0.4677	-0.64	0.025	2.37
Day 14	57	1.487	0.7779	0.01	1.340	3.49	57	0.035	0.4079	-0.66	0.000	2.13
Day 28	53	1.530	0.8173	0.09	1.409	5.10	53	0.092	0.4742	-0.55	0.015	2.32
Day 42	51	1.436	0.6108	0.40	1.344	3.36	51	-0.028	0.3848	-1.12	-0.035	0.97
EOT	60	1.362	0.7516	0.01	1.291	5.10	60	-0.055	0.4177	-1.22	0.004	1.28
FU	55	1.532	0.7083	0.01	1.430	3.68	55	0.090	0.5291	-1.45	0.077	2.47
Voriconazole (N = 30)												
Baseline	30	1.217	0.6817	0.04	1.104	3.16	-	-	-	-	-	-
Day 3	29	1.441	0.6810	0.37	1.310	3.21	29	0.183	0.3154	-0.49	0.174	1.18
Day 7	29	1.409	0.5635	0.51	1.330	2.88	29	0.151	0.4255	-1.25	0.138	1.20
Day 14	27	1.432	0.6812	0.66	1.264	3.68	27	0.148	0.3093	-0.45	0.196	0.57
Day 28	27	1.467	0.7229	0.14	1.178	3.09	27	0.245	0.3841	-0.33	0.218	1.65
Day 42	25	1.340	0.6062	0.00	1.312	2.69	25	0.104	0.4003	-1.29	0.100	0.73
EOT	30	1.289	0.5375	0.00	1.210	2.98	30	0.072	0.4732	-1.63	0.075	1.20
FU	30	1.324	0.5724	0.11	1.287	2.34	30	0.106	0.5026	-1.25	0.039	1.42
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	1.397	0.7360	0.00	1.238	3.82	-	-	-	-	-	-
Day 3	73	1.485	0.9326	0.03	1.319	6.33	73	0.088	0.5992	-1.43	0.022	2.50
Day 7	71	1.447	0.8273	0.04	1.360	5.49	71	0.041	0.4634	-0.94	0.000	2.37
Day 14	69	1.415	0.7503	0.01	1.320	3.49	69	-0.012	0.4217	-1.04	-0.020	2.13
Day 28	64	1.445	0.7878	0.09	1.387	5.10	64	0.034	0.5059	-1.29	0.000	2.32
Day 42	61	1.360	0.6143	0.06	1.310	3.36	61	-0.077	0.4354	-1.43	-0.066	0.97
EOT	73	1.309	0.7065	0.01	1.270	5.10	73	-0.088	0.4371	-1.59	-0.030	1.28
FU	66	1.467	0.6741	0.01	1.405	3.68	66	0.052	0.5227	-1.45	0.070	2.47

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Monocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	0.443	0.1956	0.00	0.465	0.81	-	-	-	-	-	-
Day 3	60	0.434	0.1943	0.00	0.410	0.96	60	-0.009	0.1305	-0.35	0.000	0.44
Day 7	58	0.400	0.1688	0.00	0.382	0.79	58	-0.042	0.1237	-0.33	-0.029	0.29
Day 14	57	0.416	0.1857	0.00	0.383	1.13	57	-0.032	0.2194	-0.46	-0.049	1.13
Day 28	53	0.400	0.1855	0.00	0.400	0.94	53	-0.055	0.1835	-0.51	-0.050	0.63
Day 42	51	0.422	0.1542	0.18	0.390	0.96	51	-0.047	0.1825	-0.52	-0.020	0.47
EOT	60	0.403	0.1556	0.00	0.431	0.74	60	-0.040	0.1539	-0.56	-0.025	0.34
FU	55	0.450	0.1640	0.01	0.440	0.89	55	-0.015	0.1800	-0.51	-0.010	0.60
Voriconazole (N = 30)												
Baseline	30	0.402	0.2545	0.00	0.375	1.36	-	-	-	-	-	-
Day 3	29	0.457	0.2205	0.20	0.400	1.39	29	0.041	0.1847	-0.51	0.025	0.46
Day 7	29	0.432	0.2214	0.16	0.370	1.30	29	0.016	0.3638	-1.10	0.000	1.28
Day 14	27	0.441	0.1460	0.24	0.400	0.88	27	0.002	0.1958	-0.48	0.030	0.37
Day 28	27	0.438	0.1968	0.24	0.380	1.25	27	0.025	0.3217	-0.80	0.017	1.25
Day 42	25	0.432	0.1896	0.19	0.397	1.17	25	0.017	0.3465	-1.03	-0.014	1.17
EOT	30	0.429	0.2618	0.04	0.345	1.30	30	0.027	0.4177	-1.21	-0.015	1.28
FU	30	0.390	0.1269	0.19	0.396	0.71	30	-0.012	0.2915	-1.15	-0.009	0.52
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	0.435	0.1937	0.00	0.448	0.86	-	-	-	-	-	-
Day 3	73	0.425	0.1881	0.00	0.410	0.96	73	-0.010	0.1440	-0.54	0.000	0.44
Day 7	71	0.380	0.1680	0.00	0.378	0.79	71	-0.054	0.1416	-0.70	-0.030	0.29
Day 14	69	0.397	0.1916	0.00	0.378	1.13	69	-0.042	0.2217	-0.61	-0.050	1.13
Day 28	64	0.392	0.1742	0.00	0.392	0.94	64	-0.052	0.1793	-0.51	-0.045	0.63
Day 42	61	0.396	0.1605	0.08	0.368	0.96	61	-0.059	0.1958	-0.72	-0.040	0.47
EOT	73	0.398	0.1629	0.00	0.425	0.79	73	-0.037	0.1569	-0.56	-0.030	0.37
FU	66	0.446	0.1843	0.01	0.435	1.16	66	-0.007	0.1730	-0.51	0.003	0.60

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Neutrophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	4.691	2.0467	0.00	4.490	9.84	-	-	-	-	-	-
Day 3	60	4.422	1.9211	0.00	4.116	9.70	60	-0.270	1.3363	-5.22	-0.102	2.99
Day 7	58	4.220	1.7506	0.00	4.082	9.30	58	-0.479	1.4856	-4.45	-0.195	3.69
Day 14	57	4.267	1.5042	0.06	4.217	7.53	57	-0.500	1.2892	-4.02	-0.184	3.02
Day 28	53	4.292	1.9316	0.36	4.070	10.58	53	-0.607	2.0184	-5.18	-0.745	8.95
Day 42	51	4.399	1.7005	0.83	4.148	8.46	51	-0.589	1.2923	-4.14	-0.415	2.65
EOT	60	4.471	1.9071	0.06	4.428	10.58	60	-0.221	1.9562	-4.61	-0.315	8.95
FU	55	4.393	2.3760	0.60	4.202	17.25	55	-0.537	2.0996	-4.47	-0.630	11.01
Voriconazole (N = 30)												
Baseline	30	4.302	1.7896	0.02	4.405	8.09	-	-	-	-	-	-
Day 3	29	4.557	1.8179	1.12	4.600	8.12	29	0.108	0.9958	-1.82	0.050	2.43
Day 7	29	4.766	2.8366	1.95	3.939	15.92	29	0.317	3.1741	-1.89	-0.433	15.90
Day 14	27	4.804	2.0163	1.71	4.138	9.97	27	0.121	1.1434	-1.56	0.061	2.20
Day 28	27	3.863	1.3054	1.73	3.513	6.56	27	-0.632	1.2413	-2.79	-0.572	3.36
Day 42	25	4.405	1.7465	1.99	4.154	8.11	25	-0.065	1.8879	-1.95	-0.240	7.79
EOT	30	4.620	2.8076	1.78	3.740	15.92	30	0.318	3.5644	-3.02	-0.218	15.90
FU	30	3.945	2.1439	1.08	3.121	11.41	30	-0.357	1.9345	-3.44	-0.580	6.37
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	4.779	2.1023	0.00	4.490	11.40	-	-	-	-	-	-
Day 3	73	4.456	1.9281	0.00	4.170	9.70	73	-0.323	1.3619	-5.22	-0.176	2.99
Day 7	71	4.259	1.6795	0.00	4.163	9.30	71	-0.528	1.6553	-6.75	-0.200	3.69
Day 14	69	4.409	1.5240	0.06	4.300	8.47	69	-0.417	1.2869	-4.02	-0.060	3.02
Day 28	64	4.285	1.8869	0.36	4.098	10.58	64	-0.552	1.8941	-5.18	-0.660	8.95
Day 42	61	4.259	1.6491	0.83	4.101	8.46	61	-0.659	1.3146	-4.14	-0.578	2.65
EOT	73	4.392	1.8721	0.06	4.396	10.58	73	-0.387	1.8837	-4.61	-0.400	8.95
FU	66	4.350	2.4361	0.60	4.221	17.25	66	-0.513	2.1191	-4.47	-0.610	11.01

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-99 血液一般検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Platelet (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	258.0	111.31	2	244.5	583	-	-	-	-	-	-
Day 3	60	269.2	124.35	2	266.0	686	60	11.3	31.05	-58	8.0	103
Day 7	58	276.0	127.59	5	258.0	642	58	17.3	39.41	-78	11.5	107
Day 14	57	272.0	111.19	4	245.0	646	57	9.1	47.64	-64	5.0	213
Day 28	53	255.9	103.83	40	248.0	595	53	-10.2	57.56	-144	-8.0	188
Day 42	51	271.2	109.48	77	259.0	716	51	-2.4	52.75	-119	-12.0	214
EOT	60	250.5	103.22	4	241.5	547	60	-7.5	62.24	-144	-7.5	150
FU	55	255.7	100.53	40	238.0	586	55	-14.5	62.91	-144	-24.0	142
Voriconazole (N = 30)												
Baseline	30	257.6	95.14	16	263.5	487	-	-	-	-	-	-
Day 3	30	260.0	86.92	26	260.0	430	30	2.4	26.25	-57	4.0	58
Day 7	30	251.2	85.35	11	240.0	424	30	-6.4	29.01	-63	-5.5	64
Day 14	28	258.8	83.32	14	256.5	412	28	-8.6	45.42	-105	-7.0	69
Day 28	27	263.6	93.23	63	238.0	545	27	-4.8	44.50	-96	-1.0	117
Day 42	25	269.7	84.96	137	249.0	499	25	-4.0	46.69	-81	-4.0	121
EOT	30	256.0	79.23	81	259.5	468	30	-1.6	52.91	-81	-3.0	121
FU	30	241.4	66.73	91	251.0	390	30	-16.2	67.22	-133	-19.0	197
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	250.5	109.03	2	241.0	583	-	-	-	-	-	-
Day 3	73	260.6	119.18	2	256.0	686	73	10.1	30.47	-58	8.0	103
Day 7	71	269.1	122.29	5	255.0	642	71	18.2	38.73	-78	14.0	107
Day 14	69	265.1	111.35	4	242.0	646	69	11.3	46.00	-64	8.0	213
Day 28	64	249.5	103.04	40	244.5	595	64	-8.8	54.21	-144	-8.5	188
Day 42	61	260.8	108.08	54	258.0	716	61	-4.6	50.05	-119	-12.0	214
EOT	73	245.8	101.70	4	240.0	547	73	-4.7	60.25	-144	-4.0	150
FU	66	248.0	100.03	25	236.0	586	66	-14.0	60.31	-144	-21.5	142

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_2.sas
Program Run: 25JUN21:17:55:50

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	ALT (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	19.5	12.60	5	16.0	65	-	-	-	-	-	-
Day 3	60	19.0	17.67	5	13.5	121	60	-0.6	13.39	-15	-1.0	97
Day 7	58	19.6	26.87	5	14.0	212	58	0.1	26.31	-38	-1.5	188
Day 14	57	18.6	12.98	7	15.0	83	57	-0.5	14.15	-48	0.0	59
Day 28	53	18.8	12.26	6	16.0	67	53	0.2	15.93	-51	2.0	53
Day 42	51	36.3	58.86	6	20.0	403	51	17.3	61.08	-50	3.0	391
EOT	60	38.7	67.30	5	17.5	403	60	19.1	69.92	-52	2.0	391
FU	55	32.5	60.80	7	17.0	442	55	14.0	62.61	-49	1.0	430
Voriconazole (N = 30)												
Baseline	30	19.5	25.35	5	13.0	143	-	-	-	-	-	-
Day 3	30	16.5	19.36	5	10.5	111	30	-3.0	6.48	-32	-1.5	4
Day 7	30	17.5	15.81	4	10.0	74	30	-2.0	23.91	-105	-1.0	66
Day 14	28	28.2	32.18	4	13.0	137	28	8.6	37.57	-106	0.5	129
Day 28	27	23.0	22.49	5	10.0	86	27	3.0	26.50	-96	1.0	67
Day 42	25	18.1	14.73	5	12.0	69	25	-2.4	26.10	-111	-1.0	45
EOT	30	23.1	26.03	4	13.5	122	30	3.6	31.58	-90	0.0	114
FU	30	16.6	12.27	2	14.0	58	30	-2.9	24.97	-116	0.5	48
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	20.5	13.80	5	17.0	67	-	-	-	-	-	-
Day 3	73	19.2	17.16	5	14.0	121	73	-1.2	12.61	-18	-1.0	97
Day 7	71	19.4	24.67	5	14.0	212	71	-1.0	24.36	-39	-2.0	188
Day 14	69	18.5	12.54	6	15.0	83	69	-1.8	14.43	-52	-1.0	59
Day 28	64	18.9	11.83	6	16.0	67	64	-1.2	16.14	-53	0.0	53
Day 42	61	37.1	57.94	6	21.0	403	61	16.5	60.64	-56	3.0	391
EOT	73	35.8	61.51	5	18.0	403	73	15.3	64.37	-52	2.0	391
FU	66	30.3	55.84	6	17.0	442	66	10.3	58.01	-50	1.0	430

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Albumin (g/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	35.5	6.21	24	36.4	47	-	-	-	-	-	-
Day 3	60	34.8	5.79	20	35.5	46	60	-0.7	2.80	-7	-1.0	6
Day 7	58	36.7	5.77	24	37.0	46	58	0.9	3.38	-9	0.5	10
Day 14	57	37.1	5.49	22	38.0	45	57	1.4	3.15	-5	1.0	10
Day 28	53	37.9	5.38	21	38.0	45	53	1.9	3.78	-7	1.0	11
Day 42	51	38.9	5.88	18	39.0	52	51	2.4	4.22	-6	2.0	13
EOT	60	37.3	6.34	22	38.0	48	60	1.8	4.08	-7	1.0	16
FU	55	37.6	5.56	20	38.0	48	55	1.5	4.34	-8	1.0	10
Voriconazole (N = 30)												
Baseline	30	34.1	5.57	24	34.0	43	-	-	-	-	-	-
Day 3	30	33.8	5.42	25	34.0	45	30	-0.3	2.48	-9	0.0	3
Day 7	30	33.6	4.79	27	33.5	44	30	-0.5	3.11	-11	0.0	5
Day 14	28	34.6	5.05	25	34.0	45	28	0.4	3.32	-11	0.5	6
Day 28	27	36.0	4.88	26	36.0	44	27	1.6	4.12	-6	1.0	11
Day 42	25	37.1	4.35	27	38.0	43	25	2.6	4.18	-5	2.0	11
EOT	30	36.1	4.62	28	37.0	44	30	2.0	5.13	-8	1.5	10
FU	30	37.1	4.52	27	38.0	46	30	3.1	5.50	-8	2.0	13
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	35.8	5.88	24	36.7	47	-	-	-	-	-	-
Day 3	73	34.8	5.66	20	35.0	46	73	-1.0	2.80	-8	-1.0	6
Day 7	71	36.5	5.74	24	37.0	46	71	0.5	3.60	-13	0.0	10
Day 14	69	36.9	5.62	22	38.0	46	69	0.9	3.46	-11	1.0	10
Day 28	64	38.0	5.31	21	38.0	49	64	1.8	3.57	-7	1.0	11
Day 42	61	38.7	5.79	18	39.0	52	61	2.1	4.01	-6	2.0	13
EOT	73	37.4	6.29	22	38.0	48	73	1.7	4.12	-11	1.0	16
FU	66	37.6	5.52	20	38.0	48	66	1.4	4.15	-8	1.0	10

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	ALP (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	59	332.1	309.74	132	246.0	1913	-	-	-	-	-	-
Day 3	59	304.1	211.91	113	261.0	1492	59	-28.1	126.72	-904	-7.0	70
Day 7	57	336.9	305.02	126	272.0	2035	57	0.5	67.63	-227	-1.0	195
Day 14	55	356.5	333.96	144	282.0	2240	55	17.7	116.05	-317	12.0	433
Day 28	52	345.3	357.88	100	270.5	2723	52	35.6	158.98	-248	15.0	916
Day 42	50	337.5	177.51	150	303.5	1167	50	25.0	141.48	-640	26.5	409
EOT	59	341.6	216.58	100	289.0	1626	59	9.5	180.56	-1091	20.0	409
FU	52	337.2	158.23	146	295.5	806	52	31.9	233.42	-1228	23.5	563
Voriconazole (N = 30)												
Baseline	29	273.6	82.67	142	269.0	514	-	-	-	-	-	-
Day 3	29	276.4	93.81	155	264.0	617	29	2.8	45.72	-67	2.0	197
Day 7	29	277.2	98.64	153	247.0	658	29	3.7	62.09	-118	6.0	238
Day 14	27	336.3	156.28	162	305.0	903	27	70.3	116.74	-56	31.0	399
Day 28	26	359.5	146.03	184	314.0	821	26	94.7	124.65	-97	70.0	518
Day 42	24	341.3	116.59	191	308.5	721	24	79.1	112.03	-82	65.0	418
EOT	29	389.3	135.55	204	347.0	758	29	115.8	114.30	-83	97.0	462
FU	28	365.8	108.40	209	352.0	612	28	92.6	97.21	-87	75.0	382
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	70	324.7	291.15	117	244.5	1913	-	-	-	-	-	-
Day 3	70	298.7	201.61	113	253.0	1492	70	-26.0	117.00	-904	-6.5	70
Day 7	68	329.1	284.75	126	254.0	2035	68	1.0	66.42	-227	0.5	195
Day 14	65	345.0	311.53	136	278.0	2240	65	14.0	116.12	-328	12.0	433
Day 28	61	334.5	334.63	100	267.0	2723	61	28.7	154.21	-317	15.0	916
Day 42	58	329.8	171.51	147	297.0	1167	58	19.6	143.50	-640	26.5	409
EOT	70	334.6	204.72	100	286.5	1626	70	9.9	173.56	-1091	19.5	409
FU	61	327.9	151.98	146	290.0	806	61	25.9	220.51	-1228	28.0	563

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	AST (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	23.7	10.19	9	20.0	54	-	-	-	-	-	-
Day 3	60	21.0	11.91	10	18.5	93	60	-2.7	12.23	-29	-2.5	79
Day 7	58	23.8	25.78	11	19.0	211	58	0.1	27.23	-29	-2.0	197
Day 14	57	24.3	19.45	12	19.0	139	57	1.1	19.43	-35	0.0	125
Day 28	53	23.1	9.62	11	21.0	60	53	0.4	11.32	-37	1.0	40
Day 42	51	33.5	36.54	10	23.0	252	51	10.5	37.65	-38	2.0	237
EOT	60	37.7	43.86	10	23.0	252	60	14.0	45.68	-38	1.0	237
FU	55	33.1	37.24	14	23.0	262	55	10.1	38.80	-33	1.0	247
Voriconazole (N = 30)												
Baseline	30	22.0	13.58	10	17.5	67	-	-	-	-	-	-
Day 3	30	18.7	8.36	10	16.0	43	30	-3.3	6.21	-25	-3.0	6
Day 7	30	25.3	17.47	13	18.5	81	30	3.3	17.23	-49	1.5	49
Day 14	28	62.2	136.07	9	24.0	723	28	39.6	135.95	-24	4.5	709
Day 28	27	33.7	27.94	11	19.0	98	27	10.9	22.87	-11	3.0	77
Day 42	25	28.8	21.65	12	22.0	112	25	5.6	21.29	-41	2.0	83
EOT	30	49.1	96.58	12	21.5	526	30	27.0	96.50	-33	1.5	512
FU	30	24.5	13.14	12	21.0	61	30	2.5	16.06	-45	1.0	46
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	24.2	11.92	8	20.0	82	-	-	-	-	-	-
Day 3	73	20.7	11.57	7	18.0	93	73	-3.5	12.12	-34	-3.0	79
Day 7	71	23.3	23.67	9	19.0	211	71	-0.9	25.62	-58	-2.0	197
Day 14	69	23.4	17.99	10	19.0	139	69	-0.4	19.76	-70	-1.0	125
Day 28	64	22.5	9.22	9	20.5	60	64	-0.9	13.49	-65	0.0	40
Day 42	61	33.6	36.31	10	23.0	252	61	9.8	38.46	-61	2.0	237
EOT	73	35.1	40.28	10	23.0	252	73	10.9	42.61	-58	1.0	237
FU	66	31.0	34.36	9	21.5	262	66	7.3	36.64	-56	1.0	247

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	BUN (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	5.09	1.776	1.4	4.64	8.9	-	-	-	-	-	-
Day 3	60	4.92	1.734	1.4	4.57	11.4	60	-0.17	1.478	-5.7	-0.02	3.6
Day 7	58	5.76	2.470	2.1	5.00	17.9	58	0.62	1.972	-4.6	0.71	10.0
Day 14	57	5.97	3.879	2.1	5.00	31.4	57	0.86	3.402	-3.9	0.64	23.6
Day 28	53	5.75	2.418	2.1	5.43	17.5	53	0.73	2.339	-4.6	0.43	13.2
Day 42	51	5.60	1.600	2.5	5.28	9.9	51	0.53	1.686	-5.0	0.57	3.6
EOT	60	6.16	4.016	3.0	5.37	31.4	60	1.06	3.753	-3.3	0.71	23.6
FU	55	4.99	1.463	2.5	4.82	9.2	55	-0.05	1.622	-4.6	0.29	4.2
Voriconazole (N = 30)												
Baseline	30	5.79	1.974	3.2	5.41	11.1	-	-	-	-	-	-
Day 3	30	5.85	1.631	2.9	5.71	9.9	30	0.06	1.192	-3.2	0.12	2.3
Day 7	30	5.57	1.718	2.5	5.36	9.3	30	-0.22	1.567	-3.0	-0.14	3.2
Day 14	28	5.52	2.036	1.4	5.27	12.4	28	-0.21	1.545	-3.2	0.18	2.6
Day 28	27	5.88	1.977	1.8	5.43	10.7	27	0.16	2.048	-3.2	0.21	4.9
Day 42	25	5.85	1.956	1.8	5.82	10.5	25	0.23	1.854	-2.3	0.14	4.0
EOT	30	5.81	1.936	1.8	5.80	11.1	30	0.02	1.768	-3.9	-0.09	4.0
FU	30	6.06	2.122	1.8	5.59	11.0	30	0.26	1.524	-2.9	0.00	4.8
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	5.20	1.856	1.4	4.64	10.0	-	-	-	-	-	-
Day 3	73	4.97	1.717	1.4	4.64	11.4	73	-0.23	1.521	-5.7	-0.07	3.6
Day 7	71	5.78	2.387	2.1	5.00	17.9	71	0.53	1.963	-4.6	0.57	10.0
Day 14	69	6.05	3.775	2.1	5.32	31.4	69	0.81	3.377	-5.0	0.57	23.6
Day 28	64	5.82	2.468	2.1	5.39	17.5	64	0.60	2.436	-5.0	0.36	13.2
Day 42	61	5.54	1.584	2.5	5.21	9.9	61	0.29	1.814	-5.7	0.46	3.6
EOT	73	6.07	3.703	3.0	5.50	31.4	73	0.87	3.488	-3.9	0.50	23.6
FU	66	5.17	1.557	2.5	4.96	9.2	66	-0.05	1.752	-5.7	0.25	4.2

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Calcium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	2.252	0.1505	1.88	2.250	2.68	-	-	-	-	-	-
Day 3	60	2.262	0.1283	1.88	2.275	2.58	60	0.010	0.0930	-0.23	0.004	0.28
Day 7	58	2.274	0.1405	1.73	2.275	2.53	58	0.019	0.0925	-0.20	0.025	0.23
Day 14	56	2.268	0.1234	1.98	2.275	2.58	56	0.010	0.0948	-0.23	0.025	0.18
Day 28	53	2.250	0.1145	2.00	2.250	2.50	53	-0.010	0.1053	-0.33	0.000	0.20
Day 42	51	2.270	0.1388	1.95	2.250	2.55	51	0.000	0.1056	-0.20	0.000	0.20
EOT	60	2.256	0.1293	1.98	2.250	2.58	60	0.005	0.1005	-0.25	0.025	0.28
FU	55	2.252	0.1330	2.05	2.250	2.53	55	-0.009	0.1049	-0.23	-0.025	0.20
Voriconazole (N = 30)												
Baseline	30	2.230	0.1147	1.95	2.225	2.50	-	-	-	-	-	-
Day 3	30	2.222	0.0980	1.98	2.225	2.48	30	-0.008	0.0826	-0.28	0.000	0.13
Day 7	30	2.204	0.1116	1.88	2.225	2.48	30	-0.026	0.1199	-0.35	0.000	0.23
Day 14	28	2.199	0.1177	1.98	2.175	2.53	28	-0.038	0.1146	-0.48	-0.025	0.10
Day 28	27	2.242	0.1312	1.98	2.225	2.58	27	0.001	0.1253	-0.28	0.025	0.30
Day 42	25	2.242	0.1101	2.03	2.250	2.55	25	-0.001	0.1147	-0.23	0.025	0.23
EOT	30	2.237	0.1172	1.93	2.250	2.50	30	0.007	0.1189	-0.28	0.013	0.23
FU	29	2.248	0.1048	2.03	2.225	2.53	29	0.014	0.1269	-0.20	0.000	0.40
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	2.253	0.1418	1.88	2.275	2.68	-	-	-	-	-	-
Day 3	73	2.256	0.1266	1.88	2.250	2.58	73	0.003	0.0950	-0.23	0.000	0.28
Day 7	71	2.271	0.1374	1.73	2.275	2.53	71	0.015	0.0973	-0.20	0.025	0.30
Day 14	68	2.266	0.1214	1.98	2.275	2.58	68	0.007	0.0926	-0.23	0.013	0.18
Day 28	63	2.255	0.1156	2.00	2.250	2.50	63	-0.003	0.1074	-0.33	0.000	0.25
Day 42	61	2.263	0.1353	1.95	2.250	2.55	61	-0.003	0.1014	-0.20	0.000	0.20
EOT	73	2.259	0.1225	1.98	2.250	2.58	73	0.006	0.0976	-0.25	0.025	0.28
FU	66	2.259	0.1285	2.05	2.250	2.53	66	-0.002	0.1094	-0.23	0.000	0.38

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Chloride (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	102.4	3.56	92	102.2	109	-	-	-	-	-	-
Day 3	60	102.0	3.45	93	102.0	109	60	-0.4	2.18	-6	-1.0	4
Day 7	58	101.6	3.98	88	102.0	109	58	-0.8	2.56	-8	-1.0	5
Day 14	57	101.4	4.22	89	103.0	109	57	-1.0	3.38	-12	-1.0	5
Day 28	53	102.4	4.26	84	103.0	110	53	-0.2	3.73	-19	0.0	7
Day 42	51	102.6	3.03	95	103.0	109	51	-0.2	3.10	-7	0.0	6
EOT	60	101.5	4.89	77	102.0	109	60	-0.9	3.79	-21	0.0	5
FU	55	103.2	2.91	96	103.0	109	55	0.5	2.79	-5	0.6	8
Voriconazole (N = 30)												
Baseline	30	102.7	3.63	92	103.0	111	-	-	-	-	-	-
Day 3	30	103.3	3.07	96	103.0	110	30	0.6	2.33	-3	0.0	7
Day 7	30	103.9	3.32	95	104.0	112	30	1.1	2.65	-4	1.0	9
Day 14	28	103.0	4.26	92	103.0	115	28	0.4	3.31	-6	0.0	9
Day 28	27	102.8	4.44	91	102.0	115	27	0.1	3.15	-6	0.0	8
Day 42	25	102.5	3.87	91	103.0	112	25	0.2	2.60	-5	1.0	8
EOT	30	104.3	3.71	96	104.0	112	30	1.5	3.61	-7	1.0	12
FU	30	104.6	2.94	98	105.0	110	30	1.9	3.71	-5	2.0	9
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	103.1	3.92	92	103.0	114	-	-	-	-	-	-
Day 3	73	102.6	4.02	93	102.7	118	73	-0.5	2.19	-6	-1.0	4
Day 7	71	102.4	4.39	88	103.0	113	71	-0.8	2.68	-8	-1.0	9
Day 14	69	102.2	4.53	89	103.0	113	69	-1.0	3.38	-12	-1.0	10
Day 28	64	102.8	4.14	84	103.0	110	64	-0.6	3.75	-19	-0.5	7
Day 42	61	103.0	3.17	95	103.0	110	61	-0.5	3.36	-12	0.0	6
EOT	73	102.2	4.99	77	103.0	112	73	-0.9	3.87	-21	-0.7	10
FU	66	103.6	3.02	96	103.9	111	66	0.1	2.92	-7	0.0	8

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Creatine kinase (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	63.6	46.67	5	50.5	242	-	-	-	-	-	-
Day 3	60	50.9	34.76	7	42.5	175	60	-12.8	18.82	-88	-9.5	23
Day 7	58	53.4	37.93	6	42.0	169	58	-11.8	26.28	-87	-12.0	109
Day 14	57	64.8	59.20	6	46.0	337	57	-1.1	58.40	-119	-6.0	328
Day 28	53	64.8	41.28	16	56.0	200	53	-2.6	29.29	-92	-1.0	132
Day 42	51	63.2	35.75	18	54.0	157	51	-5.9	26.64	-117	-1.0	37
EOT	60	69.4	65.65	12	50.0	378	60	5.8	69.29	-132	-2.0	330
FU	55	64.2	40.15	13	53.0	221	55	-2.8	32.73	-118	-3.0	140
Voriconazole (N = 30)												
Baseline	30	71.1	50.98	10	48.5	219	-	-	-	-	-	-
Day 3	30	70.4	64.10	13	49.5	355	30	-0.7	42.18	-106	0.5	136
Day 7	30	74.4	50.20	16	61.5	221	30	3.4	52.00	-106	-4.0	153
Day 14	28	1144.7	5449.76	28	80.0	28945	28	1071.7	5458.00	-86	7.0	28914
Day 28	27	90.7	86.08	22	63.0	382	27	16.1	73.41	-93	2.0	304
Day 42	25	77.6	48.06	23	60.0	227	25	0.6	31.98	-103	3.0	64
EOT	30	920.5	4631.95	16	60.0	25444	30	849.5	4639.43	-99	6.0	25413
FU	29	88.1	106.36	16	58.0	600	29	15.6	108.41	-108	2.0	558
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	64.3	44.76	5	53.0	242	-	-	-	-	-	-
Day 3	73	50.0	32.29	7	43.0	175	73	-14.2	20.89	-88	-10.0	23
Day 7	71	52.9	35.49	6	43.0	169	71	-12.7	26.81	-87	-12.0	109
Day 14	69	63.7	54.92	6	47.0	337	69	-2.8	53.65	-119	-6.0	328
Day 28	63	64.5	39.83	16	56.0	200	63	-3.1	27.91	-92	-1.0	132
Day 42	61	65.1	38.79	18	55.0	185	61	-3.9	30.85	-117	-1.0	128
EOT	73	69.5	62.56	12	52.0	378	73	5.2	65.22	-132	-2.0	330
FU	66	63.1	38.42	13	55.0	221	66	-3.6	30.92	-118	-2.5	140

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Direct Bilirubin (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	3.5	5.97	1	1.7	39	-	-	-	-	-	-
Day 3	58	2.5	1.53	0	1.7	11	58	0.0	1.17	-2	0.0	4
Day 7	57	3.9	12.02	1	1.7	92	57	0.3	7.59	-19	0.0	53
Day 14	54	4.8	20.93	0	1.7	156	54	1.7	15.93	-3	0.0	116
Day 28	51	2.0	1.09	0	1.7	7	51	-0.5	1.16	-3	0.0	3
Day 42	50	1.9	0.75	1	1.7	5	50	-0.5	1.19	-5	0.0	2
EOT	60	4.8	19.86	0	1.7	156	60	1.3	15.34	-19	0.0	116
FU	55	2.4	1.17	0	1.7	5	55	-0.1	1.09	-3	0.0	3
Voriconazole (N = 30)												
Baseline	30	3.2	4.37	1	1.9	26	-	-	-	-	-	-
Day 3	30	2.9	3.21	1	1.8	19	30	-0.3	1.60	-7	0.0	3
Day 7	30	2.1	1.33	1	1.7	9	30	-1.2	3.16	-17	0.0	1
Day 14	28	2.1	0.99	1	1.7	5	28	-0.4	0.88	-2	0.0	2
Day 28	27	1.9	0.91	0	1.7	3	27	-0.6	1.18	-3	0.0	2
Day 42	25	1.9	0.72	0	1.7	3	25	-0.6	1.01	-3	0.0	1
EOT	30	2.4	1.68	1	1.7	9	30	-0.9	3.31	-17	0.0	4
FU	29	2.1	1.01	0	1.7	5	29	-1.1	3.87	-21	0.0	2
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	3.3	5.47	1	1.7	39	-	-	-	-	-	-
Day 3	71	2.5	1.47	0	1.7	11	71	0.1	1.17	-2	0.0	4
Day 7	70	3.5	10.86	1	1.7	92	70	0.1	6.86	-19	0.0	53
Day 14	66	4.3	18.94	0	1.7	156	66	1.2	14.43	-5	0.0	116
Day 28	61	1.9	1.00	0	1.7	7	61	-0.5	1.30	-5	0.0	3
Day 42	60	1.9	0.69	1	1.7	5	60	-0.5	1.32	-5	0.0	2
EOT	73	4.3	18.02	0	1.7	156	73	1.0	13.92	-19	0.0	116
FU	66	2.3	1.10	0	1.7	5	66	-0.2	1.25	-5	0.0	3

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
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表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	GGT (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	64.2	94.96	9	27.5	458	-	-	-	-	-	-
Day 3	60	60.4	87.71	11	27.0	477	60	-3.8	18.91	-138	-1.0	19
Day 7	58	82.9	138.74	14	33.0	710	58	17.0	58.42	-39	3.8	316
Day 14	56	96.4	166.26	19	40.0	940	56	34.0	86.61	-54	12.0	559
Day 28	53	120.7	209.17	23	51.0	1255	53	65.1	144.80	-39	23.7	874
Day 42	51	130.5	136.98	22	70.0	575	51	81.8	108.28	-54	42.0	501
EOT	60	150.8	168.55	13	83.0	778	60	86.6	125.63	-195	46.5	519
FU	55	146.1	188.26	17	65.0	988	55	99.7	186.42	-221	32.0	969
Voriconazole (N = 30)												
Baseline	30	29.5	21.07	12	21.0	97	-	-	-	-	-	-
Day 3	30	29.2	21.17	10	21.0	106	30	-0.3	3.76	-12	0.0	9
Day 7	30	47.9	56.81	11	28.5	313	30	18.4	54.71	-6	4.0	294
Day 14	28	113.7	125.62	15	53.0	591	28	86.6	118.21	-6	23.5	515
Day 28	27	135.9	143.65	18	64.0	489	27	108.2	134.80	-2	46.0	455
Day 42	25	100.7	76.62	17	82.0	275	25	72.0	65.35	3	44.0	205
EOT	30	119.3	113.92	17	75.5	433	30	89.8	105.70	-1	28.5	374
FU	29	99.5	115.03	15	65.0	521	29	69.6	109.78	-20	32.0	501
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	61.9	88.07	9	28.0	458	-	-	-	-	-	-
Day 3	73	57.9	81.19	9	28.0	477	73	-4.0	17.36	-138	-1.0	19
Day 7	71	77.8	126.65	11	33.0	710	71	14.6	53.57	-39	3.0	316
Day 14	68	91.0	152.45	12	40.0	940	68	30.0	79.78	-54	12.0	559
Day 28	64	113.9	193.46	19	51.5	1255	64	58.4	134.27	-39	22.0	874
Day 42	61	125.4	131.06	20	72.0	575	61	75.3	103.60	-54	38.0	501
EOT	73	145.1	160.99	13	80.0	778	73	83.2	122.74	-195	43.0	519
FU	66	139.1	176.43	17	65.0	988	66	91.3	172.79	-221	32.0	969

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	LDH (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	176.6	61.85	89	169.0	474	-	-	-	-	-	-
Day 3	60	169.6	55.03	105	162.0	397	60	-7.0	40.02	-91	-10.5	230
Day 7	58	180.1	115.97	89	157.5	958	58	1.2	115.65	-115	-12.0	837
Day 14	56	181.5	103.80	106	165.0	871	56	7.7	104.49	-70	-6.5	750
Day 28	53	173.8	51.46	113	161.0	362	53	-0.2	36.16	-84	-7.0	145
Day 42	51	186.9	72.29	111	173.0	583	51	9.8	60.29	-79	0.0	366
EOT	60	201.5	115.46	103	169.0	871	60	25.0	114.21	-140	4.0	750
FU	55	177.3	44.97	98	172.0	345	55	4.0	39.63	-133	-2.0	128
Voriconazole (N = 30)												
Baseline	30	176.3	57.57	87	156.0	334	-	-	-	-	-	-
Day 3	30	168.3	50.02	63	163.0	320	30	-7.9	28.39	-106	-10.0	70
Day 7	30	174.7	51.38	110	160.5	321	30	-1.6	26.59	-49	-1.0	79
Day 14	28	211.3	120.71	59	184.0	747	28	31.5	118.53	-77	9.5	609
Day 28	27	194.1	62.24	121	189.0	355	27	12.7	32.50	-69	11.0	97
Day 42	25	193.2	57.61	122	180.0	337	25	13.0	33.66	-40	6.0	105
EOT	30	210.4	103.21	114	182.5	666	30	34.1	100.33	-75	16.5	528
FU	30	180.6	44.07	112	172.5	299	30	4.3	30.85	-73	10.5	70
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	184.6	66.70	89	171.0	474	-	-	-	-	-	-
Day 3	73	173.3	56.56	105	163.0	397	73	-11.3	39.77	-98	-13.0	230
Day 7	71	181.1	108.04	89	158.0	958	71	-5.6	106.58	-161	-17.0	837
Day 14	68	184.2	96.78	106	167.5	871	68	0.8	97.00	-106	-7.5	750
Day 28	64	176.9	50.76	113	164.5	362	64	-4.4	36.16	-84	-7.0	145
Day 42	61	191.6	71.14	111	175.0	583	61	8.1	60.35	-146	-1.0	366
EOT	73	202.6	107.24	103	175.0	871	73	18.0	106.33	-140	2.0	750
FU	66	180.5	45.06	98	176.0	345	66	0.0	40.87	-133	-2.5	128

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Potassium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	4.24	0.435	2.8	4.25	5.3	-	-	-	-	-	-
Day 3	60	4.46	0.525	2.8	4.40	5.9	60	0.22	0.346	-0.5	0.20	1.2
Day 7	59	4.41	0.503	2.5	4.40	5.6	59	0.16	0.446	-0.9	0.20	1.0
Day 14	57	4.40	0.484	3.8	4.30	7.1	57	0.13	0.658	-1.2	0.20	3.7
Day 28	53	4.43	0.480	2.9	4.40	5.9	53	0.16	0.444	-1.1	0.10	1.3
Day 42	51	4.45	0.408	3.6	4.40	5.7	51	0.16	0.386	-1.0	0.20	0.9
EOT	60	4.41	0.603	2.9	4.34	7.1	60	0.17	0.676	-1.1	0.10	3.7
FU	55	4.21	0.345	3.5	4.20	5.3	55	-0.07	0.428	-1.0	-0.10	1.3
Voriconazole (N = 30)												
Baseline	30	4.15	0.468	3.2	4.10	5.6	-	-	-	-	-	-
Day 3	30	4.08	0.387	3.2	4.10	5.1	30	-0.08	0.351	-1.1	-0.10	0.7
Day 7	30	4.17	0.406	2.9	4.20	4.8	30	0.02	0.421	-1.1	0.00	1.1
Day 14	28	4.28	0.513	3.6	4.15	6.0	28	0.10	0.559	-1.4	0.10	1.6
Day 28	27	4.21	0.353	3.4	4.30	4.8	27	0.03	0.473	-0.9	0.00	1.3
Day 42	25	4.26	0.320	3.8	4.20	5.0	25	0.07	0.441	-1.0	0.10	1.1
EOT	30	4.28	0.322	3.5	4.30	4.9	30	0.13	0.536	-1.3	0.10	1.4
FU	30	4.18	0.345	3.5	4.20	5.0	30	0.02	0.519	-1.3	0.00	1.8
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	4.22	0.448	2.8	4.20	5.3	-	-	-	-	-	-
Day 3	73	4.42	0.510	2.8	4.40	5.9	73	0.20	0.398	-1.0	0.20	1.2
Day 7	72	4.38	0.517	2.5	4.35	5.6	72	0.15	0.497	-1.5	0.20	1.5
Day 14	69	4.38	0.511	3.6	4.30	7.1	69	0.14	0.654	-1.2	0.20	3.7
Day 28	64	4.41	0.560	2.9	4.40	6.2	64	0.18	0.551	-1.1	0.15	2.7
Day 42	61	4.39	0.459	2.5	4.40	5.7	61	0.16	0.425	-1.4	0.20	0.9
EOT	73	4.44	0.605	2.9	4.40	7.1	73	0.21	0.662	-1.1	0.20	3.7
FU	66	4.22	0.395	3.3	4.20	5.3	66	-0.02	0.446	-1.0	0.00	1.3

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Creatinine (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	66.5	17.98	42	64.5	156	-	-	-	-	-	-
Day 3	60	73.5	20.61	45	71.2	165	60	7.0	6.92	-11	7.1	27
Day 7	58	76.0	21.11	42	73.4	160	58	9.0	9.62	-9	8.8	40
Day 14	57	77.1	35.89	42	70.7	301	57	10.1	30.98	-6	4.4	234
Day 28	53	73.3	21.91	40	69.8	169	53	7.0	11.89	-9	4.4	75
Day 42	51	71.5	19.40	44	70.7	159	51	4.7	8.88	-11	2.7	46
EOT	60	76.5	36.40	39	69.8	301	60	10.0	32.15	-17	4.0	234
FU	55	70.4	19.19	41	67.2	150	55	3.4	8.25	-14	3.5	29
Voriconazole (N = 30)												
Baseline	30	73.9	28.30	42	67.6	190	-	-	-	-	-	-
Day 3	30	79.4	26.54	44	72.9	175	30	5.6	8.05	-15	4.9	20
Day 7	30	78.6	28.99	39	71.2	190	30	4.7	8.04	-16	5.3	22
Day 14	28	76.6	32.27	44	69.8	213	28	4.3	7.06	-11	4.9	23
Day 28	27	75.3	32.57	40	68.1	208	27	3.7	9.01	-21	4.4	23
Day 42	25	76.1	35.67	38	69.0	228	25	5.6	10.60	-11	3.5	38
EOT	30	77.1	32.54	42	71.2	230	30	3.2	10.39	-16	3.1	40
FU	30	74.3	26.12	40	71.2	180	30	0.4	8.44	-15	0.0	15
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	66.6	16.95	42	64.5	156	-	-	-	-	-	-
Day 3	73	73.8	19.28	45	70.7	165	73	7.2	7.08	-11	7.1	27
Day 7	71	75.8	19.94	42	73.4	160	71	8.7	10.10	-9	8.8	40
Day 14	69	76.7	33.52	42	70.7	301	69	9.7	29.03	-18	5.3	234
Day 28	64	73.3	21.02	40	70.3	169	64	6.9	11.39	-9	4.9	75
Day 42	61	71.2	18.30	44	70.7	159	61	4.3	8.62	-11	2.7	46
EOT	73	75.5	33.38	39	70.7	301	73	8.9	29.49	-18	4.4	234
FU	66	71.3	18.46	41	69.8	150	66	4.3	9.51	-15	4.0	36

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Sodium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	138.6	3.14	129	138.0	145	-	-	-	-	-	-
Day 3	60	138.4	3.29	130	139.0	146	60	-0.2	2.16	-5	0.0	3
Day 7	58	138.2	3.61	127	139.0	144	58	-0.5	2.82	-8	-1.0	5
Day 14	57	137.3	4.56	124	139.0	144	57	-1.2	3.43	-13	-1.0	5
Day 28	53	138.4	4.65	116	139.0	145	53	-0.3	4.06	-24	0.0	6
Day 42	51	138.9	3.08	130	139.0	144	51	0.1	2.28	-6	0.0	4
EOT	60	138.3	4.81	111	139.0	145	60	-0.3	3.92	-24	0.0	5
FU	55	139.7	2.84	131	140.0	145	55	0.9	2.62	-7	1.0	8
Voriconazole (N = 30)												
Baseline	30	138.6	3.78	127	139.0	144	-	-	-	-	-	-
Day 3	30	139.3	2.88	132	140.0	144	30	0.7	2.16	-3	0.5	6
Day 7	30	139.6	2.98	130	140.0	144	30	1.1	2.84	-4	1.0	8
Day 14	28	138.9	3.57	126	139.5	144	28	0.2	2.58	-4	0.0	6
Day 28	27	138.3	3.85	125	138.0	143	27	-0.5	2.80	-6	-1.0	5
Day 42	25	138.1	3.68	126	140.0	142	25	-0.5	2.94	-8	-1.0	6
EOT	30	139.6	3.62	130	140.0	150	30	1.1	3.66	-8	1.0	8
FU	30	139.8	2.86	131	140.0	144	30	1.2	3.84	-7	1.0	9
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	139.1	3.35	129	139.0	147	-	-	-	-	-	-
Day 3	73	138.9	3.50	130	139.0	147	73	-0.3	2.17	-5	0.0	4
Day 7	71	138.7	3.74	127	140.0	146	71	-0.6	2.71	-8	-1.0	5
Day 14	69	138.1	4.63	124	139.0	149	69	-1.1	3.59	-13	-1.0	13
Day 28	64	138.8	4.45	116	139.0	145	64	-0.6	4.07	-24	-0.5	6
Day 42	61	139.1	2.98	130	140.0	144	61	-0.3	2.45	-8	0.0	4
EOT	73	138.9	4.82	111	139.0	149	73	-0.3	4.03	-24	0.0	13
FU	66	140.0	2.83	131	140.7	145	66	0.6	2.71	-7	1.0	8

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Total Bilirubin (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	10.9	9.75	2	8.6	58	-	-	-	-	-	-
Day 3	60	11.3	11.93	2	9.3	89	60	0.4	5.92	-15	0.0	32
Day 7	58	10.4	15.40	3	8.0	121	58	-0.6	10.07	-31	-1.0	65
Day 14	56	10.2	22.06	3	6.8	171	56	-0.1	15.93	-10	-1.7	115
Day 28	53	7.1	2.47	3	6.8	15	53	-2.3	3.74	-12	-1.7	4
Day 42	51	6.8	2.55	3	6.2	14	51	-2.5	3.64	-12	-1.7	5
EOT	60	10.6	21.42	3	7.4	171	60	-0.3	16.06	-31	-1.2	115
FU	55	8.7	3.73	5	7.2	24	55	-0.5	3.66	-12	0.0	10
Voriconazole (N = 30)												
Baseline	30	9.7	6.54	3	8.6	39	-	-	-	-	-	-
Day 3	30	9.4	5.44	3	8.3	29	30	-0.3	3.53	-10	0.0	9
Day 7	30	6.6	2.47	3	5.8	12	30	-3.1	5.45	-29	-2.6	2
Day 14	28	6.8	2.98	3	6.3	15	28	-1.8	2.82	-10	-1.7	5
Day 28	27	6.6	2.58	2	6.2	14	27	-2.1	2.90	-12	-1.7	3
Day 42	25	6.6	2.52	3	6.0	14	25	-1.9	2.29	-9	-1.7	2
EOT	30	7.1	3.15	3	6.1	15	30	-2.6	5.99	-29	-1.7	5
FU	30	7.7	4.33	3	6.8	26	30	-2.0	6.07	-29	-1.7	10
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	11.1	9.43	2	8.6	58	-	-	-	-	-	-
Day 3	73	11.3	10.96	2	9.6	89	73	0.2	5.83	-15	0.0	32
Day 7	71	10.1	14.02	3	7.9	121	71	-1.1	9.46	-31	-1.7	65
Day 14	68	9.9	20.03	3	6.8	171	68	-0.8	14.80	-24	-1.7	115
Day 28	64	7.4	2.68	3	6.8	15	64	-2.5	4.38	-22	-1.7	4
Day 42	61	6.9	2.61	3	6.5	14	61	-2.9	4.64	-24	-1.7	5
EOT	73	10.3	19.43	3	8.2	171	73	-0.8	14.84	-31	-1.4	115
FU	66	8.8	3.57	5	8.1	24	66	-0.9	4.48	-21	0.0	10

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-100 生化学検査値の経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Urate (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	310.5	114.95	107	318.2	577	-	-	-	-	-	-
Day 3	60	348.4	111.09	131	348.0	559	60	37.9	51.64	-208	41.6	155
Day 7	57	333.3	106.35	143	315.3	559	57	15.2	51.48	-220	17.8	143
Day 14	57	322.8	103.17	107	309.3	577	57	5.0	60.88	-268	0.0	208
Day 28	53	327.9	105.13	152	309.3	571	53	7.0	64.97	-143	5.9	149
Day 42	51	322.0	97.35	95	309.3	565	51	0.1	67.06	-226	0.0	202
EOT	60	320.0	98.09	95	312.3	580	60	9.4	72.18	-214	3.0	208
FU	55	307.2	89.02	134	297.4	541	55	-15.6	68.18	-238	-17.8	149
Voriconazole (N = 30)												
Baseline	30	275.4	88.26	83	258.8	452	-	-	-	-	-	-
Day 3	30	306.9	91.84	101	294.5	518	30	31.5	32.96	-36	35.7	119
Day 7	30	294.5	88.59	71	291.5	440	30	19.0	54.19	-71	20.8	202
Day 14	28	267.7	89.50	42	258.8	464	28	-7.0	30.98	-59	-8.9	59
Day 28	27	273.4	68.23	167	273.6	416	27	-3.5	49.75	-89	-11.9	101
Day 42	25	281.5	67.64	155	273.6	399	25	2.6	57.42	-83	-5.9	149
EOT	30	290.7	61.00	184	279.6	422	30	15.3	61.77	-83	3.0	202
FU	29	298.5	79.49	173	297.4	547	29	21.5	80.68	-89	11.9	327
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	305.1	113.81	107	303.4	577	-	-	-	-	-	-
Day 3	73	341.0	108.59	131	333.1	559	73	35.9	52.07	-208	35.7	155
Day 7	70	325.4	110.01	95	315.3	559	70	14.4	51.91	-220	17.8	143
Day 14	69	317.5	103.64	107	309.3	577	69	4.3	60.91	-268	0.0	208
Day 28	64	319.2	106.30	125	300.4	571	64	3.2	61.81	-143	0.0	149
Day 42	61	313.2	96.57	95	309.3	565	61	-3.4	63.91	-226	0.0	202
EOT	73	313.5	98.80	95	309.3	580	73	8.4	71.51	-214	0.0	208
FU	66	305.0	86.76	134	297.4	541	66	-12.7	66.35	-238	-14.9	149

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_2.sas
Program Run: 25JUN21:16:45:06

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Basophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	140	0.015	0.0343	0.00	0.000	0.24	-	-	-	-	-	-
Day 7	153	0.029	0.1457	0.00	0.010	1.76	101	0.024	0.1789	-0.16	0.000	1.76
Day 14	87	0.013	0.0237	0.00	0.000	0.16	57	-0.001	0.0408	-0.18	0.000	0.16
Day 28	75	0.033	0.1322	0.00	0.010	1.13	43	0.007	0.0577	-0.18	0.000	0.22
Day 42	115	0.023	0.0795	0.00	0.010	0.84	68	0.008	0.1135	-0.24	0.000	0.84
EOT	206	0.023	0.0883	0.00	0.010	1.13	125	0.005	0.0637	-0.24	0.000	0.45
FU	95	0.021	0.0341	0.00	0.010	0.25	51	-0.001	0.0457	-0.23	0.000	0.07
Voriconazole (N = 259)												
Baseline	142	0.016	0.0579	0.00	0.000	0.65	-	-	-	-	-	-
Day 7	155	0.030	0.1897	0.00	0.000	2.35	109	0.019	0.1665	-0.12	0.000	1.70
Day 14	82	0.016	0.0293	0.00	0.010	0.17	45	-0.010	0.1003	-0.62	0.000	0.13
Day 28	79	0.011	0.0144	0.00	0.010	0.06	43	-0.020	0.1027	-0.65	0.000	0.05
Day 42	102	0.015	0.0214	0.00	0.010	0.10	60	0.005	0.0299	-0.12	0.000	0.10
EOT	209	0.013	0.0263	0.00	0.010	0.21	126	-0.002	0.0694	-0.65	0.000	0.18
FU	105	0.018	0.0218	0.00	0.010	0.12	69	0.007	0.0296	-0.11	0.010	0.10
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	244	0.016	0.0302	0.00	0.010	0.24	-	-	-	-	-	-
Day 7	264	0.027	0.1126	0.00	0.010	1.76	190	0.016	0.1325	-0.16	0.000	1.76
Day 14	203	0.020	0.0432	0.00	0.010	0.51	146	0.003	0.0530	-0.18	0.000	0.50
Day 28	169	0.028	0.0915	0.00	0.010	1.13	116	0.005	0.0481	-0.18	0.000	0.25
Day 42	210	0.022	0.0637	0.00	0.010	0.84	139	0.005	0.0861	-0.24	0.000	0.84
Day 84	79	0.018	0.0193	0.00	0.020	0.10	62	-0.006	0.0240	-0.07	-0.010	0.07
Day 112	60	0.018	0.0190	0.00	0.015	0.11	47	-0.005	0.0240	-0.07	0.000	0.08
Day 140	57	0.019	0.0248	0.00	0.010	0.17	47	-0.004	0.0260	-0.07	0.000	0.08
Day 168	48	0.024	0.0474	0.00	0.020	0.32	40	0.003	0.0581	-0.06	0.000	0.31
Day 180	46	0.020	0.0111	0.00	0.020	0.05	37	-0.007	0.0240	-0.06	0.000	0.04
EOT	336	0.020	0.0699	0.00	0.010	1.13	222	0.001	0.0502	-0.24	0.000	0.45
FU	175	0.024	0.0432	0.00	0.020	0.45	107	0.001	0.0356	-0.23	0.000	0.09

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Eosinophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	140	0.100	0.4507	0.00	0.000	4.52	-	-	-	-	-	-
Day 7	153	0.092	0.3655	0.00	0.000	3.21	101	0.000	0.1872	-1.31	0.000	1.15
Day 14	87	0.051	0.1097	0.00	0.010	0.57	57	0.032	0.1210	-0.10	0.000	0.57
Day 28	75	0.136	0.3339	0.00	0.030	1.87	43	0.095	0.3137	-0.22	0.010	1.87
Day 42	115	0.106	0.2145	0.00	0.030	1.27	68	-0.064	0.4618	-3.38	0.010	0.40
EOT	206	0.081	0.2016	0.00	0.010	1.87	125	-0.015	0.4376	-3.87	0.000	1.87
FU	95	0.100	0.2036	0.00	0.020	1.18	51	-0.038	0.5199	-3.57	0.010	0.65
Voriconazole (N = 259)												
Baseline	142	0.053	0.1508	0.00	0.000	0.95	-	-	-	-	-	-
Day 7	155	0.068	0.1900	0.00	0.000	1.37	109	0.016	0.0912	-0.33	0.000	0.59
Day 14	83	0.057	0.1494	0.00	0.010	1.02	45	0.016	0.0880	-0.22	0.010	0.44
Day 28	79	0.087	0.1676	0.00	0.020	1.02	43	0.053	0.1330	-0.26	0.020	0.54
Day 42	102	0.109	0.2144	0.00	0.030	1.13	60	0.045	0.1341	-0.22	0.015	0.84
EOT	210	0.099	0.2415	0.00	0.020	2.38	126	0.060	0.2382	-0.22	0.010	2.34
FU	105	0.099	0.2026	0.00	0.040	1.69	69	0.066	0.2486	-0.62	0.010	1.65
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	244	0.126	0.3783	0.00	0.020	4.52	-	-	-	-	-	-
Day 7	264	0.126	0.3255	0.00	0.010	3.21	190	0.010	0.2036	-1.31	0.000	1.15
Day 14	203	0.108	0.1645	0.00	0.030	0.99	146	0.013	0.1712	-1.00	0.000	0.57
Day 28	169	0.178	0.3302	0.00	0.070	2.11	116	0.093	0.3045	-0.77	0.025	1.87
Day 42	210	0.138	0.2672	0.00	0.055	2.62	139	-0.020	0.4071	-3.38	0.010	2.25
Day 84	79	0.151	0.2116	0.00	0.070	1.13	62	-0.005	0.2754	-1.22	0.010	0.86
Day 112	60	0.173	0.1965	0.00	0.100	0.97	47	-0.015	0.3174	-1.04	0.000	0.87
Day 140	57	0.172	0.2200	0.00	0.070	1.04	47	-0.022	0.3377	-1.12	0.000	0.94
Day 168	48	0.151	0.1620	0.01	0.095	0.81	40	-0.027	0.2760	-1.11	0.015	0.44
Day 180	46	0.187	0.2105	0.00	0.105	1.05	37	0.017	0.2982	-1.19	0.010	0.95
EOT	336	0.104	0.2063	0.00	0.020	1.87	222	-0.014	0.3780	-3.87	0.000	1.87
FU	175	0.138	0.2218	0.00	0.050	1.18	107	-0.030	0.4050	-3.57	0.010	0.65

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Erythrocytes (10^12/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	208	3.02	0.667	1.6	2.90	6.0	-	-	-	-	-	-
Day 7	198	3.16	0.633	1.4	3.10	6.1	168	0.14	0.536	-2.9	0.10	1.5
Day 14	104	3.11	0.648	1.5	3.10	5.7	85	0.15	0.522	-1.5	0.20	1.2
Day 28	83	3.26	0.724	1.4	3.20	6.2	71	0.31	0.615	-1.0	0.20	2.8
Day 42	130	3.36	0.765	1.9	3.30	6.7	111	0.26	0.645	-1.3	0.30	1.7
EOT	233	3.23	0.666	1.4	3.10	5.5	192	0.20	0.616	-1.6	0.10	2.8
FU	110	3.31	0.704	2.1	3.20	6.1	87	0.27	0.661	-1.9	0.20	2.2
Voriconazole (N = 259)												
Baseline	212	3.06	0.586	1.8	3.00	5.3	-	-	-	-	-	-
Day 7	201	3.23	0.537	2.1	3.20	5.0	169	0.16	0.421	-0.9	0.20	1.9
Day 14	102	3.13	0.559	1.8	3.10	4.8	88	0.14	0.504	-1.1	0.20	1.5
Day 28	90	3.24	0.600	1.6	3.25	4.9	71	0.24	0.609	-1.1	0.30	1.7
Day 42	135	3.33	0.588	1.9	3.30	4.9	113	0.23	0.552	-2.1	0.30	1.6
EOT	235	3.24	0.612	1.7	3.20	5.6	194	0.19	0.571	-1.7	0.20	1.8
FU	117	3.35	0.718	1.6	3.20	5.1	101	0.28	0.677	-1.1	0.30	2.2
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	336	3.17	0.743	1.3	3.00	6.0	-	-	-	-	-	-
Day 7	325	3.25	0.700	1.4	3.10	6.1	281	0.07	0.496	-2.9	0.10	1.5
Day 14	227	3.31	0.757	1.5	3.20	6.0	193	0.09	0.485	-1.5	0.10	1.2
Day 28	185	3.42	0.783	1.4	3.30	6.2	163	0.20	0.513	-1.0	0.10	2.8
Day 42	229	3.49	0.798	1.9	3.40	6.7	199	0.24	0.572	-1.3	0.30	1.7
Day 84	84	3.65	0.805	2.0	3.65	6.2	74	0.11	0.553	-0.7	0.00	1.9
Day 112	65	3.73	0.831	1.9	3.60	5.2	57	0.18	0.596	-1.2	0.20	1.9
Day 140	61	3.70	0.773	2.2	3.70	5.4	54	0.14	0.521	-0.9	0.00	1.5
Day 168	50	3.88	0.728	2.2	4.05	5.4	46	0.24	0.586	-1.0	0.15	1.8
Day 180	48	3.93	0.778	1.6	4.10	5.3	44	0.18	0.550	-1.0	0.10	1.9
EOT	370	3.33	0.723	1.4	3.20	5.5	311	0.16	0.576	-1.6	0.10	2.8
FU	195	3.49	0.779	2.0	3.40	6.1	160	0.22	0.635	-2.0	0.20	2.2

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Hemoglobin (g/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	207	92.9	18.20	50	90.0	159	-	-	-	-	-	-
Day 7	198	96.9	17.34	45	94.0	165	167	3.7	16.35	-86	3.0	43
Day 14	104	95.3	17.20	46	97.0	133	85	4.4	16.20	-45	6.0	35
Day 28	83	101.0	18.75	47	104.0	165	71	10.4	19.03	-31	8.0	82
Day 42	130	104.7	21.07	56	105.0	149	111	9.6	20.27	-43	9.0	59
EOT	233	101.5	20.44	47	99.0	165	191	8.3	20.11	-47	6.0	82
FU	110	104.3	20.57	62	103.0	159	87	10.6	21.74	-58	9.0	77
Voriconazole (N = 259)												
Baseline	212	94.2	16.92	54	93.0	149	-	-	-	-	-	-
Day 7	200	98.8	15.75	64	98.0	149	168	4.4	12.71	-31	5.0	58
Day 14	102	97.1	17.02	51	96.0	148	88	4.0	14.83	-25	4.0	41
Day 28	88	101.8	19.56	42	103.5	148	69	9.1	18.49	-32	11.0	51
Day 42	135	103.8	17.78	62	103.0	152	113	8.6	17.39	-56	8.0	56
EOT	234	101.3	19.32	42	100.0	156	193	7.6	17.91	-41	8.0	68
FU	117	107.2	21.49	61	105.0	175	101	12.4	20.30	-31	13.0	62
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	334	96.6	20.19	35	92.0	161	-	-	-	-	-	-
Day 7	325	98.7	19.28	45	95.0	171	279	1.9	14.99	-86	2.0	43
Day 14	226	100.4	20.46	46	98.5	181	191	2.8	14.63	-45	3.0	35
Day 28	185	104.7	20.73	47	106.0	173	163	6.9	15.56	-31	4.0	82
Day 42	229	107.5	21.72	56	108.0	179	199	8.8	17.34	-43	8.0	59
Day 84	84	113.1	21.93	56	114.5	160	74	6.7	15.79	-22	4.0	49
Day 112	65	117.2	24.75	52	120.0	188	57	10.5	17.73	-25	10.0	51
Day 140	61	118.1	22.40	71	118.0	181	54	10.3	14.09	-13	7.5	49
Day 168	50	122.3	22.47	67	124.5	175	46	13.9	16.02	-19	11.5	54
Day 180	48	124.8	24.49	48	127.0	175	44	12.6	16.99	-26	9.5	55
EOT	370	104.2	21.77	47	101.5	175	309	7.6	18.82	-47	6.0	82
FU	195	109.3	22.74	60	108.0	178	160	10.5	20.27	-58	7.0	77

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Leukocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	202	4.11	8.165	0.2	1.15	87.1	-	-	-	-	-	-
Day 7	196	5.50	10.741	0.1	2.90	114.7	162	1.57	9.455	-15.2	0.20	110.8
Day 14	102	4.55	7.265	0.1	3.55	69.5	81	0.55	3.840	-17.9	0.10	8.9
Day 28	83	6.49	12.505	0.1	4.20	112.6	69	3.00	14.091	-11.2	1.30	112.3
Day 42	129	5.59	7.526	0.3	4.60	63.8	106	1.65	7.151	-10.7	0.40	54.3
EOT	233	5.53	10.822	0.1	3.70	112.6	187	1.34	9.715	-15.2	0.10	112.3
FU	109	6.05	7.367	0.1	4.10	59.0	83	2.15	6.497	-14.5	1.40	33.1
Voriconazole (N = 259)												
Baseline	208	4.10	7.895	0.1	1.40	88.2	-	-	-	-	-	-
Day 7	200	5.85	10.864	0.1	3.30	111.1	165	1.69	9.721	-17.0	0.40	110.2
Day 14	100	4.86	6.530	0.2	3.15	40.9	83	1.34	11.897	-81.1	1.00	37.2
Day 28	90	7.17	14.785	0.2	4.30	136.8	69	2.81	19.500	-74.4	1.50	135.2
Day 42	134	5.27	6.193	0.2	4.10	43.3	110	0.97	10.210	-79.1	0.80	41.7
EOT	234	5.25	6.453	0.2	3.60	43.3	190	1.32	9.556	-86.3	0.55	41.7
FU	117	5.19	4.569	0.2	4.50	32.2	99	1.97	6.094	-18.3	1.80	30.9
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	325	5.12	7.352	0.2	3.00	87.1	-	-	-	-	-	-
Day 7	323	5.79	8.911	0.1	4.30	114.7	270	0.71	7.568	-15.2	0.10	110.8
Day 14	223	5.46	5.850	0.1	4.90	69.5	183	-0.19	3.527	-17.9	0.00	8.9
Day 28	184	6.64	9.108	0.1	5.45	112.6	156	1.23	9.915	-11.2	0.00	112.3
Day 42	227	6.00	6.310	0.3	5.10	63.8	189	0.65	5.978	-10.7	0.00	54.3
Day 84	82	5.95	2.975	0.3	5.60	15.8	69	-1.02	3.460	-9.1	-0.80	13.0
Day 112	64	7.39	10.805	0.3	6.10	88.6	52	-0.42	8.845	-8.7	-0.95	57.5
Day 140	58	7.89	12.844	1.9	5.70	102.0	49	0.03	10.864	-8.7	-1.10	70.9
Day 168	48	6.56	2.832	2.2	6.20	16.2	41	-1.73	3.505	-9.1	-1.50	6.3
Day 180	47	6.37	2.436	1.3	6.20	11.4	40	-1.80	3.401	-9.7	-1.10	6.1
EOT	370	5.87	10.174	0.1	4.60	112.6	301	0.77	9.080	-19.1	0.00	112.3
FU	193	6.14	5.854	0.1	5.30	59.0	151	0.93	5.703	-18.1	0.10	33.1

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Lymphocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	140	1.519	7.0083	0.00	0.495	69.60	-	-	-	-	-	-
Day 7	153	1.538	6.1596	0.01	0.590	63.30	101	0.045	0.8293	-6.30	0.110	1.45
Day 14	87	1.043	1.3291	0.02	0.640	8.09	57	0.366	1.0487	-1.14	0.120	6.40
Day 28	75	1.734	4.7610	0.03	1.110	41.70	43	0.459	0.9241	-1.37	0.200	2.80
Day 42	115	1.514	4.0975	0.07	0.950	44.30	68	0.304	0.8033	-2.30	0.245	2.76
EOT	206	1.681	6.0602	0.01	0.645	63.30	125	0.192	1.0902	-6.30	0.140	5.35
FU	95	1.593	5.2359	0.00	0.870	51.40	51	0.271	1.0060	-2.51	0.200	4.80
Voriconazole (N = 259)												
Baseline	142	1.435	6.9687	0.01	0.530	82.80	-	-	-	-	-	-
Day 7	155	1.555	5.6970	0.04	0.690	68.20	109	0.171	1.9221	-14.60	0.120	12.07
Day 14	82	0.968	1.0563	0.00	0.725	5.85	45	-1.463	11.5325	-76.95	0.320	1.55
Day 28	79	2.814	15.0252	0.00	0.830	134.00	43	1.934	23.0827	-70.00	0.400	132.67
Day 42	102	1.553	4.2060	0.00	0.980	42.40	60	-0.289	11.1711	-75.02	0.255	41.07
EOT	209	1.326	3.1713	0.00	0.800	42.40	126	-0.052	8.3184	-82.71	0.185	41.07
FU	105	1.126	0.8151	0.02	0.920	4.51	69	0.521	0.9632	-2.01	0.370	3.95
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	244	1.524	5.5849	0.00	0.680	69.60	-	-	-	-	-	-
Day 7	264	1.535	4.9303	0.01	0.785	63.30	190	0.037	0.7796	-6.30	0.075	2.13
Day 14	203	1.294	1.7615	0.01	0.900	20.50	146	0.151	1.0203	-6.60	0.115	6.40
Day 28	169	1.755	3.6219	0.03	1.170	41.70	116	0.294	1.0771	-5.80	0.115	4.47
Day 42	210	1.643	3.6486	0.07	1.165	44.30	139	0.238	1.0412	-2.30	0.130	8.68
Day 84	79	1.433	0.8916	0.09	1.270	4.26	62	-0.012	0.7749	-2.68	-0.085	2.18
Day 112	60	2.795	9.1048	0.09	1.665	71.80	47	1.040	6.5627	-1.96	0.000	44.70
Day 140	57	3.168	11.9884	0.15	1.590	91.80	47	1.406	9.4646	-2.38	-0.060	64.70
Day 168	48	1.625	0.9837	0.18	1.485	4.58	40	0.044	1.0076	-2.31	-0.095	2.99
Day 180	46	1.730	0.8321	0.36	1.565	4.77	37	-0.061	0.8686	-2.44	-0.200	1.88
EOT	336	1.796	6.8601	0.01	0.840	91.80	222	0.413	4.4397	-6.30	0.060	64.70
FU	175	1.547	3.8840	0.00	1.080	51.40	107	0.160	0.8417	-2.51	0.160	4.80

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Monocytes (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	140	0.255	0.3232	0.00	0.090	1.53	-	-	-	-	-	-
Day 7	153	0.395	0.4963	0.00	0.250	3.69	101	0.125	0.3903	-1.37	0.030	1.31
Day 14	87	0.844	5.1990	0.00	0.180	48.70	57	0.012	0.3800	-1.42	0.000	0.96
Day 28	75	0.375	0.2940	0.00	0.330	1.14	43	0.114	0.4322	-1.04	0.060	1.05
Day 42	115	0.395	0.3808	0.00	0.300	2.55	68	0.100	0.3940	-1.03	0.040	1.51
EOT	206	0.570	3.3925	0.00	0.245	48.70	125	0.035	0.3681	-1.49	0.000	1.31
FU	95	0.464	0.6508	0.00	0.340	5.71	51	0.056	0.4859	-1.06	0.080	1.26
Voriconazole (N = 259)												
Baseline	142	0.413	0.6471	0.00	0.230	4.50	-	-	-	-	-	-
Day 7	155	0.510	0.6364	0.00	0.340	4.76	109	0.141	0.5275	-1.80	0.080	1.99
Day 14	82	0.667	1.9266	0.00	0.295	16.80	45	0.088	0.7868	-2.58	0.070	1.61
Day 28	79	0.466	0.4819	0.00	0.380	3.22	43	0.022	0.8933	-3.21	0.040	1.74
Day 42	102	0.463	0.4356	0.00	0.375	2.85	60	0.036	0.6295	-3.11	0.055	1.07
EOT	209	0.558	1.2732	0.00	0.320	16.80	126	0.065	0.6161	-3.10	0.040	1.99
FU	105	0.416	0.4031	0.00	0.350	2.82	69	0.123	0.5331	-1.89	0.090	1.80
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	244	0.319	0.3344	0.00	0.230	1.53	-	-	-	-	-	-
Day 7	264	0.404	0.4369	0.00	0.285	3.69	190	0.074	0.3549	-1.37	0.010	1.31
Day 14	203	0.618	3.4163	0.00	0.310	48.70	146	0.026	0.4219	-1.42	0.000	2.69
Day 28	169	0.443	0.4338	0.00	0.360	3.38	116	0.116	0.4843	-1.04	0.025	2.76
Day 42	210	0.399	0.3485	0.00	0.310	2.55	139	0.034	0.3914	-1.19	0.030	1.51
Day 84	79	0.402	0.2417	0.02	0.370	1.07	62	-0.025	0.2622	-0.58	-0.005	0.58
Day 112	60	0.434	0.4844	0.00	0.325	3.54	47	0.025	0.5586	-0.99	-0.010	2.92
Day 140	57	0.477	0.4375	0.03	0.380	3.06	47	0.052	0.5401	-0.85	-0.030	2.44
Day 168	48	0.382	0.2092	0.01	0.360	0.90	40	-0.042	0.3279	-1.01	-0.035	0.70
Day 180	46	0.440	0.2957	0.10	0.380	1.35	37	0.003	0.3556	-0.90	0.010	0.89
EOT	336	0.507	2.6671	0.00	0.270	48.70	222	0.032	0.4312	-1.49	0.000	2.44
FU	175	0.461	0.5356	0.00	0.350	5.71	107	0.054	0.4902	-1.35	0.040	2.73

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Neutrophils (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	140	3.336	4.2829	0.00	1.525	25.02	-	-	-	-	-	-
Day 7	153	3.805	3.9766	0.00	2.640	21.53	101	0.649	3.5535	-10.57	0.080	18.58
Day 14	87	3.155	2.8677	0.00	2.810	13.21	57	-0.165	3.7573	-18.81	-0.020	8.11
Day 28	75	3.668	3.0478	0.03	2.830	14.58	43	-0.033	3.7802	-11.72	-0.080	8.98
Day 42	115	3.364	2.8503	0.00	3.080	15.65	68	-0.102	3.9803	-9.69	-0.105	14.85
EOT	206	3.033	3.0907	0.00	2.480	17.81	125	-0.216	3.9515	-15.61	-0.050	14.85
FU	95	3.961	3.7002	0.00	3.450	22.81	51	0.235	4.0666	-14.24	0.130	11.77
Voriconazole (N = 259)												
Baseline	142	3.304	4.8208	0.01	1.480	29.53	-	-	-	-	-	-
Day 7	155	4.030	5.0744	0.00	2.510	31.27	109	0.511	4.8135	-16.48	0.390	28.84
Day 14	82	3.537	4.6600	0.00	2.155	27.40	45	0.923	4.4734	-11.21	0.660	17.22
Day 28	79	4.254	4.8436	0.01	2.950	28.04	43	1.125	5.7874	-15.98	0.310	15.63
Day 42	102	3.881	4.3978	0.00	2.760	33.91	60	0.318	4.8825	-12.81	0.395	24.61
EOT	209	3.608	4.5413	0.00	2.260	30.55	126	0.173	5.1719	-17.00	0.095	28.84
FU	105	3.724	3.5561	0.00	3.220	25.12	69	0.816	5.8165	-18.21	0.980	24.42
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	244	4.301	4.2276	0.00	3.595	25.02	-	-	-	-	-	-
Day 7	264	4.217	3.8015	0.00	3.525	21.53	190	-0.010	3.1317	-10.57	-0.020	18.58
Day 14	203	3.782	2.8349	0.00	3.490	15.38	146	-0.758	3.2937	-18.81	-0.380	8.11
Day 28	169	4.096	3.1970	0.03	3.220	18.29	116	-0.621	3.6070	-11.72	-0.590	15.99
Day 42	210	3.671	2.7256	0.00	3.200	15.65	139	-0.782	3.4697	-9.69	-0.830	14.85
Day 84	79	4.131	2.5276	0.25	3.650	14.30	62	-1.302	2.9880	-7.09	-1.085	12.75
Day 112	60	4.232	2.7821	0.14	3.845	13.85	47	-1.672	3.3286	-8.73	-1.410	8.14
Day 140	57	4.091	2.0216	1.05	3.700	10.41	47	-1.671	2.7966	-8.05	-1.570	4.65
Day 168	48	4.353	2.3804	1.13	3.925	13.13	40	-1.882	2.7375	-8.31	-1.360	5.04
Day 180	46	4.016	2.0157	0.56	3.340	8.00	37	-1.922	2.6447	-8.63	-0.920	1.43
EOT	336	3.465	2.9953	0.00	2.945	17.81	222	-0.671	3.7595	-17.20	-0.240	14.85
FU	175	4.146	3.1347	0.00	3.660	22.81	107	-0.600	3.8059	-16.04	-0.410	11.77

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
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表 8-101 血液一般検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Platelet (10^9/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	187	93.5	119.40	2	42.0	664	-	-	-	-	-	-
Day 7	176	126.9	166.65	4	45.5	1065	137	32.4	102.00	-149	7.0	715
Day 14	92	138.5	153.48	3	61.0	562	66	47.1	129.69	-230	6.5	504
Day 28	77	162.0	155.29	5	124.0	789	58	56.7	121.00	-235	29.5	488
Day 42	118	147.4	124.91	5	120.0	487	89	38.8	106.68	-332	25.0	347
EOT	226	122.9	136.06	3	68.0	789	169	32.4	105.12	-354	11.0	446
FU	99	137.0	118.26	6	106.0	566	72	36.8	92.27	-290	36.0	351
Voriconazole (N = 259)												
Baseline	188	88.6	116.85	3	37.5	640	-	-	-	-	-	-
Day 7	181	146.7	191.41	3	68.0	984	141	61.1	164.89	-184	15.0	872
Day 14	97	135.9	158.96	6	83.0	933	72	65.2	166.14	-430	20.0	909
Day 28	86	167.8	146.23	3	128.0	692	60	96.4	169.35	-232	34.5	668
Day 42	130	148.3	128.41	5	122.5	617	99	44.0	96.27	-263	29.0	271
EOT	227	140.3	148.32	3	92.0	947	170	50.1	136.77	-430	14.5	939
FU	109	142.6	99.02	8	126.0	414	84	49.6	93.42	-230	37.0	289
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	305	134.9	152.30	2	61.0	828	-	-	-	-	-	-
Day 7	291	164.3	182.11	4	90.0	1065	233	22.9	92.11	-329	5.0	715
Day 14	207	185.9	171.59	3	151.0	998	161	18.2	111.74	-442	4.0	504
Day 28	171	195.7	156.83	4	164.0	789	136	31.5	117.80	-534	14.0	488
Day 42	215	185.5	152.53	5	157.0	1057	169	20.9	114.34	-537	16.0	483
Day 84	82	221.9	153.76	5	209.5	1046	65	-25.2	126.85	-526	-12.0	362
Day 112	60	222.8	139.44	5	221.0	648	48	-19.0	148.02	-529	-10.5	555
Day 140	58	207.7	100.51	3	211.5	481	46	-42.8	131.38	-442	1.5	190
Day 168	49	236.8	104.49	15	245.0	635	40	-45.3	147.94	-469	-46.0	251
Day 180	45	245.3	114.34	5	235.0	664	37	-34.3	114.94	-351	-12.0	233
EOT	361	150.1	149.53	3	111.0	1046	276	16.3	112.63	-524	4.0	555
FU	182	187.0	147.45	6	161.5	945	137	21.1	115.71	-349	17.0	468

EOT: end of treatment, FU: follow up.

Program Name: t_lb_bl_1.sas
Program Run: 11JUN21:14:57:53

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	ALT (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	239	37.1	34.65	4	25.0	211	-	-	-	-	-	-
Day 7	224	40.7	40.77	4	28.5	247	211	4.3	37.41	-132	1.0	167
Day 14	107	36.6	32.11	5	28.0	210	97	7.5	34.69	-88	1.0	164
Day 28	85	29.1	19.10	4	25.0	104	78	1.3	19.15	-45	-1.0	68
Day 42	139	33.6	29.89	5	26.0	217	130	-1.5	41.19	-171	1.0	196
EOT	248	36.1	36.09	4	24.0	232	232	-0.4	42.57	-164	-0.5	196
FU	114	38.6	42.38	3	25.0	322	103	-0.7	49.67	-175	0.0	226
Voriconazole (N = 259)												
Baseline	237	37.5	45.74	3	23.0	442	-	-	-	-	-	-
Day 7	223	41.5	85.82	3	24.0	1122	206	5.2	93.75	-329	-1.0	1107
Day 14	109	40.3	52.49	4	22.0	312	97	7.8	58.82	-130	2.0	266
Day 28	95	41.9	70.75	2	21.0	610	89	11.3	72.14	-98	2.0	575
Day 42	138	32.4	45.56	4	23.0	490	127	-3.8	55.00	-191	-3.0	453
EOT	254	48.0	95.36	2	22.0	1122	233	10.1	102.17	-329	-1.0	1107
FU	118	32.6	27.75	1	24.0	157	107	-3.7	47.63	-182	1.0	125
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	372	35.0	34.16	4	23.5	244	-	-	-	-	-	-
Day 7	358	35.7	42.38	4	24.5	476	334	1.0	41.38	-132	-1.0	443
Day 14	232	32.8	33.92	4	23.0	270	211	1.1	34.78	-148	0.0	164
Day 28	192	30.9	32.28	4	21.0	284	175	-1.0	35.58	-143	-2.0	274
Day 42	237	32.5	32.58	5	24.0	217	219	-1.7	41.88	-171	1.0	207
Day 84	86	29.6	36.73	5	17.5	262	81	-6.8	46.41	-232	0.0	153
Day 112	70	30.2	31.21	7	19.5	171	67	-6.3	46.85	-228	0.0	137
Day 140	60	24.3	14.62	6	21.5	91	56	-12.5	44.01	-225	-1.0	86
Day 168	50	22.7	15.86	4	18.5	95	47	-8.1	33.74	-122	2.0	90
Day 180	50	21.3	13.44	6	17.5	81	46	-15.9	45.90	-232	-3.5	67
EOT	387	33.9	41.90	4	22.0	476	358	-1.3	48.52	-232	-1.0	443
FU	199	34.2	38.28	3	23.0	322	181	-3.0	46.69	-221	0.0	226

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Albumin (g/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	95	31.8	5.82	14	33.0	44	-	-	-	-	-	-
Day 7	93	32.2	6.26	19	32.0	45	85	-0.1	4.45	-12	0.0	11
Day 14	77	34.8	6.16	20	35.0	45	70	1.9	5.25	-15	2.0	11
Day 28	67	37.1	6.41	21	38.0	49	61	4.4	6.60	-16	6.0	20
Day 42	57	38.8	6.32	22	40.0	49	52	6.3	7.17	-10	7.0	21
EOT	100	34.4	8.33	13	35.0	51	92	2.4	8.05	-16	2.0	22
FU	64	37.5	6.84	22	38.0	49	58	4.9	7.87	-10	6.0	20
Voriconazole (N = 259)												
Baseline	99	31.0	5.59	18	31.0	44	-	-	-	-	-	-
Day 7	95	31.5	6.69	18	32.0	49	86	0.2	4.31	-11	-1.0	12
Day 14	77	33.9	7.17	20	34.0	48	70	2.0	4.93	-8	2.5	14
Day 28	63	37.4	7.67	16	38.0	51	58	5.2	6.13	-9	5.0	19
Day 42	58	37.3	6.94	18	38.0	50	52	5.0	5.77	-9	5.5	16
EOT	109	34.3	8.28	16	33.0	52	99	3.0	6.74	-16	2.0	19
FU	63	37.0	7.46	16	39.0	49	56	4.5	7.37	-23	5.5	16
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	225	32.5	6.55	14	33.0	48	-	-	-	-	-	-
Day 7	224	33.1	7.06	10	33.0	50	206	0.1	4.51	-22	1.0	12
Day 14	201	35.5	7.19	18	36.0	50	186	2.1	5.07	-17	2.0	17
Day 28	175	37.8	6.65	18	39.0	51	160	4.1	5.98	-21	4.0	21
Day 42	157	38.8	6.54	15	40.0	49	144	5.2	6.00	-10	4.5	21
Day 84	86	39.6	6.45	18	41.0	49	82	4.8	6.08	-12	4.0	23
Day 112	70	40.5	6.22	21	42.0	50	68	5.7	7.07	-11	5.5	23
Day 140	62	41.2	4.81	22	42.0	51	59	6.2	6.13	-7	7.0	20
Day 168	50	42.0	5.35	26	42.5	50	48	6.6	6.19	-6	6.0	19
Day 180	50	42.7	4.99	27	44.0	51	47	6.9	6.28	-4	7.0	18
EOT	234	35.9	8.89	10	38.0	51	216	3.1	7.94	-22	2.0	22
FU	149	39.1	6.62	19	41.0	49	137	5.4	7.45	-13	6.0	22

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	ALP (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	240	116.1	91.25	25	90.0	751	-	-	-	-	-	-
Day 7	225	130.0	91.98	37	100.0	519	213	11.8	66.54	-284	7.0	336
Day 14	110	140.4	125.06	41	113.0	1153	100	29.6	122.04	-132	8.5	1063
Day 28	88	117.6	69.49	47	97.5	419	82	15.9	68.18	-166	6.0	329
Day 42	141	126.1	158.22	35	96.0	1694	132	16.1	161.88	-418	3.0	1480
EOT	248	134.7	186.93	35	95.0	2125	233	19.8	167.24	-445	3.0	1911
FU	115	132.4	93.56	40	102.0	530	105	23.9	90.05	-206	5.0	389
Voriconazole (N = 259)												
Baseline	241	120.3	85.15	11	95.0	513	-	-	-	-	-	-
Day 7	225	142.6	114.95	33	110.0	1073	209	24.5	86.07	-179	10.0	606
Day 14	109	170.8	123.74	31	128.0	835	100	44.3	104.38	-239	25.0	416
Day 28	96	198.0	229.11	42	129.0	1883	91	72.8	210.02	-212	24.0	1576
Day 42	138	126.4	82.51	39	99.5	538	128	13.1	81.80	-273	11.0	317
EOT	254	162.3	169.91	21	111.0	1883	237	43.4	153.25	-287	14.0	1576
FU	120	134.4	130.63	36	94.0	919	110	24.1	121.80	-307	14.5	820
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	375	120.4	89.03	23	95.0	751	-	-	-	-	-	-
Day 7	360	131.2	95.07	18	100.0	858	338	10.6	64.97	-284	4.0	336
Day 14	237	133.8	111.15	22	108.0	1153	218	15.3	96.81	-244	4.5	1063
Day 28	196	122.6	82.59	16	101.0	595	181	7.2	76.19	-280	3.0	329
Day 42	241	124.2	133.83	18	96.0	1694	224	6.0	138.75	-461	1.0	1480
Day 84	87	118.9	117.79	32	92.0	975	83	-12.5	128.39	-518	-12.0	682
Day 112	70	121.7	104.69	33	97.0	706	68	-1.8	114.75	-315	-4.5	558
Day 140	61	115.2	109.06	41	93.0	840	58	-8.4	124.76	-304	-5.5	692
Day 168	49	90.1	45.18	30	80.0	246	47	-31.0	80.47	-321	-16.0	131
Day 180	50	94.5	54.50	34	85.0	351	47	-32.3	79.14	-305	-15.0	125
EOT	387	134.8	165.95	18	97.0	2125	361	13.2	149.62	-518	3.0	1911
FU	200	129.8	123.06	38	96.5	1414	184	10.8	132.03	-529	-1.5	1247

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	AST (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	239	27.3	23.80	5	21.0	175	-	-	-	-	-	-
Day 7	223	28.9	22.57	6	22.0	189	210	2.0	25.52	-126	1.0	142
Day 14	105	30.8	37.01	5	22.0	346	95	7.8	42.93	-156	3.0	337
Day 28	84	25.6	22.21	5	22.0	204	77	1.7	31.16	-139	3.0	188
Day 42	139	27.6	40.23	5	21.0	472	130	1.9	45.90	-149	2.0	447
EOT	247	30.7	38.63	4	22.0	472	231	4.2	42.98	-156	2.0	447
FU	114	32.5	33.83	11	22.0	291	103	3.8	32.22	-154	2.0	112
Voriconazole (N = 259)												
Baseline	236	29.1	30.69	4	21.0	287	-	-	-	-	-	-
Day 7	223	53.8	274.58	5	25.0	4081	205	26.5	287.73	-240	4.0	4057
Day 14	109	44.1	52.12	9	26.0	318	97	15.6	57.92	-237	7.0	294
Day 28	95	39.9	41.29	5	26.0	233	89	15.7	41.53	-76	5.0	217
Day 42	137	49.1	226.29	7	22.0	2656	125	20.8	235.93	-232	4.0	2616
EOT	254	70.4	307.16	5	24.0	4081	232	43.5	321.87	-240	5.0	4057
FU	117	30.9	26.72	7	22.0	167	105	1.1	35.70	-232	1.0	133
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	372	26.9	22.92	5	21.0	175	-	-	-	-	-	-
Day 7	357	30.0	66.36	5	21.0	1220	333	3.5	70.24	-126	0.0	1203
Day 14	230	27.2	27.84	4	21.5	346	209	2.0	33.53	-156	1.0	337
Day 28	191	26.1	22.49	5	21.0	204	174	-0.2	31.16	-139	1.0	188
Day 42	236	26.8	34.07	5	20.0	472	218	1.0	38.65	-149	1.0	447
Day 84	86	24.2	14.51	10	19.0	94	81	-4.1	28.40	-148	0.0	77
Day 112	70	25.4	16.47	8	19.0	83	67	-3.2	27.51	-144	0.0	54
Day 140	59	22.4	10.06	9	20.0	63	56	-7.4	30.32	-143	-0.5	45
Day 168	50	21.1	10.76	6	18.0	61	47	-2.9	19.19	-64	1.0	48
Day 180	50	21.1	10.23	8	18.5	67	46	-9.2	27.00	-149	-1.5	28
EOT	386	32.2	69.55	4	22.0	1220	357	5.7	74.51	-156	1.0	1203
FU	199	29.5	29.04	7	21.0	291	181	0.5	30.99	-154	1.0	112

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	BUN (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	241	5.49	3.437	1.1	5.00	39.6	-	-	-	-	-	-
Day 7	226	5.78	3.370	1.1	5.00	26.4	214	0.45	2.988	-11.1	0.35	15.7
Day 14	110	5.81	2.527	1.4	5.36	14.3	101	0.46	3.120	-10.7	0.71	10.4
Day 28	88	5.82	2.642	2.1	5.18	13.9	82	0.66	3.414	-10.7	0.36	8.6
Day 42	141	5.83	2.884	1.4	5.36	18.2	132	0.53	2.885	-10.4	0.36	8.9
EOT	248	6.50	4.685	1.1	5.36	46.1	234	1.09	3.861	-10.7	0.71	35.3
FU	115	6.57	4.185	1.4	5.71	28.6	106	1.06	4.684	-13.6	0.71	24.3
Voriconazole (N = 259)												
Baseline	241	5.71	3.365	1.1	5.00	26.4	-	-	-	-	-	-
Day 7	226	5.63	3.815	1.1	4.64	24.3	210	0.05	3.093	-11.1	-0.35	15.0
Day 14	109	5.86	3.438	0.7	5.36	25.0	100	0.36	3.163	-7.9	0.36	15.7
Day 28	96	6.33	3.968	1.1	5.36	25.7	91	0.66	3.665	-10.7	0.36	15.7
Day 42	138	5.63	2.746	1.4	5.00	21.1	128	0.58	3.135	-13.2	0.36	11.8
EOT	254	6.55	4.180	1.1	5.36	26.4	237	0.97	4.047	-13.6	0.71	25.4
FU	120	6.21	3.529	0.4	5.36	24.3	110	0.96	3.874	-10.4	0.71	21.8
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	376	6.73	5.082	1.1	5.36	43.9	-	-	-	-	-	-
Day 7	362	6.87	5.679	1.1	5.36	63.2	339	0.12	3.619	-20.3	0.00	15.7
Day 14	238	6.88	4.926	1.4	5.36	38.6	220	-0.27	4.880	-30.3	0.00	21.1
Day 28	196	6.83	5.355	1.4	5.36	52.1	181	0.21	5.789	-28.9	0.00	41.8
Day 42	242	6.54	4.751	1.4	5.36	52.8	225	0.36	4.695	-16.4	0.36	40.7
Day 84	87	6.73	4.040	0.7	5.71	24.3	83	-0.84	4.784	-19.3	0.00	11.4
Day 112	70	6.66	3.755	1.8	5.54	23.6	68	-0.42	4.972	-19.6	-0.18	15.0
Day 140	62	6.15	3.200	1.4	5.36	20.4	59	-0.88	4.450	-17.1	-0.36	11.8
Day 168	50	6.60	3.692	1.8	5.36	18.2	48	-0.43	4.567	-19.6	0.36	8.9
Day 180	50	5.86	3.184	1.4	4.64	20.4	47	-0.25	3.830	-9.6	0.36	11.8
EOT	387	7.44	6.526	1.1	5.71	63.2	362	0.75	5.739	-28.9	0.54	41.8
FU	200	6.61	4.060	1.4	5.71	28.6	185	0.24	4.769	-16.1	0.36	24.3

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Calcium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	241	2.073	0.1726	1.60	2.075	2.60	-	-	-	-	-	-
Day 7	226	2.128	0.2136	1.08	2.125	2.78	214	0.051	0.1727	-0.90	0.050	0.53
Day 14	110	2.167	0.1981	1.15	2.175	2.50	101	0.094	0.1557	-0.45	0.100	0.43
Day 28	88	2.251	0.1644	1.88	2.275	2.55	82	0.158	0.1608	-0.18	0.163	0.48
Day 42	141	2.269	0.1532	1.70	2.275	2.68	132	0.162	0.1866	-0.35	0.175	0.55
EOT	248	2.168	0.2143	1.08	2.200	2.55	234	0.097	0.2002	-0.90	0.088	0.65
FU	115	2.229	0.1843	1.58	2.275	2.65	106	0.128	0.2113	-0.35	0.150	0.65
Voriconazole (N = 259)												
Baseline	241	2.070	0.1855	1.40	2.075	2.98	-	-	-	-	-	-
Day 7	226	2.080	0.2019	1.20	2.088	2.65	210	0.000	0.1662	-0.60	0.000	0.63
Day 14	109	2.113	0.2223	1.45	2.125	2.58	100	0.044	0.2095	-0.50	0.050	0.98
Day 28	96	2.197	0.2161	1.43	2.250	2.60	91	0.126	0.2253	-0.48	0.125	0.88
Day 42	138	2.240	0.1739	1.53	2.250	2.58	128	0.144	0.2061	-0.45	0.125	0.90
EOT	254	2.145	0.2357	1.00	2.175	2.58	237	0.075	0.2266	-0.93	0.050	0.70
FU	120	2.219	0.2257	1.20	2.275	2.68	110	0.118	0.2570	-0.93	0.150	0.58
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	375	2.111	0.1862	1.60	2.125	2.75	-	-	-	-	-	-
Day 7	362	2.153	0.2088	1.08	2.150	2.78	338	0.036	0.1735	-0.90	0.050	0.68
Day 14	238	2.199	0.2092	1.15	2.225	2.78	219	0.064	0.1732	-0.60	0.075	0.68
Day 28	196	2.264	0.1602	1.88	2.275	2.60	180	0.115	0.1683	-0.35	0.100	0.48
Day 42	242	2.278	0.1533	1.70	2.300	2.68	224	0.128	0.1888	-0.45	0.125	0.70
Day 84	87	2.273	0.1855	1.73	2.300	2.70	82	0.050	0.2213	-0.75	0.050	0.83
Day 112	70	2.288	0.1616	1.78	2.313	2.63	67	0.065	0.2069	-0.60	0.100	0.53
Day 140	62	2.281	0.1793	1.38	2.300	2.58	58	0.053	0.2194	-0.80	0.075	0.48
Day 168	49	2.250	0.2036	1.45	2.275	2.60	46	0.015	0.2374	-0.73	0.025	0.58
Day 180	50	2.288	0.1444	2.00	2.325	2.53	46	0.036	0.1729	-0.53	0.050	0.40
EOT	387	2.185	0.2107	1.08	2.225	2.65	361	0.076	0.2005	-0.90	0.075	0.83
FU	200	2.244	0.1775	1.58	2.275	2.65	184	0.097	0.2138	-0.50	0.100	0.75

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Chloride (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	239	102.0	5.18	82	102.0	127	-	-	-	-	-	-
Day 7	226	102.7	5.15	88	103.0	130	213	0.5	5.07	-10	0.0	29
Day 14	110	102.3	5.59	85	102.0	122	101	0.5	6.54	-20	0.0	21
Day 28	87	102.5	4.55	91	102.0	118	81	1.3	5.35	-12	1.0	19
Day 42	141	102.6	4.54	87	103.0	111	131	0.9	5.56	-16	1.0	14
EOT	248	103.4	5.44	85	103.0	130	233	1.4	6.35	-18	1.0	29
FU	115	102.9	4.32	88	103.0	116	105	0.8	5.29	-13	1.0	12
Voriconazole (N = 259)												
Baseline	240	102.3	5.02	86	102.0	120	-	-	-	-	-	-
Day 7	225	103.2	5.13	82	104.0	120	209	0.7	4.92	-17	1.0	14
Day 14	110	103.7	4.72	89	104.0	119	100	1.1	5.40	-13	1.0	17
Day 28	96	103.8	4.19	94	104.0	115	91	1.2	5.30	-15	1.0	13
Day 42	139	102.9	4.31	86	104.0	114	129	0.2	5.03	-18	0.0	12
EOT	254	103.3	5.52	85	104.0	133	236	1.0	5.39	-17	1.0	26
FU	120	103.3	4.82	90	103.0	120	110	0.7	5.98	-13	0.5	20
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	373	102.1	5.01	82	102.0	127	-	-	-	-	-	-
Day 7	362	102.9	5.10	88	103.0	130	338	0.8	4.92	-10	0.0	29
Day 14	238	102.3	5.41	85	102.0	139	219	0.4	6.22	-20	0.0	38
Day 28	195	102.3	4.29	90	102.0	118	180	0.7	4.98	-15	1.0	19
Day 42	242	102.5	4.41	87	103.0	115	224	0.7	5.22	-16	1.0	16
Day 84	87	103.2	3.72	93	104.0	113	83	1.4	4.77	-9	1.0	16
Day 112	70	102.5	3.96	90	103.0	112	68	1.0	4.78	-10	1.0	14
Day 140	62	103.0	3.48	93	103.0	109	59	1.3	4.35	-8	1.0	10
Day 168	50	102.5	3.95	89	103.0	113	48	1.2	4.66	-12	1.0	10
Day 180	50	102.9	4.00	90	103.0	115	47	1.7	4.01	-6	2.0	11
EOT	387	103.3	5.45	85	103.0	139	360	1.3	6.42	-18	1.0	38
FU	200	103.1	4.02	88	103.0	116	183	1.3	5.24	-13	1.0	24

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Creatine kinase (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	240	38.6	41.80	5	26.0	308	-	-	-	-	-	-
Day 7	224	46.2	108.90	2	22.0	1408	212	8.7	110.92	-150	-2.0	1382
Day 14	110	33.6	45.74	6	21.0	428	100	-1.1	49.79	-153	-0.5	380
Day 28	86	30.7	27.64	7	22.5	161	80	-2.4	29.08	-108	-1.0	115
Day 42	140	36.4	37.85	5	26.0	303	131	-2.5	41.61	-237	2.0	215
EOT	248	44.6	60.66	5	28.0	591	233	7.1	62.64	-237	1.0	538
FU	115	39.7	37.59	4	26.0	219	105	3.2	44.12	-130	2.0	159
Voriconazole (N = 259)												
Baseline	239	41.3	37.94	4	29.0	197	-	-	-	-	-	-
Day 7	224	46.0	48.56	4	31.0	359	207	4.6	45.97	-162	2.0	265
Day 14	109	40.9	39.48	7	31.0	275	98	0.9	49.83	-174	3.0	205
Day 28	95	44.7	42.47	6	33.0	290	89	3.8	54.22	-174	2.0	231
Day 42	138	62.6	275.58	6	30.0	3258	127	22.7	290.10	-176	1.0	3235
EOT	254	97.2	581.18	4	34.0	8702	235	61.1	595.30	-173	4.0	8505
FU	119	47.0	65.92	2	29.0	654	108	5.6	75.36	-168	0.0	632
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	374	46.7	75.57	3	27.0	1040	-	-	-	-	-	-
Day 7	357	46.1	92.00	2	24.0	1408	334	2.6	100.94	-472	0.0	1382
Day 14	235	38.7	42.72	4	26.0	428	215	-5.0	56.50	-261	0.0	380
Day 28	193	48.8	120.77	3	27.0	1615	177	3.8	129.82	-283	1.0	1603
Day 42	240	42.2	42.41	5	28.5	310	222	0.1	52.26	-296	2.0	301
Day 84	86	53.1	44.89	7	38.5	253	81	3.2	67.79	-306	10.0	228
Day 112	70	56.2	45.68	7	41.5	275	67	8.4	60.44	-264	7.0	203
Day 140	61	60.8	45.57	5	48.0	230	57	11.9	63.97	-261	12.0	199
Day 168	50	70.2	52.43	7	59.5	260	47	21.4	58.80	-201	17.0	216
Day 180	50	68.6	58.57	8	61.5	398	46	15.7	42.02	-196	18.0	90
EOT	387	56.8	120.59	4	33.0	1615	360	13.5	131.35	-472	3.0	1603
FU	200	59.4	82.92	4	34.0	744	184	13.0	92.19	-505	6.5	692

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Direct Bilirubin (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	234	5.8	7.43	0	3.4	43	-	-	-	-	-	-
Day 7	220	5.7	8.79	0	3.4	53	203	-0.2	5.17	-22	0.0	31
Day 14	104	6.2	10.30	0	3.4	67	90	1.2	9.07	-17	0.0	53
Day 28	84	6.2	31.29	2	1.7	289	75	1.8	33.17	-29	0.0	282
Day 42	137	3.0	4.44	0	1.7	44	125	-1.7	6.56	-31	-1.7	39
EOT	247	7.4	22.49	0	1.7	289	226	1.3	20.51	-31	0.0	282
FU	111	5.0	14.62	0	1.7	147	98	-0.4	16.56	-29	-0.9	140
Voriconazole (N = 259)												
Baseline	227	5.6	6.57	0	3.4	55	-	-	-	-	-	-
Day 7	220	6.3	14.62	0	3.4	142	195	1.0	11.30	-19	0.0	113
Day 14	105	5.2	7.37	0	3.4	46	87	0.0	5.70	-12	0.0	34
Day 28	90	5.4	12.04	0	1.7	108	78	1.1	12.39	-21	0.0	99
Day 42	135	3.6	5.08	0	1.7	36	120	-0.9	5.09	-22	0.0	31
EOT	253	8.0	20.71	0	3.4	221	222	2.9	19.46	-26	0.0	210
FU	116	5.3	15.22	0	1.7	137	101	1.0	17.42	-44	0.0	133
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	363	5.5	6.97	0	3.4	43	-	-	-	-	-	-
Day 7	350	5.6	9.45	0	1.7	84	319	0.1	5.97	-22	0.0	67
Day 14	226	5.1	9.20	0	1.7	67	199	0.6	7.47	-17	0.0	53
Day 28	184	5.9	26.04	2	1.7	289	163	1.9	26.91	-29	0.0	282
Day 42	231	2.8	3.65	0	1.7	44	208	-1.4	5.50	-31	0.0	39
Day 84	85	2.3	1.25	0	1.7	7	78	-1.3	4.00	-27	0.0	5
Day 112	67	3.1	5.11	2	1.7	39	62	-0.5	6.03	-27	0.0	29
Day 140	59	2.1	1.73	2	1.7	14	53	-0.8	2.55	-12	0.0	9
Day 168	48	1.9	0.76	2	1.7	5	44	-1.2	4.36	-27	0.0	3
Day 180	49	1.8	0.41	2	1.7	3	44	-0.9	2.17	-12	0.0	2
EOT	386	7.0	21.20	0	1.7	289	349	1.5	19.55	-31	0.0	282
FU	196	3.9	11.22	0	1.7	147	174	-1.0	12.91	-31	0.0	140

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
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表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	GGT (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	242	116.0	167.90	7	68.0	1813	-	-	-	-	-	-
Day 7	225	139.9	182.38	4	78.0	1375	215	17.2	106.63	-438	4.0	607
Day 14	110	141.2	156.77	7	79.0	830	102	39.9	131.44	-195	12.0	714
Day 28	87	120.2	106.21	8	80.0	505	81	32.4	98.01	-172	16.0	429
Day 42	141	121.9	132.80	12	78.0	776	132	19.7	162.70	-1028	10.0	557
EOT	249	144.6	279.67	16	76.0	3915	235	29.5	198.81	-1028	7.0	2102
FU	115	159.6	169.57	11	69.0	759	107	56.0	199.22	-1000	8.0	671
Voriconazole (N = 259)												
Baseline	242	127.9	200.79	9	70.0	2004	-	-	-	-	-	-
Day 7	225	183.5	222.77	13	96.0	1587	210	61.8	153.20	-321	14.5	1039
Day 14	110	244.7	295.93	18	141.0	1791	101	113.6	217.91	-300	42.0	1226
Day 28	95	348.2	623.92	20	128.0	4591	90	195.7	528.13	-356	38.5	4392
Day 42	139	168.1	210.57	12	94.0	1316	129	64.5	176.96	-410	22.0	1015
EOT	254	260.5	452.65	7	110.5	4591	238	132.2	390.28	-391	26.5	4392
FU	120	161.7	312.87	15	68.5	2587	110	36.1	180.61	-330	5.5	1038
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	377	120.3	152.25	7	71.0	1813	-	-	-	-	-	-
Day 7	361	137.7	171.81	4	79.0	1375	340	15.9	109.67	-438	3.0	607
Day 14	237	140.8	168.99	7	81.0	1382	220	27.9	142.99	-517	9.0	988
Day 28	194	146.1	179.66	8	84.5	1182	179	34.7	161.03	-586	17.0	846
Day 42	242	133.1	176.56	12	80.0	1715	225	20.2	169.78	-1028	11.0	968
Day 84	87	159.6	306.01	14	80.0	1950	83	36.9	299.40	-598	9.0	1710
Day 112	70	175.0	343.50	16	79.5	1616	68	53.7	329.27	-609	17.0	1534
Day 140	61	140.9	293.33	11	75.0	2248	58	24.5	299.29	-614	10.0	1915
Day 168	50	93.6	86.49	16	62.0	390	48	-13.1	147.61	-607	3.5	208
Day 180	50	89.3	84.52	17	58.5	436	47	-27.4	144.20	-606	2.0	254
EOT	388	164.2	371.16	12	79.0	4992	363	31.7	215.81	-1028	7.0	2102
FU	200	151.0	200.87	11	64.0	1631	186	34.0	208.10	-1000	0.5	1545

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	LDH (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	232	234.1	189.98	12	187.0	1644	-	-	-	-	-	-
Day 7	221	265.2	216.14	63	212.0	2740	201	30.5	146.57	-840	15.0	1096
Day 14	106	283.2	264.21	75	202.5	1654	94	29.8	262.75	-976	5.0	1388
Day 28	83	241.7	143.12	74	201.0	1163	74	3.7	203.60	-1274	12.0	704
Day 42	137	225.0	161.34	81	185.0	1264	124	5.6	164.59	-831	-2.5	805
EOT	246	256.6	260.57	75	193.5	3310	223	26.1	264.71	-976	12.0	2851
FU	108	231.4	162.83	90	192.5	1385	97	24.1	187.55	-304	8.0	1230
Voriconazole (N = 259)												
Baseline	232	274.0	394.12	73	206.0	5665	-	-	-	-	-	-
Day 7	219	330.7	560.87	98	229.0	7339	198	62.8	573.82	-2685	20.0	7217
Day 14	106	270.1	173.16	105	222.0	1314	93	21.0	202.44	-836	33.0	590
Day 28	91	266.9	190.67	106	203.0	1240	82	32.4	176.42	-800	19.0	824
Day 42	133	261.7	498.37	87	185.0	5806	118	46.6	499.05	-762	9.5	5224
EOT	252	352.5	651.66	93	216.5	7339	227	83.3	659.37	-2685	19.0	7217
FU	115	287.5	348.32	67	200.0	3020	103	36.7	244.19	-685	20.0	1635
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	360	228.2	168.27	12	187.0	1644	-	-	-	-	-	-
Day 7	346	256.3	221.87	63	201.0	2740	313	31.8	169.16	-840	9.0	1472
Day 14	229	254.5	224.75	75	190.0	1718	204	23.5	213.31	-976	4.0	1388
Day 28	182	225.5	125.22	74	186.5	1163	162	0.7	166.16	-1274	7.5	704
Day 42	229	217.3	141.08	81	176.0	1264	205	7.2	139.39	-831	0.0	805
Day 84	83	202.7	83.63	106	174.0	621	76	-3.8	100.88	-646	0.5	209
Day 112	68	206.4	90.97	83	180.5	641	63	-8.0	106.63	-644	10.0	206
Day 140	60	206.0	74.73	111	178.0	402	54	10.1	132.91	-745	11.5	251
Day 168	47	187.1	61.05	126	164.0	383	43	6.7	64.49	-152	9.0	186
Day 180	50	185.2	54.24	119	167.0	392	45	5.8	60.87	-126	8.0	167
EOT	382	251.4	234.67	75	191.0	3310	344	27.4	241.60	-976	12.0	2851
FU	192	219.8	131.45	90	191.5	1385	172	15.2	160.43	-743	9.0	1230

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Triacylglycerol Lipase (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	95	29.9	34.50	6	19.0	260	-	-	-	-	-	-
Day 7	93	31.6	31.41	7	23.0	262	85	2.4	20.07	-57	2.0	98
Day 14	77	41.2	72.22	7	27.0	555	70	14.8	72.27	-62	4.0	502
Day 28	67	36.7	34.34	11	27.0	218	61	9.0	32.62	-73	7.0	149
Day 42	57	32.4	28.43	9	25.0	194	52	3.3	32.96	-79	3.0	163
EOT	100	30.8	31.81	6	23.0	239	92	2.4	34.21	-120	2.0	224
FU	64	38.1	51.72	9	24.5	403	58	5.6	60.46	-179	3.0	372
Voriconazole (N = 259)												
Baseline	99	29.8	40.53	7	19.0	355	-	-	-	-	-	-
Day 7	95	31.8	28.93	6	21.0	154	86	0.8	39.54	-294	1.0	115
Day 14	77	33.6	25.55	7	28.0	144	70	1.9	38.92	-276	5.0	65
Day 28	63	34.7	24.69	7	26.0	143	58	2.7	42.08	-273	5.0	77
Day 42	58	29.8	18.07	6	25.5	85	52	-3.5	45.71	-283	2.0	72
EOT	109	31.9	39.13	6	25.0	380	99	1.8	39.62	-286	2.0	220
FU	63	31.7	22.61	10	25.0	136	56	-1.9	46.94	-316	3.5	78
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	225	39.4	59.65	6	22.0	532	-	-	-	-	-	-
Day 7	224	39.1	48.55	6	25.0	539	206	-1.3	40.29	-377	2.0	108
Day 14	201	44.0	59.78	7	28.0	555	186	2.7	63.86	-379	2.0	502
Day 28	175	43.9	60.74	8	29.0	694	160	1.0	71.28	-420	3.0	535
Day 42	157	41.4	38.23	7	29.0	278	144	0.2	50.01	-344	3.0	163
Day 84	86	39.6	30.43	6	31.0	185	82	-11.6	70.80	-447	2.0	97
Day 112	70	41.2	39.04	7	30.0	252	68	-13.6	78.61	-460	0.5	102
Day 140	62	35.8	22.59	8	29.0	128	59	-20.8	81.30	-466	1.0	63
Day 168	50	33.9	17.33	8	31.5	95	48	-24.7	89.92	-491	1.0	54
Day 180	50	35.3	19.18	11	30.5	111	47	-22.7	89.25	-473	1.0	34
EOT	234	37.3	55.76	5	26.5	757	216	-2.2	78.50	-473	2.0	742
FU	149	37.8	39.54	5	28.0	403	137	-3.4	70.27	-466	2.0	372

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Amylase (U/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	95	27.9	31.16	2	18.0	199	-	-	-	-	-	-
Day 7	93	28.5	24.78	3	25.0	219	85	2.3	14.38	-43	2.0	55
Day 14	77	35.5	40.91	3	28.0	319	70	10.6	38.75	-56	4.5	253
Day 28	67	30.6	21.21	5	25.0	127	61	5.4	19.92	-37	5.0	68
Day 42	57	28.7	16.30	3	25.0	82	52	4.1	18.28	-43	4.5	67
EOT	100	29.0	25.56	1	24.0	180	92	2.1	21.74	-78	1.0	111
FU	64	32.4	35.08	4	25.0	271	58	3.6	39.91	-121	3.0	231
Voriconazole (N = 259)												
Baseline	99	24.3	22.98	4	15.0	138	-	-	-	-	-	-
Day 7	95	27.7	23.32	3	19.0	154	86	2.3	19.07	-97	2.0	76
Day 14	77	31.9	23.44	2	26.0	120	70	6.7	19.40	-99	6.5	50
Day 28	63	31.0	18.73	6	27.0	101	58	5.8	19.30	-96	6.5	42
Day 42	58	29.7	16.69	3	27.0	70	52	3.4	23.51	-91	4.5	64
EOT	109	26.3	17.93	3	23.0	120	99	1.3	17.85	-92	3.0	50
FU	63	26.7	15.15	5	23.0	80	56	0.5	20.21	-100	3.5	38
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	225	35.3	44.98	2	23.0	314	-	-	-	-	-	-
Day 7	224	34.9	37.02	2	26.5	387	206	-0.7	30.72	-283	1.0	98
Day 14	201	40.4	51.27	2	29.0	437	186	4.0	45.20	-293	2.0	256
Day 28	175	39.5	47.68	4	30.0	459	160	2.7	43.19	-309	4.0	290
Day 42	157	35.4	24.91	3	29.0	184	144	2.5	28.35	-169	4.0	103
Day 84	86	39.3	52.99	4	30.0	478	82	-3.9	41.85	-200	1.0	168
Day 112	70	41.2	62.61	5	31.0	525	68	-3.9	51.58	-210	2.0	215
Day 140	62	38.5	56.56	5	32.0	461	59	-8.3	48.66	-213	0.0	151
Day 168	50	31.4	15.76	6	28.5	95	48	-13.5	46.53	-219	0.5	40
Day 180	50	40.3	62.11	11	30.5	461	47	-8.6	50.41	-212	1.0	151
EOT	234	35.3	42.95	1	26.0	416	216	0.0	48.33	-309	1.0	402
FU	149	32.9	30.16	3	27.0	271	137	-0.7	42.51	-210	2.0	231

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Potassium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	239	3.95	0.696	2.3	3.90	7.6	-	-	-	-	-	-
Day 7	224	4.10	0.705	2.4	4.10	8.1	212	0.12	0.819	-3.8	0.10	3.2
Day 14	110	4.18	0.647	2.8	4.10	7.0	102	0.20	0.819	-3.1	0.20	2.3
Day 28	85	4.18	0.561	2.8	4.20	5.7	79	0.35	0.694	-1.0	0.30	1.8
Day 42	140	4.14	0.520	2.4	4.10	5.6	129	0.17	0.780	-3.8	0.30	2.0
EOT	249	4.07	0.707	2.3	4.10	8.1	233	0.11	0.950	-3.4	0.10	5.1
FU	115	4.16	0.586	2.3	4.10	5.6	105	0.18	0.697	-1.5	0.20	2.0
Voriconazole (N = 259)												
Baseline	239	3.87	0.654	2.0	3.90	6.6	-	-	-	-	-	-
Day 7	222	4.01	0.611	2.2	4.00	7.0	207	0.14	0.729	-2.0	0.10	3.9
Day 14	109	4.06	0.571	2.3	4.10	6.9	98	0.23	0.834	-2.4	0.20	4.0
Day 28	95	4.10	0.526	2.1	4.20	5.4	89	0.17	0.763	-2.0	0.30	1.9
Day 42	140	4.22	0.579	2.7	4.20	6.2	129	0.31	0.672	-2.2	0.40	2.3
EOT	254	4.12	0.710	2.1	4.10	7.0	235	0.24	0.842	-2.2	0.20	4.0
FU	119	4.06	0.611	2.3	4.10	7.0	108	0.12	0.805	-2.0	0.10	3.6
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	373	4.03	0.688	2.3	4.00	7.6	-	-	-	-	-	-
Day 7	359	4.21	0.731	2.4	4.20	8.1	336	0.15	0.815	-3.8	0.10	3.3
Day 14	237	4.22	0.676	2.5	4.20	7.0	219	0.14	0.828	-3.1	0.20	3.2
Day 28	191	4.28	0.566	2.8	4.30	6.0	175	0.23	0.734	-1.9	0.20	2.8
Day 42	240	4.28	0.582	2.4	4.30	7.0	220	0.20	0.787	-3.8	0.25	3.9
Day 84	86	4.37	0.547	2.8	4.40	6.4	81	0.18	0.709	-1.5	0.20	1.6
Day 112	70	4.39	0.684	2.7	4.35	6.4	67	0.21	0.821	-1.9	0.20	2.4
Day 140	62	4.55	0.609	3.2	4.40	6.4	58	0.41	0.827	-1.0	0.30	3.0
Day 168	49	4.51	0.702	3.2	4.40	6.9	46	0.32	0.782	-1.0	0.25	2.6
Day 180	50	4.41	0.455	3.5	4.30	5.7	46	0.20	0.673	-1.1	0.25	1.8
EOT	388	4.20	0.719	2.3	4.20	8.1	360	0.16	0.918	-3.4	0.10	5.1
FU	200	4.28	0.609	2.3	4.30	6.9	183	0.20	0.727	-1.8	0.20	2.1

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Creatinine (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	241	68.2	27.81	18	61.9	239	-	-	-	-	-	-
Day 7	226	73.3	43.95	18	70.7	583	214	6.1	30.90	-53	0.0	362
Day 14	109	68.1	26.56	27	61.9	150	100	4.4	20.82	-35	0.0	97
Day 28	87	72.3	29.21	27	61.9	159	81	9.5	25.95	-71	8.8	115
Day 42	141	76.2	25.50	18	70.7	186	132	7.6	22.78	-53	8.8	150
EOT	247	77.2	50.11	18	70.7	583	234	10.7	41.25	-62	8.8	371
FU	115	78.1	35.84	27	70.7	221	106	10.9	30.81	-71	8.8	159
Voriconazole (N = 259)												
Baseline	241	72.1	28.84	18	61.9	186	-	-	-	-	-	-
Day 7	224	73.3	30.56	18	61.9	203	208	2.7	20.44	-80	0.0	124
Day 14	109	75.5	37.55	18	70.7	274	100	5.0	30.60	-44	0.0	159
Day 28	95	78.8	48.10	18	70.7	415	90	10.4	45.11	-53	8.8	354
Day 42	138	75.2	30.21	27	70.7	230	128	5.5	23.74	-106	8.8	62
EOT	254	79.8	39.41	9	70.7	274	237	8.8	34.29	-106	0.0	159
FU	119	76.7	32.75	18	70.7	230	109	6.9	30.54	-80	0.0	177
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	376	84.2	51.99	18	70.7	486	-	-	-	-	-	-
Day 7	362	87.0	56.81	18	70.7	583	339	3.6	35.75	-177	0.0	362
Day 14	237	85.3	46.79	27	70.7	371	219	-2.3	34.74	-186	0.0	141
Day 28	193	88.2	53.10	27	70.7	451	178	1.9	43.11	-168	4.4	194
Day 42	242	85.6	42.12	18	79.6	354	225	4.0	43.99	-141	8.8	292
Day 84	87	98.2	62.15	27	79.6	442	83	-5.0	59.52	-150	0.0	212
Day 112	70	94.6	60.75	44	79.6	530	68	-4.3	56.87	-124	0.0	274
Day 140	62	91.5	54.75	44	79.6	460	59	-6.4	49.19	-141	0.0	203
Day 168	50	87.0	29.58	44	79.6	194	48	-8.8	42.26	-133	-4.4	62
Day 180	50	90.0	65.56	44	79.6	504	47	-0.8	53.48	-159	0.0	248
EOT	386	89.2	64.63	18	70.7	583	362	7.2	52.60	-168	0.0	371
FU	200	83.6	39.18	27	75.1	292	185	1.1	45.15	-256	0.0	159

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Sodium (mmol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	240	137.9	4.99	118	138.0	165	-	-	-	-	-	-
Day 7	226	139.1	4.79	124	139.0	157	214	1.2	4.29	-9	1.0	20
Day 14	110	139.0	4.63	124	139.0	156	102	1.0	5.38	-16	1.0	18
Day 28	87	139.5	4.03	129	140.0	148	81	1.8	4.94	-9	2.0	21
Day 42	141	140.0	3.74	129	141.0	147	131	2.1	5.06	-11	2.0	19
EOT	249	139.9	5.03	124	140.0	157	234	2.1	5.39	-16	2.0	19
FU	115	140.3	3.84	124	141.0	151	106	2.6	4.84	-10	2.0	16
Voriconazole (N = 259)												
Baseline	241	138.0	4.81	121	138.0	155	-	-	-	-	-	-
Day 7	225	139.6	4.26	121	140.0	154	210	1.5	4.72	-15	1.0	21
Day 14	110	139.7	4.86	121	140.5	150	100	1.5	5.65	-14	1.0	23
Day 28	96	140.2	4.41	127	141.0	151	91	1.8	5.30	-18	2.0	14
Day 42	140	139.5	3.94	127	140.0	148	130	0.8	4.36	-11	0.5	11
EOT	254	139.5	5.04	120	140.0	155	237	1.6	5.06	-11	2.0	23
FU	120	140.2	4.10	128	141.0	149	110	1.7	5.31	-12	2.0	15
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	375	138.1	4.80	118	138.0	165	-	-	-	-	-	-
Day 7	362	139.3	4.69	124	139.0	159	340	1.2	4.32	-10	1.0	20
Day 14	238	139.3	4.91	123	139.0	176	221	1.1	5.65	-16	1.0	39
Day 28	195	139.3	4.04	127	140.0	160	180	1.2	4.68	-13	1.0	21
Day 42	242	139.7	3.73	129	140.0	152	224	1.6	4.92	-11	1.0	19
Day 84	87	139.8	3.29	132	140.0	147	83	1.3	4.27	-7	1.0	16
Day 112	70	139.4	3.42	129	140.0	146	68	1.2	4.21	-9	1.0	13
Day 140	62	139.8	2.87	133	140.0	145	59	1.9	3.70	-6	2.0	13
Day 168	50	139.7	3.14	129	140.0	146	48	1.7	4.06	-7	2.0	11
Day 180	50	140.1	3.41	131	140.0	149	47	2.4	4.05	-8	2.0	12
EOT	388	139.9	4.99	124	140.0	164	362	2.0	5.57	-16	2.0	27
FU	200	140.3	3.57	124	141.0	151	184	2.4	4.73	-10	2.0	22

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Total Bilirubin (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	241	14.2	12.28	2	10.3	79	-	-	-	-	-	-
Day 7	225	13.2	13.85	2	8.6	92	214	-1.1	9.26	-55	-1.7	48
Day 14	109	14.0	16.30	2	8.6	96	100	0.6	16.07	-67	-1.7	89
Day 28	88	13.0	48.44	2	6.8	460	82	1.0	49.25	-67	-1.7	433
Day 42	140	8.5	7.34	2	6.8	65	131	-4.3	11.55	-68	-3.4	51
EOT	248	15.4	36.56	2	6.8	460	234	0.4	31.81	-68	-1.7	433
FU	115	11.3	21.87	2	6.8	221	106	-2.1	24.07	-63	-3.4	193
Voriconazole (N = 259)												
Baseline	236	13.3	11.70	2	10.3	94	-	-	-	-	-	-
Day 7	224	13.5	24.56	2	8.6	263	205	0.6	19.42	-44	-1.7	215
Day 14	107	11.2	11.61	2	8.6	70	95	-1.4	10.95	-43	-1.7	55
Day 28	96	12.3	24.92	2	6.8	239	91	0.5	25.07	-29	-1.7	219
Day 42	138	9.5	8.69	2	6.8	56	128	-1.8	10.36	-50	-1.7	46
EOT	253	16.5	35.86	2	8.6	374	231	3.8	33.67	-55	0.0	351
FU	120	12.1	24.37	2	6.8	233	109	0.8	27.51	-72	-1.7	224
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	375	13.0	11.60	2	10.3	79	-	-	-	-	-	-
Day 7	361	12.3	14.55	2	8.6	118	339	-0.6	9.66	-55	-1.7	86
Day 14	236	11.5	14.94	2	6.8	96	217	-0.1	12.85	-67	0.0	89
Day 28	196	11.5	38.82	2	5.1	460	181	0.9	38.64	-67	-1.7	433
Day 42	241	7.5	6.57	2	5.1	65	224	-3.6	9.86	-68	-1.7	51
Day 84	87	5.3	3.51	2	3.4	17	83	-3.5	7.10	-39	-1.7	5
Day 112	70	7.2	7.67	2	5.1	51	68	-1.7	9.08	-39	0.0	29
Day 140	62	4.8	3.40	0	3.4	22	59	-3.3	7.34	-39	-1.7	7
Day 168	50	5.0	2.85	2	5.1	15	48	-3.3	8.30	-39	-0.9	10
Day 180	50	4.7	1.94	2	4.3	10	47	-2.7	5.95	-24	0.0	3
EOT	387	14.1	33.46	2	6.8	460	361	0.7	29.53	-68	-1.7	433
FU	200	9.4	17.14	2	5.1	221	184	-2.5	19.07	-63	-1.7	193

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-102 生化学検査値の経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Urate (umol/L)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	240	171.5	94.72	6	151.7	500	-	-	-	-	-	-
Day 7	226	193.3	104.43	24	172.5	607	213	26.8	74.07	-167	23.8	363
Day 14	110	210.6	109.78	36	199.3	619	100	44.5	85.78	-167	35.7	256
Day 28	88	266.6	122.40	59	252.8	595	82	89.9	105.14	-172	86.2	482
Day 42	141	275.3	99.40	12	261.7	619	132	92.9	103.98	-178	95.2	404
EOT	248	235.7	123.37	12	229.0	690	233	68.4	107.14	-167	53.5	399
FU	115	260.3	115.93	83	249.8	696	105	92.7	100.96	-107	71.4	363
Voriconazole (N = 259)												
Baseline	241	176.4	96.24	36	148.7	512	-	-	-	-	-	-
Day 7	226	195.5	97.96	36	178.4	476	210	21.6	63.33	-286	17.8	291
Day 14	109	211.1	104.25	54	214.1	607	100	40.9	80.65	-250	29.7	232
Day 28	96	262.5	114.90	65	258.7	666	91	85.2	103.25	-155	83.3	381
Day 42	138	253.0	109.14	48	261.7	595	128	73.2	105.85	-226	68.4	327
EOT	254	244.9	120.14	54	232.0	708	237	70.0	107.27	-202	47.6	399
FU	120	280.5	121.20	59	264.7	613	110	103.0	118.63	-149	83.3	446
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	374	206.5	116.81	6	178.4	559	-	-	-	-	-	-
Day 7	361	227.5	124.94	24	208.2	672	337	22.8	78.95	-274	17.8	363
Day 14	237	253.9	126.67	36	243.9	785	217	29.4	91.40	-220	23.8	393
Day 28	196	293.7	120.51	59	285.5	595	180	62.1	106.98	-172	50.6	482
Day 42	242	298.3	115.78	12	285.5	964	225	76.8	113.09	-178	65.4	583
Day 84	87	328.4	119.92	42	309.3	684	83	46.5	121.77	-244	41.6	494
Day 112	70	321.0	110.65	71	309.3	630	68	50.6	101.66	-161	50.6	333
Day 140	60	314.2	95.42	125	318.2	583	57	42.6	110.58	-178	29.7	291
Day 168	50	326.3	109.79	113	315.2	630	48	46.2	110.01	-167	23.8	339
Day 180	50	333.6	86.68	184	327.1	541	47	52.4	109.71	-172	41.6	315
EOT	387	269.2	137.10	12	261.7	964	360	64.4	119.01	-250	47.6	583
FU	200	288.7	120.90	54	273.6	696	184	76.6	115.69	-220	59.5	506

EOT: end of treatment, FU: follow up.
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; GGT: gamma glutamyltransferase; LDH: lactate dehydrogenase

Program Name: t_lb_bio_1.sas
Program Run: 11JUN21:14:57:59

表 8-103 バイタルサインの経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Systolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	120.6	20.59	90	118.0	195	-	-	-	-	-	-
Day 1	60	116.5	17.33	84	115.0	161	60	-4.1	18.55	-67	-4.5	38
Day 2	59	115.2	15.19	84	114.0	150	59	-5.6	19.84	-65	-8.0	41
Day 3	58	114.3	15.10	87	110.5	149	58	-6.2	20.56	-85	-5.5	43
Day 7	58	115.1	14.73	90	112.5	146	58	-5.4	21.58	-92	-4.0	32
Day 14	56	122.0	18.45	81	120.5	184	56	1.6	20.11	-40	-1.0	65
Day 28	54	121.9	19.83	89	119.0	185	54	1.7	22.17	-68	2.0	67
Day 42	51	123.1	16.69	88	123.0	185	51	3.2	19.66	-58	4.0	53
EOT	60	122.2	18.85	89	119.5	173	60	1.5	21.84	-68	2.0	40
FU	32	119.7	19.63	87	119.5	171	32	-0.8	15.80	-35	-2.5	31
Voriconazole (N = 30)												
Baseline	30	119.4	17.21	91	121.5	150	-	-	-	-	-	-
Day 1	30	115.6	14.97	91	113.0	141	30	-3.8	12.73	-38	-4.0	22
Day 2	30	115.8	15.49	81	114.0	145	30	-3.6	14.44	-32	-4.0	47
Day 3	30	114.2	13.76	88	115.0	134	30	-5.2	13.63	-57	-3.0	13
Day 7	30	119.3	15.42	93	120.0	156	30	-0.1	15.56	-35	-1.0	25
Day 14	28	118.6	17.57	80	122.5	149	28	-2.3	21.44	-70	0.0	42
Day 28	28	120.9	19.29	81	120.0	153	28	0.1	21.07	-69	0.0	30
Day 42	25	122.8	18.43	95	123.0	159	25	2.0	19.38	-47	5.0	33
EOT	30	128.8	17.75	93	126.5	160	30	9.4	17.79	-22	7.5	39
FU	10	125.1	14.37	102	126.0	148	10	10.1	16.17	-12	16.5	38
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	121.6	20.38	90	118.0	195	-	-	-	-	-	-
Day 1	73	119.6	19.27	84	118.0	174	73	-2.0	17.85	-67	1.0	38
Day 2	72	115.9	15.84	83	114.0	156	72	-5.9	18.61	-65	-8.0	41
Day 3	71	115.3	15.22	87	112.0	149	71	-6.2	19.66	-85	-6.0	43
Day 7	71	116.8	15.22	90	113.0	154	71	-4.7	20.52	-92	-3.0	32
Day 14	68	123.4	18.12	81	122.5	184	68	1.7	19.82	-40	0.5	65
Day 28	64	123.3	19.44	89	122.0	185	64	2.6	22.22	-68	2.0	67
Day 42	61	123.1	16.34	88	123.0	185	61	2.6	19.81	-58	4.0	53
EOT	73	123.3	18.82	89	121.0	173	73	1.7	21.49	-68	3.0	40
FU	35	119.8	20.02	87	119.0	171	35	-2.1	19.31	-45	-4.0	38

EOT: end of treatment, FU: follow up.

Program Name: t_vs_2.sas
Program Run: 16JUN21:13:30:40

表 8-103 バイタルサインの経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Diastolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	72.1	11.14	50	69.5	101	-	-	-	-	-	-
Day 1	60	68.8	12.45	46	68.0	112	60	-3.3	10.17	-27	-2.0	22
Day 2	59	68.9	10.39	50	67.0	95	59	-3.4	9.50	-29	-2.0	17
Day 3	58	68.3	10.99	50	68.0	97	58	-3.8	10.67	-38	-3.0	20
Day 7	58	68.7	10.36	52	65.5	97	58	-3.5	9.68	-27	-4.5	20
Day 14	56	72.4	12.53	51	70.0	104	56	0.3	10.55	-23	-2.0	30
Day 28	54	73.8	11.74	53	72.0	100	54	1.8	11.06	-22	2.0	30
Day 42	51	74.5	11.55	50	75.0	101	51	2.7	11.01	-24	3.0	22
EOT	60	74.5	12.89	49	74.0	104	60	2.3	12.05	-24	3.0	30
FU	32	71.8	11.86	47	70.0	100	32	1.3	11.38	-24	1.5	24
Voriconazole (N = 30)												
Baseline	30	72.8	11.31	46	75.5	98	-	-	-	-	-	-
Day 1	30	68.3	10.96	49	68.0	94	30	-4.6	10.56	-33	-2.5	14
Day 2	30	68.3	10.45	48	69.0	88	30	-4.6	10.75	-35	-1.0	10
Day 3	30	71.0	9.75	54	71.5	96	30	-1.9	11.70	-28	-0.5	24
Day 7	30	70.8	10.39	52	71.0	87	30	-2.0	11.40	-25	-1.0	36
Day 14	28	71.8	12.60	51	71.0	111	28	-1.9	14.95	-29	0.0	35
Day 28	28	70.4	12.11	50	71.0	94	28	-3.3	11.31	-31	-3.5	20
Day 42	25	73.0	12.33	52	72.0	96	25	-0.8	12.65	-24	-1.0	22
EOT	30	74.3	10.43	51	75.0	94	30	1.5	11.81	-22	1.0	29
FU	10	71.8	11.00	57	72.5	88	10	-1.3	15.22	-26	-0.5	34
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	71.9	11.46	50	69.0	101	-	-	-	-	-	-
Day 1	73	70.0	12.44	46	69.0	112	73	-1.9	10.43	-27	-1.0	22
Day 2	72	68.9	10.87	50	67.0	97	72	-3.1	9.01	-29	-2.0	17
Day 3	71	68.6	11.16	50	68.0	97	71	-3.3	10.06	-38	-3.0	20
Day 7	71	69.6	10.59	52	68.0	98	71	-2.4	9.50	-27	-3.0	20
Day 14	68	73.0	12.36	51	71.0	104	68	1.0	10.50	-23	0.0	30
Day 28	64	74.2	11.68	53	73.5	100	64	2.5	11.59	-22	2.5	30
Day 42	61	73.7	11.49	50	75.0	101	61	2.2	11.10	-24	2.0	22
EOT	73	74.3	12.57	49	75.0	104	73	2.4	11.89	-24	3.0	30
FU	35	71.5	11.98	47	69.0	100	35	0.4	12.76	-35	1.0	24

EOT: end of treatment, FU: follow up.

Program Name: t_vs_2.sas
Program Run: 16JUN21:13:30:40

表 8-103 バイタルサインの経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Pulse Rate (BEATS/MIN)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	83.3	13.52	50	82.0	119	-	-	-	-	-	-
Day 1	60	79.2	12.55	57	76.5	112	60	-4.1	11.35	-39	-3.5	20
Day 2	59	78.9	11.00	56	78.0	113	59	-4.5	10.47	-35	-4.0	15
Day 3	58	79.0	12.62	59	75.0	107	58	-4.2	10.39	-32	-4.0	16
Day 7	58	80.0	11.51	57	78.5	109	58	-3.2	11.56	-36	-3.0	22
Day 14	56	81.0	12.14	59	80.5	110	56	-2.5	10.49	-28	-2.5	21
Day 28	54	80.8	13.27	55	78.0	110	54	-2.6	11.95	-30	-2.5	33
Day 42	51	79.2	11.25	58	78.0	104	51	-4.4	9.90	-23	-4.0	21
EOT	60	79.7	11.87	56	79.5	110	60	-3.6	12.14	-38	-4.0	33
FU	32	82.1	15.47	60	79.5	121	32	0.0	13.57	-29	-2.5	31
Voriconazole (N = 30)												
Baseline	30	84.0	15.41	55	86.5	113	-	-	-	-	-	-
Day 1	30	81.7	12.52	52	80.5	111	30	-2.2	12.66	-23	-3.5	24
Day 2	30	85.2	13.07	58	85.0	120	30	1.2	11.44	-19	2.0	26
Day 3	30	86.2	12.07	60	88.0	109	30	2.2	11.65	-14	1.5	32
Day 7	30	87.2	14.03	64	86.0	114	30	3.2	15.57	-24	1.0	52
Day 14	28	86.5	16.27	55	90.5	118	28	1.7	16.76	-25	0.5	33
Day 28	28	83.1	14.07	53	85.0	112	28	-1.7	14.53	-25	-2.5	31
Day 42	25	88.0	8.46	70	88.0	104	25	2.3	13.26	-19	-1.0	29
EOT	30	82.4	13.15	56	80.5	110	30	-1.6	12.12	-23	-3.0	22
FU	10	86.8	17.42	61	91.5	114	10	-4.3	14.19	-27	-1.5	14
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	82.9	12.91	50	83.0	119	-	-	-	-	-	-
Day 1	73	79.1	11.84	57	77.0	112	73	-3.7	10.79	-39	-3.0	20
Day 2	72	78.7	10.48	56	78.0	113	72	-4.2	10.68	-35	-3.5	15
Day 3	71	79.6	12.81	59	77.0	122	71	-3.2	11.20	-32	-3.0	38
Day 7	71	80.1	10.92	57	78.0	109	71	-2.7	11.60	-36	-3.0	22
Day 14	68	82.5	12.50	59	81.5	111	68	-0.6	11.70	-28	-1.0	26
Day 28	64	81.7	13.53	55	79.5	110	64	-1.3	12.65	-30	-2.0	33
Day 42	61	79.5	11.37	58	78.0	107	61	-3.6	11.13	-23	-4.0	33
EOT	73	79.9	12.51	51	80.0	110	73	-3.0	13.64	-38	-4.0	33
FU	35	82.5	15.85	60	80.0	121	35	-0.1	14.06	-29	-2.0	31

EOT: end of treatment, FU: follow up.

Program Name: t_vs_2.sas
Program Run: 16JUN21:13:30:40

表 8-103 バイタルサインの経時推移 - AK1820-301試験のCohort AおよびCohort A/B併合

Study/Integrated population	Temperature (C)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cohort A												
Isavuconazole (N = 60)												
Baseline	60	36.72	0.624	35.6	36.65	39.0	-	-	-	-	-	-
Day 1	60	36.71	0.593	35.6	36.60	39.8	60	-0.01	0.556	-2.1	0.00	1.8
Day 2	59	36.62	0.613	35.6	36.60	39.1	59	-0.08	0.448	-1.2	0.00	1.1
Day 3	58	36.62	0.651	35.0	36.65	39.1	58	-0.10	0.545	-1.8	-0.10	1.1
Day 7	58	36.56	0.486	35.2	36.60	38.0	58	-0.16	0.503	-2.0	-0.15	0.8
Day 14	55	36.54	0.483	35.6	36.60	37.8	55	-0.17	0.585	-2.1	-0.10	1.2
Day 28	54	36.52	0.673	35.3	36.40	39.5	54	-0.16	0.837	-3.4	-0.20	2.9
Day 42	51	36.44	0.477	35.6	36.40	37.5	51	-0.24	0.703	-3.1	-0.20	1.6
EOT	60	36.54	0.694	35.0	36.50	39.5	60	-0.18	0.753	-3.0	-0.20	2.9
FU	30	36.51	0.550	35.3	36.50	37.9	30	-0.25	0.778	-2.3	-0.30	1.3
Voriconazole (N = 30)												
Baseline	30	36.86	0.751	35.1	36.80	39.8	-	-	-	-	-	-
Day 1	30	36.90	0.445	35.9	36.90	37.9	30	0.04	0.620	-2.3	0.10	1.3
Day 2	30	36.96	0.446	36.2	36.90	38.3	30	0.10	0.526	-1.5	0.10	1.4
Day 3	30	36.88	0.419	36.1	36.85	38.0	30	0.02	0.616	-2.5	0.10	1.3
Day 7	30	36.90	0.730	35.8	36.80	40.2	30	0.04	0.990	-3.1	0.00	3.9
Day 14	28	36.93	0.683	36.1	36.70	39.5	28	0.13	0.650	-0.7	0.00	2.0
Day 28	28	36.73	0.357	36.1	36.70	37.5	28	-0.06	0.453	-0.9	-0.10	1.4
Day 42	25	36.60	0.330	35.7	36.60	37.2	25	-0.20	0.444	-1.0	-0.20	0.6
EOT	30	36.69	0.353	35.5	36.70	37.4	30	-0.17	0.709	-3.1	-0.15	1.0
FU	11	36.55	0.301	36.0	36.60	37.1	11	-0.61	0.828	-3.0	-0.40	0.0
Cohort A/B併合												
Isavuconazole (N = 73)												
Baseline	73	36.73	0.627	35.6	36.70	39.0	-	-	-	-	-	-
Day 1	73	36.73	0.579	35.6	36.60	39.8	73	0.00	0.531	-2.1	0.10	1.8
Day 2	72	36.68	0.611	35.6	36.60	39.1	72	-0.04	0.448	-1.2	0.00	1.2
Day 3	71	36.64	0.640	35.0	36.60	39.1	71	-0.09	0.544	-1.8	-0.10	1.1
Day 7	71	36.57	0.463	35.2	36.60	38.0	71	-0.16	0.522	-2.0	-0.10	0.8
Day 14	67	36.55	0.492	35.6	36.60	37.8	67	-0.15	0.582	-2.1	-0.10	1.2
Day 28	64	36.51	0.633	35.3	36.45	39.5	64	-0.17	0.798	-3.4	-0.20	2.9
Day 42	61	36.47	0.482	35.6	36.50	37.6	61	-0.22	0.689	-3.1	-0.20	1.6
EOT	73	36.54	0.648	35.0	36.50	39.5	73	-0.19	0.746	-3.0	-0.20	2.9
FU	33	36.54	0.538	35.3	36.50	37.9	33	-0.19	0.801	-2.3	-0.30	1.4

EOT: end of treatment, FU: follow up.

Program Name: t_vs_2.sas
Program Run: 16JUN21:13:30:40

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Systolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	257	121.8	17.63	84	120.0	185	-	-	-	-	-	-
Day 1 Post-dose 1	231	120.3	17.85	85	120.0	175	231	-1.7	12.83	-41	0.0	50
Day 1 Pre-dose 2	170	120.3	17.25	81	118.0	180	170	-0.8	15.14	-70	0.0	50
Day 1 Post-dose 2	146	121.6	18.34	90	118.0	172	146	1.3	13.25	-32	0.0	60
Day 1 Pre-dose 3	155	120.9	17.92	90	120.0	185	155	-0.7	15.50	-50	0.0	46
Day 1 Post-dose 3	156	120.7	17.90	70	120.0	172	156	-0.6	16.19	-60	0.0	60
Day 2 Pre-dose 1	179	119.6	17.60	80	119.0	174	179	-1.5	16.68	-57	0.0	58
Day 2 Post-dose 1	154	120.1	17.46	74	119.5	168	154	-0.7	16.30	-42	0.0	66
Day 2 Pre-dose 2	154	120.9	17.58	80	120.0	180	154	-0.8	16.60	-69	0.0	55
Day 2 Post-dose 2	152	120.0	17.84	83	120.0	172	152	-0.5	15.63	-70	0.0	37
Day 2 Pre-dose 3	154	123.0	20.34	87	120.0	185	154	0.8	18.38	-60	0.0	55
Day 2 Post-dose 3	142	120.8	18.28	87	120.0	170	142	-1.0	17.46	-60	0.0	74
Day 3 Pre-dose 1	154	124.2	18.40	83	121.5	180	154	1.0	17.93	-45	0.0	86
Day 3 Post-dose 1	123	120.8	16.73	84	120.0	172	123	-0.5	17.90	-44	0.0	50
Day 7	243	123.4	17.19	63	121.0	175	243	1.2	18.12	-52	1.0	48
Day 42	169	123.1	15.05	82	121.0	167	169	0.1	18.29	-67	0.0	40
Day 84	97	122.4	16.86	91	120.0	176	97	-0.9	16.98	-58	-2.0	40
EOT	255	123.3	17.44	63	120.0	190	255	1.5	19.40	-67	0.0	70
FU	132	123.7	18.06	79	121.0	192	132	-1.5	21.57	-81	0.0	54

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Systolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Voriconazole (N = 259)												
Baseline	258	123.5	17.89	80	120.0	180	-	-	-	-	-	-
Day 1 Post-dose 1	232	121.9	17.54	80	120.0	180	231	-1.5	12.35	-50	0.0	48
Day 1 Pre-dose 2	134	123.0	16.65	80	124.5	167	134	-0.7	14.61	-50	0.0	38
Day 1 Post-dose 2	143	122.4	17.01	79	120.0	170	143	-2.0	14.92	-61	-1.0	47
Day 1 Pre-dose 3	140	123.0	17.80	80	121.0	180	140	0.0	16.52	-50	0.0	70
Day 1 Post-dose 3	140	121.4	16.64	80	120.0	170	140	-1.5	14.77	-51	0.0	35
Day 2 Pre-dose 1	164	123.3	16.57	75	120.5	170	164	0.2	17.59	-70	0.0	54
Day 2 Post-dose 1	144	120.9	16.77	90	120.0	180	144	-1.8	16.83	-70	0.0	70
Day 2 Pre-dose 2	139	122.1	15.29	85	120.0	170	139	-1.6	17.37	-80	0.0	42
Day 2 Post-dose 2	143	124.1	16.93	90	121.0	170	143	0.1	17.31	-60	0.0	57
Day 2 Pre-dose 3	140	123.5	16.81	88	120.0	174	140	0.4	17.45	-60	0.0	40
Day 2 Post-dose 3	139	122.1	17.72	90	120.0	175	139	-1.7	15.98	-70	-1.0	50
Day 3 Pre-dose 1	139	122.6	16.81	80	120.0	165	139	0.0	16.53	-50	0.0	51
Day 3 Post-dose 1	110	121.3	14.13	90	120.0	152	110	-2.1	15.51	-50	-2.0	30
Day 7	250	123.4	18.91	85	120.0	190	249	-0.3	18.44	-59	0.0	71
Day 42	168	120.4	16.97	78	120.0	160	167	-3.8	19.86	-53	-5.0	47
Day 84	98	120.6	15.91	80	120.0	160	98	-0.8	19.24	-49	0.0	54
EOT	257	120.9	18.98	68	120.0	199	256	-2.8	22.04	-82	-1.6	59
FU	133	123.5	15.78	90	120.0	168	133	-0.3	20.53	-48	0.0	64

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Systolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	403	122.6	17.34	84	120.0	185	-	-	-	-	-	-
Day 1 Post-dose 1	343	121.4	18.20	85	120.0	188	343	-1.4	12.94	-41	0.0	50
Day 1 Pre-dose 2	280	121.5	17.64	80	120.0	180	280	-1.0	15.52	-70	0.0	50
Day 1 Post-dose 2	244	121.7	18.22	84	120.0	172	244	-0.5	13.25	-35	0.0	60
Day 1 Pre-dose 3	261	122.6	17.83	90	120.0	185	261	-0.3	15.96	-51	0.0	46
Day 1 Post-dose 3	254	122.4	17.30	70	120.0	172	254	-0.8	15.37	-60	0.0	60
Day 2 Pre-dose 1	297	119.9	17.69	80	120.0	180	297	-2.4	16.08	-57	0.0	58
Day 2 Post-dose 1	255	120.1	17.45	74	120.0	168	255	-1.9	15.86	-49	0.0	66
Day 2 Pre-dose 2	255	122.1	18.26	80	120.0	181	255	-0.6	16.73	-69	0.0	55
Day 2 Post-dose 2	247	120.5	17.59	79	120.0	172	247	-1.5	15.58	-70	0.0	38
Day 2 Pre-dose 3	252	122.6	19.33	82	120.0	185	252	-0.3	17.96	-60	0.0	60
Day 2 Post-dose 3	229	121.2	18.59	83	120.0	170	229	-1.7	17.32	-60	0.0	74
Day 3 Pre-dose 1	267	123.3	17.63	83	121.0	180	267	0.3	17.83	-45	0.0	86
Day 3 Post-dose 1	200	121.1	17.45	84	120.0	179	200	-1.1	17.54	-44	0.0	50
Day 7	379	123.7	17.41	63	120.0	175	379	1.2	18.17	-52	0.0	60
Day 42	272	123.3	15.22	82	120.0	176	272	0.3	18.08	-67	0.0	48
Day 84	186	122.7	16.06	90	120.0	176	186	-0.5	17.45	-58	0.0	58
Day 112	68	121.2	15.87	90	120.0	172	68	-1.9	17.97	-62	0.0	62
Day 140	65	123.1	16.18	100	121.0	180	65	1.9	17.08	-28	1.0	80
Day 168	55	122.7	16.68	90	120.0	170	55	2.0	17.89	-31	0.0	70
Day 180	51	123.8	15.99	90	121.0	161	51	2.9	17.54	-30	2.0	51
EOT	395	122.9	17.87	63	120.0	190	395	0.3	20.02	-67	0.0	70
FU	221	123.2	17.48	79	120.0	192	221	-0.8	20.02	-81	0.0	60

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Diastolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	257	71.6	10.43	39	70.0	110	-	-	-	-	-	-
Day 1 Post-dose 1	231	70.7	11.34	41	70.0	110	231	-1.0	9.30	-33	0.0	30
Day 1 Pre-dose 2	170	69.9	10.54	43	70.0	100	170	-1.0	10.83	-37	0.0	34
Day 1 Post-dose 2	146	70.8	10.94	48	70.0	100	146	0.0	10.75	-27	0.0	34
Day 1 Pre-dose 3	155	69.9	11.52	38	70.0	100	155	-0.8	12.62	-47	0.0	31
Day 1 Post-dose 3	156	70.7	12.01	40	70.0	105	156	0.0	11.55	-30	0.0	40
Day 2 Pre-dose 1	179	69.5	11.32	43	70.0	108	179	-1.1	11.38	-33	0.0	28
Day 2 Post-dose 1	154	70.9	10.58	48	70.0	97	154	-0.2	12.47	-35	0.0	34
Day 2 Pre-dose 2	154	71.4	11.01	39	70.0	100	154	-0.3	11.60	-36	0.0	34
Day 2 Post-dose 2	152	70.9	11.16	40	70.0	100	152	-0.3	12.21	-31	0.0	31
Day 2 Pre-dose 3	154	71.5	10.88	44	70.0	103	154	0.3	12.86	-32	0.0	46
Day 2 Post-dose 3	142	71.7	11.48	46	70.0	104	142	1.0	12.67	-36	0.0	35
Day 3 Pre-dose 1	154	72.6	10.74	45	70.0	115	154	1.0	12.08	-34	0.0	46
Day 3 Post-dose 1	123	71.7	10.28	43	70.0	95	123	0.8	12.33	-28	0.0	29
Day 7	242	73.6	11.64	38	72.0	108	242	2.0	12.49	-30	0.0	35
Day 42	169	74.0	9.98	52	75.0	107	169	2.6	11.88	-25	0.0	48
Day 84	97	74.0	10.82	49	72.0	102	97	1.7	11.51	-25	0.0	31
EOT	255	73.5	11.66	38	71.0	110	255	2.0	13.12	-30	0.0	48
FU	132	73.0	11.51	33	70.5	109	132	-0.5	14.35	-44	0.0	41

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Diastolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Voriconazole (N = 259)												
Baseline	258	73.6	11.18	49	71.5	113	-	-	-	-	-	-
Day 1 Post-dose 1	232	72.6	12.28	40	70.0	120	231	-1.0	9.34	-27	0.0	29
Day 1 Pre-dose 2	134	71.6	11.04	40	70.0	101	134	-0.9	11.58	-31	-1.0	39
Day 1 Post-dose 2	143	71.1	10.91	50	70.0	101	143	-2.3	11.06	-61	-1.0	24
Day 1 Pre-dose 3	140	72.2	11.34	50	70.0	103	140	-0.6	11.53	-47	0.0	40
Day 1 Post-dose 3	140	71.0	11.13	50	70.0	100	140	-1.9	10.89	-38	-0.5	33
Day 2 Pre-dose 1	164	72.6	11.00	30	70.0	100	164	-0.3	10.69	-33	0.0	31
Day 2 Post-dose 1	144	71.0	10.27	50	70.0	93	144	-1.6	10.30	-56	0.0	23
Day 2 Pre-dose 2	139	71.9	10.05	40	70.0	95	139	-0.8	10.80	-35	0.0	37
Day 2 Post-dose 2	143	73.1	11.60	50	71.0	100	143	0.2	11.76	-53	0.0	29
Day 2 Pre-dose 3	140	73.1	11.38	40	71.0	105	140	0.3	12.04	-32	0.0	32
Day 2 Post-dose 3	139	71.2	11.32	44	70.0	100	139	-2.0	13.02	-52	-2.0	32
Day 3 Pre-dose 1	139	72.8	11.76	40	70.0	115	139	0.1	12.57	-61	0.0	35
Day 3 Post-dose 1	110	71.0	9.64	47	70.0	98	110	-1.5	10.61	-31	-0.5	20
Day 7	250	74.5	11.00	45	75.0	103	249	0.7	12.50	-38	0.0	34
Day 42	168	74.3	12.16	40	74.5	120	167	0.1	13.41	-42	0.0	36
Day 84	98	74.4	11.64	46	70.5	100	98	1.6	13.48	-24	0.0	36
EOT	257	73.0	12.37	39	71.0	120	256	-0.8	14.09	-51	0.0	36
FU	133	75.3	10.30	40	75.0	117	133	1.0	14.92	-40	0.0	49

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Diastolic Blood Pressure (mmHg)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	403	71.9	10.36	39	70.0	111	-	-	-	-	-	-
Day 1 Post-dose 1	343	71.4	11.02	41	70.0	110	343	-0.5	8.97	-33	0.0	30
Day 1 Pre-dose 2	280	70.8	11.40	40	70.0	110	280	-0.6	10.84	-37	0.0	40
Day 1 Post-dose 2	244	71.5	11.27	48	70.0	110	244	0.2	10.49	-27	0.0	40
Day 1 Pre-dose 3	261	70.9	12.04	38	70.0	100	261	-0.2	12.59	-47	0.0	34
Day 1 Post-dose 3	254	71.5	11.79	40	70.0	105	254	0.2	11.18	-30	0.0	40
Day 2 Pre-dose 1	297	70.4	11.24	43	70.0	108	297	-0.6	11.44	-34	0.0	30
Day 2 Post-dose 1	255	71.1	10.68	39	70.0	97	255	-0.1	11.59	-38	0.0	34
Day 2 Pre-dose 2	254	71.9	11.68	39	70.0	100	254	0.3	11.34	-36	0.0	34
Day 2 Post-dose 2	247	70.6	11.09	40	70.0	100	247	-0.6	11.68	-37	0.0	31
Day 2 Pre-dose 3	252	71.9	11.15	44	70.0	103	252	0.7	12.50	-32	0.0	46
Day 2 Post-dose 3	229	71.7	11.38	46	70.0	104	229	0.9	12.25	-36	0.0	35
Day 3 Pre-dose 1	267	72.7	11.07	42	71.0	115	267	1.1	11.65	-34	0.0	46
Day 3 Post-dose 1	200	71.8	11.04	43	70.0	100	200	0.8	12.10	-30	0.0	29
Day 7	378	73.7	11.30	38	73.0	108	378	1.9	12.28	-36	0.0	35
Day 42	272	74.9	10.32	52	75.0	116	272	3.0	12.16	-26	0.5	48
Day 84	186	74.9	11.24	49	73.0	108	186	2.2	11.76	-25	0.0	34
Day 112	68	75.0	10.67	59	75.5	101	68	1.8	12.49	-30	0.0	31
Day 140	65	77.5	10.81	60	77.0	110	65	5.1	12.44	-24	6.0	40
Day 168	55	75.4	11.14	58	71.0	101	55	3.1	13.01	-30	0.0	30
Day 180	51	77.1	8.95	60	78.0	100	51	4.6	10.62	-20	1.0	30
EOT	395	73.9	11.65	38	73.0	110	395	2.0	13.44	-36	0.0	48
FU	221	73.9	12.35	33	73.0	150	221	0.5	14.39	-44	0.0	70

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Pulse Rate (BEATS/MIN)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	257	90.9	17.21	56	90.0	146	-	-	-	-	-	-
Day 1 Post-dose 1	230	89.9	16.81	60	88.0	143	230	-1.2	10.42	-40	-1.0	30
Day 1 Pre-dose 2	171	89.0	16.50	60	88.0	129	171	-3.1	12.06	-37	-1.0	26
Day 1 Post-dose 2	148	89.0	17.19	55	88.0	136	148	-3.3	12.61	-42	-2.0	28
Day 1 Pre-dose 3	154	88.0	17.35	55	85.0	136	154	-3.8	13.17	-41	-2.0	38
Day 1 Post-dose 3	152	89.9	17.94	46	88.0	153	152	-2.1	14.86	-48	-0.5	46
Day 2 Pre-dose 1	182	89.4	17.93	50	88.0	144	182	-2.6	17.18	-59	-2.5	72
Day 2 Post-dose 1	156	90.5	17.06	53	88.0	140	156	-2.1	14.75	-60	-2.0	68
Day 2 Pre-dose 2	156	88.0	17.02	49	85.0	153	156	-4.1	13.99	-65	-2.0	38
Day 2 Post-dose 2	151	87.3	16.31	53	85.0	152	151	-5.4	14.24	-60	-3.0	25
Day 2 Pre-dose 3	153	88.0	17.25	52	85.0	150	153	-4.2	14.32	-63	-4.0	25
Day 2 Post-dose 3	146	88.2	17.30	50	86.0	143	146	-4.3	13.51	-64	-3.5	26
Day 3 Pre-dose 1	153	88.9	17.34	52	86.0	160	153	-3.6	16.06	-68	-2.0	50
Day 3 Post-dose 1	121	89.3	18.54	51	85.0	155	121	-4.0	15.76	-63	-2.0	43
Day 7	239	90.0	17.72	52	88.0	170	239	-0.7	18.55	-53	-1.0	90
Day 42	164	85.6	16.05	50	84.0	149	164	-3.4	17.85	-50	-4.0	50
Day 84	95	79.2	13.20	46	79.0	127	95	-8.5	14.80	-46	-8.0	39
EOT	254	88.4	20.02	46	84.0	176	254	-2.5	20.50	-67	-4.0	90
FU	126	86.2	15.58	52	84.0	134	126	-4.1	18.54	-65	-4.0	58

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Pulse Rate (BEATS/MIN)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Voriconazole (N = 259)												
Baseline	257	88.5	16.96	56	86.0	141	-	-	-	-	-	-
Day 1 Post-dose 1	233	89.4	17.68	58	88.0	173	233	1.2	10.34	-33	1.0	50
Day 1 Pre-dose 2	132	88.8	18.35	55	85.0	157	131	-0.1	12.42	-32	0.0	34
Day 1 Post-dose 2	142	88.8	18.40	52	84.5	158	142	-0.4	13.23	-35	0.0	36
Day 1 Pre-dose 3	142	87.7	18.31	55	84.0	162	142	-1.9	14.46	-52	0.0	37
Day 1 Post-dose 3	136	89.4	19.04	60	84.0	163	136	-0.5	14.05	-43	0.0	40
Day 2 Pre-dose 1	160	89.4	20.05	58	84.0	169	160	0.1	14.21	-47	0.0	46
Day 2 Post-dose 1	145	87.9	19.07	51	84.0	165	145	-1.1	14.05	-52	0.0	38
Day 2 Pre-dose 2	140	88.6	19.02	55	86.0	155	140	-0.7	13.41	-36	0.0	34
Day 2 Post-dose 2	145	88.0	19.19	50	84.0	148	145	-1.2	13.78	-41	-1.0	34
Day 2 Pre-dose 3	142	87.5	18.50	56	82.0	156	142	-1.1	14.41	-50	0.0	36
Day 2 Post-dose 3	140	87.3	18.80	51	84.0	161	140	-2.5	14.10	-45	-1.5	34
Day 3 Pre-dose 1	139	89.5	18.72	50	88.0	144	139	0.7	16.89	-50	2.0	70
Day 3 Post-dose 1	110	88.5	16.97	51	85.0	145	110	-1.6	13.74	-45	0.0	38
Day 7	250	88.2	17.23	50	86.0	143	248	0.0	16.44	-53	0.0	58
Day 42	167	88.0	18.96	0	87.0	167	166	0.4	18.79	-82	2.0	59
Day 84	96	82.9	13.00	58	80.0	123	96	-3.6	16.24	-59	-4.0	32
EOT	257	88.5	19.41	0	85.0	167	255	0.0	18.27	-82	0.0	59
FU	129	83.9	17.24	37	82.0	140	128	-2.1	19.25	-77	0.0	63

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Pulse Rate (BEATS/MIN)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	403	89.4	17.36	46	88.0	146	-	-	-	-	-	-
Day 1 Post-dose 1	342	89.2	16.74	54	87.0	143	342	-1.0	10.36	-49	-1.0	44
Day 1 Pre-dose 2	281	88.4	16.05	57	88.0	130	281	-2.2	12.24	-52	0.0	26
Day 1 Post-dose 2	246	87.9	16.58	55	87.5	136	246	-3.0	12.73	-55	-2.0	44
Day 1 Pre-dose 3	260	88.2	16.96	55	86.0	136	260	-2.2	13.26	-53	0.0	38
Day 1 Post-dose 3	250	89.3	17.57	46	88.0	153	250	-1.6	14.43	-56	0.0	46
Day 2 Pre-dose 1	300	88.7	17.26	50	86.0	144	300	-1.7	15.66	-59	-2.0	72
Day 2 Post-dose 1	257	88.8	16.76	53	86.0	140	257	-1.6	14.07	-60	-1.0	68
Day 2 Pre-dose 2	257	87.7	16.54	49	86.0	153	257	-2.9	13.46	-65	-1.0	38
Day 2 Post-dose 2	247	87.1	16.35	53	86.0	152	247	-4.0	13.81	-60	-2.0	35
Day 2 Pre-dose 3	251	87.7	16.16	52	86.0	150	251	-3.3	14.10	-63	-2.0	30
Day 2 Post-dose 3	232	88.4	17.26	50	86.0	143	232	-3.1	14.48	-64	-2.0	52
Day 3 Pre-dose 1	266	88.3	16.38	52	86.0	160	266	-2.0	14.98	-68	0.0	50
Day 3 Post-dose 1	198	90.1	17.74	51	86.5	155	198	-2.0	15.40	-63	-1.0	45
Day 7	375	89.7	17.36	49	88.0	170	375	0.4	17.48	-53	-1.0	90
Day 42	267	84.2	15.12	50	83.0	149	267	-3.2	17.47	-52	-2.0	50
Day 84	183	80.4	13.15	46	80.0	128	183	-5.6	16.33	-46	-4.0	46
Day 112	67	83.0	14.84	50	82.0	125	67	-1.7	16.31	-50	1.0	40
Day 140	64	80.7	16.14	54	79.5	128	64	-2.5	17.14	-47	-1.5	34
Day 168	55	80.3	13.38	54	80.0	129	55	-2.6	15.73	-47	-2.0	36
Day 180	51	76.3	10.13	56	77.0	102	51	-4.9	13.73	-35	-4.0	19
EOT	394	87.3	19.32	46	84.0	176	394	-2.1	20.16	-67	-3.0	90
FU	215	84.4	16.07	52	81.0	135	215	-3.7	17.97	-65	-4.0	62

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Adjusted Temperature (C)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Isavuconazole (N = 257)												
Baseline	257	37.42	0.925	35.1	37.30	40.7	-	-	-	-	-	-
Day 1 Post-dose 1	229	37.34	0.821	35.7	37.30	40.6	229	-0.07	0.771	-3.8	0.00	2.4
Day 1 Pre-dose 2	176	37.31	0.892	35.2	37.30	39.8	176	-0.11	0.916	-3.8	0.00	2.9
Day 1 Post-dose 2	158	37.30	0.942	35.0	37.30	40.4	158	-0.10	0.872	-2.1	0.00	2.6
Day 1 Pre-dose 3	161	37.21	0.987	34.2	37.10	40.5	161	-0.23	1.031	-6.0	-0.10	3.3
Day 1 Post-dose 3	155	37.20	0.986	33.9	37.20	40.0	155	-0.26	1.024	-6.3	-0.10	2.8
Day 2 Pre-dose 1	185	37.25	0.899	34.7	37.10	40.3	185	-0.20	0.980	-5.5	-0.10	3.1
Day 2 Post-dose 1	163	37.22	0.955	35.1	37.10	41.5	163	-0.21	0.956	-2.9	0.00	3.0
Day 2 Pre-dose 2	165	37.25	0.843	35.0	37.20	39.5	165	-0.23	0.849	-3.3	-0.10	1.9
Day 2 Post-dose 2	155	37.23	0.859	35.0	37.20	39.5	155	-0.23	0.881	-3.5	-0.20	2.4
Day 2 Pre-dose 3	163	37.28	0.911	35.0	37.20	40.1	163	-0.18	0.946	-3.3	-0.10	2.2
Day 2 Post-dose 3	151	37.18	0.902	35.2	37.10	40.0	151	-0.32	0.880	-2.9	-0.20	2.5
Day 3 Pre-dose 1	155	37.26	0.874	35.1	37.20	39.7	155	-0.22	0.960	-4.3	-0.10	2.8
Day 3 Post-dose 1	132	37.17	0.786	35.5	37.20	38.9	132	-0.30	0.947	-4.2	-0.20	2.1
Day 7	240	37.13	0.870	35.0	37.05	40.0	240	-0.31	1.032	-3.5	-0.20	3.4
Day 42	166	36.92	0.687	35.5	36.85	39.5	166	-0.44	1.001	-3.9	-0.30	2.4
Day 84	96	36.85	0.714	35.4	36.95	38.7	96	-0.53	0.899	-3.2	-0.30	1.2
EOT	255	37.07	0.839	35.0	37.00	40.2	255	-0.34	1.024	-3.9	-0.30	3.4
FU	121	37.04	0.808	35.0	37.00	39.5	121	-0.31	0.941	-3.7	-0.40	3.0

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Adjusted Temperature (C)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験												
Voriconazole (N = 259)												
Baseline	258	37.33	0.974	34.6	37.20	40.3	-	-	-	-	-	-
Day 1 Post-dose 1	230	37.36	0.928	34.8	37.30	40.5	229	0.04	0.759	-3.0	0.00	2.2
Day 1 Pre-dose 2	138	37.52	0.948	35.4	37.50	39.9	138	0.09	0.854	-2.8	0.10	3.0
Day 1 Post-dose 2	145	37.39	0.917	35.5	37.30	40.6	145	0.03	0.874	-2.0	0.10	2.8
Day 1 Pre-dose 3	148	37.39	0.880	35.2	37.40	40.5	147	0.00	0.862	-3.8	0.00	2.5
Day 1 Post-dose 3	142	37.29	0.816	35.1	37.20	39.6	142	-0.06	0.837	-3.5	0.00	2.5
Day 2 Pre-dose 1	164	37.34	0.927	34.0	37.20	40.5	163	-0.04	0.978	-4.0	0.00	3.0
Day 2 Post-dose 1	149	37.25	0.814	35.9	37.10	40.3	149	-0.09	0.871	-3.3	0.00	2.5
Day 2 Pre-dose 2	147	37.49	0.880	35.8	37.50	40.8	147	0.09	0.996	-3.3	0.00	3.1
Day 2 Post-dose 2	147	37.45	0.906	35.6	37.40	40.4	147	0.01	0.929	-3.3	0.00	2.5
Day 2 Pre-dose 3	148	37.38	0.949	34.5	37.25	40.6	147	0.02	0.996	-3.3	0.00	3.0
Day 2 Post-dose 3	147	37.27	0.871	35.4	37.10	40.2	147	-0.11	0.918	-3.2	-0.10	2.8
Day 3 Pre-dose 1	141	37.34	0.889	35.4	37.20	40.8	141	0.01	0.969	-2.9	0.00	3.0
Day 3 Post-dose 1	122	37.36	0.938	35.4	37.30	40.1	122	-0.02	0.951	-2.9	0.00	2.5
Day 7	252	37.18	0.888	34.7	37.00	40.5	251	-0.16	0.988	-3.0	-0.10	3.1
Day 42	165	36.89	0.839	34.2	37.00	40.0	164	-0.43	1.085	-3.8	-0.30	2.4
Day 84	91	36.84	0.755	34.7	36.80	39.5	91	-0.47	0.849	-3.2	-0.40	1.0
EOT	256	36.99	0.945	34.2	36.90	40.0	255	-0.33	1.069	-3.8	-0.30	2.8
FU	121	36.85	0.717	35.2	36.80	39.9	121	-0.37	0.978	-3.7	-0.30	2.9

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-104 バイタルサインの経時推移 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population	Adjusted Temperature (C)											
Treatment Group	Result						Change					
Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
海外第III相試験併合												
Isavuconazole (N = 403)												
Baseline	403	37.20	0.921	35.1	37.10	40.7	-	-	-	-	-	-
Day 1 Post-dose 1	341	37.22	0.832	35.3	37.20	40.6	341	-0.02	0.699	-3.8	0.00	2.4
Day 1 Pre-dose 2	284	37.17	0.875	35.1	37.10	40.0	284	-0.03	0.837	-3.8	0.00	2.9
Day 1 Post-dose 2	252	37.18	0.875	35.0	37.20	40.4	252	-0.04	0.803	-2.1	0.00	2.6
Day 1 Pre-dose 3	264	37.13	0.934	34.2	37.00	40.5	264	-0.09	0.954	-6.0	0.00	3.3
Day 1 Post-dose 3	250	37.09	0.954	33.9	37.00	40.1	250	-0.16	0.915	-6.3	-0.05	2.8
Day 2 Pre-dose 1	299	37.12	0.855	34.7	37.10	40.3	299	-0.11	0.933	-5.5	0.00	3.1
Day 2 Post-dose 1	262	37.13	0.900	34.5	37.00	41.5	262	-0.09	0.877	-2.9	0.00	3.0
Day 2 Pre-dose 2	265	37.16	0.822	35.0	37.10	40.0	265	-0.10	0.820	-3.3	0.00	1.9
Day 2 Post-dose 2	249	37.08	0.870	33.1	37.00	39.5	249	-0.15	0.833	-3.5	-0.10	2.4
Day 2 Pre-dose 3	258	37.15	0.896	35.0	37.05	40.1	258	-0.10	0.900	-3.3	-0.10	3.0
Day 2 Post-dose 3	234	37.09	0.891	35.1	37.00	40.0	234	-0.20	0.856	-3.3	-0.10	2.5
Day 3 Pre-dose 1	268	37.12	0.826	35.1	37.00	39.9	268	-0.07	0.846	-4.3	0.00	2.8
Day 3 Post-dose 1	206	37.11	0.773	35.5	37.00	39.9	206	-0.16	0.879	-4.2	0.00	2.1
Day 7	376	37.02	0.818	35.0	36.90	40.2	376	-0.20	0.931	-3.5	-0.10	3.4
Day 42	267	36.83	0.694	35.0	36.80	40.3	267	-0.32	0.965	-3.9	-0.20	4.6
Day 84	182	36.82	0.649	35.4	36.80	38.7	182	-0.32	0.880	-3.2	-0.20	2.0
Day 112	67	36.67	0.652	35.3	36.60	38.5	67	-0.22	0.811	-2.9	-0.10	1.6
Day 140	64	36.61	0.590	35.2	36.70	37.7	64	-0.32	0.829	-3.5	-0.15	1.2
Day 168	55	36.84	0.513	35.3	36.90	38.0	55	-0.10	0.763	-2.9	0.00	1.5
Day 180	51	36.74	0.477	35.4	36.70	37.9	51	-0.20	0.698	-2.6	-0.10	1.4
EOT	395	36.96	0.832	34.6	36.90	40.3	395	-0.25	1.005	-3.9	-0.20	4.6
FU	208	36.89	0.744	35.0	36.80	39.5	208	-0.27	0.888	-3.7	-0.20	3.0

EOT: end of treatment, FU: follow up.
Adjusted Temperature: The body temperature from a route other than oral is converted to oral temperature.

Program Name: t_vs_1.sas
Program Run: 16JUN21:10:49:06

表 8-105 12誘導心電図パラメータの投与終了時点（EOT）におけるベースラインからの変化量 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population													
Treatment Group		Result						Change					
Parameter (unit)	Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
9766-CL-0104試験													
Isavuconazole (N = 257)													
Heart Rate (bpm)	Baseline	231	89.4	19.42	50	86.0	146	-	-	-	-	-	-
	EOT	250	85.8	19.53	45	83.0	161	228	-3.8	21.49	-55	-4.0	101
PR Interval (msec)	Baseline	229	143.3	23.26	88	141.0	240	-	-	-	-	-	-
	EOT	249	141.2	21.51	88	140.0	224	225	-2.2	19.25	-64	0.0	75
RR Interval (msec)	Baseline	231	703.4	152.06	410	694.0	1192	-	-	-	-	-	-
	EOT	250	734.2	158.71	373	720.5	1330	228	33.1	169.86	-627	25.5	654
QRS Interval (msec)	Baseline	231	96.3	16.17	71	95.0	171	-	-	-	-	-	-
	EOT	250	94.8	14.75	71	93.5	170	228	-1.0	12.73	-53	-1.0	67
QT Interval (msec)	Baseline	229	354.9	43.09	247	351.0	503	-	-	-	-	-	-
	EOT	250	353.6	39.60	222	355.0	470	227	-0.7	44.36	-187	1.0	129
QTcB (msec)	Baseline	229	425.9	32.31	348	426.0	524	-	-	-	-	-	-
	EOT	250	416.1	30.64	331	413.0	509	227	-10.0	34.25	-94	-11.0	102
QTcF (msec)	Baseline	229	400.3	31.52	325	401.0	517	-	-	-	-	-	-
	EOT	250	393.6	28.66	290	393.5	496	227	-6.7	32.38	-113	-8.0	94
Voriconazole (N = 259)													
Heart Rate (bpm)	Baseline	230	88.7	20.43	52	87.0	169	-	-	-	-	-	-
	EOT	252	84.6	20.30	49	82.5	197	225	-3.2	18.40	-60	-3.0	68
PR Interval (msec)	Baseline	225	142.8	26.70	102	138.0	352	-	-	-	-	-	-
	EOT	249	141.8	26.72	101	136.0	269	220	-1.8	20.36	-83	-0.5	54
RR Interval (msec)	Baseline	230	711.5	158.73	356	688.0	1162	-	-	-	-	-	-
	EOT	252	746.8	168.05	305	727.5	1223	225	27.7	151.54	-329	19.0	544
QRS Interval (msec)	Baseline	230	95.7	15.48	66	95.0	191	-	-	-	-	-	-
	EOT	252	95.4	15.96	71	92.0	182	225	-0.7	12.77	-40	0.0	59
QT Interval (msec)	Baseline	229	356.5	44.08	267	354.0	521	-	-	-	-	-	-
	EOT	252	365.0	43.59	244	364.0	519	224	6.6	42.03	-121	6.5	115
QTcB (msec)	Baseline	229	426.1	32.88	337	423.0	534	-	-	-	-	-	-
	EOT	252	425.9	32.57	342	427.0	552	224	-0.1	35.96	-79	-0.5	103
QTcF (msec)	Baseline	229	400.9	31.67	330	399.0	520	-	-	-	-	-	-
	EOT	252	404.0	30.70	326	403.0	487	224	2.4	33.37	-87	2.0	88

EOT: end of treatment

Program Name: t_12ecg_chg_3.sas
Program Run: 02JUN21:15:56:46

表 8-105 12誘導心電図パラメータの投与終了時点（EOT）におけるベースラインからの変化量 - 9766-CL-0104試験および海外第III相試験併合

Study/Integrated population Treatment Group		Result						Change					
Parameter (unit)	Visit	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
海外第III相試験併合													
Isavuconazole (N = 403)													
Heart Rate (bpm)	Baseline	372	88.4	19.19	49	86.0	146	-	-	-	-	-	-
	EOT	385	83.9	19.70	44	81.0	169	358	-4.9	21.02	-58	-5.0	101
PR Interval (msec)	Baseline	369	142.0	23.56	86	138.0	240	-	-	-	-	-	-
	EOT	382	140.4	23.31	75	138.0	224	353	-2.0	21.21	-111	0.0	80
RR Interval (msec)	Baseline	372	711.6	157.11	410	694.5	1215	-	-	-	-	-	-
	EOT	385	752.2	166.66	355	743.0	1378	358	43.7	172.78	-627	36.0	654
QRS Interval (msec)	Baseline	372	96.6	16.66	71	95.0	187	-	-	-	-	-	-
	EOT	385	96.0	16.33	71	94.0	180	358	-0.1	13.56	-53	0.0	67
QT Interval (msec)	Baseline	370	355.3	44.08	247	351.0	503	-	-	-	-	-	-
	EOT	385	355.1	39.76	222	356.0	494	357	0.4	43.86	-187	1.0	143
QTcB (msec)	Baseline	370	424.0	32.55	327	423.0	524	-	-	-	-	-	-
	EOT	385	413.1	31.64	315	412.0	510	357	-11.2	34.52	-109	-12.0	102
QTcF (msec)	Baseline	370	399.2	31.96	313	401.0	517	-	-	-	-	-	-
	EOT	385	392.2	29.02	290	392.0	496	357	-7.0	32.17	-113	-8.0	94

EOT: end of treatment

Program Name: t_12ecg_chg_3.sas
Program Run: 02JUN21:15:56:46

表 8-106 12誘導心電図パラメータの投与後異常所見 - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験		海外第III相試験併合
	Postbaseline		Postbaseline
Findings	Isavuconazole (N = 257)	Voriconazole (N = 259)	Isavuconazole (N = 403)
n	250 (97.3%)	252 (97.3%)	390 (96.8%)
Any Abnormality	110 (44.0%)	103 (40.9%)	190 (48.7%)
Hypertrophy patterns	0	1 (0.4%)	1 (0.3%)
Left ventricular hypertrophy, with secondary ST-T changes	0	0	1 (0.3%)
Left ventricular hypertrophy, without secondary ST-T changes	0	1 (0.4%)	0
ST segment changes	5 (2.0%)	3 (1.2%)	14 (3.6%)
Abnormal ST pattern in precordial leads	0	2 (0.8%)	0
Abnormal ST pattern widespread	1 (0.4%)	0	2 (0.5%)
Non specific ST depression	3 (1.2%)	0	9 (2.3%)
Non specific ST elevation	1 (0.4%)	1 (0.4%)	3 (0.8%)
T/U wave abnormalities	75 (30.0%)	75 (29.8%)	125 (32.1%)
Abnormal T pattern in precordial leads	3 (1.2%)	5 (2.0%)	3 (0.8%)
Abnormal T pattern in standard leads	1 (0.4%)	1 (0.4%)	1 (0.3%)
Abnormal T pattern widespread	3 (1.2%)	7 (2.8%)	3 (0.8%)
Absence of U wave	24 (9.6%)	27 (10.7%)	32 (8.2%)
Flat T wave	18 (7.2%)	26 (10.3%)	39 (10.0%)
Non specific T wave abnormalities	31 (12.4%)	25 (9.9%)	52 (13.3%)
T wave inversion	8 (3.2%)	6 (2.4%)	21 (5.4%)
Tall T wave	0	0	2 (0.5%)
AV conduction disorders	8 (3.2%)	17 (6.7%)	23 (5.9%)
Borderline first degree A-V block	3 (1.2%)	11 (4.4%)	7 (1.8%)
First degree A-V block	1 (0.4%)	6 (2.4%)	3 (0.8%)
Short PR interval	4 (1.6%)	2 (0.8%)	12 (3.1%)
Sinus pause	0	1 (0.4%)	0
W.P.W.	1 (0.4%)	0	2 (0.5%)
Ventricular conduction disorders	18 (7.2%)	20 (7.9%)	35 (9.0%)
Complete left bundle branch block	1 (0.4%)	1 (0.4%)	1 (0.3%)
Complete right bundle branch block	3 (1.2%)	4 (1.6%)	10 (2.6%)
Incomplete right bundle branch block	12 (4.8%)	14 (5.6%)	23 (5.9%)
Left anterior fascicular block	1 (0.4%)	3 (1.2%)	1 (0.3%)
Left posterior fascicular block	1 (0.4%)	0	1 (0.3%)

Postbaseline includes all postbaseline measurements up to 10 days following end of treatment.
n: number of patients with at least one non-missing assessment at end of treatment or postbaseline.

Program Name: t_12ecg_abn_1.sas
Program Run: 04JUN21:09:31:27

表 8-106 12誘導心電図パラメータの投与後異常所見 - 9766-CL-0104試験および海外第III相試験併合

Findings	9766-CL-0104試験 Postbaseline Isavuconazole (N = 257)	9766-CL-0104試験 Postbaseline Voriconazole (N = 259)	海外第III相試験併合 Postbaseline Isavuconazole (N = 403)
Supraventricular/junctional rhythm disorders	25 (10.0%)	23 (9.1%)	40 (10.3%)
Atrial bigeminy	1 (0.4%)	1 (0.4%)	2 (0.5%)
Atrial ectopic pace-maker	1 (0.4%)	0	3 (0.8%)
Atrial fibrillation	5 (2.0%)	3 (1.2%)	6 (1.5%)
Atrial flutter	0	1 (0.4%)	1 (0.3%)
Atrial tachycardia	0	2 (0.8%)	1 (0.3%)
Atrial trigeminy	0	1 (0.4%)	0
Coronary sinus pace-maker	1 (0.4%)	1 (0.4%)	2 (0.5%)
Couplet atrial premature beat	0	1 (0.4%)	1 (0.3%)
Isolated atrial premature beat	17 (6.8%)	15 (6.0%)	25 (6.4%)
Multifocal atrial pace-maker	0	0	1 (0.3%)
Run atrial premature beat	0	0	1 (0.3%)
Ventricular rhythm disorders	13 (5.2%)	11 (4.4%)	27 (6.9%)
Couplet ventricular premature beat	1 (0.4%)	1 (0.4%)	2 (0.5%)
Isolated ventricular premature beat, monomorphic	12 (4.8%)	11 (4.4%)	25 (6.4%)
Isolated ventricular premature beat, polymorphic	0	0	1 (0.3%)

Postbaseline includes all postbaseline measurements up to 10 days following end of treatment.
n: number of patients with at least one non-missing assessment at end of treatment or postbaseline.

Program Name: t_12ecg_abn_1.sas
Program Run: 04JUN21:09:31:27

表 8-107 SOC別の有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
Overall	21 (87.5%)	11 (91.7%)	34 (94.4%)	17 (94.4%)	23 (88.5%)	44 (93.6%)
感染症および寄生虫症	10 (41.7%)	6 (50.0%)	12 (33.3%)	4 (22.2%)	11 (42.3%)	14 (29.8%)
胃腸障害	6 (25.0%)	3 (25.0%)	11 (30.6%)	9 (50.0%)	7 (26.9%)	14 (29.8%)
臨床検査	5 (20.8%)	2 (16.7%)	11 (30.6%)	5 (27.8%)	5 (19.2%)	16 (34.0%)
肝胆道系障害	5 (20.8%)	3 (25.0%)	6 (16.7%)	7 (38.9%)	5 (19.2%)	7 (14.9%)
神経系障害	4 (16.7%)	2 (16.7%)	6 (16.7%)	4 (22.2%)	5 (19.2%)	10 (21.3%)
皮膚および皮下組織障害	6 (25.0%)	1 (8.3%)	3 (8.3%)	3 (16.7%)	6 (23.1%)	5 (10.6%)
眼障害	4 (16.7%)	4 (33.3%)	4 (11.1%)	9 (50.0%)	4 (15.4%)	6 (12.8%)
代謝および栄養障害	3 (12.5%)	1 (8.3%)	5 (13.9%)	1 (5.6%)	3 (11.5%)	8 (17.0%)
一般・全身障害および投与部位の状態	4 (16.7%)	1 (8.3%)	4 (11.1%)	0	4 (15.4%)	5 (10.6%)
呼吸器、胸郭および縦隔障害	3 (12.5%)	1 (8.3%)	4 (11.1%)	2 (11.1%)	3 (11.5%)	6 (12.8%)
腎および尿路障害	1 (4.2%)	1 (8.3%)	4 (11.1%)	1 (5.6%)	1 (3.8%)	6 (12.8%)
血管障害	4 (16.7%)	1 (8.3%)	1 (2.8%)	0	4 (15.4%)	2 (4.3%)
精神障害	2 (8.3%)	2 (16.7%)	1 (2.8%)	5 (27.8%)	2 (7.7%)	2 (4.3%)
筋骨格系および結合組織障害	1 (4.2%)	0	2 (5.6%)	4 (22.2%)	1 (3.8%)	3 (6.4%)
傷害、中毒および処置合併症	1 (4.2%)	0	2 (5.6%)	2 (11.1%)	1 (3.8%)	3 (6.4%)
心臓障害	1 (4.2%)	0	2 (5.6%)	1 (5.6%)	1 (3.8%)	5 (10.6%)
耳および迷路障害	1 (4.2%)	0	1 (2.8%)	1 (5.6%)	1 (3.8%)	1 (2.1%)
免疫系障害	1 (4.2%)	1 (8.3%)	0	0	1 (3.8%)	0
内分泌障害	1 (4.2%)	0	0	0	1 (3.8%)	1 (2.1%)
先天性、家族性および遺伝性障害	0	3 (25.0%)	0	0	0	1 (2.1%)
血液およびリンパ系障害	0	0	0	1 (5.6%)	1 (3.8%)	1 (2.1%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_soc_2a.sas
Program Run: 18JUN21:10:01:21

表 8-108 注目すべき有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

Age (years) Subgroup	Cohort A				Cohort A/B併合	
	<= 65		65 <		<= 65	65 <
	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
肝機能異常・肝炎	9 (37.5%)	4 (33.3%)	13 (36.1%)	10 (55.6%)	9 (34.6%)	15 (31.9%)
アナフィラキシー	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0
トルサード ド ポアント	0	0	1 (2.8%)	0	0	2 (4.3%)
急性膵炎	0	0	0	0	0	0
精神神経症状	2 (8.3%)	2 (16.7%)	1 (2.8%)	5 (27.8%)	2 (7.7%)	3 (6.4%)
視覚障害	3 (12.5%)	7 (58.3%)	4 (11.1%)	8 (44.4%)	3 (11.5%)	5 (10.6%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0
静脈内投与例	(N = 4)	(N = 2)	(N = 4)	(N = 0)	(N = 4)	(N = 5)
注入部位／注射部位反応	1 (25.0%)	0	2 (50.0%)	0	1 (25.0%)	2 (40.0%)
IRR	0	1 (50.0%)	0	0	0	1 (20.0%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_age_eoi_2a.sas
Program Run: 18JUN21:10:01:25

表 8-109 死亡に至った有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
Overall	2 (8.3%)	0	2 (5.6%)	0	2 (7.7%)	4 (8.5%)
呼吸器、胸郭および縦隔障害	1 (4.2%)	0	1 (2.8%)	0	1 (3.8%)	2 (4.3%)
特発性肺炎症候群	1 (4.2%)	0	0	0	1 (3.8%)	0
肺臓炎	0	0	1 (2.8%)	0	0	1 (2.1%)
誤嚥性肺炎	0	0	0	0	0	1 (2.1%)
感染症および寄生虫症	1 (4.2%)	0	1 (2.8%)	0	1 (3.8%)	1 (2.1%)
肺炎球菌感染	0	0	1 (2.8%)	0	0	1 (2.1%)
副鼻腔炎	1 (4.2%)	0	0	0	1 (3.8%)	0
神経系障害	1 (4.2%)	0	0	0	1 (3.8%)	0
大脳基底核梗塞	1 (4.2%)	0	0	0	1 (3.8%)	0
心臓障害	0	0	0	0	0	1 (2.1%)
急性心筋梗塞	0	0	0	0	0	1 (2.1%)
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (2.1%)
死亡	0	0	0	0	0	1 (2.1%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_2a.sas
Program Run: 18JUN21:10:01:30

表 8-110 重篤な有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
Overall	5 (20.8%)	0	8 (22.2%)	3 (16.7%)	5 (19.2%)	12 (25.5%)
感染症および寄生虫症	2 (8.3%)	0	4 (11.1%)	2 (11.1%)	2 (7.7%)	6 (12.8%)
肺炎	0	0	2 (5.6%)	1 (5.6%)	0	2 (4.3%)
感染性胸水	1 (4.2%)	0	1 (2.8%)	0	1 (3.8%)	1 (2.1%)
気管支炎	0	0	1 (2.8%)	0	0	1 (2.1%)
肺炎球菌感染	0	0	1 (2.8%)	0	0	1 (2.1%)
副鼻腔炎	1 (4.2%)	0	0	0	1 (3.8%)	0
アスペルギルス感染	0	0	0	1 (5.6%)	0	0
菌血症	0	0	0	0	0	1 (2.1%)
蜂巣炎	0	0	0	0	0	1 (2.1%)
呼吸器、胸郭および縦隔障害	2 (8.3%)	0	2 (5.6%)	0	2 (7.7%)	3 (6.4%)
喀血	0	0	1 (2.8%)	0	0	1 (2.1%)
特発性肺炎症候群	1 (4.2%)	0	0	0	1 (3.8%)	0
肺臓炎	0	0	1 (2.8%)	0	0	1 (2.1%)
気胸	1 (4.2%)	0	0	0	1 (3.8%)	0
誤嚥性肺炎	0	0	0	0	0	1 (2.1%)
肝胆道系障害	0	0	1 (2.8%)	1 (5.6%)	0	1 (2.1%)
胆嚢炎	0	0	1 (2.8%)	0	0	1 (2.1%)
薬物性肝障害	0	0	0	1 (5.6%)	0	0
筋骨格系および結合組織障害	1 (4.2%)	0	0	1 (5.6%)	1 (3.8%)	0
筋力低下	1 (4.2%)	0	0	0	1 (3.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_ser_2a.sas
Program Run: 18JUN21:10:01:35

表 8-110 重篤な有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
横紋筋融解症	0	0	0	1 (5.6%)	0	0
内分泌障害	1 (4.2%)	0	0	0	1 (3.8%)	0
抗利尿ホルモン不適合分泌	1 (4.2%)	0	0	0	1 (3.8%)	0
代謝および栄養障害	0	0	1 (2.8%)	0	0	1 (2.1%)
低ナトリウム血症	0	0	1 (2.8%)	0	0	1 (2.1%)
神経系障害	1 (4.2%)	0	0	0	1 (3.8%)	0
大脳基底核梗塞	1 (4.2%)	0	0	0	1 (3.8%)	0
腎および尿路障害	0	0	1 (2.8%)	0	0	1 (2.1%)
腎機能障害	0	0	1 (2.8%)	0	0	1 (2.1%)
心臓障害	0	0	0	0	0	2 (4.3%)
急性心筋梗塞	0	0	0	0	0	1 (2.1%)
急性心不全	0	0	0	0	0	1 (2.1%)
血液およびリンパ系障害	0	0	0	0	0	1 (2.1%)
好中球減少症	0	0	0	0	0	1 (2.1%)
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (2.1%)
死亡	0	0	0	0	0	1 (2.1%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_ser_2a.sas
Program Run: 18JUN21:10:01:35

表 8-111 投与中止に至った有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
Overall	3 (12.5%)	0	7 (19.4%)	4 (22.2%)	3 (11.5%)	8 (17.0%)
肝胆道系障害	0	0	2 (5.6%)	2 (11.1%)	0	2 (4.3%)
肝機能異常	0	0	2 (5.6%)	1 (5.6%)	0	2 (4.3%)
薬物性肝障害	0	0	0	1 (5.6%)	0	0
感染症および寄生虫症	1 (4.2%)	0	1 (2.8%)	0	1 (3.8%)	1 (2.1%)
感染性胸水	1 (4.2%)	0	0	0	1 (3.8%)	0
肺炎球菌感染	0	0	1 (2.8%)	0	0	1 (2.1%)
代謝および栄養障害	0	0	2 (5.6%)	0	0	2 (4.3%)
高カリウム血症	0	0	1 (2.8%)	0	0	1 (2.1%)
低ナトリウム血症	0	0	1 (2.8%)	0	0	1 (2.1%)
神経系障害	1 (4.2%)	0	0	1 (5.6%)	1 (3.8%)	0
感覚鈍麻	1 (4.2%)	0	0	0	1 (3.8%)	0
多発ニューロパチー	0	0	0	1 (5.6%)	0	0
臨床検査	1 (4.2%)	0	0	0	1 (3.8%)	1 (2.1%)
肝機能検査値上昇	1 (4.2%)	0	0	0	1 (3.8%)	0
心電図異常	0	0	0	0	0	1 (2.1%)
耳および迷路障害	1 (4.2%)	0	0	0	1 (3.8%)	0
耳管開放	1 (4.2%)	0	0	0	1 (3.8%)	0
胃腸障害	0	0	1 (2.8%)	0	0	1 (2.1%)
悪心	0	0	1 (2.8%)	0	0	1 (2.1%)
一般・全身障害および投与部位の状態	0	0	1 (2.8%)	0	0	1 (2.1%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_2a.sas
Program Run: 16JUN21:13:31:15

表 8-111 投与中止に至った有害事象（年齢別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 24)	VRC (N = 12)	ISA (N = 36)	VRC (N = 18)	ISA (N = 26)	ISA (N = 47)
注射部位蕁麻疹	0	0	1 (2.8%)	0	0	1 (2.1%)
腎および尿路障害	0	0	1 (2.8%)	0	0	1 (2.1%)
腎機能障害	0	0	1 (2.8%)	0	0	1 (2.1%)
呼吸器、胸郭および縦隔障害	1 (4.2%)	0	0	0	1 (3.8%)	0
呼吸困難	1 (4.2%)	0	0	0	1 (3.8%)	0
口腔咽頭不快感	1 (4.2%)	0	0	0	1 (3.8%)	0
皮膚および皮下組織障害	1 (4.2%)	0	0	0	1 (3.8%)	0
冷汗	1 (4.2%)	0	0	0	1 (3.8%)	0
眼障害	0	0	0	1 (5.6%)	0	0
視力障害	0	0	0	1 (5.6%)	0	0
筋骨格系および結合組織障害	0	0	0	1 (5.6%)	0	0
横紋筋融解症	0	0	0	1 (5.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_2a.sas
Program Run: 16JUN21:13:31:15

表 8-112 SOC別の有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
Overall	192 (95.5%)	197 (98.0%)	55 (98.2%)	58 (100.0%)	302 (95.0%)	84 (98.8%)
胃腸障害	133 (66.2%)	143 (71.1%)	41 (73.2%)	37 (63.8%)	199 (62.6%)	58 (68.2%)
感染症および寄生虫症	115 (57.2%)	126 (62.7%)	37 (66.1%)	32 (55.2%)	188 (59.1%)	55 (64.7%)
全身障害および投与局所様態	114 (56.7%)	107 (53.2%)	34 (60.7%)	37 (63.8%)	165 (51.9%)	51 (60.0%)
呼吸器、胸郭および縦隔障害	114 (56.7%)	113 (56.2%)	29 (51.8%)	34 (58.6%)	167 (52.5%)	39 (45.9%)
代謝および栄養障害	80 (39.8%)	95 (47.3%)	28 (50.0%)	26 (44.8%)	127 (39.9%)	43 (50.6%)
神経系障害	71 (35.3%)	68 (33.8%)	24 (42.9%)	21 (36.2%)	107 (33.6%)	38 (44.7%)
皮膚および皮下組織障害	62 (30.8%)	89 (44.3%)	24 (42.9%)	21 (36.2%)	93 (29.2%)	32 (37.6%)
臨床検査	63 (31.3%)	77 (38.3%)	22 (39.3%)	19 (32.8%)	91 (28.6%)	28 (32.9%)
血液およびリンパ系障害	60 (29.9%)	70 (34.8%)	17 (30.4%)	12 (20.7%)	85 (26.7%)	21 (24.7%)
精神障害	52 (25.9%)	59 (29.4%)	18 (32.1%)	27 (46.6%)	75 (23.6%)	30 (35.3%)
筋骨格系および結合組織障害	56 (27.9%)	59 (29.4%)	13 (23.2%)	18 (31.0%)	89 (28.0%)	20 (23.5%)
血管障害	52 (25.9%)	60 (29.9%)	15 (26.8%)	17 (29.3%)	78 (24.5%)	23 (27.1%)
腎および尿路障害	43 (21.4%)	44 (21.9%)	12 (21.4%)	14 (24.1%)	62 (19.5%)	19 (22.4%)
心臓障害	28 (13.9%)	47 (23.4%)	15 (26.8%)	10 (17.2%)	44 (13.8%)	24 (28.2%)
眼障害	30 (14.9%)	48 (23.9%)	9 (16.1%)	21 (36.2%)	43 (13.5%)	15 (17.6%)
傷害、中毒および処置合併症	20 (10.0%)	30 (14.9%)	13 (23.2%)	9 (15.5%)	35 (11.0%)	20 (23.5%)
肝胆道系障害	18 (9.0%)	33 (16.4%)	5 (8.9%)	9 (15.5%)	31 (9.7%)	8 (9.4%)
免疫系障害	15 (7.5%)	23 (11.4%)	5 (8.9%)	2 (3.4%)	23 (7.2%)	6 (7.1%)
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）	14 (7.0%)	16 (8.0%)	5 (8.9%)	15 (25.9%)	21 (6.6%)	8 (9.4%)
耳および迷路障害	13 (6.5%)	11 (5.5%)	1 (1.8%)	2 (3.4%)	18 (5.7%)	3 (3.5%)
生殖系および乳房障害	8 (4.0%)	10 (5.0%)	0	3 (5.2%)	16 (5.0%)	1 (1.2%)
内分泌障害	3 (1.5%)	3 (1.5%)	2 (3.6%)	0	8 (2.5%)	2 (2.4%)
先天性、家族性および遺伝性障害	1 (0.5%)	1 (0.5%)	2 (3.6%)	1 (1.7%)	1 (0.3%)	2 (2.4%)
社会環境	0	0	0	1 (1.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_soc_1a.sas
Program Run: 04JUN21:14:51:04

表 8-113 注目すべき有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

Age (years) Subgroup	9766-CL-0104試験				海外第III相試験併合	
	<= 65		65 <		<= 65	65 <
	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
肝機能異常・肝炎	41 (20.4%)	66 (32.8%)	12 (21.4%)	16 (27.6%)	66 (20.8%)	16 (18.8%)
アナフィラキシー	1 (0.5%)	3 (1.5%)	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
重度皮膚障害	2 (1.0%)	2 (1.0%)	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
心電図QT短縮	1 (0.5%)	0	0	0	1 (0.3%)	0
トルサード ド ポアント	12 (6.0%)	17 (8.5%)	3 (5.4%)	2 (3.4%)	13 (4.1%)	5 (5.9%)
急性膵炎	0	0	0	0	1 (0.3%)	0
精神神経症状	54 (26.9%)	58 (28.9%)	19 (33.9%)	21 (36.2%)	77 (24.2%)	33 (38.8%)
視覚障害	19 (9.5%)	30 (14.9%)	4 (7.1%)	17 (29.3%)	22 (6.9%)	9 (10.6%)
皮膚または子宮の悪性腫瘍	0	0	1 (1.8%)	0	0	1 (1.2%)
静脈内投与例	(N = 201)	(N = 201)	(N = 56)	(N = 58)	(N = 279)	(N = 78)
注入部位／注射部位反応	8 (4.0%)	3 (1.5%)	3 (5.4%)	1 (1.7%)	12 (4.3%)	4 (5.1%)
IRR	58 (28.9%)	62 (30.8%)	12 (21.4%)	14 (24.1%)	81 (29.0%)	21 (26.9%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_age_eoi_1a.sas
Program Run: 09JUN21:14:07:13

表 8-114 死亡に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
Overall	47 (23.4%)	55 (27.4%)	15 (26.8%)	17 (29.3%)	74 (23.3%)	32 (37.6%)
感染症および寄生虫症	18 (9.0%)	17 (8.5%)	10 (17.9%)	1 (1.7%)	33 (10.4%)	16 (18.8%)
敗血症性ショック	6 (3.0%)	4 (2.0%)	2 (3.6%)	0	9 (2.8%)	3 (3.5%)
敗血症	5 (2.5%)	5 (2.5%)	2 (3.6%)	0	5 (1.6%)	3 (3.5%)
アスペルギルス症	2 (1.0%)	2 (1.0%)	1 (1.8%)	0	2 (0.6%)	2 (2.4%)
真菌感染	2 (1.0%)	1 (0.5%)	1 (1.8%)	1 (1.7%)	2 (0.6%)	1 (1.2%)
肺炎	1 (0.5%)	2 (1.0%)	0	0	3 (0.9%)	0
ムコール症	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
アシネトバクター性菌血症	1 (0.5%)	0	0	0	1 (0.3%)	0
気管支肺アスペルギルス症	0	0	1 (1.8%)	0	0	1 (1.2%)
心内膜炎	0	0	1 (1.8%)	0	0	1 (1.2%)
フサリウム感染	0	0	1 (1.8%)	0	0	1 (1.2%)
感染	1 (0.5%)	0	0	0	1 (0.3%)	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	1 (0.3%)	0
クレブシエラ性敗血症	0	1 (0.5%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
真菌性肺炎	0	0	0	0	1 (0.3%)	1 (1.2%)
細菌性敗血症	0	0	0	0	1 (0.3%)	0
蓄膿	0	0	0	0	1 (0.3%)	0
真菌性敗血症	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_1a.sas
Program Run: 04JUN21:14:51:22

表 8-114 死亡に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
肺感染	0	0	0	0	1 (0.3%)	0
シュードモナス菌性肺感染	0	0	0	0	1 (0.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (1.2%)
原発性異型肺炎	0	0	0	0	0	1 (1.2%)
真菌性副鼻腔炎	0	0	0	0	1 (0.3%)	0
ブドウ球菌性敗血症	0	0	0	0	1 (0.3%)	0
呼吸器、胸郭および縦隔障害	13 (6.5%)	10 (5.0%)	1 (1.8%)	2 (3.4%)	16 (5.0%)	2 (2.4%)
呼吸不全	5 (2.5%)	5 (2.5%)	1 (1.8%)	1 (1.7%)	6 (1.9%)	1 (1.2%)
急性呼吸不全	3 (1.5%)	1 (0.5%)	0	0	4 (1.3%)	0
喀血	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
肺出血	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	0
呼吸窮迫	1 (0.5%)	0	0	0	1 (0.3%)	0
急性呼吸窮迫症候群	0	1 (0.5%)	0	0	0	0
肺塞栓症	0	0	0	1 (1.7%)	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸困難	0	0	0	0	1 (0.3%)	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）	6 (3.0%)	10 (5.0%)	4 (7.1%)	11 (19.0%)	10 (3.1%)	7 (8.2%)
急性骨髄性白血病	2 (1.0%)	1 (0.5%)	1 (1.8%)	6 (10.3%)	3 (0.9%)	1 (1.2%)
多発性骨髄腫	1 (0.5%)	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
悪性新生物進行	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
芽球発症	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_1a.sas
Program Run: 04JUN21:14:51:22

表 8-114 死亡に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
再発慢性リンパ性白血病	0	0	1 (1.8%)	0	0	1 (1.2%)
骨髄異形成症候群	0	0	1 (1.8%)	0	0	1 (1.2%)
再発急性骨髄性白血病	0	2 (1.0%)	0	2 (3.4%)	1 (0.3%)	0
慢性リンパ性白血病	0	1 (0.5%)	0	1 (1.7%)	0	1 (1.2%)
再発急性リンパ性白血病	0	1 (0.5%)	0	0	1 (0.3%)	0
Ｂ細胞性リンパ腫	0	0	0	1 (1.7%)	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
リンパ腫	0	1 (0.5%)	0	0	0	0
新生物進行	0	0	0	1 (1.7%)	0	0
白血病再発	0	0	0	0	0	1 (1.2%)
心臓障害	4 (2.0%)	4 (2.0%)	0	1 (1.7%)	5 (1.6%)	2 (2.4%)
心停止	1 (0.5%)	3 (1.5%)	0	0	1 (0.3%)	0
心肺停止	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	2 (2.4%)
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.3%)	0
心膜炎	1 (0.5%)	0	0	0	1 (0.3%)	0
急性心筋梗塞	0	0	0	1 (1.7%)	0	0
急性心不全	0	0	0	0	1 (0.3%)	0
神経系障害	2 (1.0%)	6 (3.0%)	1 (1.8%)	1 (1.7%)	2 (0.6%)	3 (3.5%)
頭蓋内出血	1 (0.5%)	2 (1.0%)	1 (1.8%)	1 (1.7%)	1 (0.3%)	1 (1.2%)
神経毒性	1 (0.5%)	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_1a.sas
Program Run: 04JUN21:14:51:22

表 8-114 死亡に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
脳出血	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	0	2 (2.4%)
全身障害および投与局所様態	2 (1.0%)	8 (4.0%)	0	0	4 (1.3%)	3 (3.5%)
多臓器不全	1 (0.5%)	6 (3.0%)	0	0	2 (0.6%)	0
死亡	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	2 (2.4%)
心突然死	0	1 (0.5%)	0	0	0	0
全身健康状態低下	0	0	0	0	0	1 (1.2%)
血管障害	1 (0.5%)	0	1 (1.8%)	1 (1.7%)	1 (0.3%)	2 (2.4%)
出血	0	0	1 (1.8%)	0	0	1 (1.2%)
血液量減少性ショック	1 (0.5%)	0	0	0	1 (0.3%)	0
深部静脈血栓症	0	0	0	1 (1.7%)	0	0
動脈炎	0	0	0	0	0	1 (1.2%)
血液およびリンパ系障害	1 (0.5%)	1 (0.5%)	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
出血性障害	1 (0.5%)	0	0	0	1 (0.3%)	0
血小板減少症	0	0	1 (1.8%)	0	0	1 (1.2%)
汎血球減少症	0	1 (0.5%)	0	0	0	0
免疫系障害	1 (0.5%)	0	0	0	2 (0.6%)	0
急性移植片対宿主病	1 (0.5%)	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_1a.sas
Program Run: 04JUN21:14:51:22

表 8-114 死亡に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
移植片対宿主病	0	0	0	0	1 (0.3%)	0
腎および尿路障害	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
腎不全	0	0	1 (1.8%)	0	0	1 (1.2%)
急性腎不全	0	0	0	0	1 (0.3%)	0
肝胆道系障害	1 (0.5%)	0	0	0	1 (0.3%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.3%)	0
代謝および栄養障害	0	1 (0.5%)	0	1 (1.7%)	0	0
低血糖症	0	0	0	1 (1.7%)	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0
胃腸障害	0	0	0	1 (1.7%)	0	0
直腸出血	0	0	0	1 (1.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_death_1a.sas
Program Run: 04JUN21:14:51:22

表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
Overall	99 (49.3%)	116 (57.7%)	35 (62.5%)	33 (56.9%)	166 (52.2%)	57 (67.1%)
感染症および寄生虫症	35 (17.4%)	52 (25.9%)	16 (28.6%)	9 (15.5%)	80 (25.2%)	26 (30.6%)
敗血症性ショック	12 (6.0%)	10 (5.0%)	2 (3.6%)	0	16 (5.0%)	4 (4.7%)
敗血症	5 (2.5%)	8 (4.0%)	2 (3.6%)	0	7 (2.2%)	3 (3.5%)
肺炎	4 (2.0%)	9 (4.5%)	1 (1.8%)	1 (1.7%)	11 (3.5%)	1 (1.2%)
アスペルギルス症	2 (1.0%)	3 (1.5%)	2 (3.6%)	0	4 (1.3%)	3 (3.5%)
真菌感染	2 (1.0%)	2 (1.0%)	1 (1.8%)	1 (1.7%)	3 (0.9%)	1 (1.2%)
サイトメガロウイルス感染	2 (1.0%)	1 (0.5%)	0	1 (1.7%)	4 (1.3%)	0
気管支肺アスペルギルス症	1 (0.5%)	1 (0.5%)	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
シュードモナス性敗血症	0	1 (0.5%)	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
大腸菌性敗血症	1 (0.5%)	0	0	1 (1.7%)	2 (0.6%)	0
尿路感染	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	1 (1.2%)
蜂巣炎	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
クレブシエラ性菌血症	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
クレブシエラ性敗血症	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
ムコール症	0	0	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
クロストリジウム・ディフィシレ大腸炎	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
腸球菌性菌血症	1 (0.5%)	0	0	0	2 (0.6%)	0
ブドウ球菌感染	0	0	1 (1.8%)	0	0	2 (2.4%)
アシネトバクター性菌血症	1 (0.5%)	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
Program Run: 04JUN21:14:51:27

表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
肺炎球菌性気管支炎	1 (0.5%)	0	0	0	1 (0.3%)	0
気管支肺炎	1 (0.5%)	0	0	0	1 (0.3%)	0
脳アスペルギルス症	1 (0.5%)	0	0	0	1 (0.3%)	0
サイトメガロウイルス血症	1 (0.5%)	0	0	0	1 (0.3%)	0
ヘルペス脳炎	0	0	1 (1.8%)	0	0	1 (1.2%)
心内膜炎	0	0	1 (1.8%)	0	0	1 (1.2%)
フサリウム感染	0	0	1 (1.8%)	0	0	1 (1.2%)
感染	1 (0.5%)	0	0	0	1 (0.3%)	0
注入部位感染	0	0	1 (1.8%)	0	0	1 (1.2%)
筋膿瘍	1 (0.5%)	0	0	0	1 (0.3%)	0
モラクセラ菌性肺炎	1 (0.5%)	0	0	0	1 (0.3%)	0
気道感染	1 (0.5%)	0	0	0	1 (0.3%)	0
敗血症症候群	0	0	1 (1.8%)	0	0	1 (1.2%)
皮膚感染	1 (0.5%)	0	0	0	1 (0.3%)	0
細菌性敗血症	0	2 (1.0%)	0	2 (3.4%)	1 (0.3%)	0
ブドウ球菌性菌血症	0	3 (1.5%)	0	0	1 (0.3%)	0
菌血症	0	2 (1.0%)	0	0	3 (0.9%)	0
ブドウ球菌性敗血症	0	1 (0.5%)	0	1 (1.7%)	1 (0.3%)	0
クロストリジウム性菌血症	0	2 (1.0%)	0	0	0	0
髄膜炎	0	2 (1.0%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
細菌性肺炎	0	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
帯状疱疹	0	1 (0.5%)	0	0	2 (0.6%)	0
蓄膿	0	0	0	1 (1.7%)	1 (0.3%)	0
カンピロバクター胃腸炎	0	1 (0.5%)	0	0	0	0
カテーテル関連感染	0	1 (0.5%)	0	0	0	0
感染性下痢	0	1 (0.5%)	0	0	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (1.7%)	0	0
単純ヘルペス	0	1 (0.5%)	0	0	0	0
肺膿瘍	0	1 (0.5%)	0	0	0	0
壊死性筋膜炎	0	1 (0.5%)	0	0	0	0
肺炎球菌性肺炎	0	1 (0.5%)	0	0	0	0
ブドウ球菌性肺炎	0	1 (0.5%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
シュードモナス感染	0	1 (0.5%)	0	0	0	0
膿胸	0	1 (0.5%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0
トキソプラズマ症	0	1 (0.5%)	0	0	0	0
結核	0	1 (0.5%)	0	0	0	0
細菌性尿路感染	0	1 (0.5%)	0	0	0	0

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A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
真菌性肺炎	0	0	0	0	1 (0.3%)	1 (1.2%)
接合真菌症	0	0	0	0	2 (0.6%)	0
腹部膿瘍	0	0	0	0	1 (0.3%)	0
虫垂炎	0	0	0	0	1 (0.3%)	0
ＢＫウイルス感染	0	0	0	0	1 (0.3%)	0
脳膿瘍	0	0	0	0	1 (0.3%)	0
気管支拡張症	0	0	0	0	1 (0.3%)	0
細気管支炎	0	0	0	0	1 (0.3%)	0
カテーテル留置部位感染	0	0	0	0	1 (0.3%)	0
サイトメガロウイルス性小腸炎	0	0	0	0	1 (0.3%)	0
大腸菌性菌血症	0	0	0	0	0	1 (1.2%)
真菌性敗血症	0	0	0	0	1 (0.3%)	0
ノロウイルス性胃腸炎	0	0	0	0	1 (0.3%)	0
ウイルス性胃腸炎	0	0	0	0	1 (0.3%)	0
インフルエンザ	0	0	0	0	1 (0.3%)	0
肺感染	0	0	0	0	1 (0.3%)	0
シュードモナス菌性肺感染	0	0	0	0	1 (0.3%)	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	1 (0.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (1.2%)
インフルエンザ性肺炎	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
原発性異型肺炎	0	0	0	0	0	1 (1.2%)
シュードモナス性気管支炎	0	0	0	0	1 (0.3%)	0
副鼻腔炎	0	0	0	0	0	1 (1.2%)
真菌性副鼻腔炎	0	0	0	0	1 (0.3%)	0
レンサ球菌性菌血症	0	0	0	0	1 (0.3%)	0
皮下組織膿瘍	0	0	0	0	1 (0.3%)	0
尿路性敗血症	0	0	0	0	0	1 (1.2%)
ウイルス性下痢	0	0	0	0	1 (0.3%)	0
呼吸器、胸郭および縦隔障害	34 (16.9%)	35 (17.4%)	7 (12.5%)	8 (13.8%)	51 (16.0%)	10 (11.8%)
呼吸不全	13 (6.5%)	11 (5.5%)	1 (1.8%)	1 (1.7%)	17 (5.3%)	2 (2.4%)
急性呼吸不全	5 (2.5%)	4 (2.0%)	0	1 (1.7%)	8 (2.5%)	0
呼吸困難	3 (1.5%)	1 (0.5%)	2 (3.6%)	0	4 (1.3%)	2 (2.4%)
呼吸窮迫	3 (1.5%)	2 (1.0%)	1 (1.8%)	1 (1.7%)	3 (0.9%)	1 (1.2%)
喀血	2 (1.0%)	2 (1.0%)	0	0	3 (0.9%)	1 (1.2%)
低酸素症	2 (1.0%)	1 (0.5%)	0	0	3 (0.9%)	0
肺出血	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	0
胸水	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	0
肺水腫	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	0
肺障害	0	0	1 (1.8%)	1 (1.7%)	0	1 (1.2%)
呼吸抑制	0	1 (0.5%)	1 (1.8%)	0	0	1 (1.2%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
嚥下性肺炎	1 (0.5%)	0	0	0	3 (0.9%)	0
頻呼吸	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
気管支胸膜瘻	1 (0.5%)	0	0	0	1 (0.3%)	0
気管支痙攣	0	0	1 (1.8%)	0	0	1 (1.2%)
水気胸	1 (0.5%)	0	0	0	1 (0.3%)	0
胸膜痛	0	0	1 (1.8%)	0	0	1 (1.2%)
呼吸性アシドーシス	1 (0.5%)	0	0	0	1 (0.3%)	0
鼻出血	0	2 (1.0%)	0	2 (3.4%)	0	0
肺塞栓症	0	2 (1.0%)	0	1 (1.7%)	1 (0.3%)	0
肺浸潤	0	2 (1.0%)	0	1 (1.7%)	0	0
急性呼吸窮迫症候群	0	2 (1.0%)	0	0	1 (0.3%)	0
急性肺損傷	0	1 (0.5%)	0	0	0	0
慢性閉塞性肺疾患	0	1 (0.5%)	0	0	0	0
咳嗽	0	1 (0.5%)	0	0	0	0
血胸	0	1 (0.5%)	0	0	0	0
気胸	0	1 (0.5%)	0	0	0	0
湿性咳嗽	0	1 (0.5%)	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸停止	0	1 (0.5%)	0	0	0	0
高炭酸ガス血症	0	0	0	0	1 (0.3%)	0

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A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
肺胞出血	0	0	0	0	0	1 (1.2%)
肺梗塞	0	0	0	0	1 (0.3%)	0
副鼻腔障害	0	0	0	0	0	1 (1.2%)
喘鳴	0	0	0	0	1 (0.3%)	0
血液およびリンパ系障害	18 (9.0%)	15 (7.5%)	10 (17.9%)	2 (3.4%)	23 (7.2%)	10 (11.8%)
発熱性好中球減少症	7 (3.5%)	5 (2.5%)	7 (12.5%)	0	9 (2.8%)	7 (8.2%)
汎血球減少症	2 (1.0%)	3 (1.5%)	2 (3.6%)	0	3 (0.9%)	2 (2.4%)
好中球減少症	4 (2.0%)	3 (1.5%)	0	0	4 (1.3%)	0
血小板減少症	2 (1.0%)	3 (1.5%)	1 (1.8%)	1 (1.7%)	2 (0.6%)	1 (1.2%)
無顆粒球症	2 (1.0%)	0	0	0	2 (0.6%)	0
貧血	0	2 (1.0%)	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
出血性障害	1 (0.5%)	0	0	0	1 (0.3%)	0
白血球増加症	1 (0.5%)	0	0	0	1 (0.3%)	0
脾臓梗塞	0	0	1 (1.8%)	0	0	1 (1.2%)
出血性貧血	0	0	0	1 (1.7%)	0	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
血小板減少性紫斑病	0	0	0	1 (1.7%)	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）	13 (6.5%)	16 (8.0%)	5 (8.9%)	13 (22.4%)	18 (5.7%)	8 (9.4%)
急性骨髄性白血病	2 (1.0%)	1 (0.5%)	1 (1.8%)	7 (12.1%)	3 (0.9%)	2 (2.4%)
リンパ腫	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	0

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A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
多発性骨髄腫	1 (0.5%)	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
悪性新生物進行	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
再発急性リンパ性白血病	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	0
芽球発症	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
新生物進行	1 (0.5%)	0	0	1 (1.7%)	1 (0.3%)	0
再発慢性リンパ性白血病	0	0	1 (1.8%)	0	0	1 (1.2%)
子宮内膜癌	0	0	1 (1.8%)	0	0	1 (1.2%)
髄膜転移	1 (0.5%)	0	0	0	1 (0.3%)	0
骨髄異形成症候群	0	0	1 (1.8%)	0	0	1 (1.2%)
非ホジキンリンパ腫	1 (0.5%)	0	0	0	1 (0.3%)	0
原発性体腔性リンパ腫	1 (0.5%)	0	0	0	1 (0.3%)	0
再発急性骨髄性白血病	0	3 (1.5%)	0	2 (3.4%)	2 (0.6%)	0
慢性リンパ性白血病	0	1 (0.5%)	0	1 (1.7%)	0	1 (1.2%)
急性白血病	0	1 (0.5%)	0	0	0	0
急性リンパ性白血病	0	1 (0.5%)	0	0	0	0
Ｂ細胞性リンパ腫	0	0	0	1 (1.7%)	0	0
再発Ｂ細胞性リンパ腫	0	0	0	1 (1.7%)	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
白血病	0	1 (0.5%)	0	0	0	0
肺の悪性新生物	0	0	0	1 (1.7%)	0	0
骨転移	0	1 (0.5%)	0	0	0	0
転移部痛	0	1 (0.5%)	0	0	0	0
白血病再発	0	0	0	0	0	1 (1.2%)
白血病浸潤	0	0	0	0	1 (0.3%)	0
神経系障害	13 (6.5%)	14 (7.0%)	4 (7.1%)	2 (3.4%)	17 (5.3%)	9 (10.6%)
痙攣	3 (1.5%)	1 (0.5%)	0	0	4 (1.3%)	1 (1.2%)
頭蓋内出血	1 (0.5%)	2 (1.0%)	1 (1.8%)	1 (1.7%)	1 (0.3%)	1 (1.2%)
てんかん	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	0
多発ニューロパチー	2 (1.0%)	0	0	0	2 (0.6%)	0
中枢神経系病変	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
脳症	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
虚血性脳卒中	0	0	1 (1.8%)	1 (1.7%)	0	1 (1.2%)
対麻痺	0	1 (0.5%)	1 (1.8%)	0	0	1 (1.2%)
頭痛	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
脳幹卒中	1 (0.5%)	0	0	0	1 (0.3%)	0
脳虚血	1 (0.5%)	0	0	0	1 (0.3%)	0
熱性痙攣	0	0	1 (1.8%)	0	0	1 (1.2%)
神経毒性	1 (0.5%)	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
失語症	0	1 (0.5%)	0	0	0	1 (1.2%)
脳出血	0	1 (0.5%)	0	0	0	0
浮動性めまい	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
片麻痺	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0
第 7 脳神経麻痺	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	1 (0.3%)	2 (2.4%)
脳血管発作	0	0	0	0	0	1 (1.2%)
卒中の出血性変化	0	0	0	0	1 (0.3%)	0
不全片麻痺	0	0	0	0	0	1 (1.2%)
一過性脳虚血発作	0	0	0	0	0	1 (1.2%)
全身障害および投与局所様態	9 (4.5%)	17 (8.5%)	2 (3.6%)	2 (3.4%)	14 (4.4%)	6 (7.1%)
発熱	6 (3.0%)	8 (4.0%)	2 (3.6%)	2 (3.4%)	8 (2.5%)	2 (2.4%)
多臓器不全	1 (0.5%)	7 (3.5%)	0	0	2 (0.6%)	0
死亡	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	2 (2.4%)
悪寒	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
全身健康状態低下	1 (0.5%)	0	0	0	1 (0.3%)	1 (1.2%)
無力症	1 (0.5%)	0	0	0	1 (0.3%)	0
胸痛	1 (0.5%)	0	0	0	1 (0.3%)	0
心突然死	0	1 (0.5%)	0	0	0	0
非心臓性胸痛	0	0	0	0	1 (0.3%)	1 (1.2%)
末梢性浮腫	0	0	0	0	1 (0.3%)	0
心臓障害	6 (3.0%)	11 (5.5%)	5 (8.9%)	1 (1.7%)	10 (3.1%)	9 (10.6%)
心肺停止	2 (1.0%)	2 (1.0%)	0	0	2 (0.6%)	2 (2.4%)
心停止	1 (0.5%)	5 (2.5%)	0	0	1 (0.3%)	0
心房細動	0	1 (0.5%)	1 (1.8%)	0	0	3 (3.5%)
急性心筋梗塞	0	0	1 (1.8%)	1 (1.7%)	1 (0.3%)	1 (1.2%)
不整脈	1 (0.5%)	0	0	0	1 (0.3%)	0
心原性ショック	0	0	1 (1.8%)	0	0	1 (1.2%)
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.3%)	0
心膜炎	1 (0.5%)	0	0	0	1 (0.3%)	0
洞性徐脈	0	0	1 (1.8%)	0	0	1 (1.2%)
上室性頻脈	0	0	1 (1.8%)	0	0	1 (1.2%)
心室性頻脈	0	2 (1.0%)	0	0	0	0
狭心症	0	1 (0.5%)	0	0	0	0
完全房室ブロック	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
Program Run: 04JUN21:14:51:27

表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
急性心不全	0	0	0	0	1 (0.3%)	0
電気収縮解離	0	0	0	0	1 (0.3%)	0
腎および尿路障害	7 (3.5%)	5 (2.5%)	3 (5.4%)	5 (8.6%)	13 (4.1%)	6 (7.1%)
急性腎不全	4 (2.0%)	4 (2.0%)	2 (3.6%)	4 (6.9%)	9 (2.8%)	5 (5.9%)
腎不全	2 (1.0%)	1 (0.5%)	1 (1.8%)	1 (1.7%)	3 (0.9%)	1 (1.2%)
血尿	1 (0.5%)	0	0	0	1 (0.3%)	0
胃腸障害	6 (3.0%)	10 (5.0%)	3 (5.4%)	2 (3.4%)	19 (6.0%)	8 (9.4%)
下痢	2 (1.0%)	1 (0.5%)	0	0	3 (0.9%)	1 (1.2%)
小腸閉塞	1 (0.5%)	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
悪心	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
腸出血	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
腹膜炎	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
腹痛	0	0	1 (1.8%)	0	4 (1.3%)	2 (2.4%)
大腸炎	0	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
便秘	0	0	1 (1.8%)	0	0	2 (2.4%)
胃穿孔	1 (0.5%)	0	0	0	1 (0.3%)	0
食道潰瘍	1 (0.5%)	0	0	0	1 (0.3%)	0
胃腸出血	0	2 (1.0%)	0	1 (1.7%)	1 (0.3%)	2 (2.4%)
食中毒	0	1 (0.5%)	0	0	0	0
胃腸の炎症	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
麻痺性イレウス	0	1 (0.5%)	0	0	0	0
肛門周囲痛	0	1 (0.5%)	0	0	0	0
直腸出血	0	0	0	1 (1.7%)	0	0
嘔吐	0	0	0	0	3 (0.9%)	1 (1.2%)
嚥下障害	0	0	0	0	1 (0.3%)	1 (1.2%)
潰瘍性大腸炎	0	0	0	0	1 (0.3%)	0
限局性腹腔内液貯留	0	0	0	0	1 (0.3%)	0
食道炎	0	0	0	0	1 (0.3%)	0
膵炎	0	0	0	0	1 (0.3%)	0
慢性膵炎	0	0	0	0	1 (0.3%)	0
再発性膵炎	0	0	0	0	1 (0.3%)	0
免疫系障害	3 (1.5%)	5 (2.5%)	1 (1.8%)	1 (1.7%)	7 (2.2%)	2 (2.4%)
急性腸管移植片対宿主病	1 (0.5%)	1 (0.5%)	0	1 (1.7%)	1 (0.3%)	0
急性移植片対宿主病	1 (0.5%)	1 (0.5%)	0	0	2 (0.6%)	1 (1.2%)
アナフィラキシーショック	1 (0.5%)	0	0	0	1 (0.3%)	0
過敏症	0	0	1 (1.8%)	0	0	1 (1.2%)
アナフィラキシー反応	0	2 (1.0%)	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0
移植片対宿主病	0	0	0	0	2 (0.6%)	0
肺移植拒絶反応	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
血管障害	3 (1.5%)	4 (2.0%)	1 (1.8%)	2 (3.4%)	7 (2.2%)	2 (2.4%)
低血圧	1 (0.5%)	1 (0.5%)	0	1 (1.7%)	3 (0.9%)	0
出血	0	1 (0.5%)	1 (1.8%)	0	0	1 (1.2%)
血液量減少性ショック	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
血管炎	1 (0.5%)	0	0	0	1 (0.3%)	0
深部静脈血栓症	0	0	0	1 (1.7%)	2 (0.6%)	0
ショック	0	1 (0.5%)	0	0	0	0
動脈炎	0	0	0	0	0	1 (1.2%)
肝胆道系障害	3 (1.5%)	4 (2.0%)	0	2 (3.4%)	8 (2.5%)	0
胆嚢炎	1 (0.5%)	0	0	0	2 (0.6%)	0
肝炎	1 (0.5%)	0	0	0	1 (0.3%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.3%)	0
肝不全	0	2 (1.0%)	0	0	0	0
肝機能異常	0	2 (1.0%)	0	0	0	0
高ビリルビン血症	0	1 (0.5%)	0	1 (1.7%)	0	0
急性胆嚢炎	0	0	0	1 (1.7%)	0	0
急性肝不全	0	0	0	0	1 (0.3%)	0
細胆管炎	0	0	0	0	1 (0.3%)	0
胆石症	0	0	0	0	1 (0.3%)	0
肝障害	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
臨床検査	3 (1.5%)	5 (2.5%)	0	1 (1.7%)	3 (0.9%)	0
肝機能検査異常	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
血中ナトリウム減少	1 (0.5%)	0	0	0	1 (0.3%)	0
ヘモグロビン減少	1 (0.5%)	0	0	0	1 (0.3%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	1 (1.7%)	0	0
血中ビリルビン増加	0	1 (0.5%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
肝酵素上昇	0	1 (0.5%)	0	0	0	0
傷害、中毒および処置合併症	2 (1.0%)	2 (1.0%)	1 (1.8%)	1 (1.7%)	2 (0.6%)	1 (1.2%)
薬物毒性	2 (1.0%)	0	0	0	2 (0.6%)	0
転倒・転落	0	0	1 (1.8%)	0	0	1 (1.2%)
家庭内事故	0	1 (0.5%)	0	0	0	0
大腿骨頚部骨折	0	0	0	1 (1.7%)	0	0
橈骨骨折	0	1 (0.5%)	0	0	0	0
皮膚および皮下組織障害	2 (1.0%)	2 (1.0%)	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
褥瘡性潰瘍	1 (0.5%)	0	0	0	1 (0.3%)	0
皮膚炎	1 (0.5%)	0	0	0	1 (0.3%)	0
脂肪織炎	0	0	1 (1.8%)	0	0	1 (1.2%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
発疹	0	2 (1.0%)	0	0	0	0
筋骨格系および結合組織障害	2 (1.0%)	0	1 (1.8%)	0	5 (1.6%)	2 (2.4%)
筋骨格系胸痛	1 (0.5%)	0	0	0	2 (0.6%)	1 (1.2%)
筋肉内出血	0	0	1 (1.8%)	0	0	1 (1.2%)
筋炎	1 (0.5%)	0	0	0	1 (0.3%)	0
関節炎	0	0	0	0	1 (0.3%)	0
四肢痛	0	0	0	0	0	1 (1.2%)
全身性エリテマトーデス	0	0	0	0	1 (0.3%)	0
代謝および栄養障害	1 (0.5%)	5 (2.5%)	1 (1.8%)	2 (3.4%)	7 (2.2%)	2 (2.4%)
コントロール不良の糖尿病	0	0	1 (1.8%)	0	0	1 (1.2%)
成長障害	1 (0.5%)	0	0	0	1 (0.3%)	0
脱水	0	0	0	2 (3.4%)	3 (0.9%)	0
代謝性アシドーシス	0	2 (1.0%)	0	0	0	0
低血糖症	0	0	0	1 (1.7%)	1 (0.3%)	0
高ナトリウム血症	0	1 (0.5%)	0	0	0	0
低カリウム血症	0	1 (0.5%)	0	0	0	0
過小食	0	1 (0.5%)	0	0	0	0
高カリウム血症	0	0	0	0	0	1 (1.2%)
低ナトリウム血症	0	0	0	0	1 (0.3%)	0
栄養障害	0	0	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
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表 8-115 重篤な有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
眼障害	1 (0.5%)	1 (0.5%)	1 (1.8%)	0	3 (0.9%)	1 (1.2%)
片側失明	0	0	1 (1.8%)	0	0	1 (1.2%)
視神経症	1 (0.5%)	0	0	0	1 (0.3%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0
網膜動脈閉塞	0	0	0	0	1 (0.3%)	0
網膜出血	0	0	0	0	1 (0.3%)	0
硝子体出血	0	0	0	0	1 (0.3%)	0
精神障害	1 (0.5%)	3 (1.5%)	0	3 (5.2%)	2 (0.6%)	1 (1.2%)
うつ病	1 (0.5%)	0	0	0	1 (0.3%)	0
幻視	0	0	0	2 (3.4%)	0	0
精神状態変化	0	1 (0.5%)	0	1 (1.7%)	0	0
錯乱状態	0	0	0	1 (1.7%)	1 (0.3%)	0
幻覚	0	1 (0.5%)	0	0	1 (0.3%)	0
抑うつ気分	0	0	0	1 (1.7%)	0	0
自殺企図	0	1 (0.5%)	0	0	0	0
異常行動	0	0	0	0	0	1 (1.2%)
攻撃性	0	0	0	0	0	1 (1.2%)
激越	0	0	0	0	0	1 (1.2%)
生殖系および乳房障害	0	0	0	0	0	1 (1.2%)
良性前立腺肥大症	0	0	0	0	0	1 (1.2%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_age_ser_1a.sas
Program Run: 04JUN21:14:51:27

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
Overall	29 (14.4%)	44 (21.9%)	8 (14.3%)	15 (25.9%)	44 (13.8%)	12 (14.1%)
感染症および寄生虫症	7 (3.5%)	13 (6.5%)	4 (7.1%)	2 (3.4%)	12 (3.8%)	6 (7.1%)
真菌感染	1 (0.5%)	1 (0.5%)	1 (1.8%)	0	2 (0.6%)	1 (1.2%)
敗血症性ショック	2 (1.0%)	0	0	0	4 (1.3%)	0
敗血症	1 (0.5%)	3 (1.5%)	0	0	1 (0.3%)	0
アスペルギルス症	0	1 (0.5%)	1 (1.8%)	0	1 (0.3%)	2 (2.4%)
肺炎	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
気管支肺炎	1 (0.5%)	0	0	0	1 (0.3%)	0
気管支肺アスペルギルス症	0	0	1 (1.8%)	0	0	1 (1.2%)
心内膜炎	0	0	1 (1.8%)	0	0	1 (1.2%)
感染	1 (0.5%)	0	0	0	1 (0.3%)	0
細菌性敗血症	0	1 (0.5%)	0	2 (3.4%)	0	0
肺感染	0	2 (1.0%)	0	0	0	0
髄膜炎	0	1 (0.5%)	0	0	0	0
ムコール症	0	1 (0.5%)	0	0	0	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	0	0
ブドウ球菌感染	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
脳膿瘍	0	0	0	0	1 (0.3%)	0
大腸菌性菌血症	0	0	0	0	0	1 (1.2%)
呼吸器、胸郭および縦隔障害	5 (2.5%)	5 (2.5%)	1 (1.8%)	0	5 (1.6%)	1 (1.2%)
呼吸不全	2 (1.0%)	4 (2.0%)	0	0	2 (0.6%)	0
呼吸困難	1 (0.5%)	0	1 (1.8%)	0	1 (0.3%)	1 (1.2%)
呼吸窮迫	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
急性呼吸不全	1 (0.5%)	0	0	0	1 (0.3%)	0
神経系障害	5 (2.5%)	4 (2.0%)	0	0	6 (1.9%)	1 (1.2%)
痙攣	2 (1.0%)	0	0	0	2 (0.6%)	0
てんかん	2 (1.0%)	0	0	0	2 (0.6%)	0
脳症	1 (0.5%)	0	0	0	1 (0.3%)	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0
脳血管発作	0	0	0	0	0	1 (1.2%)
卒中の出血性変化	0	0	0	0	1 (0.3%)	0
臨床検査	3 (1.5%)	4 (2.0%)	1 (1.8%)	2 (3.4%)	5 (1.6%)	1 (1.2%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
血中ビリルビン増加	2 (1.0%)	0	0	0	2 (0.6%)	0
血中ナトリウム減少	1 (0.5%)	0	0	0	1 (0.3%)	0
トランスアミナーゼ上昇	0	0	1 (1.8%)	0	0	1 (1.2%)
肝機能検査異常	0	1 (0.5%)	0	1 (1.7%)	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	1 (0.3%)	0
血中アルカリホスファターゼ増加	0	0	0	1 (1.7%)	1 (0.3%)	0
肝酵素上昇	0	1 (0.5%)	0	0	1 (0.3%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	1 (0.3%)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	1 (0.3%)	0
心臓障害	3 (1.5%)	3 (1.5%)	1 (1.8%)	0	3 (0.9%)	1 (1.2%)
心停止	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
心肺停止	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.3%)	0
上室性頻脈	0	0	1 (1.8%)	0	0	1 (1.2%)
心室性頻脈	0	1 (0.5%)	0	0	0	0
腎および尿路障害	3 (1.5%)	3 (1.5%)	0	0	5 (1.6%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
腎不全	2 (1.0%)	1 (0.5%)	0	0	2 (0.6%)	0
急性腎不全	1 (0.5%)	2 (1.0%)	0	0	3 (0.9%)	0
精神障害	2 (1.0%)	2 (1.0%)	0	4 (6.9%)	3 (0.9%)	0
錯乱状態	2 (1.0%)	0	0	2 (3.4%)	3 (0.9%)	0
幻視	0	0	0	3 (5.2%)	0	0
幻覚	0	1 (0.5%)	0	0	1 (0.3%)	0
抑うつ気分	0	0	0	1 (1.7%)	0	0
不快気分	0	1 (0.5%)	0	0	0	0
皮膚および皮下組織障害	2 (1.0%)	4 (2.0%)	0	1 (1.7%)	2 (0.6%)	0
皮膚炎	1 (0.5%)	0	0	0	1 (0.3%)	0
アレルギー性皮膚炎	1 (0.5%)	0	0	0	1 (0.3%)	0
発疹	0	3 (1.5%)	0	1 (1.7%)	0	0
薬疹	0	1 (0.5%)	0	0	0	0
胃腸障害	2 (1.0%)	2 (1.0%)	0	1 (1.7%)	4 (1.3%)	0
嘔吐	1 (0.5%)	2 (1.0%)	0	0	2 (0.6%)	0
嚥下障害	1 (0.5%)	0	0	0	1 (0.3%)	0
小腸閉塞	1 (0.5%)	0	0	0	1 (0.3%)	0
悪心	0	1 (0.5%)	0	1 (1.7%)	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
肝胆道系障害	1 (0.5%)	5 (2.5%)	0	1 (1.7%)	2 (0.6%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.3%)	0
肝不全	0	2 (1.0%)	0	0	0	0
高ビリルビン血症	0	1 (0.5%)	0	1 (1.7%)	0	0
肝機能異常	0	1 (0.5%)	0	0	0	0
肝病変	0	1 (0.5%)	0	0	0	0
肝炎	0	1 (0.5%)	0	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (1.7%)	0	0
急性肝不全	0	0	0	0	1 (0.3%)	0
血液およびリンパ系障害	0	3 (1.5%)	1 (1.8%)	0	0	1 (1.2%)
汎血球減少症	0	1 (0.5%)	1 (1.8%)	0	0	1 (1.2%)
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
脾臓病変	0	1 (0.5%)	0	0	0	0
眼障害	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
視神経症	1 (0.5%)	0	0	0	1 (0.3%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0
全身障害および投与局所様態	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0
悪寒	1 (0.5%)	1 (0.5%)	0	0	1 (0.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-116 投与中止に至った有害事象（年齢別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
Age (years) Subgroup	<= 65		65 <		<= 65	65 <
System Organ Class Preferred Term	ISA (N = 201)	VRC (N = 201)	ISA (N = 56)	VRC (N = 58)	ISA (N = 318)	ISA (N = 85)
傷害、中毒および処置合併症	1 (0.5%)	0	0	0	1 (0.3%)	0
過量投与	1 (0.5%)	0	0	0	1 (0.3%)	0
筋骨格系および結合組織障害	1 (0.5%)	0	0	0	1 (0.3%)	0
筋炎	1 (0.5%)	0	0	0	1 (0.3%)	0
血管障害	1 (0.5%)	0	0	0	1 (0.3%)	0
低血圧	1 (0.5%)	0	0	0	1 (0.3%)	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	1 (0.5%)	0	6 (10.3%)	2 (0.6%)	1 (1.2%)
急性骨髄性白血病	0	1 (0.5%)	0	3 (5.2%)	0	0
再発急性骨髄性白血病	0	0	0	1 (1.7%)	1 (0.3%)	0
慢性リンパ性白血病	0	0	0	1 (1.7%)	0	0
肺の悪性新生物	0	0	0	1 (1.7%)	0	0
白血病再発	0	0	0	0	0	1 (1.2%)
悪性新生物進行	0	0	0	0	1 (0.3%)	0
免疫系障害	0	1 (0.5%)	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0
代謝および栄養障害	0	1 (0.5%)	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_age_discon_1a.sas
Program Run: 04JUN21:14:51:32

表 8-117 SOC別の有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
Overall	47 (90.4%)	25 (96.2%)	8 (100.0%)	3 (75.0%)	54 (91.5%)	13 (92.9%)
感染症および寄生虫症	19 (36.5%)	9 (34.6%)	3 (37.5%)	1 (25.0%)	21 (35.6%)	4 (28.6%)
胃腸障害	12 (23.1%)	10 (38.5%)	5 (62.5%)	2 (50.0%)	14 (23.7%)	7 (50.0%)
臨床検査	15 (28.8%)	7 (26.9%)	1 (12.5%)	0	17 (28.8%)	4 (28.6%)
肝胆道系障害	9 (17.3%)	10 (38.5%)	2 (25.0%)	0	10 (16.9%)	2 (14.3%)
神経系障害	8 (15.4%)	6 (23.1%)	2 (25.0%)	0	10 (16.9%)	5 (35.7%)
皮膚および皮下組織障害	6 (11.5%)	3 (11.5%)	3 (37.5%)	1 (25.0%)	7 (11.9%)	4 (28.6%)
眼障害	6 (11.5%)	12 (46.2%)	2 (25.0%)	1 (25.0%)	7 (11.9%)	3 (21.4%)
代謝および栄養障害	7 (13.5%)	2 (7.7%)	1 (12.5%)	0	8 (13.6%)	3 (21.4%)
一般・全身障害および投与部位の状態	7 (13.5%)	1 (3.8%)	1 (12.5%)	0	8 (13.6%)	1 (7.1%)
呼吸器、胸郭および縦隔障害	7 (13.5%)	2 (7.7%)	0	1 (25.0%)	8 (13.6%)	1 (7.1%)
腎および尿路障害	5 (9.6%)	1 (3.8%)	0	1 (25.0%)	5 (8.5%)	2 (14.3%)
血管障害	3 (5.8%)	1 (3.8%)	2 (25.0%)	0	3 (5.1%)	3 (21.4%)
精神障害	3 (5.8%)	7 (26.9%)	0	0	3 (5.1%)	1 (7.1%)
筋骨格系および結合組織障害	2 (3.8%)	4 (15.4%)	1 (12.5%)	0	2 (3.4%)	2 (14.3%)
傷害、中毒および処置合併症	3 (5.8%)	2 (7.7%)	0	0	4 (6.8%)	0
心臓障害	2 (3.8%)	1 (3.8%)	1 (12.5%)	0	4 (6.8%)	2 (14.3%)
耳および迷路障害	2 (3.8%)	1 (3.8%)	0	0	2 (3.4%)	0
免疫系障害	1 (1.9%)	1 (3.8%)	0	0	1 (1.7%)	0
内分泌障害	0	0	1 (12.5%)	0	1 (1.7%)	1 (7.1%)
先天性、家族性および遺伝性障害	0	3 (11.5%)	0	0	1 (1.7%)	0
血液およびリンパ系障害	0	0	0	1 (25.0%)	1 (1.7%)	1 (7.1%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_soc_2.sas
Program Run: 18JUN21:10:01:39

表 8-118 注目すべき有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
肝機能異常・肝炎	19 (36.5%)	14 (53.8%)	3 (37.5%)	0	20 (33.9%)	4 (28.6%)
アナフィラキシー	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0
トルサード ド ポアント	1 (1.9%)	0	0	0	1 (1.7%)	1 (7.1%)
急性膵炎	0	0	0	0	0	0
精神神経症状	2 (3.8%)	7 (26.9%)	1 (12.5%)	0	3 (5.1%)	2 (14.3%)
視覚障害	5 (9.6%)	15 (57.7%)	2 (25.0%)	0	6 (10.2%)	2 (14.3%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0
静脈内投与例	(N = 8)	(N = 2)	(N = 0)	(N = 0)	(N = 9)	(N = 0)
注入部位／注射部位反応	3 (37.5%)	0	0	0	3 (33.3%)	0
IRR	0	1 (50.0%)	0	0	1 (11.1%)	0

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_sex_eoi_2.sas
Program Run: 18JUN21:10:01:45

表 8-119 死亡に至った有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
Overall	4 (7.7%)	0	0	0	6 (10.2%)	0
呼吸器、胸郭および縦隔障害	2 (3.8%)	0	0	0	3 (5.1%)	0
特発性肺炎症候群	1 (1.9%)	0	0	0	1 (1.7%)	0
肺臓炎	1 (1.9%)	0	0	0	1 (1.7%)	0
誤嚥性肺炎	0	0	0	0	1 (1.7%)	0
感染症および寄生虫症	2 (3.8%)	0	0	0	2 (3.4%)	0
肺炎球菌感染	1 (1.9%)	0	0	0	1 (1.7%)	0
副鼻腔炎	1 (1.9%)	0	0	0	1 (1.7%)	0
神経系障害	1 (1.9%)	0	0	0	1 (1.7%)	0
大脳基底核梗塞	1 (1.9%)	0	0	0	1 (1.7%)	0
心臓障害	0	0	0	0	1 (1.7%)	0
急性心筋梗塞	0	0	0	0	1 (1.7%)	0
一般・全身障害および投与部位の状態	0	0	0	0	1 (1.7%)	0
死亡	0	0	0	0	1 (1.7%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_death_2.sas
Program Run: 18JUN21:10:01:52

表 8-120 重篤な有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
Overall	11 (21.2%)	2 (7.7%)	2 (25.0%)	1 (25.0%)	14 (23.7%)	3 (21.4%)
感染症および寄生虫症	6 (11.5%)	1 (3.8%)	0	1 (25.0%)	7 (11.9%)	1 (7.1%)
肺炎	2 (3.8%)	1 (3.8%)	0	0	2 (3.4%)	0
感染性胸水	2 (3.8%)	0	0	0	2 (3.4%)	0
気管支炎	1 (1.9%)	0	0	0	1 (1.7%)	0
肺炎球菌感染	1 (1.9%)	0	0	0	1 (1.7%)	0
副鼻腔炎	1 (1.9%)	0	0	0	1 (1.7%)	0
アスペルギルス感染	0	0	0	1 (25.0%)	0	0
菌血症	0	0	0	0	0	1 (7.1%)
蜂巣炎	0	0	0	0	1 (1.7%)	0
呼吸器、胸郭および縦隔障害	4 (7.7%)	0	0	0	5 (8.5%)	0
喀血	1 (1.9%)	0	0	0	1 (1.7%)	0
特発性肺炎症候群	1 (1.9%)	0	0	0	1 (1.7%)	0
肺臓炎	1 (1.9%)	0	0	0	1 (1.7%)	0
気胸	1 (1.9%)	0	0	0	1 (1.7%)	0
誤嚥性肺炎	0	0	0	0	1 (1.7%)	0
肝胆道系障害	1 (1.9%)	1 (3.8%)	0	0	1 (1.7%)	0
胆嚢炎	1 (1.9%)	0	0	0	1 (1.7%)	0
薬物性肝障害	0	1 (3.8%)	0	0	0	0
筋骨格系および結合組織障害	0	1 (3.8%)	1 (12.5%)	0	0	1 (7.1%)
筋力低下	0	0	1 (12.5%)	0	0	1 (7.1%)
横紋筋融解症	0	1 (3.8%)	0	0	0	0
内分泌障害	0	0	1 (12.5%)	0	0	1 (7.1%)
抗利尿ホルモン不適合分泌	0	0	1 (12.5%)	0	0	1 (7.1%)
代謝および栄養障害	1 (1.9%)	0	0	0	1 (1.7%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_ser_2.sas
Program Run: 18JUN21:10:01:57

表 8-120 重篤な有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
低ナトリウム血症	1 (1.9%)	0	0	0	1 (1.7%)	0
神経系障害	1 (1.9%)	0	0	0	1 (1.7%)	0
大脳基底核梗塞	1 (1.9%)	0	0	0	1 (1.7%)	0
腎および尿路障害	1 (1.9%)	0	0	0	1 (1.7%)	0
腎機能障害	1 (1.9%)	0	0	0	1 (1.7%)	0
心臓障害	0	0	0	0	2 (3.4%)	0
急性心筋梗塞	0	0	0	0	1 (1.7%)	0
急性心不全	0	0	0	0	1 (1.7%)	0
血液およびリンパ系障害	0	0	0	0	0	1 (7.1%)
好中球減少症	0	0	0	0	0	1 (7.1%)
一般・全身障害および投与部位の状態	0	0	0	0	1 (1.7%)	0
死亡	0	0	0	0	1 (1.7%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_ser_2.sas
Program Run: 18JUN21:10:01:57

表 8-121 投与中止に至った有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
Overall	9 (17.3%)	4 (15.4%)	1 (12.5%)	0	9 (15.3%)	2 (14.3%)
肝胆道系障害	2 (3.8%)	2 (7.7%)	0	0	2 (3.4%)	0
肝機能異常	2 (3.8%)	1 (3.8%)	0	0	2 (3.4%)	0
薬物性肝障害	0	1 (3.8%)	0	0	0	0
感染症および寄生虫症	2 (3.8%)	0	0	0	2 (3.4%)	0
感染性胸水	1 (1.9%)	0	0	0	1 (1.7%)	0
肺炎球菌感染	1 (1.9%)	0	0	0	1 (1.7%)	0
代謝および栄養障害	2 (3.8%)	0	0	0	2 (3.4%)	0
高カリウム血症	1 (1.9%)	0	0	0	1 (1.7%)	0
低ナトリウム血症	1 (1.9%)	0	0	0	1 (1.7%)	0
神経系障害	1 (1.9%)	1 (3.8%)	0	0	1 (1.7%)	0
感覚鈍麻	1 (1.9%)	0	0	0	1 (1.7%)	0
多発ニューロパチー	0	1 (3.8%)	0	0	0	0
臨床検査	0	0	1 (12.5%)	0	0	2 (14.3%)
肝機能検査値上昇	0	0	1 (12.5%)	0	0	1 (7.1%)
心電図異常	0	0	0	0	0	1 (7.1%)
耳および迷路障害	1 (1.9%)	0	0	0	1 (1.7%)	0
耳管開放	1 (1.9%)	0	0	0	1 (1.7%)	0
胃腸障害	1 (1.9%)	0	0	0	1 (1.7%)	0
悪心	1 (1.9%)	0	0	0	1 (1.7%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_2.sas
Program Run: 18JUN21:10:02:02

表 8-121 投与中止に至った有害事象（男女別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 52)	VRC (N = 26)	ISA (N = 8)	VRC (N = 4)	ISA (N = 59)	ISA (N = 14)
一般・全身障害および投与部位の状態	1 (1.9%)	0	0	0	1 (1.7%)	0
注射部位蕁麻疹	1 (1.9%)	0	0	0	1 (1.7%)	0
腎および尿路障害	1 (1.9%)	0	0	0	1 (1.7%)	0
腎機能障害	1 (1.9%)	0	0	0	1 (1.7%)	0
呼吸器、胸郭および縦隔障害	1 (1.9%)	0	0	0	1 (1.7%)	0
呼吸困難	1 (1.9%)	0	0	0	1 (1.7%)	0
口腔咽頭不快感	1 (1.9%)	0	0	0	1 (1.7%)	0
皮膚および皮下組織障害	1 (1.9%)	0	0	0	1 (1.7%)	0
冷汗	1 (1.9%)	0	0	0	1 (1.7%)	0
眼障害	0	1 (3.8%)	0	0	0	0
視力障害	0	1 (3.8%)	0	0	0	0
筋骨格系および結合組織障害	0	1 (3.8%)	0	0	0	0
横紋筋融解症	0	1 (3.8%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_2.sas
Program Run: 18JUN21:10:02:02

表 8-122 SOC別の有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
Overall	139 (95.9%)	161 (98.8%)	108 (96.4%)	94 (97.9%)	234 (95.5%)	152 (96.2%)
胃腸障害	93 (64.1%)	110 (67.5%)	81 (72.3%)	70 (72.9%)	148 (60.4%)	109 (69.0%)
感染症および寄生虫症	87 (60.0%)	97 (59.5%)	65 (58.0%)	61 (63.5%)	148 (60.4%)	95 (60.1%)
全身障害および投与局所様態	79 (54.5%)	88 (54.0%)	69 (61.6%)	56 (58.3%)	122 (49.8%)	94 (59.5%)
呼吸器、胸郭および縦隔障害	77 (53.1%)	96 (58.9%)	66 (58.9%)	51 (53.1%)	122 (49.8%)	84 (53.2%)
代謝および栄養障害	55 (37.9%)	71 (43.6%)	53 (47.3%)	50 (52.1%)	103 (42.0%)	67 (42.4%)
神経系障害	54 (37.2%)	61 (37.4%)	41 (36.6%)	28 (29.2%)	86 (35.1%)	59 (37.3%)
皮膚および皮下組織障害	47 (32.4%)	58 (35.6%)	39 (34.8%)	52 (54.2%)	69 (28.2%)	56 (35.4%)
臨床検査	48 (33.1%)	63 (38.7%)	37 (33.0%)	33 (34.4%)	73 (29.8%)	46 (29.1%)
血液およびリンパ系障害	49 (33.8%)	47 (28.8%)	28 (25.0%)	35 (36.5%)	67 (27.3%)	39 (24.7%)
精神障害	40 (27.6%)	55 (33.7%)	30 (26.8%)	31 (32.3%)	70 (28.6%)	35 (22.2%)
筋骨格系および結合組織障害	33 (22.8%)	51 (31.3%)	36 (32.1%)	26 (27.1%)	60 (24.5%)	49 (31.0%)
血管障害	35 (24.1%)	47 (28.8%)	32 (28.6%)	30 (31.3%)	59 (24.1%)	42 (26.6%)
腎および尿路障害	26 (17.9%)	34 (20.9%)	29 (25.9%)	24 (25.0%)	46 (18.8%)	35 (22.2%)
心臓障害	23 (15.9%)	34 (20.9%)	20 (17.9%)	23 (24.0%)	39 (15.9%)	29 (18.4%)
眼障害	20 (13.8%)	43 (26.4%)	19 (17.0%)	26 (27.1%)	32 (13.1%)	26 (16.5%)
傷害、中毒および処置合併症	19 (13.1%)	26 (16.0%)	14 (12.5%)	13 (13.5%)	34 (13.9%)	21 (13.3%)
肝胆道系障害	9 (6.2%)	25 (15.3%)	14 (12.5%)	17 (17.7%)	21 (8.6%)	18 (11.4%)
免疫系障害	10 (6.9%)	18 (11.0%)	10 (8.9%)	7 (7.3%)	18 (7.3%)	11 (7.0%)
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）	8 (5.5%)	18 (11.0%)	11 (9.8%)	13 (13.5%)	16 (6.5%)	13 (8.2%)
耳および迷路障害	7 (4.8%)	11 (6.7%)	7 (6.3%)	2 (2.1%)	12 (4.9%)	9 (5.7%)
生殖系および乳房障害	2 (1.4%)	5 (3.1%)	6 (5.4%)	8 (8.3%)	10 (4.1%)	7 (4.4%)
内分泌障害	3 (2.1%)	2 (1.2%)	2 (1.8%)	1 (1.0%)	7 (2.9%)	3 (1.9%)
先天性、家族性および遺伝性障害	2 (1.4%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	1 (0.6%)
社会環境	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_soc_1.sas
Program Run: 04JUN21:14:52:00

表 8-123 注目すべき有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
肝機能異常・肝炎	29 (20.0%)	45 (27.6%)	24 (21.4%)	37 (38.5%)	52 (21.2%)	30 (19.0%)
アナフィラキシー	1 (0.7%)	2 (1.2%)	1 (0.9%)	1 (1.0%)	1 (0.4%)	1 (0.6%)
重度皮膚障害	2 (1.4%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	1 (0.6%)
心電図QT短縮	0	0	1 (0.9%)	0	0	1 (0.6%)
トルサード ド ポアント	14 (9.7%)	10 (6.1%)	1 (0.9%)	9 (9.4%)	16 (6.5%)	2 (1.3%)
急性膵炎	0	0	0	0	1 (0.4%)	0
精神神経症状	42 (29.0%)	50 (30.7%)	31 (27.7%)	29 (30.2%)	72 (29.4%)	38 (24.1%)
視覚障害	12 (8.3%)	33 (20.2%)	11 (9.8%)	14 (14.6%)	19 (7.8%)	12 (7.6%)
皮膚または子宮の悪性腫瘍	0	0	1 (0.9%)	0	0	1 (0.6%)
静脈内投与例	(N = 145)	(N = 163)	(N = 112)	(N = 96)	(N = 211)	(N = 146)
注入部位／注射部位反応	5 (3.4%)	2 (1.2%)	6 (5.4%)	2 (2.1%)	8 (3.8%)	8 (5.5%)
IRR	37 (25.5%)	46 (28.2%)	33 (29.5%)	30 (31.3%)	60 (28.4%)	42 (28.8%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_sex_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-124 死亡に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
Overall	30 (20.7%)	44 (27.0%)	32 (28.6%)	28 (29.2%)	65 (26.5%)	41 (25.9%)
感染症および寄生虫症	13 (9.0%)	14 (8.6%)	15 (13.4%)	4 (4.2%)	31 (12.7%)	18 (11.4%)
敗血症性ショック	3 (2.1%)	3 (1.8%)	5 (4.5%)	1 (1.0%)	6 (2.4%)	6 (3.8%)
敗血症	3 (2.1%)	4 (2.5%)	4 (3.6%)	1 (1.0%)	4 (1.6%)	4 (2.5%)
アスペルギルス症	2 (1.4%)	2 (1.2%)	1 (0.9%)	0	3 (1.2%)	1 (0.6%)
真菌感染	1 (0.7%)	1 (0.6%)	2 (1.8%)	1 (1.0%)	1 (0.4%)	2 (1.3%)
肺炎	1 (0.7%)	1 (0.6%)	0	1 (1.0%)	3 (1.2%)	0
ムコール症	1 (0.7%)	0	0	0	2 (0.8%)	0
アシネトバクター性菌血症	0	0	1 (0.9%)	0	0	1 (0.6%)
気管支肺アスペルギルス症	1 (0.7%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.7%)	0	0	0	1 (0.4%)	0
フサリウム感染	0	0	1 (0.9%)	0	0	1 (0.6%)
感染	0	0	1 (0.9%)	0	0	1 (0.6%)
シュードモナス性敗血症	0	1 (0.6%)	0	0	1 (0.4%)	0
クレブシエラ性敗血症	0	1 (0.6%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.6%)	0	0	0	0
真菌性肺炎	0	0	0	0	2 (0.8%)	0
細菌性敗血症	0	0	0	0	1 (0.4%)	0
蓄膿	0	0	0	0	0	1 (0.6%)
真菌性敗血症	0	0	0	0	1 (0.4%)	0
肺感染	0	0	0	0	1 (0.4%)	0
シュードモナス菌性肺感染	0	0	0	0	1 (0.4%)	0
ブラストミセス菌性肺炎	0	0	0	0	1 (0.4%)	0
原発性異型肺炎	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_death_1.sas
Program Run: 04JUN21:14:52:11

表 8-124 死亡に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
真菌性副鼻腔炎	0	0	0	0	1 (0.4%)	0
ブドウ球菌性敗血症	0	0	0	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害	9 (6.2%)	7 (4.3%)	5 (4.5%)	5 (5.2%)	12 (4.9%)	6 (3.8%)
呼吸不全	3 (2.1%)	5 (3.1%)	3 (2.7%)	1 (1.0%)	4 (1.6%)	3 (1.9%)
急性呼吸不全	2 (1.4%)	1 (0.6%)	1 (0.9%)	0	3 (1.2%)	1 (0.6%)
喀血	1 (0.7%)	0	1 (0.9%)	1 (1.0%)	2 (0.8%)	1 (0.6%)
肺出血	2 (1.4%)	0	0	1 (1.0%)	2 (0.8%)	0
呼吸窮迫	1 (0.7%)	0	0	0	1 (0.4%)	0
急性呼吸窮迫症候群	0	1 (0.6%)	0	0	0	0
肺塞栓症	0	0	0	1 (1.0%)	0	0
肺高血圧症	0	0	0	1 (1.0%)	0	0
呼吸困難	0	0	0	0	0	1 (0.6%)
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 (2.1%)	11 (6.7%)	7 (6.3%)	10 (10.4%)	9 (3.7%)	8 (5.1%)
急性骨髄性白血病	0	5 (3.1%)	3 (2.7%)	2 (2.1%)	0	4 (2.5%)
多発性骨髄腫	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
悪性新生物進行	1 (0.7%)	1 (0.6%)	0	0	3 (1.2%)	0
芽球発症	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
骨髄性白血病	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
再発慢性リンパ性白血病	1 (0.7%)	0	0	0	1 (0.4%)	0
骨髄異形成症候群	0	0	1 (0.9%)	0	0	1 (0.6%)
再発急性骨髄性白血病	0	2 (1.2%)	0	2 (2.1%)	1 (0.4%)	0
慢性リンパ性白血病	0	2 (1.2%)	0	0	1 (0.4%)	0
再発急性リンパ性白血病	0	0	0	1 (1.0%)	1 (0.4%)	0
Ｂ細胞性リンパ腫	0	0	0	1 (1.0%)	0	0
バーキット白血病	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_death_1.sas
Program Run: 04JUN21:14:52:11

表 8-124 死亡に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
リンパ腫	0	0	0	1 (1.0%)	0	0
新生物進行	0	0	0	1 (1.0%)	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
心臓障害	3 (2.1%)	2 (1.2%)	1 (0.9%)	3 (3.1%)	5 (2.0%)	2 (1.3%)
心停止	1 (0.7%)	2 (1.2%)	0	1 (1.0%)	1 (0.4%)	0
心肺停止	1 (0.7%)	0	0	1 (1.0%)	3 (1.2%)	0
うっ血性心筋症	0	0	1 (0.9%)	0	0	1 (0.6%)
心膜炎	1 (0.7%)	0	0	0	1 (0.4%)	0
急性心筋梗塞	0	0	0	1 (1.0%)	0	0
急性心不全	0	0	0	0	0	1 (0.6%)
神経系障害	0	3 (1.8%)	3 (2.7%)	4 (4.2%)	2 (0.8%)	3 (1.9%)
頭蓋内出血	0	3 (1.8%)	2 (1.8%)	0	0	2 (1.3%)
神経毒性	0	0	1 (0.9%)	0	0	1 (0.6%)
脳出血	0	0	0	1 (1.0%)	0	0
脳炎	0	0	0	1 (1.0%)	0	0
昏迷	0	0	0	1 (1.0%)	0	0
くも膜下出血	0	0	0	1 (1.0%)	0	0
脳梗塞	0	0	0	0	2 (0.8%)	0
全身障害および投与局所様態	0	5 (3.1%)	2 (1.8%)	3 (3.1%)	3 (1.2%)	4 (2.5%)
多臓器不全	0	4 (2.5%)	1 (0.9%)	2 (2.1%)	1 (0.4%)	1 (0.6%)
死亡	0	1 (0.6%)	1 (0.9%)	0	1 (0.4%)	3 (1.9%)
心突然死	0	0	0	1 (1.0%)	0	0
全身健康状態低下	0	0	0	0	1 (0.4%)	0
血管障害	2 (1.4%)	0	0	1 (1.0%)	3 (1.2%)	0
出血	1 (0.7%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_death_1.sas
Program Run: 04JUN21:14:52:11

表 8-124 死亡に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
血液量減少性ショック	1 (0.7%)	0	0	0	1 (0.4%)	0
深部静脈血栓症	0	0	0	1 (1.0%)	0	0
動脈炎	0	0	0	0	1 (0.4%)	0
血液およびリンパ系障害	1 (0.7%)	0	1 (0.9%)	1 (1.0%)	1 (0.4%)	1 (0.6%)
出血性障害	1 (0.7%)	0	0	0	1 (0.4%)	0
血小板減少症	0	0	1 (0.9%)	0	0	1 (0.6%)
汎血球減少症	0	0	0	1 (1.0%)	0	0
免疫系障害	0	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
急性移植片対宿主病	0	0	1 (0.9%)	0	0	1 (0.6%)
移植片対宿主病	0	0	0	0	1 (0.4%)	0
腎および尿路障害	0	0	1 (0.9%)	0	0	2 (1.3%)
腎不全	0	0	1 (0.9%)	0	0	1 (0.6%)
急性腎不全	0	0	0	0	0	1 (0.6%)
肝胆道系障害	1 (0.7%)	0	0	0	1 (0.4%)	0
急性肝炎	1 (0.7%)	0	0	0	1 (0.4%)	0
代謝および栄養障害	0	2 (1.2%)	0	0	0	0
低血糖症	0	1 (0.6%)	0	0	0	0
代謝性アシドーシス	0	1 (0.6%)	0	0	0	0
胃腸障害	0	1 (0.6%)	0	0	0	0
直腸出血	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_death_1.sas
Program Run: 04JUN21:14:52:11

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
Overall	75 (51.7%)	93 (57.1%)	59 (52.7%)	56 (58.3%)	140 (57.1%)	83 (52.5%)
感染症および寄生虫症	28 (19.3%)	41 (25.2%)	23 (20.5%)	20 (20.8%)	68 (27.8%)	38 (24.1%)
敗血症性ショック	7 (4.8%)	7 (4.3%)	7 (6.3%)	3 (3.1%)	12 (4.9%)	8 (5.1%)
敗血症	3 (2.1%)	5 (3.1%)	4 (3.6%)	3 (3.1%)	6 (2.4%)	4 (2.5%)
肺炎	4 (2.8%)	8 (4.9%)	1 (0.9%)	2 (2.1%)	10 (4.1%)	2 (1.3%)
アスペルギルス症	3 (2.1%)	3 (1.8%)	1 (0.9%)	0	6 (2.4%)	1 (0.6%)
真菌感染	1 (0.7%)	2 (1.2%)	2 (1.8%)	1 (1.0%)	2 (0.8%)	2 (1.3%)
サイトメガロウイルス感染	1 (0.7%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	2 (1.3%)
気管支肺アスペルギルス症	1 (0.7%)	1 (0.6%)	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
シュードモナス性敗血症	0	1 (0.6%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
大腸菌性敗血症	0	0	1 (0.9%)	1 (1.0%)	0	2 (1.3%)
尿路感染	1 (0.7%)	0	0	1 (1.0%)	2 (0.8%)	0
蜂巣炎	1 (0.7%)	0	0	1 (1.0%)	1 (0.4%)	0
クレブシエラ性菌血症	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
クレブシエラ性敗血症	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
ムコール症	1 (0.7%)	0	0	0	3 (1.2%)	0
クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.9%)	0	0	2 (1.3%)
腸球菌性菌血症	1 (0.7%)	0	0	0	1 (0.4%)	1 (0.6%)
ブドウ球菌感染	0	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
アシネトバクター性菌血症	0	0	1 (0.9%)	0	0	1 (0.6%)
肺炎球菌性気管支炎	1 (0.7%)	0	0	0	1 (0.4%)	0
気管支肺炎	1 (0.7%)	0	0	0	1 (0.4%)	0
脳アスペルギルス症	0	0	1 (0.9%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
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表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
サイトメガロウイルス血症	1 (0.7%)	0	0	0	1 (0.4%)	0
ヘルペス脳炎	1 (0.7%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.7%)	0	0	0	1 (0.4%)	0
フサリウム感染	0	0	1 (0.9%)	0	0	1 (0.6%)
感染	0	0	1 (0.9%)	0	0	1 (0.6%)
注入部位感染	1 (0.7%)	0	0	0	1 (0.4%)	0
筋膿瘍	1 (0.7%)	0	0	0	1 (0.4%)	0
モラクセラ菌性肺炎	1 (0.7%)	0	0	0	1 (0.4%)	0
気道感染	1 (0.7%)	0	0	0	1 (0.4%)	0
敗血症症候群	1 (0.7%)	0	0	0	1 (0.4%)	0
皮膚感染	0	0	1 (0.9%)	0	0	1 (0.6%)
細菌性敗血症	0	2 (1.2%)	0	2 (2.1%)	1 (0.4%)	0
ブドウ球菌性菌血症	0	1 (0.6%)	0	2 (2.1%)	0	1 (0.6%)
菌血症	0	1 (0.6%)	0	1 (1.0%)	3 (1.2%)	0
ブドウ球菌性敗血症	0	2 (1.2%)	0	0	1 (0.4%)	0
クロストリジウム性菌血症	0	1 (0.6%)	0	1 (1.0%)	0	0
髄膜炎	0	2 (1.2%)	0	0	0	0
細菌性肺炎	0	1 (0.6%)	0	0	3 (1.2%)	0
帯状疱疹	0	0	0	1 (1.0%)	0	2 (1.3%)
蓄膿	0	0	0	1 (1.0%)	0	1 (0.6%)
カンピロバクター胃腸炎	0	0	0	1 (1.0%)	0	0
カテーテル関連感染	0	0	0	1 (1.0%)	0	0
感染性下痢	0	0	0	1 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
ヘリコバクター胃潰瘍	0	1 (0.6%)	0	0	0	0
単純ヘルペス	0	1 (0.6%)	0	0	0	0
肺膿瘍	0	1 (0.6%)	0	0	0	0
壊死性筋膜炎	0	0	0	1 (1.0%)	0	0
肺炎球菌性肺炎	0	1 (0.6%)	0	0	0	0
ブドウ球菌性肺炎	0	1 (0.6%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0
シュードモナス感染	0	0	0	1 (1.0%)	0	0
膿胸	0	1 (0.6%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.6%)	0	0	0	0
全身性カンジダ	0	0	0	1 (1.0%)	0	0
トキソプラズマ症	0	0	0	1 (1.0%)	0	0
結核	0	1 (0.6%)	0	0	0	0
細菌性尿路感染	0	0	0	1 (1.0%)	0	0
真菌性肺炎	0	0	0	0	2 (0.8%)	0
接合真菌症	0	0	0	0	1 (0.4%)	1 (0.6%)
腹部膿瘍	0	0	0	0	1 (0.4%)	0
虫垂炎	0	0	0	0	0	1 (0.6%)
ＢＫウイルス感染	0	0	0	0	0	1 (0.6%)
脳膿瘍	0	0	0	0	0	1 (0.6%)
気管支拡張症	0	0	0	0	1 (0.4%)	0
細気管支炎	0	0	0	0	1 (0.4%)	0
カテーテル留置部位感染	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.6%)
大腸菌性菌血症	0	0	0	0	1 (0.4%)	0
真菌性敗血症	0	0	0	0	1 (0.4%)	0
ノロウイルス性胃腸炎	0	0	0	0	1 (0.4%)	0
ウイルス性胃腸炎	0	0	0	0	1 (0.4%)	0
インフルエンザ	0	0	0	0	1 (0.4%)	0
肺感染	0	0	0	0	1 (0.4%)	0
シュードモナス菌性肺感染	0	0	0	0	1 (0.4%)	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	1 (0.4%)	0
ブラストミセス菌性肺炎	0	0	0	0	1 (0.4%)	0
インフルエンザ性肺炎	0	0	0	0	1 (0.4%)	0
原発性異型肺炎	0	0	0	0	0	1 (0.6%)
シュードモナス性気管支炎	0	0	0	0	0	1 (0.6%)
副鼻腔炎	0	0	0	0	1 (0.4%)	0
真菌性副鼻腔炎	0	0	0	0	1 (0.4%)	0
レンサ球菌性菌血症	0	0	0	0	1 (0.4%)	0
皮下組織膿瘍	0	0	0	0	0	1 (0.6%)
尿路性敗血症	0	0	0	0	0	1 (0.6%)
ウイルス性下痢	0	0	0	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害	25 (17.2%)	26 (16.0%)	16 (14.3%)	17 (17.7%)	39 (15.9%)	22 (13.9%)
呼吸不全	6 (4.1%)	7 (4.3%)	8 (7.1%)	5 (5.2%)	9 (3.7%)	10 (6.3%)
急性呼吸不全	4 (2.8%)	4 (2.5%)	1 (0.9%)	1 (1.0%)	6 (2.4%)	2 (1.3%)
呼吸困難	2 (1.4%)	1 (0.6%)	3 (2.7%)	0	2 (0.8%)	4 (2.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
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表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
呼吸窮迫	3 (2.1%)	3 (1.8%)	1 (0.9%)	0	3 (1.2%)	1 (0.6%)
喀血	1 (0.7%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	2 (1.3%)
低酸素症	2 (1.4%)	1 (0.6%)	0	0	3 (1.2%)	0
肺出血	2 (1.4%)	0	0	1 (1.0%)	2 (0.8%)	0
胸水	1 (0.7%)	1 (0.6%)	0	0	2 (0.8%)	0
肺水腫	1 (0.7%)	0	0	1 (1.0%)	2 (0.8%)	0
肺障害	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
呼吸抑制	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
嚥下性肺炎	0	0	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
頻呼吸	1 (0.7%)	0	0	0	2 (0.8%)	0
気管支胸膜瘻	1 (0.7%)	0	0	0	1 (0.4%)	0
気管支痙攣	1 (0.7%)	0	0	0	1 (0.4%)	0
水気胸	0	0	1 (0.9%)	0	0	1 (0.6%)
胸膜痛	1 (0.7%)	0	0	0	1 (0.4%)	0
呼吸性アシドーシス	1 (0.7%)	0	0	0	1 (0.4%)	0
鼻出血	0	3 (1.8%)	0	1 (1.0%)	0	0
肺塞栓症	0	2 (1.2%)	0	1 (1.0%)	1 (0.4%)	0
肺浸潤	0	1 (0.6%)	0	2 (2.1%)	0	0
急性呼吸窮迫症候群	0	2 (1.2%)	0	0	1 (0.4%)	0
急性肺損傷	0	0	0	1 (1.0%)	0	0
慢性閉塞性肺疾患	0	1 (0.6%)	0	0	0	0
咳嗽	0	0	0	1 (1.0%)	0	0
血胸	0	0	0	1 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
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表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
気胸	0	1 (0.6%)	0	0	0	0
湿性咳嗽	0	1 (0.6%)	0	0	0	0
肺高血圧症	0	0	0	1 (1.0%)	0	0
呼吸停止	0	0	0	1 (1.0%)	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.6%)
肺胞出血	0	0	0	0	1 (0.4%)	0
肺梗塞	0	0	0	0	0	1 (0.6%)
副鼻腔障害	0	0	0	0	1 (0.4%)	0
喘鳴	0	0	0	0	1 (0.4%)	0
血液およびリンパ系障害	14 (9.7%)	8 (4.9%)	14 (12.5%)	9 (9.4%)	18 (7.3%)	15 (9.5%)
発熱性好中球減少症	8 (5.5%)	2 (1.2%)	6 (5.4%)	3 (3.1%)	10 (4.1%)	6 (3.8%)
汎血球減少症	1 (0.7%)	2 (1.2%)	3 (2.7%)	1 (1.0%)	1 (0.4%)	4 (2.5%)
好中球減少症	3 (2.1%)	0	1 (0.9%)	3 (3.1%)	3 (1.2%)	1 (0.6%)
血小板減少症	1 (0.7%)	1 (0.6%)	2 (1.8%)	3 (3.1%)	1 (0.4%)	2 (1.3%)
無顆粒球症	0	0	2 (1.8%)	0	0	2 (1.3%)
貧血	0	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	1 (0.6%)
出血性障害	1 (0.7%)	0	0	0	1 (0.4%)	0
白血球増加症	0	0	1 (0.9%)	0	0	1 (0.6%)
脾臓梗塞	1 (0.7%)	0	0	0	1 (0.4%)	0
出血性貧血	0	1 (0.6%)	0	0	0	0
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0
血小板減少性紫斑病	0	0	0	1 (1.0%)	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）	7 (4.8%)	17 (10.4%)	11 (9.8%)	12 (12.5%)	13 (5.3%)	13 (8.2%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
急性骨髄性白血病	0	6 (3.7%)	3 (2.7%)	2 (2.1%)	1 (0.4%)	4 (2.5%)
リンパ腫	1 (0.7%)	0	1 (0.9%)	1 (1.0%)	1 (0.4%)	1 (0.6%)
多発性骨髄腫	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
悪性新生物進行	1 (0.7%)	1 (0.6%)	0	0	3 (1.2%)	0
再発急性リンパ性白血病	1 (0.7%)	0	0	1 (1.0%)	2 (0.8%)	0
芽球発症	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
骨髄性白血病	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
新生物進行	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
再発慢性リンパ性白血病	1 (0.7%)	0	0	0	1 (0.4%)	0
子宮内膜癌	0	0	1 (0.9%)	0	0	1 (0.6%)
髄膜転移	1 (0.7%)	0	0	0	1 (0.4%)	0
骨髄異形成症候群	0	0	1 (0.9%)	0	0	1 (0.6%)
非ホジキンリンパ腫	0	0	1 (0.9%)	0	0	1 (0.6%)
原発性体腔性リンパ腫	1 (0.7%)	0	0	0	1 (0.4%)	0
再発急性骨髄性白血病	0	3 (1.8%)	0	2 (2.1%)	1 (0.4%)	1 (0.6%)
慢性リンパ性白血病	0	2 (1.2%)	0	0	1 (0.4%)	0
急性白血病	0	0	0	1 (1.0%)	0	0
急性リンパ性白血病	0	0	0	1 (1.0%)	0	0
Ｂ細胞性リンパ腫	0	0	0	1 (1.0%)	0	0
再発Ｂ細胞性リンパ腫	0	0	0	1 (1.0%)	0	0
バーキット白血病	0	1 (0.6%)	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.6%)	0	0	0	0
白血病	0	0	0	1 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
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表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
肺の悪性新生物	0	1 (0.6%)	0	0	0	0
骨転移	0	1 (0.6%)	0	0	0	0
転移部痛	0	1 (0.6%)	0	0	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
白血病浸潤	0	0	0	0	0	1 (0.6%)
神経系障害	10 (6.9%)	11 (6.7%)	7 (6.3%)	5 (5.2%)	17 (6.9%)	9 (5.7%)
痙攣	3 (2.1%)	1 (0.6%)	0	0	5 (2.0%)	0
頭蓋内出血	0	3 (1.8%)	2 (1.8%)	0	0	2 (1.3%)
てんかん	1 (0.7%)	1 (0.6%)	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
多発ニューロパチー	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
中枢神経系病変	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
脳症	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
虚血性脳卒中	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
対麻痺	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
頭痛	1 (0.7%)	0	0	0	2 (0.8%)	0
脳幹卒中	1 (0.7%)	0	0	0	1 (0.4%)	0
脳虚血	0	0	1 (0.9%)	0	0	1 (0.6%)
熱性痙攣	1 (0.7%)	0	0	0	1 (0.4%)	0
神経毒性	0	0	1 (0.9%)	0	0	1 (0.6%)
失語症	0	0	0	1 (1.0%)	1 (0.4%)	0
脳出血	0	0	0	1 (1.0%)	0	0
浮動性めまい	0	1 (0.6%)	0	0	0	0
脳炎	0	0	0	1 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
大発作痙攣	0	1 (0.6%)	0	0	0	0
片麻痺	0	0	0	1 (1.0%)	0	0
昏迷	0	0	0	1 (1.0%)	0	0
くも膜下出血	0	0	0	1 (1.0%)	0	0
振戦	0	1 (0.6%)	0	0	0	0
第７脳神経麻痺	0	0	0	1 (1.0%)	0	0
脳梗塞	0	0	0	0	3 (1.2%)	0
脳血管発作	0	0	0	0	0	1 (0.6%)
卒中の出血性変化	0	0	0	0	0	1 (0.6%)
不全片麻痺	0	0	0	0	0	1 (0.6%)
一過性脳虚血発作	0	0	0	0	1 (0.4%)	0
全身障害および投与局所様態	6 (4.1%)	12 (7.4%)	5 (4.5%)	7 (7.3%)	12 (4.9%)	8 (5.1%)
発熱	4 (2.8%)	6 (3.7%)	4 (3.6%)	4 (4.2%)	5 (2.0%)	5 (3.2%)
多臓器不全	0	5 (3.1%)	1 (0.9%)	2 (2.1%)	1 (0.4%)	1 (0.6%)
死亡	0	1 (0.6%)	1 (0.9%)	0	1 (0.4%)	3 (1.9%)
悪寒	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
全身健康状態低下	1 (0.7%)	0	0	0	2 (0.8%)	0
無力症	1 (0.7%)	0	0	0	1 (0.4%)	0
胸痛	0	0	1 (0.9%)	0	0	1 (0.6%)
心突然死	0	0	0	1 (1.0%)	0	0
非心臓性胸痛	0	0	0	0	2 (0.8%)	0
末梢性浮腫	0	0	0	0	0	1 (0.6%)
心臓障害	9 (6.2%)	6 (3.7%)	2 (1.8%)	6 (6.3%)	15 (6.1%)	4 (2.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
心肺停止	2 (1.4%)	1 (0.6%)	0	1 (1.0%)	4 (1.6%)	0
心停止	1 (0.7%)	2 (1.2%)	0	3 (3.1%)	1 (0.4%)	0
心房細動	1 (0.7%)	1 (0.6%)	0	0	2 (0.8%)	1 (0.6%)
急性心筋梗塞	1 (0.7%)	0	0	1 (1.0%)	2 (0.8%)	0
不整脈	0	0	1 (0.9%)	0	0	1 (0.6%)
心原性ショック	1 (0.7%)	0	0	0	1 (0.4%)	0
うっ血性心筋症	0	0	1 (0.9%)	0	0	1 (0.6%)
心膜炎	1 (0.7%)	0	0	0	1 (0.4%)	0
洞性徐脈	1 (0.7%)	0	0	0	1 (0.4%)	0
上室性頻脈	1 (0.7%)	0	0	0	1 (0.4%)	0
心室性頻脈	0	2 (1.2%)	0	0	0	0
狭心症	0	0	0	1 (1.0%)	0	0
完全房室ブロック	0	0	0	0	1 (0.4%)	0
急性心不全	0	0	0	0	0	1 (0.6%)
電気収縮解離	0	0	0	0	1 (0.4%)	0
腎および尿路障害	7 (4.8%)	6 (3.7%)	3 (2.7%)	4 (4.2%)	14 (5.7%)	5 (3.2%)
急性腎不全	5 (3.4%)	5 (3.1%)	1 (0.9%)	3 (3.1%)	12 (4.9%)	2 (1.3%)
腎不全	2 (1.4%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	2 (1.3%)
血尿	0	0	1 (0.9%)	0	0	1 (0.6%)
胃腸障害	5 (3.4%)	6 (3.7%)	4 (3.6%)	6 (6.3%)	18 (7.3%)	9 (5.7%)
下痢	1 (0.7%)	0	1 (0.9%)	1 (1.0%)	3 (1.2%)	1 (0.6%)
小腸閉塞	0	0	2 (1.8%)	0	0	2 (1.3%)
悪心	1 (0.7%)	1 (0.6%)	0	0	3 (1.2%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
腸出血	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
腹膜炎	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
腹痛	1 (0.7%)	0	0	0	5 (2.0%)	1 (0.6%)
大腸炎	0	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
便秘	0	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
胃穿孔	0	0	1 (0.9%)	0	0	1 (0.6%)
食道潰瘍	1 (0.7%)	0	0	0	1 (0.4%)	0
胃腸出血	0	1 (0.6%)	0	2 (2.1%)	2 (0.8%)	1 (0.6%)
食中毒	0	0	0	1 (1.0%)	0	0
胃腸の炎症	0	1 (0.6%)	0	0	0	0
麻痺性イレウス	0	0	0	1 (1.0%)	0	0
肛門周囲痛	0	0	0	1 (1.0%)	0	0
直腸出血	0	1 (0.6%)	0	0	0	0
嘔吐	0	0	0	0	4 (1.6%)	0
嚥下障害	0	0	0	0	1 (0.4%)	1 (0.6%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.6%)
限局性腹腔内液貯留	0	0	0	0	0	1 (0.6%)
食道炎	0	0	0	0	1 (0.4%)	0
膵炎	0	0	0	0	1 (0.4%)	0
慢性膵炎	0	0	0	0	1 (0.4%)	0
再発性膵炎	0	0	0	0	1 (0.4%)	0
免疫系障害	2 (1.4%)	4 (2.5%)	2 (1.8%)	2 (2.1%)	7 (2.9%)	2 (1.3%)
急性腸管移植片対宿主病	0	1 (0.6%)	1 (0.9%)	1 (1.0%)	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
急性移植片対宿主病	0	1 (0.6%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
アナフィラキシーショック	1 (0.7%)	0	0	0	1 (0.4%)	0
過敏症	1 (0.7%)	0	0	0	1 (0.4%)	0
アナフィラキシー反応	0	1 (0.6%)	0	1 (1.0%)	0	0
急性肝移植片対宿主病	0	1 (0.6%)	0	0	0	0
移植片対宿主病	0	0	0	0	2 (0.8%)	0
肺移植拒絶反応	0	0	0	0	1 (0.4%)	0
血管障害	3 (2.1%)	3 (1.8%)	1 (0.9%)	3 (3.1%)	7 (2.9%)	2 (1.3%)
低血圧	1 (0.7%)	1 (0.6%)	0	1 (1.0%)	3 (1.2%)	0
出血	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
血液量減少性ショック	1 (0.7%)	0	0	1 (1.0%)	1 (0.4%)	0
血管炎	0	0	1 (0.9%)	0	0	1 (0.6%)
深部静脈血栓症	0	0	0	1 (1.0%)	1 (0.4%)	1 (0.6%)
ショック	0	1 (0.6%)	0	0	0	0
動脈炎	0	0	0	0	1 (0.4%)	0
肝胆道系障害	2 (1.4%)	5 (3.1%)	1 (0.9%)	1 (1.0%)	6 (2.4%)	2 (1.3%)
胆嚢炎	1 (0.7%)	0	0	0	2 (0.8%)	0
肝炎	0	0	1 (0.9%)	0	0	1 (0.6%)
急性肝炎	1 (0.7%)	0	0	0	1 (0.4%)	0
肝不全	0	2 (1.2%)	0	0	0	0
肝機能異常	0	1 (0.6%)	0	1 (1.0%)	0	0
高ビリルビン血症	0	2 (1.2%)	0	0	0	0
急性胆嚢炎	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
急性肝不全	0	0	0	0	1 (0.4%)	0
細胆管炎	0	0	0	0	0	1 (0.6%)
胆石症	0	0	0	0	1 (0.4%)	0
肝障害	0	0	0	0	1 (0.4%)	0
臨床検査	2 (1.4%)	3 (1.8%)	1 (0.9%)	3 (3.1%)	2 (0.8%)	1 (0.6%)
肝機能検査異常	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
血中ナトリウム減少	1 (0.7%)	0	0	0	1 (0.4%)	0
ヘモグロビン減少	1 (0.7%)	0	0	0	1 (0.4%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	1 (1.0%)	0	0
血中ビリルビン増加	0	0	0	1 (1.0%)	0	0
心電図ＱＴ延長	0	1 (0.6%)	0	0	0	0
肝酵素上昇	0	0	0	1 (1.0%)	0	0
傷害、中毒および処置合併症	2 (1.4%)	3 (1.8%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
薬物毒性	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
転倒・転落	1 (0.7%)	0	0	0	1 (0.4%)	0
家庭内事故	0	1 (0.6%)	0	0	0	0
大腿骨頚部骨折	0	1 (0.6%)	0	0	0	0
橈骨骨折	0	1 (0.6%)	0	0	0	0
皮膚および皮下組織障害	2 (1.4%)	1 (0.6%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	1 (0.6%)
褥瘡性潰瘍	0	0	1 (0.9%)	0	0	1 (0.6%)
皮膚炎	1 (0.7%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
脂肪織炎	1 (0.7%)	0	0	0	1 (0.4%)	0
発疹	0	1 (0.6%)	0	1 (1.0%)	0	0
筋骨格系および結合組織障害	2 (1.4%)	0	1 (0.9%)	0	5 (2.0%)	2 (1.3%)
筋骨格系胸痛	0	0	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
筋肉内出血	1 (0.7%)	0	0	0	1 (0.4%)	0
筋炎	1 (0.7%)	0	0	0	1 (0.4%)	0
関節炎	0	0	0	0	1 (0.4%)	0
四肢痛	0	0	0	0	1 (0.4%)	0
全身性エリテマトーデス	0	0	0	0	0	1 (0.6%)
代謝および栄養障害	0	3 (1.8%)	2 (1.8%)	4 (4.2%)	6 (2.4%)	3 (1.9%)
コントロール不良の糖尿病	0	0	1 (0.9%)	0	0	1 (0.6%)
成長障害	0	0	1 (0.9%)	0	0	1 (0.6%)
脱水	0	1 (0.6%)	0	1 (1.0%)	3 (1.2%)	0
代謝性アシドーシス	0	1 (0.6%)	0	1 (1.0%)	0	0
低血糖症	0	1 (0.6%)	0	0	0	1 (0.6%)
高ナトリウム血症	0	0	0	1 (1.0%)	0	0
低カリウム血症	0	0	0	1 (1.0%)	0	0
過小食	0	1 (0.6%)	0	0	0	0
高カリウム血症	0	0	0	0	1 (0.4%)	0
低ナトリウム血症	0	0	0	0	1 (0.4%)	0
栄養障害	0	0	0	0	1 (0.4%)	0
眼障害	0	0	2 (1.8%)	1 (1.0%)	1 (0.4%)	3 (1.9%)
片側失明	0	0	1 (0.9%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-125 重篤な有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
視神経症	0	0	1 (0.9%)	0	0	1 (0.6%)
眼瞼浮腫	0	0	0	1 (1.0%)	0	0
網膜動脈閉塞	0	0	0	0	1 (0.4%)	0
網膜出血	0	0	0	0	0	1 (0.6%)
硝子体出血	0	0	0	0	0	1 (0.6%)
精神障害	1 (0.7%)	5 (3.1%)	0	1 (1.0%)	3 (1.2%)	0
うつ病	1 (0.7%)	0	0	0	1 (0.4%)	0
幻視	0	2 (1.2%)	0	0	0	0
精神状態変化	0	2 (1.2%)	0	0	0	0
錯乱状態	0	1 (0.6%)	0	0	1 (0.4%)	0
幻覚	0	1 (0.6%)	0	0	1 (0.4%)	0
抑うつ気分	0	1 (0.6%)	0	0	0	0
自殺企図	0	0	0	1 (1.0%)	0	0
異常行動	0	0	0	0	1 (0.4%)	0
攻撃性	0	0	0	0	1 (0.4%)	0
激越	0	0	0	0	1 (0.4%)	0
生殖系および乳房障害	0	0	0	0	1 (0.4%)	0
良性前立腺肥大症	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_sex_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
Overall	19 (13.1%)	43 (26.4%)	18 (16.1%)	16 (16.7%)	32 (13.1%)	24 (15.2%)
感染症および寄生虫症	5 (3.4%)	10 (6.1%)	6 (5.4%)	5 (5.2%)	10 (4.1%)	8 (5.1%)
真菌感染	0	1 (0.6%)	2 (1.8%)	0	1 (0.4%)	2 (1.3%)
敗血症性ショック	1 (0.7%)	0	1 (0.9%)	0	2 (0.8%)	2 (1.3%)
敗血症	1 (0.7%)	3 (1.8%)	0	0	1 (0.4%)	0
アスペルギルス症	0	1 (0.6%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
肺炎	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
気管支肺炎	1 (0.7%)	0	0	0	1 (0.4%)	0
気管支肺アスペルギルス症	1 (0.7%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.7%)	0	0	0	1 (0.4%)	0
感染	0	0	1 (0.9%)	0	0	1 (0.6%)
細菌性敗血症	0	2 (1.2%)	0	1 (1.0%)	0	0
肺感染	0	1 (0.6%)	0	1 (1.0%)	0	0
髄膜炎	0	1 (0.6%)	0	0	0	0
ムコール症	0	0	0	1 (1.0%)	0	0
シュードモナス性敗血症	0	1 (0.6%)	0	0	0	0
ブドウ球菌感染	0	0	0	1 (1.0%)	0	0
全身性カンジダ	0	0	0	1 (1.0%)	0	0
脳膿瘍	0	0	0	0	0	1 (0.6%)
大腸菌性菌血症	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
呼吸器、胸郭および縦隔障害	3 (2.1%)	4 (2.5%)	3 (2.7%)	1 (1.0%)	3 (1.2%)	3 (1.9%)
呼吸不全	1 (0.7%)	3 (1.8%)	1 (0.9%)	1 (1.0%)	1 (0.4%)	1 (0.6%)
呼吸困難	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
呼吸窮迫	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
急性呼吸不全	0	0	1 (0.9%)	0	0	1 (0.6%)
神経系障害	2 (1.4%)	2 (1.2%)	3 (2.7%)	2 (2.1%)	2 (0.8%)	5 (3.2%)
痙攣	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
てんかん	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
脳症	0	0	1 (0.9%)	0	0	1 (0.6%)
大発作痙攣	0	1 (0.6%)	0	0	0	0
昏迷	0	0	0	1 (1.0%)	0	0
くも膜下出血	0	0	0	1 (1.0%)	0	0
振戦	0	1 (0.6%)	0	0	0	0
脳血管発作	0	0	0	0	0	1 (0.6%)
卒中の出血性変化	0	0	0	0	0	1 (0.6%)
臨床検査	3 (2.1%)	4 (2.5%)	1 (0.9%)	2 (2.1%)	5 (2.0%)	1 (0.6%)
血中ビリルビン増加	1 (0.7%)	0	1 (0.9%)	0	1 (0.4%)	1 (0.6%)
血中ナトリウム減少	1 (0.7%)	0	0	0	1 (0.4%)	0
トランスアミナーゼ上昇	1 (0.7%)	0	0	0	1 (0.4%)	0
肝機能検査異常	0	2 (1.2%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
アラニン・アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	1 (0.4%)	0
血中アルカリホスファターゼ増加	0	0	0	1 (1.0%)	1 (0.4%)	0
肝酵素上昇	0	0	0	1 (1.0%)	1 (0.4%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.6%)	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	1 (0.4%)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	1 (0.4%)	0
心臓障害	3 (2.1%)	2 (1.2%)	1 (0.9%)	1 (1.0%)	3 (1.2%)	1 (0.6%)
心停止	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
心肺停止	1 (0.7%)	0	0	1 (1.0%)	1 (0.4%)	0
うっ血性心筋症	0	0	1 (0.9%)	0	0	1 (0.6%)
上室性頻脈	1 (0.7%)	0	0	0	1 (0.4%)	0
心室性頻脈	0	1 (0.6%)	0	0	0	0
腎および尿路障害	3 (2.1%)	1 (0.6%)	0	2 (2.1%)	5 (2.0%)	0
腎不全	2 (1.4%)	0	0	1 (1.0%)	2 (0.8%)	0
急性腎不全	1 (0.7%)	1 (0.6%)	0	1 (1.0%)	3 (1.2%)	0
精神障害	1 (0.7%)	6 (3.7%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
錯乱状態	1 (0.7%)	2 (1.2%)	1 (0.9%)	0	2 (0.8%)	1 (0.6%)
幻視	0	3 (1.8%)	0	0	0	0
幻覚	0	1 (0.6%)	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
抑うつ気分	0	1 (0.6%)	0	0	0	0
不快気分	0	1 (0.6%)	0	0	0	0
皮膚および皮下組織障害	1 (0.7%)	3 (1.8%)	1 (0.9%)	2 (2.1%)	1 (0.4%)	1 (0.6%)
皮膚炎	1 (0.7%)	0	0	0	1 (0.4%)	0
アレルギー性皮膚炎	0	0	1 (0.9%)	0	0	1 (0.6%)
発疹	0	2 (1.2%)	0	2 (2.1%)	0	0
薬疹	0	1 (0.6%)	0	0	0	0
胃腸障害	1 (0.7%)	2 (1.2%)	1 (0.9%)	1 (1.0%)	2 (0.8%)	2 (1.3%)
嘔吐	0	2 (1.2%)	1 (0.9%)	0	0	2 (1.3%)
嚥下障害	1 (0.7%)	0	0	0	1 (0.4%)	0
小腸閉塞	0	0	1 (0.9%)	0	0	1 (0.6%)
悪心	0	1 (0.6%)	0	1 (1.0%)	1 (0.4%)	0
肝胆道系障害	1 (0.7%)	4 (2.5%)	0	2 (2.1%)	2 (0.8%)	0
急性肝炎	1 (0.7%)	0	0	0	1 (0.4%)	0
肝不全	0	2 (1.2%)	0	0	0	0
高ビリルビン血症	0	2 (1.2%)	0	0	0	0
肝機能異常	0	0	0	1 (1.0%)	0	0
肝病変	0	0	0	1 (1.0%)	0	0
肝炎	0	1 (0.6%)	0	0	0	0
高トランスアミナーゼ血症	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
急性肝不全	0	0	0	0	1 (0.4%)	0
血液およびリンパ系障害	0	2 (1.2%)	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
汎血球減少症	0	1 (0.6%)	1 (0.9%)	0	0	1 (0.6%)
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0
脾臓病変	0	0	0	1 (1.0%)	0	0
眼障害	0	0	1 (0.9%)	1 (1.0%)	0	1 (0.6%)
視神経症	0	0	1 (0.9%)	0	0	1 (0.6%)
眼瞼浮腫	0	0	0	1 (1.0%)	0	0
全身障害および投与局所様態	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
悪寒	1 (0.7%)	1 (0.6%)	0	0	1 (0.4%)	0
傷害、中毒および処置合併症	1 (0.7%)	0	0	0	1 (0.4%)	0
過量投与	1 (0.7%)	0	0	0	1 (0.4%)	0
筋骨格系および結合組織障害	1 (0.7%)	0	0	0	1 (0.4%)	0
筋炎	1 (0.7%)	0	0	0	1 (0.4%)	0
血管障害	1 (0.7%)	0	0	0	1 (0.4%)	0
低血圧	1 (0.7%)	0	0	0	1 (0.4%)	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	7 (4.3%)	0	0	2 (0.8%)	1 (0.6%)
急性骨髄性白血病	0	4 (2.5%)	0	0	0	0
再発急性骨髄性白血病	0	1 (0.6%)	0	0	0	1 (0.6%)
慢性リンパ性白血病	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-126 投与中止に至った有害事象（男女別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Male		Female		Male	Female
System Organ Class Preferred Term	ISA (N = 145)	VRC (N = 163)	ISA (N = 112)	VRC (N = 96)	ISA (N = 245)	ISA (N = 158)
肺の悪性新生物	0	1 (0.6%)	0	0	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
悪性新生物進行	0	0	0	0	1 (0.4%)	0
免疫系障害	0	0	0	1 (1.0%)	0	0
急性肝移植片対宿主病	0	0	0	1 (1.0%)	0	0
代謝および栄養障害	0	0	0	1 (1.0%)	0	0
代謝性アシドーシス	0	0	0	1 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_sex_discon_1.sas
Program Run: 04JUN21:14:52:20

表 8-127 SOC別の有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
Overall	10 (100.0%)	4 (80.0%)	14 (87.5%)	6 (85.7%)	31 (91.2%)	18 (100.0%)	13 (100.0%)	17 (89.5%)	37 (90.2%)
感染症および寄生虫症	5 (50.0%)	2 (40.0%)	5 (31.3%)	3 (42.9%)	12 (35.3%)	5 (27.8%)	5 (38.5%)	6 (31.6%)	14 (34.1%)
胃腸障害	4 (40.0%)	2 (40.0%)	4 (25.0%)	2 (28.6%)	9 (26.5%)	8 (44.4%)	4 (30.8%)	6 (31.6%)	11 (26.8%)
臨床検査	0	0	4 (25.0%)	0	12 (35.3%)	7 (38.9%)	1 (7.7%)	6 (31.6%)	14 (34.1%)
肝胆道系障害	2 (20.0%)	0	1 (6.3%)	3 (42.9%)	8 (23.5%)	7 (38.9%)	2 (15.4%)	1 (5.3%)	9 (22.0%)
神経系障害	2 (20.0%)	0	5 (31.3%)	3 (42.9%)	3 (8.8%)	3 (16.7%)	4 (30.8%)	7 (36.8%)	4 (9.8%)
皮膚および皮下組織障害	3 (30.0%)	1 (20.0%)	1 (6.3%)	0	5 (14.7%)	3 (16.7%)	3 (23.1%)	2 (10.5%)	6 (14.6%)
眼障害	2 (20.0%)	2 (40.0%)	2 (12.5%)	1 (14.3%)	4 (11.8%)	10 (55.6%)	2 (15.4%)	3 (15.8%)	5 (12.2%)
代謝および栄養障害	2 (20.0%)	0	3 (18.8%)	0	3 (8.8%)	2 (11.1%)	3 (23.1%)	4 (21.1%)	4 (9.8%)
一般・全身障害および投与部位の状態	1 (10.0%)	0	2 (12.5%)	0	5 (14.7%)	1 (5.6%)	2 (15.4%)	2 (10.5%)	5 (12.2%)
呼吸器、胸郭および縦隔障害	2 (20.0%)	1 (20.0%)	3 (18.8%)	0	2 (5.9%)	2 (11.1%)	2 (15.4%)	5 (26.3%)	2 (4.9%)
腎および尿路障害	1 (10.0%)	1 (20.0%)	0	0	4 (11.8%)	1 (5.6%)	2 (15.4%)	1 (5.3%)	4 (9.8%)
血管障害	2 (20.0%)	0	1 (6.3%)	1 (14.3%)	2 (5.9%)	0	2 (15.4%)	2 (10.5%)	2 (4.9%)
精神障害	0	0	0	2 (28.6%)	3 (8.8%)	5 (27.8%)	1 (7.7%)	0	3 (7.3%)
筋骨格系および結合組織障害	1 (10.0%)	0	2 (12.5%)	0	0	4 (22.2%)	1 (7.7%)	3 (15.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_soc_2.sas
Program Run: 16JUN21:17:57:39

表 8-127 SOC別の有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
傷害、中毒および処置合併症	0	0	2 (12.5%)	1 (14.3%)	1 (2.9%)	1 (5.6%)	0	2 (10.5%)	2 (4.9%)
心臓障害	1 (10.0%)	0	1 (6.3%)	0	1 (2.9%)	1 (5.6%)	1 (7.7%)	3 (15.8%)	2 (4.9%)
耳および迷路障害	0	0	1 (6.3%)	0	1 (2.9%)	1 (5.6%)	0	1 (5.3%)	1 (2.4%)
免疫系障害	0	0	0	0	1 (2.9%)	1 (5.6%)	0	0	1 (2.4%)
内分泌障害	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	1 (2.4%)
先天性、家族性および遺伝性障害	0	0	0	1 (14.3%)	0	2 (11.1%)	0	0	1 (2.4%)
血液およびリンパ系障害	0	1 (20.0%)	0	0	0	0	0	1 (5.3%)	1 (2.4%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_soc_2.sas
Program Run: 16JUN21:17:57:39

表 8-128 注目すべき有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

Weight (kg) Subgroup	Cohort A						Cohort A/B併合		
	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
肝機能異常・肝炎	2 (20.0%)	0	4 (25.0%)	3 (42.9%)	16 (47.1%)	11 (61.1%)	2 (15.4%)	4 (21.1%)	18 (43.9%)
アナフィラキシー	0	0	0	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0	0	0	0
トルサード ド ポアント	0	0	0	0	1 (2.9%)	0	1 (7.7%)	0	1 (2.4%)
急性膵炎	0	0	0	0	0	0	0	0	0
精神神経症状	1 (10.0%)	0	0	2 (28.6%)	2 (5.9%)	5 (27.8%)	2 (15.4%)	1 (5.3%)	2 (4.9%)
視覚障害	2 (20.0%)	1 (20.0%)	2 (12.5%)	2 (28.6%)	3 (8.8%)	12 (66.7%)	2 (15.4%)	2 (10.5%)	4 (9.8%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0	0	0	0
静脈内投与例	(N = 1)	(N = 0)	(N = 1)	(N = 0)	(N = 6)	(N = 2)	(N = 1)	(N = 2)	(N = 6)
注入部位／注射部位反応	0	0	0	0	3 (50.0%)	0	0	0	3 (50.0%)
IRR	0	0	0	0	0	1 (50.0%)	0	1 (50.0%)	0

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_weight_eoi_2.sas
Program Run: 16JUN21:17:57:43

表 8-129 死亡に至った有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
Overall	1 (10.0%)	0	1 (6.3%)	0	2 (5.9%)	0	2 (15.4%)	2 (10.5%)	2 (4.9%)
呼吸器、胸郭および縦隔障害	1 (10.0%)	0	0	0	1 (2.9%)	0	1 (7.7%)	1 (5.3%)	1 (2.4%)
特発性肺炎症候群	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
肺臓炎	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
誤嚥性肺炎	0	0	0	0	0	0	0	1 (5.3%)	0
感染症および寄生虫症	0	0	1 (6.3%)	0	1 (2.9%)	0	0	1 (5.3%)	1 (2.4%)
肺炎球菌感染	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
副鼻腔炎	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
神経系障害	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
大脳基底核梗塞	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
心臓障害	0	0	0	0	0	0	0	1 (5.3%)	0
急性心筋梗塞	0	0	0	0	0	0	0	1 (5.3%)	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (7.7%)	0	0
死亡	0	0	0	0	0	0	1 (7.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_2.sas
Program Run: 16JUN21:17:57:51

表 8-130 重篤な有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
Overall	4 (40.0%)	1 (20.0%)	3 (18.8%)	1 (14.3%)	6 (17.6%)	1 (5.6%)	5 (38.5%)	5 (26.3%)	7 (17.1%)
感染症および寄生虫症	1 (10.0%)	1 (20.0%)	2 (12.5%)	1 (14.3%)	3 (8.8%)	0	1 (7.7%)	3 (15.8%)	4 (9.8%)
肺炎	1 (10.0%)	0	0	1 (14.3%)	1 (2.9%)	0	1 (7.7%)	0	1 (2.4%)
感染性胸水	0	0	1 (6.3%)	0	1 (2.9%)	0	0	1 (5.3%)	1 (2.4%)
気管支炎	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
肺炎球菌感染	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
副鼻腔炎	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
アスペルギルス感染	0	1 (20.0%)	0	0	0	0	0	0	0
菌血症	0	0	0	0	0	0	0	1 (5.3%)	0
蜂巣炎	0	0	0	0	0	0	0	0	1 (2.4%)
呼吸器、胸郭および縦隔障害	1 (10.0%)	0	2 (12.5%)	0	1 (2.9%)	0	1 (7.7%)	3 (15.8%)	1 (2.4%)
喀血	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_ser_2.sas
Program Run: 16JUN21:17:57:56

表 8-130 重篤な有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
特発性肺炎症候群	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
肺臓炎	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
気胸	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
誤嚥性肺炎	0	0	0	0	0	0	0	1 (5.3%)	0
肝胆道系障害	0	0	0	0	1 (2.9%)	1 (5.6%)	0	0	1 (2.4%)
胆嚢炎	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
薬物性肝障害	0	0	0	0	0	1 (5.6%)	0	0	0
筋骨格系および結合組織障害	1 (10.0%)	0	0	0	0	1 (5.6%)	1 (7.7%)	0	0
筋力低下	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
横紋筋融解症	0	0	0	0	0	1 (5.6%)	0	0	0
内分泌障害	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
抗利尿ホルモン不適合分泌	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_ser_2.sas
Program Run: 16JUN21:17:57:56

表 8-130 重篤な有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
代謝および栄養障害	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
低ナトリウム血症	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
神経系障害	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
大脳基底核梗塞	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
腎および尿路障害	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
腎機能障害	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
心臓障害	0	0	0	0	0	0	0	1 (5.3%)	1 (2.4%)
急性心筋梗塞	0	0	0	0	0	0	0	1 (5.3%)	0
急性心不全	0	0	0	0	0	0	0	0	1 (2.4%)
血液およびリンパ系障害	0	0	0	0	0	0	0	1 (5.3%)	0
好中球減少症	0	0	0	0	0	0	0	1 (5.3%)	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (7.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_ser_2.sas
Program Run: 16JUN21:17:57:56

表 8-130 重篤な有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
死亡	0	0	0	0	0	0	1 (7.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_ser_2.sas
Program Run: 16JUN21:17:57:56

表 8-131 投与中止に至った有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
Overall	1 (10.0%)	0	5 (31.3%)	0	4 (11.8%)	4 (22.2%)	1 (7.7%)	6 (31.6%)	4 (9.8%)
肝胆道系障害	0	0	0	0	2 (5.9%)	2 (11.1%)	0	0	2 (4.9%)
肝機能異常	0	0	0	0	2 (5.9%)	1 (5.6%)	0	0	2 (4.9%)
薬物性肝障害	0	0	0	0	0	1 (5.6%)	0	0	0
感染症および寄生虫症	0	0	2 (12.5%)	0	0	0	0	2 (10.5%)	0
感染性胸水	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
肺炎球菌感染	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
代謝および栄養障害	1 (10.0%)	0	1 (6.3%)	0	0	0	1 (7.7%)	1 (5.3%)	0
高カリウム血症	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
低ナトリウム血症	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
神経系障害	0	0	1 (6.3%)	0	0	1 (5.6%)	0	1 (5.3%)	0
感覚鈍麻	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_2.sas
Program Run: 16JUN21:17:58:00

表 8-131 投与中止に至った有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
多発ニューロパチー	0	0	0	0	0	1 (5.6%)	0	0	0
臨床検査	0	0	0	0	1 (2.9%)	0	0	1 (5.3%)	1 (2.4%)
肝機能検査値上昇	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
心電図異常	0	0	0	0	0	0	0	1 (5.3%)	0
耳および迷路障害	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
耳管開放	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
胃腸障害	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
悪心	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
一般・全身障害および投与部位の状態	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
注射部位蕁麻疹	0	0	0	0	1 (2.9%)	0	0	0	1 (2.4%)
腎および尿路障害	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0
腎機能障害	1 (10.0%)	0	0	0	0	0	1 (7.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_2.sas
Program Run: 16JUN21:17:58:00

表 8-131 投与中止に至った有害事象（体重別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Weight (kg) Subgroup	< 40		>= 40 to < 50		>= 50		< 40	>= 40 to < 50	>= 50
System Organ Class Preferred Term	ISA (N = 10)	VRC (N = 5)	ISA (N = 16)	VRC (N = 7)	ISA (N = 34)	VRC (N = 18)	ISA (N = 13)	ISA (N = 19)	ISA (N = 41)
呼吸器、胸郭および縦隔障害	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
呼吸困難	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
口腔咽頭不快感	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
皮膚および皮下組織障害	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
冷汗	0	0	1 (6.3%)	0	0	0	0	1 (5.3%)	0
眼障害	0	0	0	0	0	1 (5.6%)	0	0	0
視力障害	0	0	0	0	0	1 (5.6%)	0	0	0
筋骨格系および結合組織障害	0	0	0	0	0	1 (5.6%)	0	0	0
横紋筋融解症	0	0	0	0	0	1 (5.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_2.sas
Program Run: 16JUN21:17:58:00

表 8-132 SOC別の有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
Overall	23 (88.5%)	25 (100.0%)	121 (98.4%)	120 (97.6%)	103 (95.4%)	110 (99.1%)	40 (93.0%)	182 (96.3%)	163 (95.9%)
胃腸障害	13 (50.0%)	18 (72.0%)	84 (68.3%)	90 (73.2%)	77 (71.3%)	72 (64.9%)	18 (41.9%)	124 (65.6%)	115 (67.6%)
感染症および寄生虫症	14 (53.8%)	15 (60.0%)	74 (60.2%)	70 (56.9%)	64 (59.3%)	73 (65.8%)	24 (55.8%)	114 (60.3%)	105 (61.8%)
全身障害および投与局所様態	10 (38.5%)	11 (44.0%)	72 (58.5%)	70 (56.9%)	66 (61.1%)	63 (56.8%)	16 (37.2%)	103 (54.5%)	96 (56.5%)
呼吸器、胸郭および縦隔障害	16 (61.5%)	15 (60.0%)	66 (53.7%)	69 (56.1%)	61 (56.5%)	63 (56.8%)	20 (46.5%)	94 (49.7%)	92 (54.1%)
代謝および栄養障害	11 (42.3%)	18 (72.0%)	51 (41.5%)	58 (47.2%)	46 (42.6%)	45 (40.5%)	17 (39.5%)	77 (40.7%)	76 (44.7%)
神経系障害	7 (26.9%)	7 (28.0%)	49 (39.8%)	35 (28.5%)	39 (36.1%)	47 (42.3%)	14 (32.6%)	73 (38.6%)	57 (33.5%)
皮膚および皮下組織障害	7 (26.9%)	11 (44.0%)	41 (33.3%)	54 (43.9%)	38 (35.2%)	45 (40.5%)	9 (20.9%)	59 (31.2%)	57 (33.5%)
臨床検査	6 (23.1%)	5 (20.0%)	41 (33.3%)	52 (42.3%)	38 (35.2%)	39 (35.1%)	9 (20.9%)	56 (29.6%)	53 (31.2%)
血液およびリンパ系障害	9 (34.6%)	8 (32.0%)	35 (28.5%)	37 (30.1%)	33 (30.6%)	37 (33.3%)	12 (27.9%)	49 (25.9%)	45 (26.5%)
精神障害	4 (15.4%)	5 (20.0%)	38 (30.9%)	38 (30.9%)	28 (25.9%)	43 (38.7%)	6 (14.0%)	51 (27.0%)	47 (27.6%)
筋骨格系および結合組織障害	5 (19.2%)	7 (28.0%)	32 (26.0%)	33 (26.8%)	32 (29.6%)	37 (33.3%)	7 (16.3%)	50 (26.5%)	52 (30.6%)
血管障害	8 (30.8%)	7 (28.0%)	31 (25.2%)	37 (30.1%)	28 (25.9%)	33 (29.7%)	10 (23.3%)	41 (21.7%)	50 (29.4%)
腎および尿路障害	3 (11.5%)	4 (16.0%)	29 (23.6%)	31 (25.2%)	23 (21.3%)	23 (20.7%)	4 (9.3%)	39 (20.6%)	38 (22.4%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_soc_1.sas
Program Run: 04JUN21:14:52:53

表 8-132 SOC別の有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
心臓障害	4 (15.4%)	5 (20.0%)	18 (14.6%)	29 (23.6%)	21 (19.4%)	23 (20.7%)	5 (11.6%)	29 (15.3%)	33 (19.4%)
眼障害	5 (19.2%)	6 (24.0%)	16 (13.0%)	31 (25.2%)	18 (16.7%)	32 (28.8%)	6 (14.0%)	24 (12.7%)	27 (15.9%)
傷害、中毒および処置合併症	1 (3.8%)	3 (12.0%)	18 (14.6%)	15 (12.2%)	14 (13.0%)	21 (18.9%)	2 (4.7%)	27 (14.3%)	26 (15.3%)
肝胆道系障害	3 (11.5%)	2 (8.0%)	11 (8.9%)	24 (19.5%)	9 (8.3%)	16 (14.4%)	7 (16.3%)	17 (9.0%)	15 (8.8%)
免疫系障害	1 (3.8%)	0	9 (7.3%)	14 (11.4%)	10 (9.3%)	11 (9.9%)	1 (2.3%)	12 (6.3%)	16 (9.4%)
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 (3.8%)	3 (12.0%)	9 (7.3%)	15 (12.2%)	9 (8.3%)	13 (11.7%)	1 (2.3%)	13 (6.9%)	15 (8.8%)
耳および迷路障害	1 (3.8%)	0	9 (7.3%)	3 (2.4%)	4 (3.7%)	10 (9.0%)	1 (2.3%)	12 (6.3%)	8 (4.7%)
生殖系および乳房障害	0	2 (8.0%)	6 (4.9%)	8 (6.5%)	2 (1.9%)	3 (2.7%)	1 (2.3%)	10 (5.3%)	6 (3.5%)
内分泌障害	1 (3.8%)	0	3 (2.4%)	3 (2.4%)	1 (0.9%)	0	1 (2.3%)	6 (3.2%)	3 (1.8%)
先天性、家族性および遺伝性障害	2 (7.7%)	0	0	1 (0.8%)	1 (0.9%)	1 (0.9%)	2 (4.7%)	0	1 (0.6%)
社会環境	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_soc_1.sas
Program Run: 04JUN21:14:52:53

表 8-133 注目すべき有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

Weight (kg) Subgroup	9766-CL-0104試験						海外第III相試験併合		
	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肝機能異常・肝炎	5 (19.2%)	6 (24.0%)	27 (22.0%)	44 (35.8%)	21 (19.4%)	32 (28.8%)	9 (20.9%)	43 (22.8%)	30 (17.6%)
アナフィラキシー	0	0	0	3 (2.4%)	2 (1.9%)	0	0	0	2 (1.2%)
重度皮膚障害	0	0	1 (0.8%)	0	2 (1.9%)	2 (1.8%)	0	1 (0.5%)	2 (1.2%)
心電図QT短縮	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
トルサード ド ポアント	1 (3.8%)	1 (4.0%)	9 (7.3%)	10 (8.1%)	5 (4.6%)	8 (7.2%)	1 (2.3%)	9 (4.8%)	8 (4.7%)
急性膵炎	0	0	0	0	0	0	0	0	1 (0.6%)
精神神経症状	4 (15.4%)	3 (12.0%)	41 (33.3%)	36 (29.3%)	28 (25.9%)	40 (36.0%)	7 (16.3%)	54 (28.6%)	48 (28.2%)
視覚障害	2 (7.7%)	2 (8.0%)	10 (8.1%)	22 (17.9%)	11 (10.2%)	23 (20.7%)	3 (7.0%)	12 (6.3%)	15 (8.8%)
皮膚または子宮の悪性腫瘍	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
静脈内投与例	(N = 26)	(N = 25)	(N = 123)	(N = 123)	(N = 108)	(N = 111)	(N = 34)	(N = 164)	(N = 158)
注入部位／注射部位反応	0	0	6 (4.9%)	3 (2.4%)	5 (4.6%)	1 (0.9%)	0	10 (6.1%)	6 (3.8%)
IRR	7 (26.9%)	9 (36.0%)	38 (30.9%)	33 (26.8%)	25 (23.1%)	34 (30.6%)	11 (32.4%)	48 (29.3%)	42 (26.6%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_weight_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
Overall	7 (26.9%)	5 (20.0%)	39 (31.7%)	35 (28.5%)	16 (14.8%)	32 (28.8%)	10 (23.3%)	52 (27.5%)	43 (25.3%)
感染症および寄生虫症	3 (11.5%)	1 (4.0%)	20 (16.3%)	8 (6.5%)	5 (4.6%)	9 (8.1%)	5 (11.6%)	26 (13.8%)	18 (10.6%)
敗血症性ショック	1 (3.8%)	0	6 (4.9%)	2 (1.6%)	1 (0.9%)	2 (1.8%)	1 (2.3%)	7 (3.7%)	4 (2.4%)
敗血症	0	0	6 (4.9%)	4 (3.3%)	1 (0.9%)	1 (0.9%)	0	6 (3.2%)	2 (1.2%)
アスペルギルス症	1 (3.8%)	0	1 (0.8%)	0	1 (0.9%)	2 (1.8%)	1 (2.3%)	2 (1.1%)	1 (0.6%)
真菌感染	0	0	3 (2.4%)	1 (0.8%)	0	1 (0.9%)	0	3 (1.6%)	0
肺炎	0	1 (4.0%)	0	0	1 (0.9%)	1 (0.9%)	0	0	3 (1.8%)
ムコール症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	1 (0.6%)
アシネトバクター性菌血症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
気管支肺アスペルギルス症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心内膜炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
感染	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
シュードモナス性敗血症	0	0	0	1 (0.8%)	0	0	0	0	1 (0.6%)
クレブシエラ性敗血症	0	0	0	0	0	1 (0.9%)	0	0	0
シュードモナス性菌血症	0	0	0	0	0	1 (0.9%)	0	0	0
ステノトロフォモナス性敗血症	0	0	0	0	0	1 (0.9%)	0	0	0
真菌性肺炎	0	0	0	0	0	0	0	0	2 (1.2%)
細菌性敗血症	0	0	0	0	0	0	0	0	1 (0.6%)
蓄膿	0	0	0	0	0	0	0	1 (0.5%)	0
真菌性敗血症	0	0	0	0	0	0	0	0	1 (0.6%)
肺感染	0	0	0	0	0	0	1 (2.3%)	0	0
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (0.6%)
ブラストミセス菌性肺炎	0	0	0	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
原発性異型肺炎	0	0	0	0	0	0	1 (2.3%)	0	0
真菌性副鼻腔炎	0	0	0	0	0	0	0	1 (0.5%)	0
ブドウ球菌性敗血症	0	0	0	0	0	0	0	1 (0.5%)	0
呼吸器、胸郭および縦隔障害	2 (7.7%)	1 (4.0%)	10 (8.1%)	5 (4.1%)	2 (1.9%)	6 (5.4%)	2 (4.7%)	11 (5.8%)	5 (2.9%)
呼吸不全	1 (3.8%)	0	4 (3.3%)	1 (0.8%)	1 (0.9%)	5 (4.5%)	1 (2.3%)	4 (2.1%)	2 (1.2%)
急性呼吸不全	0	0	2 (1.6%)	0	1 (0.9%)	1 (0.9%)	0	3 (1.6%)	1 (0.6%)
喀血	1 (3.8%)	0	1 (0.8%)	1 (0.8%)	0	0	1 (2.3%)	1 (0.5%)	1 (0.6%)
肺出血	0	1 (4.0%)	2 (1.6%)	0	0	0	0	2 (1.1%)	0
呼吸窮迫	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
急性呼吸窮迫症候群	0	0	0	1 (0.8%)	0	0	0	0	0
肺塞栓症	0	0	0	1 (0.8%)	0	0	0	0	0
肺高血圧症	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
呼吸困難	0	0	0	0	0	0	0	0	1 (0.6%)
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 (3.8%)	2 (8.0%)	5 (4.1%)	11 (8.9%)	4 (3.7%)	8 (7.2%)	1 (2.3%)	8 (4.2%)	8 (4.7%)
急性骨髄性白血病	1 (3.8%)	1 (4.0%)	1 (0.8%)	3 (2.4%)	1 (0.9%)	3 (2.7%)	1 (2.3%)	1 (0.5%)	2 (1.2%)
多発性骨髄腫	0	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
悪性新生物進行	0	1 (4.0%)	0	0	1 (0.9%)	0	0	1 (0.5%)	2 (1.2%)
芽球発症	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)
骨髄性白血病	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
骨髄異形成症候群	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	0	0	1 (0.8%)	0	3 (2.7%)	0	1 (0.5%)	0
慢性リンパ性白血病	0	0	0	2 (1.6%)	0	0	0	1 (0.5%)	0
再発急性リンパ性白血病	0	0	0	1 (0.8%)	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
B細胞性リンパ腫	0	0	0	1 (0.8%)	0	0	0	0	0
バーキット白血病	0	0	0	0	0	1 (0.9%)	0	0	0
リンパ腫	0	0	0	0	0	1 (0.9%)	0	0	0
新生物進行	0	0	0	1 (0.8%)	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.6%)
心臓障害	0	1 (4.0%)	2 (1.6%)	2 (1.6%)	2 (1.9%)	2 (1.8%)	0	3 (1.6%)	4 (2.4%)
心停止	0	0	0	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
心肺停止	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	2 (1.2%)
うっ血性心筋症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心膜炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
急性心筋梗塞	0	1 (4.0%)	0	0	0	0	0	0	0
急性心不全	0	0	0	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
神経系障害	1 (3.8%)	0	2 (1.6%)	3 (2.4%)	0	4 (3.6%)	1 (2.3%)	3 (1.6%)	0
頭蓋内出血	0	0	2 (1.6%)	0	0	3 (2.7%)	0	2 (1.1%)	0
神経毒性	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
脳出血	0	0	0	1 (0.8%)	0	0	0	0	0
脳炎	0	0	0	0	0	1 (0.9%)	0	0	0
昏迷	0	0	0	1 (0.8%)	0	0	0	0	0
くも膜下出血	0	0	0	1 (0.8%)	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	0	1 (0.5%)	0
全身障害および投与局所様態	0	0	1 (0.8%)	4 (3.3%)	1 (0.9%)	4 (3.6%)	1 (2.3%)	3 (1.6%)	3 (1.8%)
多臓器不全	0	0	0	3 (2.4%)	1 (0.9%)	3 (2.7%)	0	1 (0.5%)	1 (0.6%)
死亡	0	0	1 (0.8%)	1 (0.8%)	0	0	1 (2.3%)	2 (1.1%)	1 (0.6%)
心突然死	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
全身健康状態低下	0	0	0	0	0	0	0	0	1 (0.6%)
血管障害	0	0	1 (0.8%)	1 (0.8%)	1 (0.9%)	0	0	1 (0.5%)	2 (1.2%)
出血	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
血液量減少性ショック	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	0	0	1 (0.8%)	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	0	1 (0.6%)
血液およびリンパ系障害	0	0	1 (0.8%)	1 (0.8%)	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
出血性障害	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
血小板減少症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
汎血球減少症	0	0	0	1 (0.8%)	0	0	0	0	0
免疫系障害	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	1 (0.6%)
急性移植片対宿主病	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-134 死亡に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
移植片対宿主病	0	0	0	0	0	0	0	0	1 (0.6%)
腎および尿路障害	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	1 (0.6%)
腎不全	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
急性腎不全	0	0	0	0	0	0	0	0	1 (0.6%)
肝胆道系障害	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
急性肝炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
代謝および栄養障害	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
低血糖症	0	0	0	1 (0.8%)	0	0	0	0	0
代謝性アシドーシス	0	0	0	0	0	1 (0.9%)	0	0	0
胃腸障害	0	0	0	1 (0.8%)	0	0	0	0	0
直腸出血	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_death_1.sas
Program Run: 04JUN21:14:53:04

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
Overall	11 (42.3%)	13 (52.0%)	71 (57.7%)	69 (56.1%)	52 (48.1%)	67 (60.4%)	20 (46.5%)	104 (55.0%)	98 (57.6%)
感染症および寄生虫症	4 (15.4%)	4 (16.0%)	27 (22.0%)	23 (18.7%)	20 (18.5%)	34 (30.6%)	10 (23.3%)	45 (23.8%)	51 (30.0%)
敗血症性ショック	2 (7.7%)	1 (4.0%)	6 (4.9%)	4 (3.3%)	6 (5.6%)	5 (4.5%)	2 (4.7%)	8 (4.2%)	10 (5.9%)
敗血症	0	0	6 (4.9%)	7 (5.7%)	1 (0.9%)	1 (0.9%)	0	7 (3.7%)	3 (1.8%)
肺炎	0	1 (4.0%)	0	0	5 (4.6%)	9 (8.1%)	1 (2.3%)	2 (1.1%)	9 (5.3%)
アスペルギルス症	1 (3.8%)	0	1 (0.8%)	0	2 (1.9%)	3 (2.7%)	1 (2.3%)	3 (1.6%)	3 (1.8%)
真菌感染	0	0	3 (2.4%)	2 (1.6%)	0	1 (0.9%)	0	3 (1.6%)	1 (0.6%)
サイトメガロウイルス感染	0	0	1 (0.8%)	1 (0.8%)	1 (0.9%)	1 (0.9%)	1 (2.3%)	1 (0.5%)	2 (1.2%)
気管支肺アスペルギルス症	0	0	2 (1.6%)	1 (0.8%)	0	0	0	2 (1.1%)	0
シュードモナス性敗血症	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	3 (1.8%)
大腸菌性敗血症	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	2 (1.2%)
尿路感染	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
蜂巣炎	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
クレブシエラ性菌血症	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
クレブシエラ性敗血症	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
ムコール症	0	0	1 (0.8%)	0	0	0	1 (2.3%)	1 (0.5%)	1 (0.6%)
クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.8%)	0	0	0	0	2 (1.1%)	0
腸球菌性菌血症	0	0	0	0	1 (0.9%)	0	0	0	2 (1.2%)
ブドウ球菌感染	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	1 (0.6%)
アシネトバクター性菌血症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
肺炎球菌性気管支炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
気管支肺炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
脳アスペルギルス症	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
サイトメガロウイルス血症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
ヘルペス脳炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
心内膜炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
感染	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
注入部位感染	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
筋膿瘍	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
モラクセラ菌性肺炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
気道感染	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
敗血症症候群	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
皮膚感染	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
細菌性敗血症	0	1 (4.0%)	0	1 (0.8%)	0	2 (1.8%)	0	0	1 (0.6%)
ブドウ球菌性菌血症	0	1 (4.0%)	0	0	0	2 (1.8%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
菌血症	0	1 (4.0%)	0	1 (0.8%)	0	0	0	0	3 (1.8%)
ブドウ球菌性敗血症	0	0	0	1 (0.8%)	0	1 (0.9%)	0	1 (0.5%)	0
クロストリジウム性菌血症	0	0	0	0	0	2 (1.8%)	0	0	0
髄膜炎	0	0	0	0	0	2 (1.8%)	0	0	0
細菌性肺炎	0	0	0	1 (0.8%)	0	0	0	0	3 (1.8%)
帯状疱疹	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	1 (0.6%)
蓄膿	0	1 (4.0%)	0	0	0	0	0	1 (0.5%)	0
カンピロバクター胃腸炎	0	0	0	1 (0.8%)	0	0	0	0	0
カテーテル関連感染	0	1 (4.0%)	0	0	0	0	0	0	0
感染性下痢	0	1 (4.0%)	0	0	0	0	0	0	0
ヘリコバクター胃潰瘍	0	0	0	0	0	1 (0.9%)	0	0	0
単純ヘルペス	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肺膿瘍	0	0	0	0	0	1 (0.9%)	0	0	0
壊死性筋膜炎	0	0	0	0	0	1 (0.9%)	0	0	0
肺炎球菌性肺炎	0	0	0	0	0	1 (0.9%)	0	0	0
ブドウ球菌性肺炎	0	0	0	1 (0.8%)	0	0	0	0	0
シュードモナス性菌血症	0	0	0	0	0	1 (0.9%)	0	0	0
シュードモナス感染	0	0	0	0	0	1 (0.9%)	0	0	0
膿胸	0	0	0	0	0	1 (0.9%)	0	0	0
ステノトロフォモナス性敗血症	0	0	0	0	0	1 (0.9%)	0	0	0
全身性カンジダ	0	0	0	1 (0.8%)	0	0	0	0	0
トキソプラズマ症	0	0	0	1 (0.8%)	0	0	0	0	0
結核	0	0	0	0	0	1 (0.9%)	0	0	0
細菌性尿路感染	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
真菌性肺炎	0	0	0	0	0	0	0	0	2 (1.2%)
接合真菌症	0	0	0	0	0	0	0	2 (1.1%)	0
腹部膿瘍	0	0	0	0	0	0	0	1 (0.5%)	0
虫垂炎	0	0	0	0	0	0	1 (2.3%)	0	0
ＢＫウイルス感染	0	0	0	0	0	0	0	0	1 (0.6%)
脳膿瘍	0	0	0	0	0	0	0	1 (0.5%)	0
気管支拡張症	0	0	0	0	0	0	0	0	1 (0.6%)
細気管支炎	0	0	0	0	0	0	0	1 (0.5%)	0
カテーテル留置部位感染	0	0	0	0	0	0	0	1 (0.5%)	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	0	0	1 (0.5%)	0
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (0.6%)
真菌性敗血症	0	0	0	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
ノロウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (0.6%)
ウイルス性胃腸炎	0	0	0	0	0	0	0	1 (0.5%)	0
インフルエンザ	0	0	0	0	0	0	0	1 (0.5%)	0
肺感染	0	0	0	0	0	0	1 (2.3%)	0	0
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (0.6%)
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	0	0	0	1 (0.6%)
ブラストミセス菌性肺炎	0	0	0	0	0	0	0	1 (0.5%)	0
インフルエンザ性肺炎	0	0	0	0	0	0	0	0	1 (0.6%)
原発性異型肺炎	0	0	0	0	0	0	1 (2.3%)	0	0
シュードモナス性気管支炎	0	0	0	0	0	0	1 (2.3%)	0	0
副鼻腔炎	0	0	0	0	0	0	0	0	1 (0.6%)
真菌性副鼻腔炎	0	0	0	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
レンサ球菌性菌血症	0	0	0	0	0	0	0	1 (0.5%)	0
皮下組織膿瘍	0	0	0	0	0	0	0	1 (0.5%)	0
尿路性敗血症	0	0	0	0	0	0	0	1 (0.5%)	0
ウイルス性下痢	0	0	0	0	0	0	0	0	1 (0.6%)
呼吸器、胸郭および縦隔障害	4 (15.4%)	4 (16.0%)	18 (14.6%)	17 (13.8%)	19 (17.6%)	22 (19.8%)	5 (11.6%)	26 (13.8%)	30 (17.6%)
呼吸不全	1 (3.8%)	1 (4.0%)	6 (4.9%)	4 (3.3%)	7 (6.5%)	7 (6.3%)	1 (2.3%)	6 (3.2%)	12 (7.1%)
急性呼吸不全	0	1 (4.0%)	2 (1.6%)	0	3 (2.8%)	4 (3.6%)	0	5 (2.6%)	3 (1.8%)
呼吸困難	0	0	2 (1.6%)	1 (0.8%)	3 (2.8%)	0	0	2 (1.1%)	4 (2.4%)
呼吸窮迫	0	0	3 (2.4%)	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	3 (1.6%)	1 (0.6%)
喀血	1 (3.8%)	0	1 (0.8%)	2 (1.6%)	0	0	2 (4.7%)	1 (0.5%)	1 (0.6%)
低酸素症	0	0	0	0	2 (1.9%)	1 (0.9%)	0	0	3 (1.8%)
肺出血	0	1 (4.0%)	2 (1.6%)	0	0	0	0	2 (1.1%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
胸水	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	2 (1.2%)
肺水腫	0	0	0	0	1 (0.9%)	1 (0.9%)	0	1 (0.5%)	1 (0.6%)
肺障害	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
呼吸抑制	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
嚥下性肺炎	0	0	1 (0.8%)	0	0	0	0	2 (1.1%)	1 (0.6%)
頻呼吸	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	1 (0.6%)
気管支胸膜瘻	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
気管支痙攣	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
水気胸	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
胸膜痛	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
呼吸性アシドーシス	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
鼻出血	0	0	0	2 (1.6%)	0	2 (1.8%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肺塞栓症	0	0	0	1 (0.8%)	0	2 (1.8%)	0	1 (0.5%)	0
肺浸潤	0	0	0	2 (1.6%)	0	1 (0.9%)	0	0	0
急性呼吸窮迫症候群	0	0	0	1 (0.8%)	0	1 (0.9%)	0	1 (0.5%)	0
急性肺損傷	0	0	0	0	0	1 (0.9%)	0	0	0
慢性閉塞性肺疾患	0	0	0	0	0	1 (0.9%)	0	0	0
咳嗽	0	1 (4.0%)	0	0	0	0	0	0	0
血胸	0	0	0	1 (0.8%)	0	0	0	0	0
気胸	0	0	0	1 (0.8%)	0	0	0	0	0
湿性咳嗽	0	0	0	1 (0.8%)	0	0	0	0	0
肺高血圧症	0	0	0	1 (0.8%)	0	0	0	0	0
呼吸停止	0	1 (4.0%)	0	0	0	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肺胞出血	0	0	0	0	0	0	0	0	1 (0.6%)
肺梗塞	0	0	0	0	0	0	0	1 (0.5%)	0
副鼻腔障害	0	0	0	0	0	0	0	1 (0.5%)	0
喘鳴	0	0	0	0	0	0	0	0	1 (0.6%)
血液およびリンパ系障害	1 (3.8%)	3 (12.0%)	16 (13.0%)	10 (8.1%)	11 (10.2%)	4 (3.6%)	1 (2.3%)	18 (9.5%)	14 (8.2%)
発熱性好中球減少症	1 (3.8%)	1 (4.0%)	7 (5.7%)	2 (1.6%)	6 (5.6%)	2 (1.8%)	1 (2.3%)	8 (4.2%)	7 (4.1%)
汎血球減少症	0	0	2 (1.6%)	3 (2.4%)	2 (1.9%)	0	0	2 (1.1%)	3 (1.8%)
好中球減少症	0	3 (12.0%)	1 (0.8%)	0	3 (2.8%)	0	0	1 (0.5%)	3 (1.8%)
血小板減少症	0	1 (4.0%)	2 (1.6%)	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	2 (1.1%)	1 (0.6%)
無顆粒球症	0	0	2 (1.6%)	0	0	0	0	2 (1.1%)	0
貧血	0	0	1 (0.8%)	2 (1.6%)	0	0	0	2 (1.1%)	1 (0.6%)
出血性障害	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
白血球増加症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
脾臓梗塞	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
出血性貧血	0	0	0	0	0	1 (0.9%)	0	0	0
微小血管症性溶血性貧血	0	0	0	1 (0.8%)	0	0	0	0	0
血小板減少性紫斑病	0	0	0	1 (0.8%)	0	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）	1 (3.8%)	3 (12.0%)	9 (7.3%)	14 (11.4%)	8 (7.4%)	12 (10.8%)	1 (2.3%)	12 (6.3%)	13 (7.6%)
急性骨髄性白血病	1 (3.8%)	1 (4.0%)	1 (0.8%)	3 (2.4%)	1 (0.9%)	4 (3.6%)	1 (2.3%)	1 (0.5%)	3 (1.8%)
リンパ腫	0	0	1 (0.8%)	0	1 (0.9%)	1 (0.9%)	0	1 (0.5%)	1 (0.6%)
多発性骨髄腫	0	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
悪性新生物進行	0	1 (4.0%)	0	0	1 (0.9%)	0	0	1 (0.5%)	2 (1.2%)
再発急性リンパ性白血病	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	2 (1.2%)
芽球発症	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
骨髄性白血病	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
新生物進行	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
子宮内膜癌	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
髄膜転移	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
骨髄異形成症候群	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
非ホジキンリンパ腫	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
原発性体腔性リンパ腫	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	0	0	1 (0.8%)	0	4 (3.6%)	0	1 (0.5%)	1 (0.6%)
慢性リンパ性白血病	0	0	0	2 (1.6%)	0	0	0	1 (0.5%)	0
急性白血病	0	0	0	0	0	1 (0.9%)	0	0	0
急性リンパ性白血病	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
B細胞性リンパ腫	0	0	0	1 (0.8%)	0	0	0	0	0
再発B細胞性リンパ腫	0	0	0	1 (0.8%)	0	0	0	0	0
バーキット白血病	0	0	0	0	0	1 (0.9%)	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	0	0	1 (0.8%)	0	0	0	0	0
白血病	0	0	0	0	0	1 (0.9%)	0	0	0
肺の悪性新生物	0	0	0	1 (0.8%)	0	0	0	0	0
骨転移	0	0	0	0	0	1 (0.9%)	0	0	0
転移部痛	0	1 (4.0%)	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.6%)
白血病浸潤	0	0	0	0	0	0	0	0	1 (0.6%)
神経系障害	2 (7.7%)	2 (8.0%)	10 (8.1%)	5 (4.1%)	5 (4.6%)	9 (8.1%)	3 (7.0%)	16 (8.5%)	6 (3.5%)
痙攣	0	0	3 (2.4%)	1 (0.8%)	0	0	0	5 (2.6%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
頭蓋内出血	0	0	2 (1.6%)	0	0	3 (2.7%)	0	2 (1.1%)	0
てんかん	0	0	2 (1.6%)	1 (0.8%)	0	0	0	2 (1.1%)	0
多発ニューロパチー	0	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
中枢神経系病変	1 (3.8%)	1 (4.0%)	0	0	0	0	1 (2.3%)	0	0
脳症	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
虚血性脳卒中	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
対麻痺	0	1 (4.0%)	1 (0.8%)	0	0	0	0	1 (0.5%)	0
頭痛	0	0	0	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
脳幹卒中	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
脳虚血	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
熱性痙攣	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
神経毒性	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
失語症	0	0	0	1 (0.8%)	0	0	0	1 (0.5%)	0
脳出血	0	0	0	1 (0.8%)	0	0	0	0	0
浮動性めまい	0	0	0	0	0	1 (0.9%)	0	0	0
脳炎	0	0	0	0	0	1 (0.9%)	0	0	0
大発作痙攣	0	0	0	0	0	1 (0.9%)	0	0	0
片麻痺	0	0	0	1 (0.8%)	0	0	0	0	0
昏迷	0	0	0	1 (0.8%)	0	0	0	0	0
くも膜下出血	0	0	0	1 (0.8%)	0	0	0	0	0
振戦	0	0	0	0	0	1 (0.9%)	0	0	0
第７脳神経麻痺	0	0	0	1 (0.8%)	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	0	2 (1.1%)	0
脳血管発作	0	0	0	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
卒中の出血性変化	0	0	0	0	0	0	1 (2.3%)	0	0
不全片麻痺	0	0	0	0	0	0	0	1 (0.5%)	0
一過性脳虚血発作	0	0	0	0	0	0	0	0	1 (0.6%)
全身障害および投与局所様態	0	2 (8.0%)	5 (4.1%)	9 (7.3%)	6 (5.6%)	8 (7.2%)	1 (2.3%)	7 (3.7%)	12 (7.1%)
発熱	0	2 (8.0%)	3 (2.4%)	4 (3.3%)	5 (4.6%)	4 (3.6%)	0	3 (1.6%)	7 (4.1%)
多臓器不全	0	0	0	4 (3.3%)	1 (0.9%)	3 (2.7%)	0	1 (0.5%)	1 (0.6%)
死亡	0	0	1 (0.8%)	1 (0.8%)	0	0	1 (2.3%)	2 (1.1%)	1 (0.6%)
悪寒	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
全身健康状態低下	0	0	0	0	1 (0.9%)	0	0	0	2 (1.2%)
無力症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
胸痛	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
心突然死	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
非心臓性胸痛	0	0	0	0	0	0	0	0	2 (1.2%)
末梢性浮腫	0	0	0	0	0	0	0	1 (0.5%)	0
心臓障害	1 (3.8%)	2 (8.0%)	3 (2.4%)	4 (3.3%)	7 (6.5%)	6 (5.4%)	1 (2.3%)	5 (2.6%)	13 (7.6%)
心肺停止	1 (3.8%)	0	1 (0.8%)	1 (0.8%)	0	1 (0.9%)	1 (2.3%)	1 (0.5%)	2 (1.2%)
心停止	0	1 (4.0%)	0	2 (1.6%)	1 (0.9%)	2 (1.8%)	0	0	1 (0.6%)
心房細動	0	0	0	0	1 (0.9%)	1 (0.9%)	0	1 (0.5%)	2 (1.2%)
急性心筋梗塞	0	1 (4.0%)	0	0	1 (0.9%)	0	0	0	2 (1.2%)
不整脈	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
心原性ショック	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
うっ血性心筋症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心膜炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
洞性徐脈	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
上室性頻脈	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心室性頻脈	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
狭心症	0	0	0	0	0	1 (0.9%)	0	0	0
完全房室ブロック	0	0	0	0	0	0	0	0	1 (0.6%)
急性心不全	0	0	0	0	0	0	0	1 (0.5%)	0
電気収縮解離	0	0	0	0	0	0	0	0	1 (0.6%)
腎および尿路障害	0	1 (4.0%)	4 (3.3%)	6 (4.9%)	6 (5.6%)	3 (2.7%)	0	8 (4.2%)	11 (6.5%)
急性腎不全	0	1 (4.0%)	2 (1.6%)	4 (3.3%)	4 (3.7%)	3 (2.7%)	0	5 (2.6%)	9 (5.3%)
腎不全	0	0	1 (0.8%)	2 (1.6%)	2 (1.9%)	0	0	2 (1.1%)	2 (1.2%)
血尿	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
胃腸障害	2 (7.7%)	2 (8.0%)	3 (2.4%)	5 (4.1%)	4 (3.7%)	5 (4.5%)	3 (7.0%)	11 (5.8%)	13 (7.6%)
下痢	0	1 (4.0%)	2 (1.6%)	0	0	0	0	2 (1.1%)	2 (1.2%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
小腸閉塞	2 (7.7%)	0	0	0	0	0	2 (4.7%)	0	0
悪心	0	0	0	0	1 (0.9%)	1 (0.9%)	0	1 (0.5%)	2 (1.2%)
腸出血	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
腹膜炎	1 (3.8%)	0	0	0	0	1 (0.9%)	1 (2.3%)	0	0
腹痛	0	0	0	0	1 (0.9%)	0	0	2 (1.1%)	4 (2.4%)
大腸炎	1 (3.8%)	0	0	0	0	0	1 (2.3%)	1 (0.5%)	0
便秘	0	0	0	0	1 (0.9%)	0	0	0	2 (1.2%)
胃穿孔	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
食道潰瘍	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
胃腸出血	0	0	0	1 (0.8%)	0	2 (1.8%)	0	2 (1.1%)	1 (0.6%)
食中毒	0	0	0	1 (0.8%)	0	0	0	0	0
胃腸の炎症	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
麻痺性イレウス	0	0	0	0	0	1 (0.9%)	0	0	0
肛門周囲痛	0	1 (4.0%)	0	0	0	0	0	0	0
直腸出血	0	0	0	1 (0.8%)	0	0	0	0	0
嘔吐	0	0	0	0	0	0	1 (2.3%)	1 (0.5%)	2 (1.2%)
嚥下障害	0	0	0	0	0	0	0	1 (0.5%)	1 (0.6%)
潰瘍性大腸炎	0	0	0	0	0	0	0	1 (0.5%)	0
限局性腹腔内液貯留	0	0	0	0	0	0	0	0	1 (0.6%)
食道炎	0	0	0	0	0	0	0	1 (0.5%)	0
膵炎	0	0	0	0	0	0	0	0	1 (0.6%)
慢性膵炎	0	0	0	0	0	0	0	0	1 (0.6%)
再発性膵炎	0	0	0	0	0	0	0	0	1 (0.6%)
免疫系障害	0	0	2 (1.6%)	5 (4.1%)	2 (1.9%)	1 (0.9%)	0	3 (1.6%)	6 (3.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
急性腸管移植片対宿主病	0	0	0	2 (1.6%)	1 (0.9%)	0	0	0	1 (0.6%)
急性移植片対宿主病	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	2 (1.2%)
アナフィラキシーショック	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
過敏症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
アナフィラキシー反応	0	0	0	2 (1.6%)	0	0	0	0	0
急性肝移植片対宿主病	0	0	0	0	0	1 (0.9%)	0	0	0
移植片対宿主病	0	0	0	0	0	0	0	1 (0.5%)	1 (0.6%)
肺移植拒絶反応	0	0	0	0	0	0	0	0	1 (0.6%)
血管障害	0	1 (4.0%)	2 (1.6%)	4 (3.3%)	2 (1.9%)	1 (0.9%)	0	4 (2.1%)	5 (2.9%)
低血圧	0	0	0	2 (1.6%)	1 (0.9%)	0	0	0	3 (1.8%)
出血	0	0	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)
血液量減少性ショック	0	1 (4.0%)	1 (0.8%)	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
血管炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	0	0	1 (0.8%)	0	0	0	2 (1.1%)	0
ショック	0	0	0	1 (0.8%)	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	0	1 (0.6%)
肝胆道系障害	0	0	2 (1.6%)	4 (3.3%)	1 (0.9%)	2 (1.8%)	2 (4.7%)	4 (2.1%)	2 (1.2%)
胆嚢炎	0	0	0	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
肝炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
急性肝炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
肝不全	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
肝機能異常	0	0	0	2 (1.6%)	0	0	0	0	0
高ビリルビン血症	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
急性胆嚢炎	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
急性肝不全	0	0	0	0	0	0	0	1 (0.5%)	0
細胆管炎	0	0	0	0	0	0	1 (2.3%)	0	0
胆石症	0	0	0	0	0	0	0	0	1 (0.6%)
肝障害	0	0	0	0	0	0	1 (2.3%)	0	0
臨床検査	0	0	1 (0.8%)	1 (0.8%)	2 (1.9%)	5 (4.5%)	0	1 (0.5%)	2 (1.2%)
肝機能検査異常	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
血中ナトリウム減少	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
ヘモグロビン減少	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
アラニン・アミノトランスフェラーゼ増加	0	0	0	0	0	1 (0.9%)	0	0	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	1 (0.9%)	0	0	0
血中アルカリホスファターゼ増加	0	0	0	0	0	1 (0.9%)	0	0	0
血中ビリルビン増加	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
心電図ＱＴ延長	0	0	0	0	0	1 (0.9%)	0	0	0
肝酵素上昇	0	0	0	1 (0.8%)	0	0	0	0	0
傷害、中毒および処置合併症	0	0	2 (1.6%)	1 (0.8%)	1 (0.9%)	2 (1.8%)	0	2 (1.1%)	1 (0.6%)
薬物毒性	0	0	2 (1.6%)	0	0	0	0	2 (1.1%)	0
転倒・転落	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
家庭内事故	0	0	0	0	0	1 (0.9%)	0	0	0
大腿骨頚部骨折	0	0	0	0	0	1 (0.9%)	0	0	0
橈骨骨折	0	0	0	1 (0.8%)	0	0	0	0	0
皮膚および皮下組織障害	0	0	1 (0.8%)	0	2 (1.9%)	2 (1.8%)	0	1 (0.5%)	2 (1.2%)
褥瘡性潰瘍	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
皮膚炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
脂肪織炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
発疹	0	0	0	0	0	2 (1.8%)	0	0	0
筋骨格系および結合組織障害	0	0	1 (0.8%)	0	2 (1.9%)	0	1 (2.3%)	1 (0.5%)	5 (2.9%)
筋骨格系胸痛	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	2 (1.2%)
筋肉内出血	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
筋炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
関節炎	0	0	0	0	0	0	1 (2.3%)	0	0
四肢痛	0	0	0	0	0	0	0	0	1 (0.6%)
全身性エリテマトーデス	0	0	0	0	0	0	0	0	1 (0.6%)
代謝および栄養障害	0	2 (8.0%)	2 (1.6%)	4 (3.3%)	0	1 (0.9%)	1 (2.3%)	4 (2.1%)	4 (2.4%)
コントロール不良の糖尿病	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
成長障害	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
脱水	0	0	0	2 (1.6%)	0	0	0	2 (1.1%)	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
代謝性アシドーシス	0	1 (4.0%)	0	0	0	1 (0.9%)	0	0	0
低血糖症	0	0	0	1 (0.8%)	0	0	0	0	1 (0.6%)
高ナトリウム血症	0	0	0	1 (0.8%)	0	0	0	0	0
低カリウム血症	0	0	0	1 (0.8%)	0	0	0	0	0
過小食	0	1 (4.0%)	0	0	0	0	0	0	0
高カリウム血症	0	0	0	0	0	0	0	0	1 (0.6%)
低ナトリウム血症	0	0	0	0	0	0	1 (2.3%)	0	0
栄養障害	0	0	0	0	0	0	0	0	1 (0.6%)
眼障害	1 (3.8%)	0	1 (0.8%)	0	0	1 (0.9%)	1 (2.3%)	3 (1.6%)	0
片側失明	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
視神経症	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
眼瞼浮腫	0	0	0	0	0	1 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
網膜動脈閉塞	0	0	0	0	0	0	0	1 (0.5%)	0
網膜出血	0	0	0	0	0	0	0	1 (0.5%)	0
硝子体出血	0	0	0	0	0	0	0	1 (0.5%)	0
精神障害	0	0	1 (0.8%)	1 (0.8%)	0	5 (4.5%)	0	2 (1.1%)	1 (0.6%)
うつ病	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
幻視	0	0	0	0	0	2 (1.8%)	0	0	0
精神状態変化	0	0	0	0	0	2 (1.8%)	0	0	0
錯乱状態	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	0
幻覚	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	0
抑うつ気分	0	0	0	0	0	1 (0.9%)	0	0	0
自殺企図	0	0	0	1 (0.8%)	0	0	0	0	0
異常行動	0	0	0	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-135 重篤な有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
攻撃性	0	0	0	0	0	0	0	0	1 (0.6%)
激越	0	0	0	0	0	0	0	0	1 (0.6%)
生殖系および乳房障害	0	0	0	0	0	0	0	0	1 (0.6%)
良性前立腺肥大症	0	0	0	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_weight_ser_1.sas
Program Run: 04JUN21:14:53:08

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
Overall	4 (15.4%)	1 (4.0%)	21 (17.1%)	29 (23.6%)	12 (11.1%)	29 (26.1%)	6 (14.0%)	31 (16.4%)	19 (11.2%)
感染症および寄生虫症	2 (7.7%)	1 (4.0%)	8 (6.5%)	7 (5.7%)	1 (0.9%)	7 (6.3%)	2 (4.7%)	12 (6.3%)	4 (2.4%)
真菌感染	0	0	2 (1.6%)	0	0	1 (0.9%)	0	2 (1.1%)	1 (0.6%)
敗血症性ショック	0	0	1 (0.8%)	0	1 (0.9%)	0	0	2 (1.1%)	2 (1.2%)
敗血症	0	0	1 (0.8%)	2 (1.6%)	0	1 (0.9%)	0	1 (0.5%)	0
アスペルギルス症	1 (3.8%)	0	0	0	0	1 (0.9%)	1 (2.3%)	2 (1.1%)	0
肺炎	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
気管支肺炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
気管支肺アスペルギルス症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心内膜炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
感染	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
細菌性敗血症	0	1 (4.0%)	0	0	0	2 (1.8%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肺感染	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
髄膜炎	0	0	0	0	0	1 (0.9%)	0	0	0
ムコール症	0	0	0	1 (0.8%)	0	0	0	0	0
シュードモナス性敗血症	0	0	0	1 (0.8%)	0	0	0	0	0
ブドウ球菌感染	0	0	0	1 (0.8%)	0	0	0	0	0
全身性カンジダ	0	0	0	1 (0.8%)	0	0	0	0	0
脳膿瘍	0	0	0	0	0	0	0	1 (0.5%)	0
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (0.6%)
呼吸器、胸郭および縦隔障害	0	0	3 (2.4%)	2 (1.6%)	3 (2.8%)	3 (2.7%)	0	3 (1.6%)	3 (1.8%)
呼吸不全	0	0	0	1 (0.8%)	2 (1.9%)	3 (2.7%)	0	0	2 (1.2%)
呼吸困難	0	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
呼吸窮迫	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
急性呼吸不全	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
神経系障害	0	0	4 (3.3%)	2 (1.6%)	1 (0.9%)	2 (1.8%)	1 (2.3%)	5 (2.6%)	1 (0.6%)
痙攣	0	0	2 (1.6%)	0	0	0	0	2 (1.1%)	0
てんかん	0	0	2 (1.6%)	0	0	0	0	2 (1.1%)	0
脳症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
大発作痙攣	0	0	0	0	0	1 (0.9%)	0	0	0
昏迷	0	0	0	1 (0.8%)	0	0	0	0	0
くも膜下出血	0	0	0	1 (0.8%)	0	0	0	0	0
振戦	0	0	0	0	0	1 (0.9%)	0	0	0
脳血管発作	0	0	0	0	0	0	0	1 (0.5%)	0
卒中の出血性変化	0	0	0	0	0	0	1 (2.3%)	0	0
臨床検査	0	0	1 (0.8%)	1 (0.8%)	3 (2.8%)	5 (4.5%)	0	2 (1.1%)	4 (2.4%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
血中ビリルビン増加	0	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.5%)	1 (0.6%)
血中ナトリウム減少	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
トランスアミナーゼ上昇	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
肝機能検査異常	0	0	0	0	0	2 (1.8%)	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	0
血中アルカリホスファターゼ増加	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	0
肝酵素上昇	0	0	0	1 (0.8%)	0	0	0	0	1 (0.6%)
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	1 (0.9%)	0	0	0
心電図ＱＴ延長	0	0	0	0	0	1 (0.9%)	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	0	0	1 (0.5%)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	0	1 (0.5%)	0
心臓障害	0	0	3 (2.4%)	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	3 (1.6%)	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
心停止	0	0	0	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)
心肺停止	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
うっ血性心筋症	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
上室性頻脈	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
心室性頻脈	0	0	0	1 (0.8%)	0	0	0	0	0
腎および尿路障害	0	1 (4.0%)	0	1 (0.8%)	3 (2.8%)	1 (0.9%)	0	2 (1.1%)	3 (1.8%)
腎不全	0	0	0	0	2 (1.9%)	1 (0.9%)	0	0	2 (1.2%)
急性腎不全	0	1 (4.0%)	0	1 (0.8%)	1 (0.9%)	0	0	2 (1.1%)	1 (0.6%)
精神障害	0	0	1 (0.8%)	2 (1.6%)	1 (0.9%)	4 (3.6%)	0	2 (1.1%)	1 (0.6%)
錯乱状態	0	0	1 (0.8%)	1 (0.8%)	1 (0.9%)	1 (0.9%)	0	2 (1.1%)	1 (0.6%)
幻視	0	0	0	1 (0.8%)	0	2 (1.8%)	0	0	0
幻覚	0	0	0	0	0	1 (0.9%)	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
抑うつ気分	0	0	0	0	0	1 (0.9%)	0	0	0
不快気分	0	0	0	1 (0.8%)	0	0	0	0	0
皮膚および皮下組織障害	0	0	0	2 (1.6%)	2 (1.9%)	3 (2.7%)	0	0	2 (1.2%)
皮膚炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
アレルギー性皮膚炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
発疹	0	0	0	1 (0.8%)	0	3 (2.7%)	0	0	0
薬疹	0	0	0	1 (0.8%)	0	0	0	0	0
胃腸障害	1 (3.8%)	0	0	1 (0.8%)	1 (0.9%)	2 (1.8%)	2 (4.7%)	0	2 (1.2%)
嘔吐	1 (3.8%)	0	0	1 (0.8%)	0	1 (0.9%)	2 (4.7%)	0	0
嚥下障害	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
小腸閉塞	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
悪心	0	0	0	0	0	2 (1.8%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
肝胆道系障害	0	0	1 (0.8%)	4 (3.3%)	0	2 (1.8%)	0	2 (1.1%)	0
急性肝炎	0	0	1 (0.8%)	0	0	0	0	1 (0.5%)	0
肝不全	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
高ビリルビン血症	0	0	0	1 (0.8%)	0	1 (0.9%)	0	0	0
肝機能異常	0	0	0	1 (0.8%)	0	0	0	0	0
肝病変	0	0	0	1 (0.8%)	0	0	0	0	0
肝炎	0	0	0	0	0	1 (0.9%)	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (0.8%)	0	0	0	0	0
急性肝不全	0	0	0	0	0	0	0	1 (0.5%)	0
血液およびリンパ系障害	0	0	1 (0.8%)	3 (2.4%)	0	0	0	1 (0.5%)	0
汎血球減少症	0	0	1 (0.8%)	1 (0.8%)	0	0	0	1 (0.5%)	0
微小血管症性溶血性貧血	0	0	0	1 (0.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
脾臓病変	0	0	0	1 (0.8%)	0	0	0	0	0
眼障害	1 (3.8%)	0	0	0	0	1 (0.9%)	1 (2.3%)	0	0
視神経症	1 (3.8%)	0	0	0	0	0	1 (2.3%)	0	0
眼瞼浮腫	0	0	0	0	0	1 (0.9%)	0	0	0
全身障害および投与局所様態	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
悪寒	0	0	1 (0.8%)	0	0	1 (0.9%)	0	1 (0.5%)	0
傷害、中毒および処置合併症	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
過量投与	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
筋骨格系および結合組織障害	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
筋炎	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
血管障害	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)
低血圧	0	0	0	0	1 (0.9%)	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-136 投与中止に至った有害事象（体重別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Weight (kg) Subgroup	< 50		>= 50 to < 70		>= 70		< 50	>= 50 to < 70	>= 70
System Organ Class Preferred Term	ISA (N = 26)	VRC (N = 25)	ISA (N = 123)	VRC (N = 123)	ISA (N = 108)	VRC (N = 111)	ISA (N = 43)	ISA (N = 189)	ISA (N = 170)
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	4 (3.3%)	0	3 (2.7%)	0	1 (0.5%)	2 (1.2%)
急性骨髄性白血病	0	0	0	2 (1.6%)	0	2 (1.8%)	0	0	0
再発急性骨髄性白血病	0	0	0	0	0	1 (0.9%)	0	0	1 (0.6%)
慢性リンパ性白血病	0	0	0	1 (0.8%)	0	0	0	0	0
肺の悪性新生物	0	0	0	1 (0.8%)	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.6%)
悪性新生物進行	0	0	0	0	0	0	0	1 (0.5%)	0
免疫系障害	0	0	0	1 (0.8%)	0	0	0	0	0
急性肝移植片対宿主病	0	0	0	1 (0.8%)	0	0	0	0	0
代謝および栄養障害	0	1 (4.0%)	0	0	0	0	0	0	0
代謝性アシドーシス	0	1 (4.0%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_weight_discon_1.sas
Program Run: 04JUN21:14:53:14

表 8-137 SOC別の有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
Overall	26 (92.9%)	15 (88.2%)	29 (93.5%)	11 (100.0%)	0	2 (100.0%)	29 (93.5%)	35 (94.6%)	3 (60.0%)
感染症および寄生虫症	11 (39.3%)	6 (35.3%)	11 (35.5%)	3 (27.3%)	0	1 (50.0%)	11 (35.5%)	13 (35.1%)	1 (20.0%)
胃腸障害	9 (32.1%)	6 (35.3%)	8 (25.8%)	5 (45.5%)	0	1 (50.0%)	10 (32.3%)	10 (27.0%)	1 (20.0%)
臨床検査	5 (17.9%)	4 (23.5%)	11 (35.5%)	3 (27.3%)	0	0	7 (22.6%)	12 (32.4%)	2 (40.0%)
肝胆道系障害	4 (14.3%)	4 (23.5%)	7 (22.6%)	5 (45.5%)	0	1 (50.0%)	4 (12.9%)	7 (18.9%)	1 (20.0%)
神経系障害	7 (25.0%)	4 (23.5%)	3 (9.7%)	2 (18.2%)	0	0	9 (29.0%)	6 (16.2%)	0
皮膚および皮下組織障害	6 (21.4%)	2 (11.8%)	3 (9.7%)	2 (18.2%)	0	0	6 (19.4%)	4 (10.8%)	1 (20.0%)
眼障害	5 (17.9%)	7 (41.2%)	3 (9.7%)	5 (45.5%)	0	1 (50.0%)	5 (16.1%)	5 (13.5%)	0
代謝および栄養障害	5 (17.9%)	0	3 (9.7%)	1 (9.1%)	0	1 (50.0%)	6 (19.4%)	4 (10.8%)	1 (20.0%)
一般・全身障害および投与部位の状態	4 (14.3%)	0	4 (12.9%)	0	0	1 (50.0%)	5 (16.1%)	4 (10.8%)	0
呼吸器、胸郭および縦隔障害	5 (17.9%)	1 (5.9%)	2 (6.5%)	1 (9.1%)	0	1 (50.0%)	6 (19.4%)	3 (8.1%)	0
腎および尿路障害	1 (3.6%)	1 (5.9%)	4 (12.9%)	1 (9.1%)	0	0	2 (6.5%)	5 (13.5%)	0
血管障害	4 (14.3%)	1 (5.9%)	1 (3.2%)	0	0	0	4 (12.9%)	2 (5.4%)	0
精神障害	1 (3.6%)	4 (23.5%)	2 (6.5%)	1 (9.1%)	0	2 (100.0%)	2 (6.5%)	2 (5.4%)	0
筋骨格系および結合組織障害	2 (7.1%)	3 (17.6%)	1 (3.2%)	1 (9.1%)	0	0	2 (6.5%)	2 (5.4%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_soc_2.sas
Program Run: 16JUN21:17:58:04

表 8-137 SOC別の有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
傷害、中毒および処置合併症	2 (7.1%)	0	1 (3.2%)	2 (18.2%)	0	0	2 (6.5%)	1 (2.7%)	1 (20.0%)
心臓障害	2 (7.1%)	1 (5.9%)	1 (3.2%)	0	0	0	3 (9.7%)	2 (5.4%)	1 (20.0%)
耳および迷路障害	1 (3.6%)	1 (5.9%)	1 (3.2%)	0	0	0	1 (3.2%)	1 (2.7%)	0
免疫系障害	0	0	1 (3.2%)	0	0	1 (50.0%)	0	1 (2.7%)	0
内分泌障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	1 (20.0%)
先天性、家族性および遺伝性障害	0	1 (5.9%)	0	1 (9.1%)	0	1 (50.0%)	0	1 (2.7%)	0
血液およびリンパ系障害	0	1 (5.9%)	0	0	0	0	0	2 (5.4%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_soc_2.sas
Program Run: 16JUN21:17:58:04

表 8-138 注目すべき有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

BMI (kg/m^2) Subgroup	Cohort A						Cohort A/B併合		
	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
肝機能異常・肝炎	7 (25.0%)	7 (41.2%)	15 (48.4%)	6 (54.5%)	0	1 (50.0%)	7 (22.6%)	15 (40.5%)	2 (40.0%)
アナフィラキシー	0	0	0	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0	0	0	0
トルサード ド ポアント	0	0	1 (3.2%)	0	0	0	0	2 (5.4%)	0
急性膵炎	0	0	0	0	0	0	0	0	0
精神神経症状	1 (3.6%)	4 (23.5%)	2 (6.5%)	1 (9.1%)	0	2 (100.0%)	3 (9.7%)	2 (5.4%)	0
視覚障害	5 (17.9%)	7 (41.2%)	2 (6.5%)	6 (54.5%)	0	2 (100.0%)	5 (16.1%)	3 (8.1%)	0
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0	0	0	0
静脈内投与例	(N = 2)	(N = 1)	(N = 6)	(N = 0)	(N = 0)	(N = 1)	(N = 3)	(N = 6)	(N = 0)
注入部位／注射部位反応	0	0	3 (50.0%)	0	0	0	0	3 (50.0%)	0
IRR	0	0	0	0	0	1 (100.0%)	1 (33.3%)	0	0

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.
BMI : body mass index

Program Name: t_ae_bmi_eoi_2.sas
Program Run: 16JUN21:17:58:08

表 8-139 死亡に至った有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
Overall	2 (7.1%)	0	2 (6.5%)	0	0	0	4 (12.9%)	2 (5.4%)	0
呼吸器、胸郭および縦隔障害	1 (3.6%)	0	1 (3.2%)	0	0	0	2 (6.5%)	1 (2.7%)	0
特発性肺炎症候群	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
肺臓炎	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
誤嚥性肺炎	0	0	0	0	0	0	1 (3.2%)	0	0
感染症および寄生虫症	1 (3.6%)	0	1 (3.2%)	0	0	0	1 (3.2%)	1 (2.7%)	0
肺炎球菌感染	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
副鼻腔炎	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
神経系障害	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
大脳基底核梗塞	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
心臓障害	0	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_2.sas
Program Run: 16JUN21:17:58:13

表 8-139 死亡に至った有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
急性心筋梗塞	0	0	0	0	0	0	1 (3.2%)	0	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (3.2%)	0	0
死亡	0	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_2.sas
Program Run: 16JUN21:17:58:13

表 8-140 重篤な有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
Overall	7 (25.0%)	2 (11.8%)	6 (19.4%)	1 (9.1%)	0	0	9 (29.0%)	7 (18.9%)	1 (20.0%)
感染症および寄生虫症	3 (10.7%)	2 (11.8%)	3 (9.7%)	0	0	0	3 (9.7%)	4 (10.8%)	1 (20.0%)
肺炎	1 (3.6%)	1 (5.9%)	1 (3.2%)	0	0	0	1 (3.2%)	1 (2.7%)	0
感染性胸水	1 (3.6%)	0	1 (3.2%)	0	0	0	1 (3.2%)	1 (2.7%)	0
気管支炎	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
肺炎球菌感染	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
副鼻腔炎	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
アスペルギルス感染	0	1 (5.9%)	0	0	0	0	0	0	0
菌血症	0	0	0	0	0	0	0	1 (2.7%)	0
蜂巣炎	0	0	0	0	0	0	0	0	1 (20.0%)
呼吸器、胸郭および縦隔障害	3 (10.7%)	0	1 (3.2%)	0	0	0	4 (12.9%)	1 (2.7%)	0
喀血	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_ser_2.sas
Program Run: 16JUN21:17:58:17

表 8-140 重篤な有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2)									
Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
特発性肺炎症候群	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
肺臓炎	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
気胸	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
誤嚥性肺炎	0	0	0	0	0	0	1 (3.2%)	0	0
肝胆道系障害	0	0	1 (3.2%)	1 (9.1%)	0	0	0	1 (2.7%)	0
胆嚢炎	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
薬物性肝障害	0	0	0	1 (9.1%)	0	0	0	0	0
筋骨格系および結合組織障害	1 (3.6%)	0	0	1 (9.1%)	0	0	1 (3.2%)	0	0
筋力低下	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
横紋筋融解症	0	0	0	1 (9.1%)	0	0	0	0	0
内分泌障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
抗利尿ホルモン不適合分泌	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_ser_2.sas
Program Run: 16JUN21:17:58:17

表 8-140 重篤な有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
代謝および栄養障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
低ナトリウム血症	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
神経系障害	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
大脳基底核梗塞	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
腎および尿路障害	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
腎機能障害	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
心臓障害	0	0	0	0	0	0	1 (3.2%)	0	1 (20.0%)
急性心筋梗塞	0	0	0	0	0	0	1 (3.2%)	0	0
急性心不全	0	0	0	0	0	0	0	0	1 (20.0%)
血液およびリンパ系障害	0	0	0	0	0	0	0	1 (2.7%)	0
好中球減少症	0	0	0	0	0	0	0	1 (2.7%)	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_ser_2.sas
Program Run: 16JUN21:17:58:17

表 8-140 重篤な有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
死亡	0	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_ser_2.sas
Program Run: 16JUN21:17:58:17

表 8-141 投与中止に至った有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
Overall	6 (21.4%)	1 (5.9%)	4 (12.9%)	2 (18.2%)	0	1 (50.0%)	6 (19.4%)	5 (13.5%)	0
肝胆道系障害	0	0	2 (6.5%)	1 (9.1%)	0	1 (50.0%)	0	2 (5.4%)	0
肝機能異常	0	0	2 (6.5%)	0	0	1 (50.0%)	0	2 (5.4%)	0
薬物性肝障害	0	0	0	1 (9.1%)	0	0	0	0	0
感染症および寄生虫症	2 (7.1%)	0	0	0	0	0	2 (6.5%)	0	0
感染性胸水	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
肺炎球菌感染	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
代謝および栄養障害	2 (7.1%)	0	0	0	0	0	2 (6.5%)	0	0
高カリウム血症	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
低ナトリウム血症	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
神経系障害	1 (3.6%)	0	0	1 (9.1%)	0	0	1 (3.2%)	0	0
感覚鈍麻	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_2.sas
Program Run: 16JUN21:17:58:22

表 8-141 投与中止に至った有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
多発ニューロパチー	0	0	0	1 (9.1%)	0	0	0	0	0
臨床検査	0	0	1 (3.2%)	0	0	0	0	2 (5.4%)	0
肝機能検査値上昇	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
心電図異常	0	0	0	0	0	0	0	1 (2.7%)	0
耳および迷路障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
耳管開放	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
胃腸障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
悪心	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
一般・全身障害および投与部位の状態	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
注射部位蕁麻疹	0	0	1 (3.2%)	0	0	0	0	1 (2.7%)	0
腎および尿路障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
腎機能障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_2.sas
Program Run: 16JUN21:17:58:22

表 8-141 投与中止に至った有害事象（BMI別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
BMI (kg/m^2) Subgroup	< 18.5		>= 18.5 to < 25		>= 25		< 18.5	>= 18.5 to < 25	>= 25
System Organ Class Preferred Term	ISA (N = 28)	VRC (N = 17)	ISA (N = 31)	VRC (N = 11)	ISA (N = 1)	VRC (N = 2)	ISA (N = 31)	ISA (N = 37)	ISA (N = 5)
呼吸器、胸郭および縦隔障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
呼吸困難	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
口腔咽頭不快感	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
皮膚および皮下組織障害	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
冷汗	1 (3.6%)	0	0	0	0	0	1 (3.2%)	0	0
眼障害	0	1 (5.9%)	0	0	0	0	0	0	0
視力障害	0	1 (5.9%)	0	0	0	0	0	0	0
筋骨格系および結合組織障害	0	0	0	1 (9.1%)	0	0	0	0	0
横紋筋融解症	0	0	0	1 (9.1%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_2.sas
Program Run: 16JUN21:17:58:22

表 8-142 SOC別の有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
Overall	146 (95.4%)	166 (98.2%)	68 (97.1%)	58 (98.3%)	26 (96.3%)	22 (100.0%)	229 (95.4%)	101 (96.2%)	48 (96.0%)
胃腸障害	104 (68.0%)	123 (72.8%)	48 (68.6%)	34 (57.6%)	18 (66.7%)	17 (77.3%)	151 (62.9%)	72 (68.6%)	30 (60.0%)
感染症および寄生虫症	88 (57.5%)	99 (58.6%)	47 (67.1%)	36 (61.0%)	14 (51.9%)	16 (72.7%)	144 (60.0%)	68 (64.8%)	28 (56.0%)
全身障害および投与局所様態	89 (58.2%)	97 (57.4%)	38 (54.3%)	27 (45.8%)	17 (63.0%)	15 (68.2%)	129 (53.8%)	53 (50.5%)	29 (58.0%)
呼吸器、胸郭および縦隔障害	86 (56.2%)	98 (58.0%)	34 (48.6%)	31 (52.5%)	20 (74.1%)	10 (45.5%)	122 (50.8%)	50 (47.6%)	31 (62.0%)
代謝および栄養障害	60 (39.2%)	83 (49.1%)	32 (45.7%)	20 (33.9%)	15 (55.6%)	12 (54.5%)	95 (39.6%)	47 (44.8%)	27 (54.0%)
神経系障害	62 (40.5%)	56 (33.1%)	26 (37.1%)	22 (37.3%)	7 (25.9%)	6 (27.3%)	93 (38.8%)	39 (37.1%)	12 (24.0%)
皮膚および皮下組織障害	46 (30.1%)	78 (46.2%)	28 (40.0%)	16 (27.1%)	10 (37.0%)	14 (63.6%)	70 (29.2%)	36 (34.3%)	17 (34.0%)
臨床検査	45 (29.4%)	68 (40.2%)	26 (37.1%)	16 (27.1%)	11 (40.7%)	10 (45.5%)	67 (27.9%)	31 (29.5%)	17 (34.0%)
血液およびリンパ系障害	48 (31.4%)	46 (27.2%)	21 (30.0%)	21 (35.6%)	8 (29.6%)	10 (45.5%)	67 (27.9%)	28 (26.7%)	11 (22.0%)
精神障害	41 (26.8%)	54 (32.0%)	19 (27.1%)	19 (32.2%)	9 (33.3%)	8 (36.4%)	59 (24.6%)	31 (29.5%)	13 (26.0%)
筋骨格系および結合組織障害	35 (22.9%)	54 (32.0%)	24 (34.3%)	15 (25.4%)	9 (33.3%)	6 (27.3%)	57 (23.8%)	34 (32.4%)	17 (34.0%)
血管障害	36 (23.5%)	52 (30.8%)	21 (30.0%)	15 (25.4%)	8 (29.6%)	5 (22.7%)	51 (21.3%)	32 (30.5%)	16 (32.0%)
腎および尿路障害	30 (19.6%)	33 (19.5%)	21 (30.0%)	14 (23.7%)	4 (14.8%)	8 (36.4%)	43 (17.9%)	28 (26.7%)	10 (20.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_soc_1.sas
Program Run: 04JUN21:14:53:42

表 8-142 SOC別の有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1 BMI (kg/m^2) Subgroup	9766-CL-0104試験						海外第III相試験併合		
	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
心臓障害	20 (13.1%)	37 (21.9%)	19 (27.1%)	15 (25.4%)	3 (11.1%)	3 (13.6%)	34 (14.2%)	25 (23.8%)	7 (14.0%)
眼障害	23 (15.0%)	49 (29.0%)	9 (12.9%)	11 (18.6%)	7 (25.9%)	8 (36.4%)	34 (14.2%)	13 (12.4%)	10 (20.0%)
傷害、中毒および処置合併症	18 (11.8%)	28 (16.6%)	14 (20.0%)	6 (10.2%)	1 (3.7%)	5 (22.7%)	28 (11.7%)	20 (19.0%)	7 (14.0%)
肝胆道系障害	12 (7.8%)	28 (16.6%)	9 (12.9%)	7 (11.9%)	2 (7.4%)	6 (27.3%)	23 (9.6%)	12 (11.4%)	4 (8.0%)
免疫系障害	12 (7.8%)	14 (8.3%)	4 (5.7%)	6 (10.2%)	4 (14.8%)	4 (18.2%)	15 (6.3%)	7 (6.7%)	7 (14.0%)
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）	13 (8.5%)	18 (10.7%)	4 (5.7%)	10 (16.9%)	2 (7.4%)	1 (4.5%)	17 (7.1%)	8 (7.6%)	4 (8.0%)
耳および迷路障害	11 (7.2%)	11 (6.5%)	2 (2.9%)	1 (1.7%)	1 (3.7%)	1 (4.5%)	14 (5.8%)	5 (4.8%)	2 (4.0%)
生殖系および乳房障害	5 (3.3%)	11 (6.5%)	3 (4.3%)	0	0	2 (9.1%)	11 (4.6%)	5 (4.8%)	1 (2.0%)
内分泌障害	3 (2.0%)	2 (1.2%)	1 (1.4%)	0	0	0	6 (2.5%)	1 (1.0%)	2 (4.0%)
先天性、家族性および遺伝性障害	2 (1.3%)	1 (0.6%)	1 (1.4%)	0	0	1 (4.5%)	2 (0.8%)	1 (1.0%)	0
社会環境	0	0	0	1 (1.7%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_soc_1.sas
Program Run: 04JUN21:14:53:42

表 8-143 注目すべき有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

BMI (kg/m^2) Subgroup	9766-CL-0104試験						海外第III相試験併合		
	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肝機能異常・肝炎	29 (19.0%)	55 (32.5%)	18 (25.7%)	16 (27.1%)	4 (14.8%)	10 (45.5%)	50 (20.8%)	21 (20.0%)	9 (18.0%)
アナフィラキシー	0	3 (1.8%)	1 (1.4%)	0	1 (3.7%)	0	0	1 (1.0%)	1 (2.0%)
重度皮膚障害	0	2 (1.2%)	2 (2.9%)	0	0	0	0	2 (1.9%)	0
心電図QT短縮	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
トルサード ド ポアント	11 (7.2%)	10 (5.9%)	4 (5.7%)	4 (6.8%)	0	3 (13.6%)	11 (4.6%)	5 (4.8%)	2 (4.0%)
急性膵炎	0	0	0	0	0	0	0	1 (1.0%)	0
精神神経症状	43 (28.1%)	49 (29.0%)	21 (30.0%)	18 (30.5%)	8 (29.6%)	7 (31.8%)	61 (25.4%)	33 (31.4%)	14 (28.0%)
視覚障害	13 (8.5%)	34 (20.1%)	5 (7.1%)	9 (15.3%)	5 (18.5%)	3 (13.6%)	17 (7.1%)	7 (6.7%)	6 (12.0%)
皮膚または子宮の悪性腫瘍	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
静脈内投与例	(N = 153)	(N = 169)	(N = 70)	(N = 59)	(N = 27)	(N = 22)	(N = 208)	(N = 97)	(N = 44)
注入部位／注射部位反応	6 (3.9%)	4 (2.4%)	5 (7.1%)	0	0	0	10 (4.8%)	5 (5.2%)	1 (2.3%)
IRR	44 (28.8%)	52 (30.8%)	16 (22.9%)	15 (25.4%)	9 (33.3%)	5 (22.7%)	62 (29.8%)	24 (24.7%)	14 (31.8%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.
BMI : body mass index

Program Name: t_ae_bmi_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
Overall	44 (28.8%)	42 (24.9%)	14 (20.0%)	20 (33.9%)	2 (7.4%)	4 (18.2%)	65 (27.1%)	27 (25.7%)	11 (22.0%)
感染症および寄生虫症	22 (14.4%)	12 (7.1%)	6 (8.6%)	5 (8.5%)	0	0	35 (14.6%)	10 (9.5%)	4 (8.0%)
敗血症性ショック	6 (3.9%)	3 (1.8%)	2 (2.9%)	1 (1.7%)	0	0	8 (3.3%)	4 (3.8%)	0
敗血症	4 (2.6%)	3 (1.8%)	3 (4.3%)	1 (1.7%)	0	0	4 (1.7%)	3 (2.9%)	1 (2.0%)
アスペルギルス症	3 (2.0%)	1 (0.6%)	0	1 (1.7%)	0	0	4 (1.7%)	0	0
真菌感染	3 (2.0%)	1 (0.6%)	0	1 (1.7%)	0	0	3 (1.3%)	0	0
肺炎	1 (0.7%)	1 (0.6%)	0	1 (1.7%)	0	0	1 (0.4%)	1 (1.0%)	1 (2.0%)
ムコール症	1 (0.7%)	0	0	0	0	0	2 (0.8%)	0	0
アシネトバクター性菌血症	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
気管支肺アスペルギルス症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心内膜炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
フサリウム感染	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
感染	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
シュードモナス性敗血症	0	1 (0.6%)	0	0	0	0	0	1 (1.0%)	0
クレブシエラ性敗血症	0	1 (0.6%)	0	0	0	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0	0	0	0
ステノトロフォモナス性敗血症	0	0	0	1 (1.7%)	0	0	0	0	0
真菌性肺炎	0	0	0	0	0	0	2 (0.8%)	0	0
細菌性敗血症	0	0	0	0	0	0	0	0	1 (2.0%)
蓄膿	0	0	0	0	0	0	1 (0.4%)	0	0
真菌性敗血症	0	0	0	0	0	0	1 (0.4%)	0	0
肺感染	0	0	0	0	0	0	1 (0.4%)	0	0
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (2.0%)
ブラストミセス菌性肺炎	0	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
原発性異型肺炎	0	0	0	0	0	0	1 (0.4%)	0	0
真菌性副鼻腔炎	0	0	0	0	0	0	1 (0.4%)	0	0
ブドウ球菌性敗血症	0	0	0	0	0	0	1 (0.4%)	0	0
呼吸器、胸郭および縦隔障害	11 (7.2%)	5 (3.0%)	1 (1.4%)	3 (5.1%)	0	2 (9.1%)	12 (5.0%)	2 (1.9%)	2 (4.0%)
呼吸不全	4 (2.6%)	2 (1.2%)	1 (1.4%)	2 (3.4%)	0	1 (4.5%)	4 (1.7%)	2 (1.9%)	0
急性呼吸不全	3 (2.0%)	0	0	0	0	1 (4.5%)	4 (1.7%)	0	0
喀血	2 (1.3%)	0	0	1 (1.7%)	0	0	2 (0.8%)	0	1 (2.0%)
肺出血	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
呼吸窮迫	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
肺塞栓症	0	1 (0.6%)	0	0	0	0	0	0	0
肺高血圧症	0	1 (0.6%)	0	0	0	0	0	0	0
呼吸困難	0	0	0	0	0	0	0	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
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 (4.6%)	14 (8.3%)	3 (4.3%)	5 (8.5%)	0	1 (4.5%)	10 (4.2%)	7 (6.7%)	0
急性骨髄性白血病	2 (1.3%)	5 (3.0%)	1 (1.4%)	1 (1.7%)	0	0	2 (0.8%)	2 (1.9%)	0
多発性骨髄腫	1 (0.7%)	0	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
悪性新生物進行	1 (0.7%)	1 (0.6%)	0	0	0	0	2 (0.8%)	1 (1.0%)	0
芽球発症	0	0	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
骨髄性白血病	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
再発慢性リンパ性白血病	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
骨髄異形成症候群	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
再発急性骨髄性白血病	0	1 (0.6%)	0	2 (3.4%)	0	1 (4.5%)	1 (0.4%)	0	0
慢性リンパ性白血病	0	2 (1.2%)	0	0	0	0	1 (0.4%)	0	0
再発急性リンパ性白血病	0	1 (0.6%)	0	0	0	0	0	1 (1.0%)	0
Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
バーキット白血病	0	1 (0.6%)	0	0	0	0	0	0	0
リンパ腫	0	0	0	1 (1.7%)	0	0	0	0	0
新生物進行	0	1 (0.6%)	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	1 (1.0%)	0
心臓障害	1 (0.7%)	2 (1.2%)	2 (2.9%)	2 (3.4%)	1 (3.7%)	0	2 (0.8%)	3 (2.9%)	2 (4.0%)
心停止	0	1 (0.6%)	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
心肺停止	0	0	1 (1.4%)	1 (1.7%)	0	0	0	2 (1.9%)	1 (2.0%)
うっ血性心筋症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心膜炎	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
急性心筋梗塞	0	1 (0.6%)	0	0	0	0	0	0	0
急性心不全	0	0	0	0	0	0	1 (0.4%)	0	0
神経系障害	3 (2.0%)	3 (1.8%)	0	3 (5.1%)	0	0	4 (1.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
頭蓋内出血	2 (1.3%)	0	0	3 (5.1%)	0	0	2 (0.8%)	0	0
神経毒性	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
脳出血	0	1 (0.6%)	0	0	0	0	0	0	0
昏迷	0	1 (0.6%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	1 (0.4%)	0	0
全身障害および投与局所様態	1 (0.7%)	6 (3.6%)	0	1 (1.7%)	1 (3.7%)	1 (4.5%)	4 (1.7%)	2 (1.9%)	1 (2.0%)
多臓器不全	0	5 (3.0%)	0	1 (1.7%)	1 (3.7%)	0	1 (0.4%)	0	1 (2.0%)
死亡	1 (0.7%)	1 (0.6%)	0	0	0	0	3 (1.3%)	1 (1.0%)	0
心突然死	0	0	0	0	0	1 (4.5%)	0	0	0
全身健康状態低下	0	0	0	0	0	0	0	1 (1.0%)	0
血管障害	1 (0.7%)	1 (0.6%)	1 (1.4%)	0	0	0	1 (0.4%)	2 (1.9%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
出血	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
血液量減少性ショック	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
深部静脈血栓症	0	1 (0.6%)	0	0	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	1 (1.0%)	0
血液およびリンパ系障害	1 (0.7%)	0	1 (1.4%)	1 (1.7%)	0	0	1 (0.4%)	1 (1.0%)	0
出血性障害	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
血小板減少症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
汎血球減少症	0	0	0	1 (1.7%)	0	0	0	0	0
免疫系障害	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	1 (2.0%)
急性移植片対宿主病	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
移植片対宿主病	0	0	0	0	0	0	0	0	1 (2.0%)
腎および尿路障害	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-144 死亡に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
腎不全	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
急性腎不全	0	0	0	0	0	0	0	0	1 (2.0%)
肝胆道系障害	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
急性肝炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
代謝および栄養障害	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
低血糖症	0	1 (0.6%)	0	0	0	0	0	0	0
代謝性アシドーシス	0	0	0	1 (1.7%)	0	0	0	0	0
胃腸障害	0	1 (0.6%)	0	0	0	0	0	0	0
直腸出血	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_death_1.sas
Program Run: 04JUN21:14:53:53

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
Overall	79 (51.6%)	93 (55.0%)	39 (55.7%)	34 (57.6%)	13 (48.1%)	13 (59.1%)	128 (53.3%)	63 (60.0%)	28 (56.0%)
感染症および寄生虫症	30 (19.6%)	39 (23.1%)	15 (21.4%)	12 (20.3%)	5 (18.5%)	6 (27.3%)	60 (25.0%)	30 (28.6%)	15 (30.0%)
敗血症性ショック	7 (4.6%)	8 (4.7%)	5 (7.1%)	1 (1.7%)	2 (7.4%)	1 (4.5%)	10 (4.2%)	7 (6.7%)	3 (6.0%)
敗血症	4 (2.6%)	5 (3.0%)	3 (4.3%)	1 (1.7%)	0	0	5 (2.1%)	3 (2.9%)	2 (4.0%)
肺炎	3 (2.0%)	4 (2.4%)	2 (2.9%)	3 (5.1%)	0	3 (13.6%)	7 (2.9%)	4 (3.8%)	1 (2.0%)
アスペルギルス症	3 (2.0%)	2 (1.2%)	0	1 (1.7%)	0	0	5 (2.1%)	1 (1.0%)	0
真菌感染	3 (2.0%)	2 (1.2%)	0	1 (1.7%)	0	0	3 (1.3%)	1 (1.0%)	0
サイトメガロウイルス感染	1 (0.7%)	1 (0.6%)	0	1 (1.7%)	1 (3.7%)	0	3 (1.3%)	0	1 (2.0%)
気管支肺アスペルギルス症	2 (1.3%)	1 (0.6%)	0	0	0	0	2 (0.8%)	0	0
シュードモナス性敗血症	0	1 (0.6%)	1 (1.4%)	0	0	0	0	3 (2.9%)	0
大腸菌性敗血症	0	1 (0.6%)	0	0	1 (3.7%)	0	0	1 (1.0%)	1 (2.0%)
尿路感染	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	1 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
蜂巣炎	0	0	0	1 (1.7%)	1 (3.7%)	0	0	0	1 (2.0%)
クレブシエラ性菌血症	0	0	1 (1.4%)	0	0	1 (4.5%)	0	1 (1.0%)	0
クレブシエラ性敗血症	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	0
ムコール症	1 (0.7%)	0	0	0	0	0	3 (1.3%)	0	0
クロストリジウム・ディフィシレ大腸炎	1 (0.7%)	0	0	0	0	0	2 (0.8%)	0	0
腸球菌性菌血症	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	1 (2.0%)
ブドウ球菌感染	0	0	1 (1.4%)	0	0	0	0	2 (1.9%)	0
アシネトバクター性菌血症	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
肺炎球菌性気管支炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
気管支肺炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
脳アスペルギルス症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
サイトメガロウイルス血症	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
ヘルペス脳炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
心内膜炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
フサリウム感染	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
感染	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
注入部位感染	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
筋膿瘍	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
モラクセラ菌性肺炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
気道感染	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
敗血症症候群	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
皮膚感染	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
細菌性敗血症	0	3 (1.8%)	0	1 (1.7%)	0	0	0	0	1 (2.0%)
ブドウ球菌性菌血症	0	2 (1.2%)	0	0	0	1 (4.5%)	0	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
菌血症	0	2 (1.2%)	0	0	0	0	0	2 (1.9%)	1 (2.0%)
ブドウ球菌性敗血症	0	1 (0.6%)	0	1 (1.7%)	0	0	1 (0.4%)	0	0
クロストリジウム性菌血症	0	0	0	2 (3.4%)	0	0	0	0	0
細菌性肺炎	0	1 (0.6%)	0	0	0	0	1 (0.4%)	1 (1.0%)	1 (2.0%)
帯状疱疹	0	0	0	0	0	1 (4.5%)	1 (0.4%)	1 (1.0%)	0
蓄膿	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
カンピロバクター胃腸炎	0	1 (0.6%)	0	0	0	0	0	0	0
カテーテル関連感染	0	1 (0.6%)	0	0	0	0	0	0	0
感染性下痢	0	1 (0.6%)	0	0	0	0	0	0	0
ヘリコバクター胃潰瘍	0	1 (0.6%)	0	0	0	0	0	0	0
肺膿瘍	0	1 (0.6%)	0	0	0	0	0	0	0
髄膜炎	0	0	0	1 (1.7%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
壊死性筋膜炎	0	0	0	0	0	1 (4.5%)	0	0	0
肺炎球菌性肺炎	0	1 (0.6%)	0	0	0	0	0	0	0
ブドウ球菌性肺炎	0	1 (0.6%)	0	0	0	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0	0	0	0
シュードモナス感染	0	0	0	0	0	1 (4.5%)	0	0	0
膿胸	0	1 (0.6%)	0	0	0	0	0	0	0
ステノトロフォモナス性敗血症	0	0	0	1 (1.7%)	0	0	0	0	0
全身性カンジダ	0	1 (0.6%)	0	0	0	0	0	0	0
トキソプラズマ症	0	1 (0.6%)	0	0	0	0	0	0	0
結核	0	1 (0.6%)	0	0	0	0	0	0	0
細菌性尿路感染	0	1 (0.6%)	0	0	0	0	0	0	0
真菌性肺炎	0	0	0	0	0	0	2 (0.8%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
接合真菌症	0	0	0	0	0	0	2 (0.8%)	0	0
腹部膿瘍	0	0	0	0	0	0	1 (0.4%)	0	0
虫垂炎	0	0	0	0	0	0	1 (0.4%)	0	0
ＢＫウイルス感染	0	0	0	0	0	0	0	0	1 (2.0%)
脳膿瘍	0	0	0	0	0	0	1 (0.4%)	0	0
気管支拡張症	0	0	0	0	0	0	0	1 (1.0%)	0
細気管支炎	0	0	0	0	0	0	1 (0.4%)	0	0
カテーテル留置部位感染	0	0	0	0	0	0	1 (0.4%)	0	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	0	1 (0.4%)	0	0
大腸菌性菌血症	0	0	0	0	0	0	0	1 (1.0%)	0
真菌性敗血症	0	0	0	0	0	0	1 (0.4%)	0	0
ノロウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
ウイルス性胃腸炎	0	0	0	0	0	0	1 (0.4%)	0	0
インフルエンザ	0	0	0	0	0	0	1 (0.4%)	0	0
肺感染	0	0	0	0	0	0	1 (0.4%)	0	0
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (2.0%)
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	0	0	0	1 (2.0%)
ブラストミセス菌性肺炎	0	0	0	0	0	0	1 (0.4%)	0	0
インフルエンザ性肺炎	0	0	0	0	0	0	0	0	1 (2.0%)
原発性異型肺炎	0	0	0	0	0	0	1 (0.4%)	0	0
シュードモナス性気管支炎	0	0	0	0	0	0	1 (0.4%)	0	0
副鼻腔炎	0	0	0	0	0	0	0	1 (1.0%)	0
真菌性副鼻腔炎	0	0	0	0	0	0	1 (0.4%)	0	0
レンサ球菌性菌血症	0	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
皮下組織膿瘍	0	0	0	0	0	0	1 (0.4%)	0	0
尿路性敗血症	0	0	0	0	0	0	0	1 (1.0%)	0
ウイルス性下痢	0	0	0	0	0	0	0	0	1 (2.0%)
呼吸器、胸郭および縦隔障害	20 (13.1%)	26 (15.4%)	11 (15.7%)	10 (16.9%)	8 (29.6%)	4 (18.2%)	32 (13.3%)	15 (14.3%)	12 (24.0%)
呼吸不全	4 (2.6%)	6 (3.6%)	7 (10.0%)	3 (5.1%)	2 (7.4%)	1 (4.5%)	6 (2.5%)	9 (8.6%)	3 (6.0%)
急性呼吸不全	3 (2.0%)	1 (0.6%)	0	3 (5.1%)	2 (7.4%)	1 (4.5%)	6 (2.5%)	0	2 (4.0%)
呼吸困難	3 (2.0%)	1 (0.6%)	1 (1.4%)	0	1 (3.7%)	0	3 (1.3%)	1 (1.0%)	2 (4.0%)
呼吸窮迫	3 (2.0%)	2 (1.2%)	1 (1.4%)	0	0	1 (4.5%)	3 (1.3%)	1 (1.0%)	0
喀血	2 (1.3%)	1 (0.6%)	0	1 (1.7%)	0	0	3 (1.3%)	0	1 (2.0%)
低酸素症	1 (0.7%)	1 (0.6%)	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	1 (2.0%)
胸水	0	0	0	0	1 (3.7%)	1 (4.5%)	1 (0.4%)	0	1 (2.0%)
肺水腫	0	0	0	1 (1.7%)	1 (3.7%)	0	1 (0.4%)	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肺障害	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	0
肺出血	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
呼吸抑制	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	0
嚥下性肺炎	1 (0.7%)	0	0	0	0	0	2 (0.8%)	1 (1.0%)	0
頻呼吸	1 (0.7%)	0	0	0	0	0	1 (0.4%)	1 (1.0%)	0
気管支胸膜瘻	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
気管支痙攣	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
水気胸	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
胸膜痛	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
呼吸性アシドーシス	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
鼻出血	0	4 (2.4%)	0	0	0	0	0	0	0
肺塞栓症	0	1 (0.6%)	0	1 (1.7%)	0	1 (4.5%)	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肺浸潤	0	3 (1.8%)	0	0	0	0	0	0	0
急性呼吸窮迫症候群	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
急性肺損傷	0	0	0	1 (1.7%)	0	0	0	0	0
慢性閉塞性肺疾患	0	0	0	1 (1.7%)	0	0	0	0	0
咳嗽	0	1 (0.6%)	0	0	0	0	0	0	0
血胸	0	1 (0.6%)	0	0	0	0	0	0	0
気胸	0	1 (0.6%)	0	0	0	0	0	0	0
湿性咳嗽	0	1 (0.6%)	0	0	0	0	0	0	0
肺高血圧症	0	1 (0.6%)	0	0	0	0	0	0	0
呼吸停止	0	1 (0.6%)	0	0	0	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	0	1 (0.4%)	0	0
肺胞出血	0	0	0	0	0	0	0	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肺梗塞	0	0	0	0	0	0	1 (0.4%)	0	0
副鼻腔障害	0	0	0	0	0	0	1 (0.4%)	0	0
喘鳴	0	0	0	0	0	0	0	1 (1.0%)	0
血液およびリンパ系障害	17 (11.1%)	11 (6.5%)	7 (10.0%)	3 (5.1%)	4 (14.8%)	1 (4.5%)	19 (7.9%)	9 (8.6%)	5 (10.0%)
発熱性好中球減少症	9 (5.9%)	2 (1.2%)	3 (4.3%)	1 (1.7%)	2 (7.4%)	1 (4.5%)	10 (4.2%)	4 (3.8%)	2 (4.0%)
汎血球減少症	2 (1.3%)	2 (1.2%)	1 (1.4%)	1 (1.7%)	1 (3.7%)	0	2 (0.8%)	2 (1.9%)	1 (2.0%)
好中球減少症	1 (0.7%)	3 (1.8%)	2 (2.9%)	0	1 (3.7%)	0	1 (0.4%)	2 (1.9%)	1 (2.0%)
血小板減少症	2 (1.3%)	3 (1.8%)	0	1 (1.7%)	1 (3.7%)	0	2 (0.8%)	0	1 (2.0%)
無顆粒球症	2 (1.3%)	0	0	0	0	0	2 (0.8%)	0	0
貧血	1 (0.7%)	1 (0.6%)	0	0	0	0	2 (0.8%)	0	1 (2.0%)
出血性障害	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
白血球増加症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
脾臓梗塞	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
出血性貧血	0	1 (0.6%)	0	0	0	0	0	0	0
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0	0	0	0
血小板減少性紫斑病	0	1 (0.6%)	0	0	0	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）	12 (7.8%)	17 (10.1%)	4 (5.7%)	9 (15.3%)	2 (7.4%)	1 (4.5%)	15 (6.3%)	8 (7.6%)	3 (6.0%)
急性骨髄性白血病	2 (1.3%)	5 (3.0%)	1 (1.4%)	2 (3.4%)	0	0	2 (0.8%)	3 (2.9%)	0
リンパ腫	1 (0.7%)	0	0	1 (1.7%)	1 (3.7%)	0	1 (0.4%)	0	1 (2.0%)
多発性骨髄腫	1 (0.7%)	0	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
悪性新生物進行	1 (0.7%)	1 (0.6%)	0	0	0	0	2 (0.8%)	1 (1.0%)	0
再発急性リンパ性白血病	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	1 (1.0%)	0
芽球発症	0	0	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
骨髄性白血病	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
新生物進行	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
再発慢性リンパ性白血病	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
子宮内膜癌	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
髄膜転移	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
骨髄異形成症候群	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
非ホジキンリンパ腫	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
原発性体腔性リンパ腫	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
再発急性骨髄性白血病	0	1 (0.6%)	0	3 (5.1%)	0	1 (4.5%)	1 (0.4%)	0	1 (2.0%)
慢性リンパ性白血病	0	2 (1.2%)	0	0	0	0	1 (0.4%)	0	0
急性白血病	0	0	0	1 (1.7%)	0	0	0	0	0
Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0	0	0	0
再発Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
バーキット白血病	0	1 (0.6%)	0	0	0	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.6%)	0	0	0	0	0	0	0
白血病	0	0	0	1 (1.7%)	0	0	0	0	0
肺の悪性新生物	0	1 (0.6%)	0	0	0	0	0	0	0
骨転移	0	0	0	1 (1.7%)	0	0	0	0	0
転移部痛	0	1 (0.6%)	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	1 (1.0%)	0
白血病浸潤	0	0	0	0	0	0	0	1 (1.0%)	0
神経系障害	13 (8.5%)	8 (4.7%)	3 (4.3%)	6 (10.2%)	1 (3.7%)	0	20 (8.3%)	4 (3.8%)	1 (2.0%)
痙攣	3 (2.0%)	1 (0.6%)	0	0	0	0	5 (2.1%)	0	0
頭蓋内出血	2 (1.3%)	0	0	3 (5.1%)	0	0	2 (0.8%)	0	0
てんかん	2 (1.3%)	1 (0.6%)	0	0	0	0	2 (0.8%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
多発ニューロパチー	2 (1.3%)	0	0	0	0	0	2 (0.8%)	0	0
中枢神経系病変	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
脳症	0	0	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
虚血性脳卒中	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
対麻痺	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
頭痛	0	0	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
脳幹卒中	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
脳虚血	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
熱性痙攣	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
神経毒性	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
失語症	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
脳出血	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
浮動性めまい	0	0	0	1 (1.7%)	0	0	0	0	0
片麻痺	0	1 (0.6%)	0	0	0	0	0	0	0
昏迷	0	1 (0.6%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0	0	0	0
振戦	0	0	0	1 (1.7%)	0	0	0	0	0
第７脳神経麻痺	0	1 (0.6%)	0	0	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	2 (0.8%)	0	0
脳血管発作	0	0	0	0	0	0	1 (0.4%)	0	0
卒中の出血性変化	0	0	0	0	0	0	1 (0.4%)	0	0
不全片麻痺	0	0	0	0	0	0	1 (0.4%)	0	0
一過性脳虚血発作	0	0	0	0	0	0	0	1 (1.0%)	0
全身障害および投与局所様態	5 (3.3%)	13 (7.7%)	3 (4.3%)	5 (8.5%)	2 (7.4%)	1 (4.5%)	8 (3.3%)	8 (7.6%)	3 (6.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
発熱	3 (2.0%)	7 (4.1%)	3 (4.3%)	3 (5.1%)	1 (3.7%)	0	3 (1.3%)	5 (4.8%)	1 (2.0%)
多臓器不全	0	5 (3.0%)	0	2 (3.4%)	1 (3.7%)	0	1 (0.4%)	0	1 (2.0%)
死亡	1 (0.7%)	1 (0.6%)	0	0	0	0	3 (1.3%)	1 (1.0%)	0
悪寒	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0
全身健康状態低下	1 (0.7%)	0	0	0	0	0	1 (0.4%)	1 (1.0%)	0
無力症	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
胸痛	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
心突然死	0	0	0	0	0	1 (4.5%)	0	0	0
非心臓性胸痛	0	0	0	0	0	0	0	1 (1.0%)	1 (2.0%)
末梢性浮腫	0	0	0	0	0	0	1 (0.4%)	0	0
心臓障害	3 (2.0%)	6 (3.6%)	6 (8.6%)	3 (5.1%)	1 (3.7%)	2 (9.1%)	5 (2.1%)	10 (9.5%)	3 (6.0%)
心肺停止	1 (0.7%)	1 (0.6%)	1 (1.4%)	1 (1.7%)	0	0	1 (0.4%)	2 (1.9%)	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
心停止	0	2 (1.2%)	1 (1.4%)	2 (3.4%)	0	0	0	1 (1.0%)	0
急性心筋梗塞	0	1 (0.6%)	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
不整脈	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
心原性ショック	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
うっ血性心筋症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心膜炎	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
洞性徐脈	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
上室性頻脈	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心室性頻脈	0	1 (0.6%)	0	0	0	1 (4.5%)	0	0	0
心房細動	0	1 (0.6%)	0	0	0	0	0	1 (1.0%)	1 (2.0%)
狭心症	0	0	0	0	0	1 (4.5%)	0	0	0
完全房室ブロック	0	0	0	0	0	0	0	1 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
急性心不全	0	0	0	0	0	0	1 (0.4%)	0	0
電気収縮解離	0	0	0	0	0	0	0	1 (1.0%)	0
腎および尿路障害	5 (3.3%)	7 (4.1%)	3 (4.3%)	2 (3.4%)	2 (7.4%)	1 (4.5%)	9 (3.8%)	6 (5.7%)	4 (8.0%)
急性腎不全	3 (2.0%)	5 (3.0%)	2 (2.9%)	2 (3.4%)	1 (3.7%)	1 (4.5%)	6 (2.5%)	5 (4.8%)	3 (6.0%)
腎不全	1 (0.7%)	2 (1.2%)	1 (1.4%)	0	1 (3.7%)	0	2 (0.8%)	1 (1.0%)	1 (2.0%)
血尿	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
胃腸障害	5 (3.3%)	8 (4.7%)	3 (4.3%)	3 (5.1%)	1 (3.7%)	0	13 (5.4%)	9 (8.6%)	5 (10.0%)
下痢	1 (0.7%)	1 (0.6%)	1 (1.4%)	0	0	0	1 (0.4%)	2 (1.9%)	1 (2.0%)
小腸閉塞	2 (1.3%)	0	0	0	0	0	2 (0.8%)	0	0
悪心	0	1 (0.6%)	0	0	1 (3.7%)	0	1 (0.4%)	1 (1.0%)	1 (2.0%)
腸出血	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
腹膜炎	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
腹痛	0	0	1 (1.4%)	0	0	0	2 (0.8%)	3 (2.9%)	1 (2.0%)
大腸炎	1 (0.7%)	0	0	0	0	0	2 (0.8%)	0	0
便秘	0	0	1 (1.4%)	0	0	0	0	2 (1.9%)	0
胃穿孔	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
食道潰瘍	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
胃腸出血	0	1 (0.6%)	0	2 (3.4%)	0	0	1 (0.4%)	2 (1.9%)	0
食中毒	0	1 (0.6%)	0	0	0	0	0	0	0
胃腸の炎症	0	1 (0.6%)	0	0	0	0	0	0	0
肛門周囲痛	0	1 (0.6%)	0	0	0	0	0	0	0
直腸出血	0	1 (0.6%)	0	0	0	0	0	0	0
嘔吐	0	0	0	0	0	0	2 (0.8%)	2 (1.9%)	0
嚥下障害	0	0	0	0	0	0	1 (0.4%)	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
潰瘍性大腸炎	0	0	0	0	0	0	1 (0.4%)	0	0
限局性腹腔内液貯留	0	0	0	0	0	0	0	0	1 (2.0%)
食道炎	0	0	0	0	0	0	1 (0.4%)	0	0
膵炎	0	0	0	0	0	0	0	1 (1.0%)	0
慢性膵炎	0	0	0	0	0	0	0	1 (1.0%)	0
再発性膵炎	0	0	0	0	0	0	0	1 (1.0%)	0
免疫系障害	2 (1.3%)	5 (3.0%)	0	0	2 (7.4%)	1 (4.5%)	3 (1.3%)	2 (1.9%)	4 (8.0%)
急性腸管移植片対宿主病	0	2 (1.2%)	0	0	1 (3.7%)	0	0	0	1 (2.0%)
急性移植片対宿主病	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	1 (1.0%)	1 (2.0%)
アナフィラキシーショック	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
過敏症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
アナフィラキシー反応	0	2 (1.2%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
急性肝移植片対宿主病	0	0	0	0	0	1 (4.5%)	0	0	0
移植片対宿主病	0	0	0	0	0	0	1 (0.4%)	0	1 (2.0%)
肺移植拒絶反応	0	0	0	0	0	0	0	1 (1.0%)	0
血管障害	1 (0.7%)	4 (2.4%)	3 (4.3%)	1 (1.7%)	0	0	3 (1.3%)	4 (3.8%)	2 (4.0%)
低血圧	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	2 (4.0%)
出血	0	0	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
血液量減少性ショック	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
血管炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
深部静脈血栓症	0	1 (0.6%)	0	0	0	0	2 (0.8%)	0	0
ショック	0	1 (0.6%)	0	0	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	1 (1.0%)	0
肝胆道系障害	3 (2.0%)	4 (2.4%)	0	1 (1.7%)	0	1 (4.5%)	7 (2.9%)	0	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
胆嚢炎	1 (0.7%)	0	0	0	0	0	2 (0.8%)	0	0
肝炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
急性肝炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
肝不全	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
肝機能異常	0	2 (1.2%)	0	0	0	0	0	0	0
高ビリルビン血症	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
急性胆嚢炎	0	0	0	0	0	1 (4.5%)	0	0	0
急性肝不全	0	0	0	0	0	0	1 (0.4%)	0	0
細胆管炎	0	0	0	0	0	0	1 (0.4%)	0	0
胆石症	0	0	0	0	0	0	0	0	1 (2.0%)
肝障害	0	0	0	0	0	0	1 (0.4%)	0	0
臨床検査	1 (0.7%)	1 (0.6%)	1 (1.4%)	3 (5.1%)	1 (3.7%)	1 (4.5%)	1 (0.4%)	1 (1.0%)	1 (2.0%)

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肝機能検査異常	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	0
血中ナトリウム減少	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
ヘモグロビン減少	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
アラニン・アミノトランスフェラーゼ増加	0	0	0	1 (1.7%)	0	0	0	0	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	1 (1.7%)	0	0	0	0	0
血中ビリルビン増加	0	0	0	0	0	1 (4.5%)	0	0	0
心電図ＱＴ延長	0	0	0	1 (1.7%)	0	0	0	0	0
肝酵素上昇	0	0	0	1 (1.7%)	0	0	0	0	0
傷害、中毒および処置合併症	1 (0.7%)	2 (1.2%)	2 (2.9%)	1 (1.7%)	0	0	1 (0.4%)	2 (1.9%)	0
薬物毒性	1 (0.7%)	0	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
転倒・転落	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
家庭内事故	0	0	0	1 (1.7%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
大腿骨頚部骨折	0	1 (0.6%)	0	0	0	0	0	0	0
橈骨骨折	0	1 (0.6%)	0	0	0	0	0	0	0
皮膚および皮下組織障害	1 (0.7%)	0	2 (2.9%)	1 (1.7%)	0	1 (4.5%)	1 (0.4%)	2 (1.9%)	0
褥瘡性潰瘍	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
皮膚炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
脂肪織炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
発疹	0	0	0	1 (1.7%)	0	1 (4.5%)	0	0	0
筋骨格系および結合組織障害	0	0	3 (4.3%)	0	0	0	1 (0.4%)	5 (4.8%)	1 (2.0%)
筋骨格系胸痛	0	0	1 (1.4%)	0	0	0	0	2 (1.9%)	1 (2.0%)
筋肉内出血	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
筋炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
関節炎	0	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
四肢痛	0	0	0	0	0	0	0	1 (1.0%)	0
全身性エリテマトーデス	0	0	0	0	0	0	0	1 (1.0%)	0
代謝および栄養障害	2 (1.3%)	6 (3.6%)	0	1 (1.7%)	0	0	5 (2.1%)	2 (1.9%)	2 (4.0%)
コントロール不良の糖尿病	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
成長障害	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
脱水	0	2 (1.2%)	0	0	0	0	2 (0.8%)	1 (1.0%)	0
代謝性アシドーシス	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
低血糖症	0	1 (0.6%)	0	0	0	0	0	0	1 (2.0%)
高ナトリウム血症	0	1 (0.6%)	0	0	0	0	0	0	0
低カリウム血症	0	1 (0.6%)	0	0	0	0	0	0	0
過小食	0	1 (0.6%)	0	0	0	0	0	0	0
高カリウム血症	0	0	0	0	0	0	0	1 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
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表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
低ナトリウム血症	0	0	0	0	0	0	1 (0.4%)	0	0
栄養障害	0	0	0	0	0	0	0	0	1 (2.0%)
眼障害	2 (1.3%)	0	0	1 (1.7%)	0	0	4 (1.7%)	0	0
片側失明	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
視神経症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
眼瞼浮腫	0	0	0	1 (1.7%)	0	0	0	0	0
網膜動脈閉塞	0	0	0	0	0	0	1 (0.4%)	0	0
網膜出血	0	0	0	0	0	0	1 (0.4%)	0	0
硝子体出血	0	0	0	0	0	0	1 (0.4%)	0	0
精神障害	1 (0.7%)	2 (1.2%)	0	2 (3.4%)	0	2 (9.1%)	2 (0.8%)	1 (1.0%)	0
うつ病	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
幻視	0	0	0	1 (1.7%)	0	1 (4.5%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-145 重篤な有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
精神状態変化	0	0	0	2 (3.4%)	0	0	0	0	0
錯乱状態	0	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0
幻覚	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
抑うつ気分	0	0	0	0	0	1 (4.5%)	0	0	0
自殺企図	0	1 (0.6%)	0	0	0	0	0	0	0
異常行動	0	0	0	0	0	0	0	1 (1.0%)	0
攻撃性	0	0	0	0	0	0	0	1 (1.0%)	0
激越	0	0	0	0	0	0	0	1 (1.0%)	0
生殖系および乳房障害	0	0	0	0	0	0	0	1 (1.0%)	0
良性前立腺肥大症	0	0	0	0	0	0	0	1 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_bmi_ser_1.sas
Program Run: 04JUN21:18:10:17

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
Overall	23 (15.0%)	31 (18.3%)	10 (14.3%)	19 (32.2%)	4 (14.8%)	5 (22.7%)	36 (15.0%)	15 (14.3%)	5 (10.0%)
感染症および寄生虫症	9 (5.9%)	9 (5.3%)	2 (2.9%)	6 (10.2%)	0	0	13 (5.4%)	5 (4.8%)	0
真菌感染	2 (1.3%)	0	0	1 (1.7%)	0	0	2 (0.8%)	1 (1.0%)	0
敗血症性ショック	0	0	2 (2.9%)	0	0	0	1 (0.4%)	3 (2.9%)	0
敗血症	1 (0.7%)	2 (1.2%)	0	1 (1.7%)	0	0	1 (0.4%)	0	0
アスペルギルス症	1 (0.7%)	1 (0.6%)	0	0	0	0	3 (1.3%)	0	0
肺炎	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0
気管支肺炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
気管支肺アスペルギルス症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心内膜炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
感染	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
細菌性敗血症	0	2 (1.2%)	0	1 (1.7%)	0	0	0	0	0
肺感染	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
髄膜炎	0	0	0	1 (1.7%)	0	0	0	0	0
ムコール症	0	1 (0.6%)	0	0	0	0	0	0	0
シュードモナス性敗血症	0	1 (0.6%)	0	0	0	0	0	0	0
ブドウ球菌感染	0	1 (0.6%)	0	0	0	0	0	0	0
全身性カンジダ	0	0	0	1 (1.7%)	0	0	0	0	0
脳膿瘍	0	0	0	0	0	0	1 (0.4%)	0	0
大腸菌性菌血症	0	0	0	0	0	0	0	1 (1.0%)	0
呼吸器、胸郭および縦隔障害	3 (2.0%)	3 (1.8%)	2 (2.9%)	1 (1.7%)	1 (3.7%)	1 (4.5%)	3 (1.3%)	2 (1.9%)	1 (2.0%)
呼吸不全	0	2 (1.2%)	2 (2.9%)	1 (1.7%)	0	1 (4.5%)	0	2 (1.9%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
呼吸困難	1 (0.7%)	0	0	0	1 (3.7%)	0	1 (0.4%)	0	1 (2.0%)
呼吸窮迫	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
急性呼吸不全	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
神経系障害	4 (2.6%)	2 (1.2%)	1 (1.4%)	1 (1.7%)	0	0	6 (2.5%)	1 (1.0%)	0
痙攣	2 (1.3%)	0	0	0	0	0	2 (0.8%)	0	0
てんかん	2 (1.3%)	0	0	0	0	0	2 (0.8%)	0	0
脳症	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
昏迷	0	1 (0.6%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0	0	0	0
振戦	0	0	0	1 (1.7%)	0	0	0	0	0
脳血管発作	0	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2)								>= 25 to <	
Subgroup	< 25		>= 25 to < 30		>= 30		< 25	30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
卒中の出血性変化	0	0	0	0	0	0	1 (0.4%)	0	0
臨床検査	2 (1.3%)	2 (1.2%)	2 (2.9%)	3 (5.1%)	0	0	3 (1.3%)	3 (2.9%)	0
血中ビリルビン増加	1 (0.7%)	0	1 (1.4%)	0	0	0	1 (0.4%)	1 (1.0%)	0
血中ナトリウム減少	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
トランスアミナーゼ上昇	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
肝機能検査異常	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
肝酵素上昇	0	0	0	1 (1.7%)	0	0	0	1 (1.0%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0	0	0	0
心電図ＱＴ延長	0	0	0	1 (1.7%)	0	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	0	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
血中乳酸脱水素酵素増加	0	0	0	0	0	0	1 (0.4%)	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	1 (0.4%)	0	0
心臓障害	2 (1.3%)	2 (1.2%)	2 (2.9%)	1 (1.7%)	0	0	2 (0.8%)	2 (1.9%)	0
心停止	0	1 (0.6%)	1 (1.4%)	0	0	0	0	1 (1.0%)	0
心肺停止	0	0	1 (1.4%)	1 (1.7%)	0	0	0	1 (1.0%)	0
うっ血性心筋症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
上室性頻脈	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
心室性頻脈	0	1 (0.6%)	0	0	0	0	0	0	0
腎および尿路障害	0	2 (1.2%)	2 (2.9%)	0	1 (3.7%)	0	2 (0.8%)	2 (1.9%)	1 (2.0%)
腎不全	0	0	1 (1.4%)	0	1 (3.7%)	0	0	1 (1.0%)	1 (2.0%)
急性腎不全	0	2 (1.2%)	1 (1.4%)	0	0	0	2 (0.8%)	1 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
精神障害	1 (0.7%)	3 (1.8%)	1 (1.4%)	1 (1.7%)	0	2 (9.1%)	2 (0.8%)	1 (1.0%)	0
錯乱状態	1 (0.7%)	1 (0.6%)	1 (1.4%)	1 (1.7%)	0	0	2 (0.8%)	1 (1.0%)	0
幻視	0	1 (0.6%)	0	1 (1.7%)	0	1 (4.5%)	0	0	0
幻覚	0	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
抑うつ気分	0	0	0	0	0	1 (4.5%)	0	0	0
不快気分	0	1 (0.6%)	0	0	0	0	0	0	0
皮膚および皮下組織障害	0	3 (1.8%)	1 (1.4%)	1 (1.7%)	1 (3.7%)	1 (4.5%)	0	1 (1.0%)	1 (2.0%)
皮膚炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
アレルギー性皮膚炎	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
発疹	0	2 (1.2%)	0	1 (1.7%)	0	1 (4.5%)	0	0	0
薬疹	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
胃腸障害	1 (0.7%)	0	0	3 (5.1%)	1 (3.7%)	0	3 (1.3%)	0	1 (2.0%)
嘔吐	1 (0.7%)	0	0	2 (3.4%)	0	0	2 (0.8%)	0	0
嚥下障害	0	0	0	0	1 (3.7%)	0	0	0	1 (2.0%)
小腸閉塞	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
悪心	0	0	0	2 (3.4%)	0	0	1 (0.4%)	0	0
肝胆道系障害	1 (0.7%)	3 (1.8%)	0	3 (5.1%)	0	0	2 (0.8%)	0	0
急性肝炎	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
肝不全	0	1 (0.6%)	0	1 (1.7%)	0	0	0	0	0
高ビリルビン血症	0	2 (1.2%)	0	0	0	0	0	0	0
肝機能異常	0	0	0	1 (1.7%)	0	0	0	0	0
肝病変	0	0	0	1 (1.7%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2)								>= 25 to <	
Subgroup	< 25		>= 25 to < 30		>= 30		< 25	30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肝炎	0	1 (0.6%)	0	0	0	0	0	0	0
高トランスアミナーゼ血症	0	1 (0.6%)	0	0	0	0	0	0	0
急性肝不全	0	0	0	0	0	0	1 (0.4%)	0	0
血液およびリンパ系障害	1 (0.7%)	2 (1.2%)	0	1 (1.7%)	0	0	1 (0.4%)	0	0
汎血球減少症	1 (0.7%)	1 (0.6%)	0	0	0	0	1 (0.4%)	0	0
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0	0	0	0
脾臓病変	0	0	0	1 (1.7%)	0	0	0	0	0
眼障害	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0
視神経症	1 (0.7%)	0	0	0	0	0	1 (0.4%)	0	0
眼瞼浮腫	0	0	0	1 (1.7%)	0	0	0	0	0
全身障害および投与局所様態	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
悪寒	1 (0.7%)	0	0	1 (1.7%)	0	0	1 (0.4%)	0	0
傷害、中毒および処置合併症	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
過量投与	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
筋骨格系および結合組織障害	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
筋炎	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
血管障害	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	0
低血圧	0	0	1 (1.4%)	0	0	0	0	1 (1.0%)	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	4 (2.4%)	0	1 (1.7%)	0	1 (4.5%)	1 (0.4%)	1 (1.0%)	1 (2.0%)
急性骨髄性白血病	0	2 (1.2%)	0	1 (1.7%)	0	0	0	0	0
再発急性骨髄性白血病	0	0	0	0	0	1 (4.5%)	0	0	1 (2.0%)
慢性リンパ性白血病	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-146 投与中止に至った有害事象（BMI別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
BMI (kg/m^2) Subgroup	< 25		>= 25 to < 30		>= 30		< 25	>= 25 to < 30	>= 30
System Organ Class Preferred Term	ISA (N = 153)	VRC (N = 169)	ISA (N = 70)	VRC (N = 59)	ISA (N = 27)	VRC (N = 22)	ISA (N = 240)	ISA (N = 105)	ISA (N = 50)
肺の悪性新生物	0	1 (0.6%)	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	1 (1.0%)	0
悪性新生物進行	0	0	0	0	0	0	1 (0.4%)	0	0
免疫系障害	0	1 (0.6%)	0	0	0	0	0	0	0
急性肝移植片対宿主病	0	1 (0.6%)	0	0	0	0	0	0	0
代謝および栄養障害	0	1 (0.6%)	0	0	0	0	0	0	0
代謝性アシドーシス	0	1 (0.6%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMI : body mass index

Program Name: t_ae_bmi_discon_1.sas
Program Run: 04JUN21:14:54:03

表 8-147 SOC別の有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
Overall	204 (96.7%)	189 (99.0%)	1 (100.0%)	1 (100.0%)	41 (93.2%)	63 (96.9%)	1 (100.0%)	1 (100.0%)	307 (96.2%)	11 (100.0%)	63 (92.6%)	5 (100.0%)
胃腸障害	146 (69.2%)	137 (71.7%)	1 (100.0%)	1 (100.0%)	26 (59.1%)	41 (63.1%)	1 (100.0%)	1 (100.0%)	211 (66.1%)	6 (54.5%)	38 (55.9%)	2 (40.0%)
感染症および寄生虫症	124 (58.8%)	120 (62.8%)	1 (100.0%)	1 (100.0%)	26 (59.1%)	37 (56.9%)	1 (100.0%)	0	196 (61.4%)	7 (63.6%)	37 (54.4%)	3 (60.0%)
全身障害および投与局所様態	133 (63.0%)	114 (59.7%)	1 (100.0%)	1 (100.0%)	13 (29.5%)	29 (44.6%)	1 (100.0%)	0	190 (59.6%)	3 (27.3%)	19 (27.9%)	4 (80.0%)
呼吸器、胸郭および縦隔障害	120 (56.9%)	112 (58.6%)	0	1 (100.0%)	22 (50.0%)	33 (50.8%)	1 (100.0%)	1 (100.0%)	174 (54.5%)	1 (9.1%)	28 (41.2%)	3 (60.0%)
代謝および栄養障害	86 (40.8%)	88 (46.1%)	0	0	21 (47.7%)	32 (49.2%)	1 (100.0%)	0	135 (42.3%)	3 (27.3%)	30 (44.1%)	2 (40.0%)
神経系障害	86 (40.8%)	75 (39.3%)	0	0	9 (20.5%)	14 (21.5%)	0	0	126 (39.5%)	4 (36.4%)	13 (19.1%)	2 (40.0%)
皮膚および皮下組織障害	74 (35.1%)	85 (44.5%)	0	1 (100.0%)	12 (27.3%)	24 (36.9%)	0	0	105 (32.9%)	1 (9.1%)	19 (27.9%)	0
臨床検査	74 (35.1%)	79 (41.4%)	1 (100.0%)	0	10 (22.7%)	17 (26.2%)	0	0	101 (31.7%)	3 (27.3%)	15 (22.1%)	0
血液およびリンパ系障害	66 (31.3%)	67 (35.1%)	0	0	10 (22.7%)	14 (21.5%)	1 (100.0%)	1 (100.0%)	89 (27.9%)	1 (9.1%)	15 (22.1%)	1 (20.0%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_soc_1.sas
Program Run: 04JUN21:14:54:07

表 8-147 SOC別の有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
精神障害	64 (30.3%)	68 (35.6%)	1 (100.0%)	0	4 (9.1%)	17 (26.2%)	1 (100.0%)	0	91 (28.5%)	3 (27.3%)	9 (13.2%)	2 (40.0%)
筋骨格系および結合組織障害	61 (28.9%)	62 (32.5%)	0	0	8 (18.2%)	15 (23.1%)	0	0	92 (28.8%)	1 (9.1%)	15 (22.1%)	1 (20.0%)
血管障害	56 (26.5%)	65 (34.0%)	0	0	11 (25.0%)	12 (18.5%)	0	0	89 (27.9%)	0	11 (16.2%)	1 (20.0%)
腎および尿路障害	48 (22.7%)	51 (26.7%)	1 (100.0%)	0	5 (11.4%)	7 (10.8%)	1 (100.0%)	0	69 (21.6%)	2 (18.2%)	9 (13.2%)	1 (20.0%)
心臓障害	38 (18.0%)	43 (22.5%)	0	1 (100.0%)	5 (11.4%)	11 (16.9%)	0	1 (100.0%)	60 (18.8%)	1 (9.1%)	7 (10.3%)	0
眼障害	34 (16.1%)	49 (25.7%)	0	1 (100.0%)	5 (11.4%)	18 (27.7%)	0	0	49 (15.4%)	1 (9.1%)	8 (11.8%)	0
傷害、中毒および処置合併症	29 (13.7%)	30 (15.7%)	0	0	4 (9.1%)	9 (13.8%)	0	0	48 (15.0%)	1 (9.1%)	6 (8.8%)	0
肝胆道系障害	18 (8.5%)	31 (16.2%)	0	0	4 (9.1%)	11 (16.9%)	1 (100.0%)	0	31 (9.7%)	0	5 (7.4%)	3 (60.0%)
免疫系障害	17 (8.1%)	22 (11.5%)	1 (100.0%)	0	2 (4.5%)	3 (4.6%)	0	0	26 (8.2%)	1 (9.1%)	2 (2.9%)	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）	17 (8.1%)	29 (15.2%)	0	0	2 (4.5%)	2 (3.1%)	0	0	26 (8.2%)	1 (9.1%)	2 (2.9%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_soc_1.sas
Program Run: 04JUN21:14:54:07

表 8-147 SOC別の有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
耳および迷路障害	13 (6.2%)	12 (6.3%)	0	0	1 (2.3%)	1 (1.5%)	0	0	18 (5.6%)	0	3 (4.4%)	0
生殖系および乳房障害	7 (3.3%)	8 (4.2%)	0	0	1 (2.3%)	5 (7.7%)	0	0	14 (4.4%)	1 (9.1%)	2 (2.9%)	0
内分泌障害	4 (1.9%)	3 (1.6%)	0	0	1 (2.3%)	0	0	0	9 (2.8%)	0	1 (1.5%)	0
先天性、家族性および遺伝性障害	3 (1.4%)	2 (1.0%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
社会環境	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_soc_1.sas
Program Run: 04JUN21:14:54:07

表 8-148 注目すべき有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
肝機能異常・肝炎	45 (21.3%)	70 (36.6%)	0	0	7 (15.9%)	12 (18.5%)	1 (100.0%)	0	67 (21.0%)	2 (18.2%)	10 (14.7%)	3 (60.0%)
アナフィラキシー	2 (0.9%)	2 (1.0%)	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
重度皮膚障害	3 (1.4%)	2 (1.0%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
心電図QT短縮	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
トルサード ド ポアント	13 (6.2%)	10 (5.2%)	0	0	2 (4.5%)	7 (10.8%)	0	1 (100.0%)	16 (5.0%)	0	2 (2.9%)	0
急性膵炎	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
精神神経症状	66 (31.3%)	63 (33.0%)	1 (100.0%)	0	5 (11.4%)	15 (23.1%)	1 (100.0%)	0	95 (29.8%)	3 (27.3%)	10 (14.7%)	2 (40.0%)
視覚障害	21 (10.0%)	36 (18.8%)	0	1 (100.0%)	2 (4.5%)	9 (13.8%)	0	0	27 (8.5%)	1 (9.1%)	3 (4.4%)	0
皮膚または子宮の悪性腫瘍	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
静脈内投与例	(N = 211)	(N = 191)	(N = 1)	(N = 1)	(N = 44)	(N = 65)	(N = 1)	(N = 1)	(N = 289)	(N = 6)	(N = 59)	(N = 3)
注入部位／注射部位反応	9 (4.3%)	4 (2.1%)	0	0	2 (4.5%)	0	0	0	14 (4.8%)	0	2 (3.4%)	0
IRR	58 (27.5%)	57 (29.8%)	0	0	11 (25.0%)	19 (29.2%)	1 (100.0%)	0	84 (29.1%)	3 (50.0%)	14 (23.7%)	1 (33.3%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_race_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
Overall	45 (21.3%)	57 (29.8%)	0	0	17 (38.6%)	13 (20.0%)	0	1 (100.0%)	86 (27.0%)	1 (9.1%)	18 (26.5%)	1 (20.0%)
感染症および寄生虫症	20 (9.5%)	13 (6.8%)	0	0	8 (18.2%)	5 (7.7%)	0	0	40 (12.5%)	0	8 (11.8%)	1 (20.0%)
敗血症性ショック	5 (2.4%)	3 (1.6%)	0	0	3 (6.8%)	1 (1.5%)	0	0	9 (2.8%)	0	3 (4.4%)	0
敗血症	4 (1.9%)	3 (1.6%)	0	0	3 (6.8%)	2 (3.1%)	0	0	5 (1.6%)	0	3 (4.4%)	0
アスペルギルス症	3 (1.4%)	2 (1.0%)	0	0	0	0	0	0	4 (1.3%)	0	0	0
真菌感染	2 (0.9%)	2 (1.0%)	0	0	1 (2.3%)	0	0	0	2 (0.6%)	0	1 (1.5%)	0
肺炎	1 (0.5%)	0	0	0	0	2 (3.1%)	0	0	3 (0.9%)	0	0	0
ムコール症	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
アシネトバクター性菌血症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
気管支肺アスペルギルス症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心内膜炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
フサリウム感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
クレブシエラ性敗血症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
シュードモナス性菌血症	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
真菌性肺炎	0	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
細菌性敗血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
蓄膿	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
真菌性敗血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肺感染	0	0	0	0	0	0	0	0	0	0	0	1 (20.0%)
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ブラストミセス菌性肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
原発性異型肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
真菌性副鼻腔炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ブドウ球菌性敗血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
呼吸器、胸郭および縦隔障害	9 (4.3%)	8 (4.2%)	0	0	5 (11.4%)	4 (6.2%)	0	0	12 (3.8%)	1 (9.1%)	5 (7.4%)	0
呼吸不全	3 (1.4%)	3 (1.6%)	0	0	3 (6.8%)	3 (4.6%)	0	0	3 (0.9%)	1 (9.1%)	3 (4.4%)	0
急性呼吸不全	3 (1.4%)	1 (0.5%)	0	0	0	0	0	0	4 (1.3%)	0	0	0
喀血	1 (0.5%)	1 (0.5%)	0	0	1 (2.3%)	0	0	0	2 (0.6%)	0	1 (1.5%)	0
肺出血	1 (0.5%)	0	0	0	1 (2.3%)	1 (1.5%)	0	0	1 (0.3%)	0	1 (1.5%)	0
呼吸窮迫	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
急性呼吸窮迫症候群	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺塞栓症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
呼吸困難	0	0	0	0	0	0	0	0	1 (0.3%)	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）	8 (3.8%)	20 (10.5%)	0	0	2 (4.5%)	1 (1.5%)	0	0	15 (4.7%)	0	2 (2.9%)	0
急性骨髄性白血病	1 (0.5%)	7 (3.7%)	0	0	2 (4.5%)	0	0	0	2 (0.6%)	0	2 (2.9%)	0
多発性骨髄腫	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
悪性新生物進行	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
芽球発症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
再発慢性リンパ性白血病	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
骨髄異形成症候群	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
再発急性骨髄性白血病	0	4 (2.1%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
慢性リンパ性白血病	0	2 (1.0%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
再発急性リンパ性白血病	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
B細胞性リンパ腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
リンパ腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
新生物進行	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心臓障害	3 (1.4%)	1 (0.5%)	0	0	1 (2.3%)	2 (3.1%)	0	1 (100.0%)	6 (1.9%)	0	1 (1.5%)	0
心停止	1 (0.5%)	1 (0.5%)	0	0	0	1 (1.5%)	0	1 (100.0%)	1 (0.3%)	0	0	0
心肺停止	1 (0.5%)	0	0	0	0	0	0	0	3 (0.9%)	0	0	0
うっ血性心筋症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
心膜炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
急性心筋梗塞	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
急性心不全	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
神経系障害	3 (1.4%)	7 (3.7%)	0	0	0	0	0	0	4 (1.3%)	0	1 (1.5%)	0
頭蓋内出血	2 (0.9%)	3 (1.6%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
神経毒性	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脳出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	0	0	1 (0.3%)	0	1 (1.5%)	0
全身障害および投与局所様態	2 (0.9%)	7 (3.7%)	0	0	0	1 (1.5%)	0	0	7 (2.2%)	0	0	0
多臓器不全	1 (0.5%)	6 (3.1%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
死亡	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	4 (1.3%)	0	0	0
心突然死	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
全身健康状態低下	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血管障害	1 (0.5%)	1 (0.5%)	0	0	1 (2.3%)	0	0	0	2 (0.6%)	0	1 (1.5%)	0
出血	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血液量減少性ショック	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
深部静脈血栓症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血液およびリンパ系障害	2 (0.9%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
出血性障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血小板減少症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
汎血球減少症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
免疫系障害	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
急性移植片対宿主病	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-149 死亡に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
移植片対宿主病	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
腎および尿路障害	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
腎不全	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
急性腎不全	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝胆道系障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
急性肝炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
代謝および栄養障害	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
低血糖症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
胃腸障害	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
直腸出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_death_1.sas
Program Run: 04JUN21:14:54:21

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
Overall	110 (52.1%)	112 (58.6%)	1 (100.0%)	1 (100.0%)	22 (50.0%)	34 (52.3%)	1 (100.0%)	1 (100.0%)	182 (57.1%)	6 (54.5%)	32 (47.1%)	3 (60.0%)
感染症および寄生虫症	37 (17.5%)	48 (25.1%)	1 (100.0%)	0	12 (27.3%)	13 (20.0%)	1 (100.0%)	0	85 (26.6%)	2 (18.2%)	16 (23.5%)	3 (60.0%)
敗血症性ショック	8 (3.8%)	5 (2.6%)	0	0	6 (13.6%)	5 (7.7%)	0	0	14 (4.4%)	0	6 (8.8%)	0
敗血症	4 (1.9%)	5 (2.6%)	0	0	3 (6.8%)	3 (4.6%)	0	0	7 (2.2%)	0	3 (4.4%)	0
肺炎	5 (2.4%)	7 (3.7%)	0	0	0	3 (4.6%)	0	0	10 (3.1%)	1 (9.1%)	0	1 (20.0%)
アスペルギルス症	4 (1.9%)	3 (1.6%)	0	0	0	0	0	0	7 (2.2%)	0	0	0
真菌感染	2 (0.9%)	3 (1.6%)	0	0	1 (2.3%)	0	0	0	3 (0.9%)	0	1 (1.5%)	0
サイトメガロウイルス感染	2 (0.9%)	2 (1.0%)	0	0	0	0	0	0	4 (1.3%)	0	0	0
気管支肺アスペルギルス症	2 (0.9%)	0	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
シュードモナス性敗血症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
大腸菌性敗血症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
尿路感染	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
蜂巣炎	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
クレブシエラ性菌血症	0	1 (0.5%)	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
クレブシエラ性敗血症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
ムコール症	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	1 (1.5%)	0
クロストリジウム・ディフィシレ大腸炎	0	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	0	1 (1.5%)	0
腸球菌性菌血症	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
ブドウ球菌感染	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
アシネトバクター性菌血症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
肺炎球菌性気管支炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
気管支肺炎	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
脳アスペルギルス症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
サイトメガロウイルス血症	0	0	1 (100.0%)	0	0	0	0	0	0	1 (9.1%)	0	0
ヘルペス脳炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心内膜炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
フサリウム感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
注入部位感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
筋膿瘍	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
モラクセラ菌性肺炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
気道感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
敗血症症候群	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
皮膚感染	0	0	0	0	0	0	1 (100.0%)	0	0	0	0	1 (20.0%)
細菌性敗血症	0	3 (1.6%)	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
ブドウ球菌性菌血症	0	2 (1.0%)	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
菌血症	0	1 (0.5%)	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
ブドウ球菌性敗血症	0	1 (0.5%)	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
クロストリジウム性菌血症	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
髄膜炎	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
細菌性肺炎	0	1 (0.5%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
帯状疱疹	0	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
蓄膿	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
カンピロバクター胃腸炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
カテーテル関連感染	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
感染性下痢	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
ヘリコバクター胃潰瘍	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
単純ヘルペス	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺膿瘍	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
壊死性筋膜炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺炎球菌性肺炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
ブドウ球菌性肺炎	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
シュードモナス性菌血症	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
シュードモナス感染	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
膿胸	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
トキソプラズマ症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
結核	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
細菌性尿路感染	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
真菌性肺炎	0	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
接合真菌症	0	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
腹部膿瘍	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0
虫垂炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ＢＫウイルス感染	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脳膿瘍	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
気管支拡張症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
細気管支炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
カテーテル留置部位感染	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
真菌性敗血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ノロウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
インフルエンザ	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肺感染	0	0	0	0	0	0	0	0	0	0	0	1 (20.0%)
シュードモナス菌性肺感染	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ブラストミセス菌性肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
インフルエンザ性肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
原発性異型肺炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
シュードモナス性気管支炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
副鼻腔炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
真菌性副鼻腔炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
レンサ球菌性菌血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
皮下組織膿瘍	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
尿路性敗血症	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0
ウイルス性下痢	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
呼吸器、胸郭および縦隔障害	32 (15.2%)	31 (16.2%)	0	1 (100.0%)	8 (18.2%)	11 (16.9%)	1 (100.0%)	0	51 (16.0%)	1 (9.1%)	8 (11.8%)	1 (20.0%)
呼吸不全	9 (4.3%)	8 (4.2%)	0	0	4 (9.1%)	4 (6.2%)	1 (100.0%)	0	13 (4.1%)	1 (9.1%)	4 (5.9%)	1 (20.0%)
急性呼吸不全	5 (2.4%)	4 (2.1%)	0	0	0	1 (1.5%)	0	0	8 (2.5%)	0	0	0
呼吸困難	5 (2.4%)	0	0	0	0	1 (1.5%)	0	0	6 (1.9%)	0	0	0
呼吸窮迫	4 (1.9%)	2 (1.0%)	0	0	0	1 (1.5%)	0	0	4 (1.3%)	0	0	0
喀血	1 (0.5%)	1 (0.5%)	0	1 (100.0%)	1 (2.3%)	0	0	0	3 (0.9%)	0	1 (1.5%)	0
低酸素症	2 (0.9%)	0	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
肺出血	1 (0.5%)	0	0	0	1 (2.3%)	1 (1.5%)	0	0	1 (0.3%)	0	1 (1.5%)	0
胸水	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
肺水腫	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
肺障害	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
呼吸抑制	0	0	0	0	1 (2.3%)	1 (1.5%)	0	0	0	0	1 (1.5%)	0
嚥下性肺炎	1 (0.5%)	0	0	0	0	0	0	0	3 (0.9%)	0	0	0
頻呼吸	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
気管支胸膜瘻	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
気管支痙攣	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
水気胸	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
胸膜痛	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
呼吸性アシドーシス	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
鼻出血	0	4 (2.1%)	0	0	0	0	0	0	0	0	0	0
肺塞栓症	0	3 (1.6%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
肺浸潤	0	3 (1.6%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性呼吸窮迫症候群	0	2 (1.0%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
急性肺損傷	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
慢性閉塞性肺疾患	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
咳嗽	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
血胸	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
気胸	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
湿性咳嗽	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
呼吸停止	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肺胞出血	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
肺梗塞	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
副鼻腔障害	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
喘鳴	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血液およびリンパ系障害	24 (11.4%)	11 (5.8%)	0	0	3 (6.8%)	5 (7.7%)	1 (100.0%)	1 (100.0%)	28 (8.8%)	0	4 (5.9%)	1 (20.0%)
発熱性好中球減少症	12 (5.7%)	3 (1.6%)	0	0	2 (4.5%)	1 (1.5%)	0	1 (100.0%)	14 (4.4%)	0	2 (2.9%)	0
汎血球減少症	2 (0.9%)	1 (0.5%)	0	0	1 (2.3%)	2 (3.1%)	1 (100.0%)	0	3 (0.9%)	0	1 (1.5%)	1 (20.0%)
好中球減少症	4 (1.9%)	2 (1.0%)	0	0	0	1 (1.5%)	0	0	4 (1.3%)	0	0	0
血小板減少症	3 (1.4%)	1 (0.5%)	0	0	0	3 (4.6%)	0	0	3 (0.9%)	0	0	0
無顆粒球症	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
貧血	1 (0.5%)	2 (1.0%)	0	0	0	0	0	0	2 (0.6%)	0	1 (1.5%)	0
出血性障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
白血球増加症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脾臓梗塞	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
出血性貧血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
血小板減少性紫斑病	0	1 (0.5%)	0	0	0	0	0	0	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）	16 (7.6%)	27 (14.1%)	0	0	2 (4.5%)	2 (3.1%)	0	0	24 (7.5%)	0	2 (2.9%)	0
急性骨髄性白血病	1 (0.5%)	8 (4.2%)	0	0	2 (4.5%)	0	0	0	3 (0.9%)	0	2 (2.9%)	0
リンパ腫	2 (0.9%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
多発性骨髄腫	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
悪性新生物進行	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
再発急性リンパ性白血病	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
芽球発症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
新生物進行	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
再発慢性リンパ性白血病	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
子宮内膜癌	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
髄膜転移	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
骨髄異形成症候群	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
非ホジキンリンパ腫	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
原発性体腔性リンパ腫	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
再発急性骨髄性白血病	0	5 (2.6%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
慢性リンパ性白血病	0	2 (1.0%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
急性リンパ性白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
再発Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺の悪性新生物	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
骨転移	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
転移部痛	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
白血病浸潤	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
神経系障害	15 (7.1%)	14 (7.3%)	0	0	2 (4.5%)	2 (3.1%)	0	0	20 (6.3%)	2 (18.2%)	4 (5.9%)	0
痙攣	1 (0.5%)	1 (0.5%)	0	0	2 (4.5%)	0	0	0	2 (0.6%)	1 (9.1%)	2 (2.9%)	0
頭蓋内出血	2 (0.9%)	3 (1.6%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
てんかん	2 (0.9%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
多発ニューロパチー	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
中枢神経系病変	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
脳症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
虚血性脳卒中	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
対麻痺	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
頭痛	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
脳幹卒中	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脳虚血	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
熱性痙攣	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
神経毒性	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
失語症	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
脳出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
浮動性めまい	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
大発作痙攣	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
片麻痺	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
くも膜下出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
第７脳神経麻痺	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	0	0	1 (0.3%)	0	2 (2.9%)	0
脳血管発作	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
卒中の出血性変化	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
不全片麻痺	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
一過性脳虚血発作	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
全身障害および投与局所様態	11 (5.2%)	13 (6.8%)	0	1 (100.0%)	0	5 (7.7%)	0	0	20 (6.3%)	0	0	0
発熱	8 (3.8%)	6 (3.1%)	0	1 (100.0%)	0	3 (4.6%)	0	0	10 (3.1%)	0	0	0
多臓器不全	1 (0.5%)	6 (3.1%)	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
死亡	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	4 (1.3%)	0	0	0
悪寒	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
全身健康状態低下	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
無力症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
胸痛	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心突然死	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
非心臓性胸痛	0	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
末梢性浮腫	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心臓障害	9 (4.3%)	6 (3.1%)	0	0	2 (4.5%)	4 (6.2%)	0	1 (100.0%)	16 (5.0%)	0	3 (4.4%)	0
心肺停止	1 (0.5%)	0	0	0	1 (2.3%)	1 (1.5%)	0	0	3 (0.9%)	0	1 (1.5%)	0
心停止	1 (0.5%)	2 (1.0%)	0	0	0	2 (3.1%)	0	1 (100.0%)	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
心房細動	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	1 (1.5%)	0
急性心筋梗塞	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
不整脈	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心原性ショック	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
うっ血性心筋症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
心膜炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
洞性徐脈	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
上室性頻脈	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心室性頻脈	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
狭心症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
完全房室ブロック	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性心不全	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
電気収縮解離	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
腎および尿路障害	10 (4.7%)	10 (5.2%)	0	0	0	0	0	0	18 (5.6%)	0	1 (1.5%)	0
急性腎不全	6 (2.8%)	8 (4.2%)	0	0	0	0	0	0	13 (4.1%)	0	1 (1.5%)	0
腎不全	3 (1.4%)	2 (1.0%)	0	0	0	0	0	0	4 (1.3%)	0	0	0
血尿	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
胃腸障害	9 (4.3%)	10 (5.2%)	0	0	0	2 (3.1%)	0	0	21 (6.6%)	2 (18.2%)	3 (4.4%)	1 (20.0%)
下痢	2 (0.9%)	1 (0.5%)	0	0	0	0	0	0	4 (1.3%)	0	0	0
小腸閉塞	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
悪心	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
腸出血	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
腹膜炎	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
腹痛	1 (0.5%)	0	0	0	0	0	0	0	4 (1.3%)	1 (9.1%)	1 (1.5%)	0
大腸炎	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
便秘	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
胃穿孔	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
食道潰瘍	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
胃腸出血	0	3 (1.6%)	0	0	0	0	0	0	2 (0.6%)	0	1 (1.5%)	0
食中毒	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
胃腸の炎症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
麻痺性イレウス	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肛門周囲痛	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
直腸出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
嘔吐	0	0	0	0	0	0	0	0	3 (0.9%)	0	0	1 (20.0%)
嚥下障害	0	0	0	0	0	0	0	0	1 (0.3%)	1 (9.1%)	0	0
潰瘍性大腸炎	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0
限局性腹腔内液貯留	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
食道炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
膵炎	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
慢性膵炎	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
再発性膵炎	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
免疫系障害	4 (1.9%)	6 (3.1%)	0	0	0	0	0	0	9 (2.8%)	0	0	0
急性腸管移植片対宿主病	1 (0.5%)	2 (1.0%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性移植片対宿主病	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
アナフィラキシーショック	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
過敏症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
アナフィラキシー反応	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
移植片対宿主病	0	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
肺移植拒絶反応	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血管障害	3 (1.4%)	4 (2.1%)	0	0	1 (2.3%)	2 (3.1%)	0	0	8 (2.5%)	0	1 (1.5%)	0
低血圧	1 (0.5%)	2 (1.0%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
出血	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
血液量減少性ショック	0	0	0	0	1 (2.3%)	1 (1.5%)	0	0	0	0	1 (1.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
血管炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
深部静脈血栓症	0	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0
ショック	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝胆道系障害	2 (0.9%)	4 (2.1%)	0	0	1 (2.3%)	2 (3.1%)	0	0	6 (1.9%)	0	1 (1.5%)	1 (20.0%)
胆嚢炎	1 (0.5%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
肝炎	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
急性肝炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝不全	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
肝機能異常	0	0	0	0	0	2 (3.1%)	0	0	0	0	0	0
高ビリルビン血症	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性胆嚢炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
急性肝不全	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
細胆管炎	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
胆石症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝障害	0	0	0	0	0	0	0	0	0	0	0	1 (20.0%)
臨床検査	3 (1.4%)	6 (3.1%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
肝機能検査異常	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
血中ナトリウム減少	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
ヘモグロビン減少	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
血中アルカリホスファターゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
血中ビリルビン増加	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肝酵素上昇	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
傷害、中毒および処置合併症	3 (1.4%)	2 (1.0%)	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
薬物毒性	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
転倒・転落	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
家庭内事故	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
大腿骨頚部骨折	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
橈骨骨折	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
皮膚および皮下組織障害	3 (1.4%)	2 (1.0%)	0	0	0	0	0	0	3 (0.9%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
褥瘡性潰瘍	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
皮膚炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脂肪織炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
発疹	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
筋骨格系および結合組織障害	3 (1.4%)	0	0	0	0	0	0	0	6 (1.9%)	0	1 (1.5%)	0
筋骨格系胸痛	1 (0.5%)	0	0	0	0	0	0	0	3 (0.9%)	0	0	0
筋肉内出血	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
筋炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
関節炎	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0
四肢痛	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
全身性エリテマトーデス	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
代謝および栄養障害	2 (0.9%)	5 (2.6%)	0	0	0	2 (3.1%)	0	0	7 (2.2%)	1 (9.1%)	1 (1.5%)	0
コントロール不良の糖尿病	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
成長障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
脱水	0	2 (1.0%)	0	0	0	0	0	0	2 (0.6%)	1 (9.1%)	0	0
代謝性アシドーシス	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
低血糖症	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
高ナトリウム血症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
低カリウム血症	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
過小食	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
高カリウム血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
低ナトリウム血症	0	0	0	0	0	0	0	0	0	0	1 (1.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
栄養障害	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
眼障害	1 (0.5%)	1 (0.5%)	0	0	1 (2.3%)	0	0	0	3 (0.9%)	0	1 (1.5%)	0
片側失明	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
視神経症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
網膜動脈閉塞	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
網膜出血	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
硝子体出血	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
精神障害	1 (0.5%)	5 (2.6%)	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
うつ病	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
幻視	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-150 重篤な有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
精神状態変化	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
錯乱状態	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
幻覚	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
抑うつ気分	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
自殺企図	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
異常行動	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
攻撃性	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
激越	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
生殖系および乳房障害	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
良性前立腺肥大症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_race_ser_1.sas
Program Run: 04JUN21:14:54:26

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
Overall	27 (12.8%)	46 (24.1%)	0	0	10 (22.7%)	12 (18.5%)	0	0	43 (13.5%)	2 (18.2%)	11 (16.2%)	0
感染症および寄生虫症	6 (2.8%)	11 (5.8%)	0	0	5 (11.4%)	4 (6.2%)	0	0	13 (4.1%)	0	5 (7.4%)	0
真菌感染	1 (0.5%)	1 (0.5%)	0	0	1 (2.3%)	0	0	0	2 (0.6%)	0	1 (1.5%)	0
敗血症性ショック	1 (0.5%)	0	0	0	1 (2.3%)	0	0	0	3 (0.9%)	0	1 (1.5%)	0
敗血症	0	1 (0.5%)	0	0	1 (2.3%)	2 (3.1%)	0	0	0	0	1 (1.5%)	0
アスペルギルス症	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
肺炎	0	0	0	0	1 (2.3%)	1 (1.5%)	0	0	0	0	1 (1.5%)	0
気管支肺炎	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
気管支肺アスペルギルス症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心内膜炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
感染	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
細菌性敗血症	0	3 (1.6%)	0	0	0	0	0	0	0	0	0	0
肺感染	0	0	0	0	0	2 (3.1%)	0	0	0	0	0	0
髄膜炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
ムコール症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
ブドウ球菌感染	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脳膿瘍	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
呼吸器、胸郭および縦隔障害	4 (1.9%)	2 (1.0%)	0	0	2 (4.5%)	3 (4.6%)	0	0	4 (1.3%)	0	2 (2.9%)	0
呼吸不全	1 (0.5%)	2 (1.0%)	0	0	1 (2.3%)	2 (3.1%)	0	0	1 (0.3%)	0	1 (1.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
呼吸困難	1 (0.5%)	0	0	0	1 (2.3%)	0	0	0	1 (0.3%)	0	1 (1.5%)	0
呼吸窮迫	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
急性呼吸不全	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
神経系障害	3 (1.4%)	4 (2.1%)	0	0	2 (4.5%)	0	0	0	4 (1.3%)	1 (9.1%)	2 (2.9%)	0
痙攣	0	0	0	0	2 (4.5%)	0	0	0	0	0	2 (2.9%)	0
てんかん	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
脳症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
大発作痙攣	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
脳血管発作	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
卒中の出血性変化	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
臨床検査	4 (1.9%)	6 (3.1%)	0	0	0	0	0	0	5 (1.6%)	1 (9.1%)	0	0
血中ビリルビン増加	2 (0.9%)	0	0	0	0	0	0	0	2 (0.6%)	0	0	0
血中ナトリウム減少	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
トランスアミナーゼ上昇	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝機能検査異常	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	1 (9.1%)	0	0
血中アルカリホスファターゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	1 (9.1%)	0	0
肝酵素上昇	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	0	0	0	0	1 (9.1%)	0	0
γ－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 (9.1%)	0	0
心臓障害	3 (1.4%)	1 (0.5%)	0	0	1 (2.3%)	1 (1.5%)	0	0	3 (0.9%)	0	1 (1.5%)	0
心停止	1 (0.5%)	0	0	0	0	1 (1.5%)	0	0	1 (0.3%)	0	0	0
心肺停止	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
うっ血性心筋症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
上室性頻脈	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
心室性頻脈	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
腎および尿路障害	3 (1.4%)	3 (1.6%)	0	0	0	0	0	0	4 (1.3%)	0	1 (1.5%)	0
腎不全	2 (0.9%)	1 (0.5%)	0	0	0	0	0	0	2 (0.6%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
急性腎不全	1 (0.5%)	2 (1.0%)	0	0	0	0	0	0	2 (0.6%)	0	1 (1.5%)	0
精神障害	2 (0.9%)	5 (2.6%)	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
錯乱状態	2 (0.9%)	2 (1.0%)	0	0	0	0	0	0	3 (0.9%)	0	0	0
幻視	0	3 (1.6%)	0	0	0	0	0	0	0	0	0	0
幻覚	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
抑うつ気分	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
不快気分	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
皮膚および皮下組織障害	2 (0.9%)	4 (2.1%)	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
皮膚炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
アレルギー性皮膚炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
発疹	0	3 (1.6%)	0	0	0	1 (1.5%)	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
薬疹	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
胃腸障害	2 (0.9%)	2 (1.0%)	0	0	0	1 (1.5%)	0	0	4 (1.3%)	0	0	0
嘔吐	1 (0.5%)	1 (0.5%)	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
嚥下障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
小腸閉塞	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
悪心	0	2 (1.0%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝胆道系障害	1 (0.5%)	5 (2.6%)	0	0	0	1 (1.5%)	0	0	2 (0.6%)	0	0	0
急性肝炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
肝不全	0	2 (1.0%)	0	0	0	0	0	0	0	0	0	0
高ビリルビン血症	0	1 (0.5%)	0	0	0	1 (1.5%)	0	0	0	0	0	0
肝機能異常	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
肝病変	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肝炎	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
高トランスアミナーゼ血症	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
急性肝不全	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血液およびリンパ系障害	0	3 (1.6%)	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
汎血球減少症	0	1 (0.5%)	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
脾臓病変	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
眼障害	0	1 (0.5%)	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
視神経症	0	0	0	0	1 (2.3%)	0	0	0	0	0	1 (1.5%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
全身障害および投与局所様態	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
悪寒	1 (0.5%)	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0
傷害、中毒および処置合併症	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
過量投与	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
筋骨格系および結合組織障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
筋炎	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
血管障害	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
低血圧	1 (0.5%)	0	0	0	0	0	0	0	1 (0.3%)	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	6 (3.1%)	0	0	0	1 (1.5%)	0	0	3 (0.9%)	0	0	0
急性骨髄性白血病	0	4 (2.1%)	0	0	0	0	0	0	0	0	0	0
再発急性骨髄性白血病	0	1 (0.5%)	0	0	0	0	0	0	1 (0.3%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-151 投与中止に至った有害事象（人種別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験								海外第III相試験併合			
	White		Black or African American		Asian		Other		White	Black or African American	Asian	Other
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 191)	ISA (N = 1)	VRC (N = 1)	ISA (N = 44)	VRC (N = 65)	ISA (N = 1)	VRC (N = 1)	ISA (N = 319)	ISA (N = 11)	ISA (N = 68)	ISA (N = 5)
慢性リンパ性白血病	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
肺の悪性新生物	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
悪性新生物進行	0	0	0	0	0	0	0	0	1 (0.3%)	0	0	0
免疫系障害	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
急性肝移植片対宿主病	0	0	0	0	0	1 (1.5%)	0	0	0	0	0	0
代謝および栄養障害	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_race_discon_1.sas
Program Run: 04JUN21:14:54:31

表 8-152 アジア人における死亡に至った有害事象の国別の発現割合 - 9766-CL-0104試験

	9766-CL-0104試験	
	Isavuconazole	Voriconazole
	Asian (N = 44)	Asian (N = 65)
BEL	0	1 (1.5%)
CHN	1 (2.3%)	4 (6.2%)
IND	4 (9.1%)	2 (3.1%)
KOR	7 (15.9%)	0
MYS	1 (2.3%)	0
THA	4 (9.1%)	6 (9.2%)

BEL: BELGIUM, CHN: CHINA, IND: INDIA, KOR: SOUTH KOREA, MYS: MALAYSIA, THA: THAILAND

Program Name: t_ae_country_death_1.sas
Program Run: 04JUN21:15:20:14

表 8-153 SOC別の有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
Overall	53 (98.1%)	51 (100.0%)	194 (95.6%)	204 (98.1%)	78 (97.5%)	308 (95.4%)
胃腸障害	37 (68.5%)	41 (80.4%)	137 (67.5%)	139 (66.8%)	51 (63.8%)	206 (63.8%)
感染症および寄生虫症	40 (74.1%)	42 (82.4%)	112 (55.2%)	116 (55.8%)	62 (77.5%)	181 (56.0%)
全身障害および投与局所様態	33 (61.1%)	28 (54.9%)	115 (56.7%)	116 (55.8%)	46 (57.5%)	170 (52.6%)
呼吸器、胸郭および縦隔障害	28 (51.9%)	33 (64.7%)	115 (56.7%)	114 (54.8%)	42 (52.5%)	164 (50.8%)
代謝および栄養障害	22 (40.7%)	26 (51.0%)	86 (42.4%)	95 (45.7%)	35 (43.8%)	135 (41.8%)
神経系障害	19 (35.2%)	14 (27.5%)	76 (37.4%)	75 (36.1%)	27 (33.8%)	118 (36.5%)
皮膚および皮下組織障害	18 (33.3%)	28 (54.9%)	68 (33.5%)	82 (39.4%)	26 (32.5%)	99 (30.7%)
臨床検査	24 (44.4%)	27 (52.9%)	61 (30.0%)	69 (33.2%)	31 (38.8%)	88 (27.2%)
血液およびリンパ系障害	13 (24.1%)	17 (33.3%)	64 (31.5%)	65 (31.3%)	19 (23.8%)	87 (26.9%)
精神障害	17 (31.5%)	20 (39.2%)	53 (26.1%)	66 (31.7%)	27 (33.8%)	78 (24.1%)
筋骨格系および結合組織障害	14 (25.9%)	19 (37.3%)	55 (27.1%)	58 (27.9%)	18 (22.5%)	91 (28.2%)
血管障害	13 (24.1%)	11 (21.6%)	54 (26.6%)	66 (31.7%)	22 (27.5%)	79 (24.5%)
腎および尿路障害	19 (35.2%)	19 (37.3%)	36 (17.7%)	39 (18.8%)	26 (32.5%)	55 (17.0%)
心臓障害	8 (14.8%)	14 (27.5%)	35 (17.2%)	43 (20.7%)	14 (17.5%)	54 (16.7%)
眼障害	9 (16.7%)	16 (31.4%)	30 (14.8%)	53 (25.5%)	13 (16.3%)	45 (13.9%)
傷害、中毒および処置合併症	7 (13.0%)	9 (17.6%)	26 (12.8%)	30 (14.4%)	12 (15.0%)	43 (13.3%)
肝胆道系障害	6 (11.1%)	13 (25.5%)	17 (8.4%)	29 (13.9%)	10 (12.5%)	29 (9.0%)
免疫系障害	12 (22.2%)	13 (25.5%)	8 (3.9%)	12 (5.8%)	19 (23.8%)	10 (3.1%)
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）	4 (7.4%)	6 (11.8%)	15 (7.4%)	25 (12.0%)	7 (8.8%)	22 (6.8%)
耳および迷路障害	2 (3.7%)	7 (13.7%)	12 (5.9%)	6 (2.9%)	4 (5.0%)	17 (5.3%)
生殖系および乳房障害	1 (1.9%)	2 (3.9%)	7 (3.4%)	11 (5.3%)	4 (5.0%)	13 (4.0%)
内分泌障害	1 (1.9%)	2 (3.9%)	4 (2.0%)	1 (0.5%)	4 (5.0%)	6 (1.9%)
先天性、家族性および遺伝性障害	0	1 (2.0%)	3 (1.5%)	1 (0.5%)	0	3 (0.9%)
社会環境	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_soc_1.sas
Program Run: 04JUN21:15:20:14

表 8-154 注目すべき有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
肝機能異常・肝炎	18 (33.3%)	23 (45.1%)	35 (17.2%)	59 (28.4%)	25 (31.3%)	57 (17.6%)
アナフィラキシー	1 (1.9%)	1 (2.0%)	1 (0.5%)	2 (1.0%)	1 (1.3%)	1 (0.3%)
重度皮膚障害	0	0	3 (1.5%)	2 (1.0%)	0	3 (0.9%)
心電図QT短縮	0	0	1 (0.5%)	0	0	1 (0.3%)
トルサード ド ポアント	1 (1.9%)	2 (3.9%)	14 (6.9%)	17 (8.2%)	1 (1.3%)	17 (5.3%)
急性膵炎	0	0	0	0	0	1 (0.3%)
精神神経症状	16 (29.6%)	20 (39.2%)	57 (28.1%)	59 (28.4%)	23 (28.8%)	87 (26.9%)
視覚障害	8 (14.8%)	12 (23.5%)	15 (7.4%)	35 (16.8%)	9 (11.3%)	22 (6.8%)
皮膚または子宮の悪性腫瘍	0	0	1 (0.5%)	0	0	1 (0.3%)
静脈内投与例	(N = 54)	(N = 51)	(N = 203)	(N = 208)	(N = 74)	(N = 283)
注入部位／注射部位反応	3 (5.6%)	1 (2.0%)	8 (3.9%)	3 (1.4%)	4 (5.4%)	12 (4.2%)
IRR	14 (25.9%)	16 (31.4%)	56 (27.6%)	60 (28.8%)	21 (28.4%)	81 (28.6%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-155 死亡に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
Overall	14 (25.9%)	17 (33.3%)	48 (23.6%)	55 (26.4%)	27 (33.8%)	79 (24.5%)
感染症および寄生虫症	5 (9.3%)	8 (15.7%)	23 (11.3%)	10 (4.8%)	14 (17.5%)	35 (10.8%)
敗血症性ショック	1 (1.9%)	1 (2.0%)	7 (3.4%)	3 (1.4%)	4 (5.0%)	8 (2.5%)
敗血症	0	3 (5.9%)	7 (3.4%)	2 (1.0%)	1 (1.3%)	7 (2.2%)
アスペルギルス症	2 (3.7%)	0	1 (0.5%)	2 (1.0%)	2 (2.5%)	2 (0.6%)
真菌感染	0	1 (2.0%)	3 (1.5%)	1 (0.5%)	0	3 (0.9%)
肺炎	0	0	1 (0.5%)	2 (1.0%)	0	3 (0.9%)
ムコール症	0	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
アシネトバクター性菌血症	0	0	1 (0.5%)	0	0	1 (0.3%)
気管支肺アスペルギルス症	1 (1.9%)	0	0	0	1 (1.3%)	0
心内膜炎	0	0	1 (0.5%)	0	0	1 (0.3%)
フサリウム感染	1 (1.9%)	0	0	0	1 (1.3%)	0
感染	0	0	1 (0.5%)	0	0	1 (0.3%)
シュードモナス性敗血症	0	1 (2.0%)	0	0	1 (1.3%)	0
クレブシエラ性敗血症	0	0	0	1 (0.5%)	0	0
シュードモナス性菌血症	0	1 (2.0%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (2.0%)	0	0	0	0
真菌性肺炎	0	0	0	0	0	2 (0.6%)
細菌性敗血症	0	0	0	0	0	1 (0.3%)
蓄膿	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_death_1.sas
Program Run: 04JUN21:14:54:51

表 8-155 死亡に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
真菌性敗血症	0	0	0	0	0	1 (0.3%)
肺感染	0	0	0	0	0	1 (0.3%)
シュードモナス菌性肺感染	0	0	0	0	1 (1.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.3%)
原発性異型肺炎	0	0	0	0	0	1 (0.3%)
真菌性副鼻腔炎	0	0	0	0	1 (1.3%)	0
ブドウ球菌性敗血症	0	0	0	0	0	1 (0.3%)
呼吸器、胸郭および縦隔障害	2 (3.7%)	1 (2.0%)	12 (5.9%)	11 (5.3%)	2 (2.5%)	16 (5.0%)
呼吸不全	0	0	6 (3.0%)	6 (2.9%)	0	7 (2.2%)
急性呼吸不全	0	1 (2.0%)	3 (1.5%)	0	0	4 (1.2%)
喀血	0	0	2 (1.0%)	1 (0.5%)	0	3 (0.9%)
肺出血	1 (1.9%)	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
呼吸窮迫	1 (1.9%)	0	0	0	1 (1.3%)	0
急性呼吸窮迫症候群	0	0	0	1 (0.5%)	0	0
肺塞栓症	0	0	0	1 (0.5%)	0	0
肺高血圧症	0	0	0	1 (0.5%)	0	0
呼吸困難	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)	2 (3.7%)	4 (7.8%)	8 (3.9%)	17 (8.2%)	3 (3.8%)	14 (4.3%)
急性骨髄性白血病	0	1 (2.0%)	3 (1.5%)	6 (2.9%)	1 (1.3%)	3 (0.9%)
多発性骨髄腫	0	0	2 (1.0%)	0	0	2 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_death_1.sas
Program Run: 04JUN21:14:54:51

表 8-155 死亡に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
悪性新生物進行	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	2 (0.6%)
芽球発症	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
骨髄性白血病	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
再発慢性リンパ性白血病	1 (1.9%)	0	0	0	1 (1.3%)	0
骨髄異形成症候群	0	0	1 (0.5%)	0	0	1 (0.3%)
再発急性骨髄性白血病	0	3 (5.9%)	0	1 (0.5%)	0	1 (0.3%)
慢性リンパ性白血病	0	0	0	2 (1.0%)	0	1 (0.3%)
再発急性リンパ性白血病	0	0	0	1 (0.5%)	0	1 (0.3%)
Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
バーキット白血病	0	0	0	1 (0.5%)	0	0
リンパ腫	0	0	0	1 (0.5%)	0	0
新生物進行	0	0	0	1 (0.5%)	0	0
白血病再発	0	0	0	0	0	1 (0.3%)
心臓障害	1 (1.9%)	0	3 (1.5%)	5 (2.4%)	1 (1.3%)	6 (1.9%)
心停止	0	0	1 (0.5%)	3 (1.4%)	0	1 (0.3%)
心肺停止	0	0	1 (0.5%)	1 (0.5%)	0	3 (0.9%)
うっ血性心筋症	1 (1.9%)	0	0	0	1 (1.3%)	0
心膜炎	0	0	1 (0.5%)	0	0	1 (0.3%)
急性心筋梗塞	0	0	0	1 (0.5%)	0	0
急性心不全	0	0	0	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_death_1.sas
Program Run: 04JUN21:14:54:51

表 8-155 死亡に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
神経系障害	1 (1.9%)	1 (2.0%)	2 (1.0%)	6 (2.9%)	1 (1.3%)	4 (1.2%)
頭蓋内出血	0	0	2 (1.0%)	3 (1.4%)	0	2 (0.6%)
神経毒性	1 (1.9%)	0	0	0	1 (1.3%)	0
脳出血	0	0	0	1 (0.5%)	0	0
脳炎	0	0	0	1 (0.5%)	0	0
昏迷	0	1 (2.0%)	0	0	0	0
くも膜下出血	0	0	0	1 (0.5%)	0	0
脳梗塞	0	0	0	0	0	2 (0.6%)
全身障害および投与局所様態	1 (1.9%)	3 (5.9%)	1 (0.5%)	5 (2.4%)	3 (3.8%)	4 (1.2%)
多臓器不全	1 (1.9%)	3 (5.9%)	0	3 (1.4%)	2 (2.5%)	0
死亡	0	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
心突然死	0	0	0	1 (0.5%)	0	0
全身健康状態低下	0	0	0	0	0	1 (0.3%)
血管障害	1 (1.9%)	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
出血	0	0	1 (0.5%)	0	0	1 (0.3%)
血液量減少性ショック	1 (1.9%)	0	0	0	1 (1.3%)	0
深部静脈血栓症	0	0	0	1 (0.5%)	0	0
動脈炎	0	0	0	0	0	1 (0.3%)
血液およびリンパ系障害	0	0	2 (1.0%)	1 (0.5%)	0	2 (0.6%)
出血性障害	0	0	1 (0.5%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_death_1.sas
Program Run: 04JUN21:14:54:51

表 8-155 死亡に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
血小板減少症	0	0	1 (0.5%)	0	0	1 (0.3%)
汎血球減少症	0	0	0	1 (0.5%)	0	0
免疫系障害	1 (1.9%)	0	0	0	2 (2.5%)	0
急性移植片対宿主病	1 (1.9%)	0	0	0	1 (1.3%)	0
移植片対宿主病	0	0	0	0	1 (1.3%)	0
腎および尿路障害	0	0	1 (0.5%)	0	0	2 (0.6%)
腎不全	0	0	1 (0.5%)	0	0	1 (0.3%)
急性腎不全	0	0	0	0	0	1 (0.3%)
肝胆道系障害	0	0	1 (0.5%)	0	0	1 (0.3%)
急性肝炎	0	0	1 (0.5%)	0	0	1 (0.3%)
代謝および栄養障害	0	1 (2.0%)	0	1 (0.5%)	0	0
低血糖症	0	0	0	1 (0.5%)	0	0
代謝性アシドーシス	0	1 (2.0%)	0	0	0	0
胃腸障害	0	0	0	1 (0.5%)	0	0
直腸出血	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_death_1.sas
Program Run: 04JUN21:14:54:51

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
Overall	33 (61.1%)	35 (68.6%)	101 (49.8%)	114 (54.8%)	53 (66.3%)	170 (52.6%)
感染症および寄生虫症	13 (24.1%)	22 (43.1%)	38 (18.7%)	39 (18.8%)	30 (37.5%)	76 (23.5%)
敗血症性ショック	2 (3.7%)	2 (3.9%)	12 (5.9%)	8 (3.8%)	6 (7.5%)	14 (4.3%)
敗血症	0	4 (7.8%)	7 (3.4%)	4 (1.9%)	2 (2.5%)	8 (2.5%)
肺炎	2 (3.7%)	4 (7.8%)	3 (1.5%)	6 (2.9%)	4 (5.0%)	8 (2.5%)
アスペルギルス症	2 (3.7%)	1 (2.0%)	2 (1.0%)	2 (1.0%)	3 (3.8%)	4 (1.2%)
真菌感染	0	1 (2.0%)	3 (1.5%)	2 (1.0%)	0	4 (1.2%)
サイトメガロウイルス感染	2 (3.7%)	2 (3.9%)	0	0	2 (2.5%)	2 (0.6%)
気管支肺アスペルギルス症	1 (1.9%)	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
シュードモナス性敗血症	0	1 (2.0%)	1 (0.5%)	0	1 (1.3%)	2 (0.6%)
大腸菌性敗血症	1 (1.9%)	0	0	1 (0.5%)	2 (2.5%)	0
尿路感染	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	1 (0.3%)
蜂巣炎	1 (1.9%)	1 (2.0%)	0	0	1 (1.3%)	0
クレブシエラ性菌血症	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
クレブシエラ性敗血症	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
ムコール症	0	0	1 (0.5%)	0	1 (1.3%)	2 (0.6%)
クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
腸球菌性菌血症	0	0	1 (0.5%)	0	0	2 (0.6%)
ブドウ球菌感染	0	0	1 (0.5%)	0	0	2 (0.6%)
アシネトバクター性菌血症	0	0	1 (0.5%)	0	0	1 (0.3%)
肺炎球菌性気管支炎	1 (1.9%)	0	0	0	1 (1.3%)	0
気管支肺炎	0	0	1 (0.5%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
脳アスペルギルス症	1 (1.9%)	0	0	0	1 (1.3%)	0
サイトメガロウイルス血症	1 (1.9%)	0	0	0	1 (1.3%)	0
ヘルペス脳炎	1 (1.9%)	0	0	0	1 (1.3%)	0
心内膜炎	0	0	1 (0.5%)	0	0	1 (0.3%)
フサリウム感染	1 (1.9%)	0	0	0	1 (1.3%)	0
感染	0	0	1 (0.5%)	0	0	1 (0.3%)
注入部位感染	0	0	1 (0.5%)	0	0	1 (0.3%)
筋膿瘍	0	0	1 (0.5%)	0	0	1 (0.3%)
モラクセラ菌性肺炎	0	0	1 (0.5%)	0	0	1 (0.3%)
気道感染	0	0	1 (0.5%)	0	0	1 (0.3%)
敗血症症候群	0	0	1 (0.5%)	0	0	1 (0.3%)
皮膚感染	0	0	1 (0.5%)	0	0	1 (0.3%)
細菌性敗血症	0	0	0	4 (1.9%)	0	1 (0.3%)
ブドウ球菌性菌血症	0	0	0	3 (1.4%)	0	1 (0.3%)
菌血症	0	1 (2.0%)	0	1 (0.5%)	2 (2.5%)	1 (0.3%)
ブドウ球菌性敗血症	0	0	0	2 (1.0%)	0	1 (0.3%)
クロストリジウム性菌血症	0	1 (2.0%)	0	1 (0.5%)	0	0
髄膜炎	0	1 (2.0%)	0	1 (0.5%)	0	0
細菌性肺炎	0	1 (2.0%)	0	0	1 (1.3%)	2 (0.6%)
帯状疱疹	0	1 (2.0%)	0	0	0	2 (0.6%)
蓄膿	0	0	0	1 (0.5%)	1 (1.3%)	0
カンピロバクター胃腸炎	0	1 (2.0%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
カテーテル関連感染	0	0	0	1 (0.5%)	0	0
感染性下痢	0	0	0	1 (0.5%)	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (0.5%)	0	0
単純ヘルペス	0	1 (2.0%)	0	0	0	0
肺膿瘍	0	1 (2.0%)	0	0	0	0
壊死性筋膜炎	0	0	0	1 (0.5%)	0	0
肺炎球菌性肺炎	0	0	0	1 (0.5%)	0	0
ブドウ球菌性肺炎	0	0	0	1 (0.5%)	0	0
シュードモナス性菌血症	0	1 (2.0%)	0	0	0	0
シュードモナス感染	0	0	0	1 (0.5%)	0	0
膿胸	0	0	0	1 (0.5%)	0	0
ステノトロフォモナス性敗血症	0	1 (2.0%)	0	0	0	0
全身性カンジダ	0	0	0	1 (0.5%)	0	0
トキソプラズマ症	0	1 (2.0%)	0	0	0	0
結核	0	1 (2.0%)	0	0	0	0
細菌性尿路感染	0	0	0	1 (0.5%)	0	0
真菌性肺炎	0	0	0	0	0	2 (0.6%)
接合真菌症	0	0	0	0	1 (1.3%)	1 (0.3%)
腹部膿瘍	0	0	0	0	0	1 (0.3%)
虫垂炎	0	0	0	0	0	1 (0.3%)
ＢＫウイルス感染	0	0	0	0	0	1 (0.3%)
脳膿瘍	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
気管支拡張症	0	0	0	0	0	1 (0.3%)
細気管支炎	0	0	0	0	0	1 (0.3%)
カテーテル留置部位感染	0	0	0	0	0	1 (0.3%)
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.3%)
大腸菌性菌血症	0	0	0	0	0	1 (0.3%)
真菌性敗血症	0	0	0	0	0	1 (0.3%)
ノロウイルス性胃腸炎	0	0	0	0	1 (1.3%)	0
ウイルス性胃腸炎	0	0	0	0	1 (1.3%)	0
インフルエンザ	0	0	0	0	1 (1.3%)	0
肺感染	0	0	0	0	0	1 (0.3%)
シュードモナス菌性肺感染	0	0	0	0	1 (1.3%)	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	1 (1.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.3%)
インフルエンザ性肺炎	0	0	0	0	0	1 (0.3%)
原発性異型肺炎	0	0	0	0	0	1 (0.3%)
シュードモナス性気管支炎	0	0	0	0	0	1 (0.3%)
副鼻腔炎	0	0	0	0	0	1 (0.3%)
真菌性副鼻腔炎	0	0	0	0	1 (1.3%)	0
レンサ球菌性菌血症	0	0	0	0	0	1 (0.3%)
皮下組織膿瘍	0	0	0	0	0	1 (0.3%)
尿路性敗血症	0	0	0	0	0	1 (0.3%)
ウイルス性下痢	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
呼吸器、胸郭および縦隔障害	10 (18.5%)	12 (23.5%)	31 (15.3%)	31 (14.9%)	17 (21.3%)	44 (13.6%)
呼吸不全	3 (5.6%)	1 (2.0%)	11 (5.4%)	11 (5.3%)	5 (6.3%)	14 (4.3%)
急性呼吸不全	0	3 (5.9%)	5 (2.5%)	2 (1.0%)	1 (1.3%)	7 (2.2%)
呼吸困難	1 (1.9%)	1 (2.0%)	4 (2.0%)	0	1 (1.3%)	5 (1.5%)
呼吸窮迫	1 (1.9%)	1 (2.0%)	3 (1.5%)	2 (1.0%)	1 (1.3%)	3 (0.9%)
喀血	0	1 (2.0%)	2 (1.0%)	1 (0.5%)	0	4 (1.2%)
低酸素症	1 (1.9%)	1 (2.0%)	1 (0.5%)	0	2 (2.5%)	1 (0.3%)
肺出血	1 (1.9%)	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
胸水	0	1 (2.0%)	1 (0.5%)	0	0	2 (0.6%)
肺水腫	1 (1.9%)	1 (2.0%)	0	0	2 (2.5%)	0
肺障害	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
呼吸抑制	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
嚥下性肺炎	1 (1.9%)	0	0	0	3 (3.8%)	0
頻呼吸	0	0	1 (0.5%)	0	0	2 (0.6%)
気管支胸膜瘻	0	0	1 (0.5%)	0	0	1 (0.3%)
気管支痙攣	0	0	1 (0.5%)	0	0	1 (0.3%)
水気胸	1 (1.9%)	0	0	0	1 (1.3%)	0
胸膜痛	0	0	1 (0.5%)	0	0	1 (0.3%)
呼吸性アシドーシス	1 (1.9%)	0	0	0	1 (1.3%)	0
鼻出血	0	1 (2.0%)	0	3 (1.4%)	0	0
肺塞栓症	0	1 (2.0%)	0	2 (1.0%)	0	1 (0.3%)
肺浸潤	0	2 (3.9%)	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
急性呼吸窮迫症候群	0	0	0	2 (1.0%)	0	1 (0.3%)
急性肺損傷	0	0	0	1 (0.5%)	0	0
慢性閉塞性肺疾患	0	0	0	1 (0.5%)	0	0
咳嗽	0	0	0	1 (0.5%)	0	0
血胸	0	0	0	1 (0.5%)	0	0
気胸	0	1 (2.0%)	0	0	0	0
湿性咳嗽	0	1 (2.0%)	0	0	0	0
肺高血圧症	0	0	0	1 (0.5%)	0	0
呼吸停止	0	0	0	1 (0.5%)	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.3%)
肺胞出血	0	0	0	0	1 (1.3%)	0
肺梗塞	0	0	0	0	1 (1.3%)	0
副鼻腔障害	0	0	0	0	0	1 (0.3%)
喘鳴	0	0	0	0	0	1 (0.3%)
血液およびリンパ系障害	4 (7.4%)	2 (3.9%)	24 (11.8%)	15 (7.2%)	5 (6.3%)	28 (8.7%)
発熱性好中球減少症	2 (3.7%)	0	12 (5.9%)	5 (2.4%)	2 (2.5%)	14 (4.3%)
汎血球減少症	0	0	4 (2.0%)	3 (1.4%)	0	5 (1.5%)
好中球減少症	1 (1.9%)	0	3 (1.5%)	3 (1.4%)	1 (1.3%)	3 (0.9%)
血小板減少症	0	0	3 (1.5%)	4 (1.9%)	0	3 (0.9%)
無顆粒球症	1 (1.9%)	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
貧血	0	2 (3.9%)	1 (0.5%)	0	1 (1.3%)	2 (0.6%)
出血性障害	0	0	1 (0.5%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
白血球増加症	0	0	1 (0.5%)	0	0	1 (0.3%)
脾臓梗塞	0	0	1 (0.5%)	0	0	1 (0.3%)
出血性貧血	0	0	0	1 (0.5%)	0	0
微小血管症性溶血性貧血	0	0	0	1 (0.5%)	0	0
血小板減少性紫斑病	0	0	0	1 (0.5%)	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 (7.4%)	6 (11.8%)	14 (6.9%)	23 (11.1%)	5 (6.3%)	21 (6.5%)
急性骨髄性白血病	0	1 (2.0%)	3 (1.5%)	7 (3.4%)	1 (1.3%)	4 (1.2%)
リンパ腫	2 (3.7%)	0	0	1 (0.5%)	2 (2.5%)	0
多発性骨髄腫	0	0	2 (1.0%)	0	0	2 (0.6%)
悪性新生物進行	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	2 (0.6%)
再発急性リンパ性白血病	0	0	1 (0.5%)	1 (0.5%)	0	2 (0.6%)
芽球発症	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
骨髄性白血病	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
新生物進行	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
再発慢性リンパ性白血病	1 (1.9%)	0	0	0	1 (1.3%)	0
子宮内膜癌	0	0	1 (0.5%)	0	0	1 (0.3%)
髄膜転移	0	0	1 (0.5%)	0	0	1 (0.3%)
骨髄異形成症候群	0	0	1 (0.5%)	0	0	1 (0.3%)
非ホジキンリンパ腫	0	0	1 (0.5%)	0	0	1 (0.3%)
原発性体腔性リンパ腫	0	0	1 (0.5%)	0	0	1 (0.3%)
再発急性骨髄性白血病	0	3 (5.9%)	0	2 (1.0%)	0	2 (0.6%)
慢性リンパ性白血病	0	0	0	2 (1.0%)	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
急性白血病	0	0	0	1 (0.5%)	0	0
急性リンパ性白血病	0	1 (2.0%)	0	0	0	0
Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
再発Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
バーキット白血病	0	0	0	1 (0.5%)	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (2.0%)	0	0	0	0
白血病	0	0	0	1 (0.5%)	0	0
肺の悪性新生物	0	0	0	1 (0.5%)	0	0
骨転移	0	0	0	1 (0.5%)	0	0
転移部痛	0	0	0	1 (0.5%)	0	0
白血病再発	0	0	0	0	0	1 (0.3%)
白血病浸潤	0	0	0	0	1 (1.3%)	0
神経系障害	5 (9.3%)	3 (5.9%)	12 (5.9%)	13 (6.3%)	7 (8.8%)	19 (5.9%)
痙攣	1 (1.9%)	1 (2.0%)	2 (1.0%)	0	2 (2.5%)	3 (0.9%)
頭蓋内出血	0	0	2 (1.0%)	3 (1.4%)	0	2 (0.6%)
てんかん	0	0	2 (1.0%)	1 (0.5%)	0	2 (0.6%)
多発ニューロパチー	1 (1.9%)	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
中枢神経系病変	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
脳症	0	1 (2.0%)	1 (0.5%)	0	0	1 (0.3%)
虚血性脳卒中	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
対麻痺	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
頭痛	0	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)

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Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
脳幹卒中	1 (1.9%)	0	0	0	1 (1.3%)	0
脳虚血	1 (1.9%)	0	0	0	1 (1.3%)	0
熱性痙攣	0	0	1 (0.5%)	0	0	1 (0.3%)
神経毒性	1 (1.9%)	0	0	0	1 (1.3%)	0
失語症	0	0	0	1 (0.5%)	0	1 (0.3%)
脳出血	0	0	0	1 (0.5%)	0	0
浮動性めまい	0	0	0	1 (0.5%)	0	0
脳炎	0	0	0	1 (0.5%)	0	0
大発作痙攣	0	0	0	1 (0.5%)	0	0
片麻痺	0	0	0	1 (0.5%)	0	0
昏迷	0	1 (2.0%)	0	0	0	0
くも膜下出血	0	0	0	1 (0.5%)	0	0
振戦	0	0	0	1 (0.5%)	0	0
第７脳神経麻痺	0	0	0	1 (0.5%)	0	0
脳梗塞	0	0	0	0	0	3 (0.9%)
脳血管発作	0	0	0	0	0	1 (0.3%)
卒中の出血性変化	0	0	0	0	0	1 (0.3%)
不全片麻痺	0	0	0	0	0	1 (0.3%)
一過性脳虚血発作	0	0	0	0	0	1 (0.3%)
全身障害および投与局所様態	3 (5.6%)	4 (7.8%)	8 (3.9%)	15 (7.2%)	6 (7.5%)	14 (4.3%)
発熱	3 (5.6%)	2 (3.9%)	5 (2.5%)	8 (3.8%)	4 (5.0%)	6 (1.9%)
多臓器不全	1 (1.9%)	3 (5.9%)	0	4 (1.9%)	2 (2.5%)	0

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Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
死亡	0	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
悪寒	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
全身健康状態低下	1 (1.9%)	0	0	0	1 (1.3%)	1 (0.3%)
無力症	0	0	1 (0.5%)	0	0	1 (0.3%)
胸痛	0	0	1 (0.5%)	0	0	1 (0.3%)
心突然死	0	0	0	1 (0.5%)	0	0
非心臓性胸痛	0	0	0	0	0	2 (0.6%)
末梢性浮腫	0	0	0	0	1 (1.3%)	0
心臓障害	1 (1.9%)	1 (2.0%)	10 (4.9%)	11 (5.3%)	4 (5.0%)	15 (4.6%)
心肺停止	0	0	2 (1.0%)	2 (1.0%)	0	4 (1.2%)
心停止	0	0	1 (0.5%)	5 (2.4%)	0	1 (0.3%)
心房細動	0	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
急性心筋梗塞	0	0	1 (0.5%)	1 (0.5%)	0	2 (0.6%)
不整脈	0	0	1 (0.5%)	0	0	1 (0.3%)
心原性ショック	0	0	1 (0.5%)	0	0	1 (0.3%)
うっ血性心筋症	1 (1.9%)	0	0	0	1 (1.3%)	0
心膜炎	0	0	1 (0.5%)	0	0	1 (0.3%)
洞性徐脈	0	0	1 (0.5%)	0	0	1 (0.3%)
上室性頻脈	0	0	1 (0.5%)	0	0	1 (0.3%)
心室性頻脈	0	0	0	2 (1.0%)	0	0
狭心症	0	1 (2.0%)	0	0	0	0
完全房室ブロック	0	0	0	0	1 (1.3%)	0

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Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
急性心不全	0	0	0	0	0	1 (0.3%)
電気収縮解離	0	0	0	0	1 (1.3%)	0
腎および尿路障害	3 (5.6%)	4 (7.8%)	7 (3.4%)	6 (2.9%)	7 (8.8%)	12 (3.7%)
急性腎不全	2 (3.7%)	4 (7.8%)	4 (2.0%)	4 (1.9%)	6 (7.5%)	8 (2.5%)
腎不全	1 (1.9%)	0	2 (1.0%)	2 (1.0%)	1 (1.3%)	3 (0.9%)
血尿	0	0	1 (0.5%)	0	0	1 (0.3%)
胃腸障害	2 (3.7%)	3 (5.9%)	7 (3.4%)	9 (4.3%)	5 (6.3%)	22 (6.8%)
下痢	0	0	2 (1.0%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
小腸閉塞	0	0	2 (1.0%)	0	0	2 (0.6%)
悪心	0	1 (2.0%)	1 (0.5%)	0	0	3 (0.9%)
腸出血	1 (1.9%)	1 (2.0%)	0	0	1 (1.3%)	0
腹膜炎	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
腹痛	0	0	1 (0.5%)	0	0	6 (1.9%)
大腸炎	0	0	1 (0.5%)	0	0	2 (0.6%)
便秘	0	0	1 (0.5%)	0	0	2 (0.6%)
胃穿孔	0	0	1 (0.5%)	0	0	1 (0.3%)
食道潰瘍	1 (1.9%)	0	0	0	1 (1.3%)	0
胃腸出血	0	1 (2.0%)	0	2 (1.0%)	1 (1.3%)	2 (0.6%)
食中毒	0	0	0	1 (0.5%)	0	0
胃腸の炎症	0	0	0	1 (0.5%)	0	0
麻痺性イレウス	0	0	0	1 (0.5%)	0	0
肛門周囲痛	0	0	0	1 (0.5%)	0	0

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Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
直腸出血	0	0	0	1 (0.5%)	0	0
嘔吐	0	0	0	0	0	4 (1.2%)
嚥下障害	0	0	0	0	0	2 (0.6%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.3%)
限局性腹腔内液貯留	0	0	0	0	0	1 (0.3%)
食道炎	0	0	0	0	1 (1.3%)	0
膵炎	0	0	0	0	0	1 (0.3%)
慢性膵炎	0	0	0	0	0	1 (0.3%)
再発性膵炎	0	0	0	0	0	1 (0.3%)
免疫系障害	3 (5.6%)	2 (3.9%)	1 (0.5%)	4 (1.9%)	7 (8.8%)	2 (0.6%)
急性腸管移植片対宿主病	1 (1.9%)	0	0	2 (1.0%)	1 (1.3%)	0
急性移植片対宿主病	1 (1.9%)	0	0	1 (0.5%)	3 (3.8%)	0
アナフィラキシーショック	1 (1.9%)	0	0	0	1 (1.3%)	0
過敏症	0	0	1 (0.5%)	0	0	1 (0.3%)
アナフィラキシー反応	0	1 (2.0%)	0	1 (0.5%)	0	0
急性肝移植片対宿主病	0	1 (2.0%)	0	0	0	0
移植片対宿主病	0	0	0	0	2 (2.5%)	0
肺移植拒絶反応	0	0	0	0	0	1 (0.3%)
血管障害	1 (1.9%)	0	3 (1.5%)	6 (2.9%)	3 (3.8%)	6 (1.9%)
低血圧	0	0	1 (0.5%)	2 (1.0%)	1 (1.3%)	2 (0.6%)
出血	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
血液量減少性ショック	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	0

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Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
血管炎	0	0	1 (0.5%)	0	0	1 (0.3%)
深部静脈血栓症	0	0	0	1 (0.5%)	1 (1.3%)	1 (0.3%)
ショック	0	0	0	1 (0.5%)	0	0
動脈炎	0	0	0	0	0	1 (0.3%)
肝胆道系障害	1 (1.9%)	3 (5.9%)	2 (1.0%)	3 (1.4%)	2 (2.5%)	6 (1.9%)
胆嚢炎	0	0	1 (0.5%)	0	0	2 (0.6%)
肝炎	1 (1.9%)	0	0	0	1 (1.3%)	0
急性肝炎	0	0	1 (0.5%)	0	0	1 (0.3%)
肝不全	0	2 (3.9%)	0	0	0	0
肝機能異常	0	1 (2.0%)	0	1 (0.5%)	0	0
高ビリルビン血症	0	1 (2.0%)	0	1 (0.5%)	0	0
急性胆嚢炎	0	0	0	1 (0.5%)	0	0
急性肝不全	0	0	0	0	1 (1.3%)	0
細胆管炎	0	0	0	0	0	1 (0.3%)
胆石症	0	0	0	0	0	1 (0.3%)
肝障害	0	0	0	0	0	1 (0.3%)
臨床検査	1 (1.9%)	1 (2.0%)	2 (1.0%)	5 (2.4%)	1 (1.3%)	2 (0.6%)
肝機能検査異常	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	0
血中ナトリウム減少	0	0	1 (0.5%)	0	0	1 (0.3%)
ヘモグロビン減少	0	0	1 (0.5%)	0	0	1 (0.3%)
アラニン・アミノトランスフェラーゼ増加	0	1 (2.0%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (2.0%)	0	0	0	0

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Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
血中アルカリホスファターゼ増加	0	0	0	1 (0.5%)	0	0
血中ビリルビン増加	0	0	0	1 (0.5%)	0	0
心電図ＱＴ延長	0	0	0	1 (0.5%)	0	0
肝酵素上昇	0	0	0	1 (0.5%)	0	0
傷害、中毒および処置合併症	1 (1.9%)	1 (2.0%)	2 (1.0%)	2 (1.0%)	1 (1.3%)	2 (0.6%)
薬物毒性	1 (1.9%)	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
転倒・転落	0	0	1 (0.5%)	0	0	1 (0.3%)
家庭内事故	0	0	0	1 (0.5%)	0	0
大腿骨頚部骨折	0	0	0	1 (0.5%)	0	0
橈骨骨折	0	1 (2.0%)	0	0	0	0
皮膚および皮下組織障害	1 (1.9%)	1 (2.0%)	2 (1.0%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
褥瘡性潰瘍	0	0	1 (0.5%)	0	0	1 (0.3%)
皮膚炎	1 (1.9%)	0	0	0	1 (1.3%)	0
脂肪織炎	0	0	1 (0.5%)	0	0	1 (0.3%)
発疹	0	1 (2.0%)	0	1 (0.5%)	0	0
筋骨格系および結合組織障害	2 (3.7%)	0	1 (0.5%)	0	2 (2.5%)	5 (1.5%)
筋骨格系胸痛	1 (1.9%)	0	0	0	1 (1.3%)	2 (0.6%)
筋肉内出血	0	0	1 (0.5%)	0	0	1 (0.3%)
筋炎	1 (1.9%)	0	0	0	1 (1.3%)	0
関節炎	0	0	0	0	0	1 (0.3%)
四肢痛	0	0	0	0	0	1 (0.3%)
全身性エリテマトーデス	0	0	0	0	0	1 (0.3%)

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Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
代謝および栄養障害	0	3 (5.9%)	2 (1.0%)	4 (1.9%)	0	9 (2.8%)
コントロール不良の糖尿病	0	0	1 (0.5%)	0	0	1 (0.3%)
成長障害	0	0	1 (0.5%)	0	0	1 (0.3%)
脱水	0	0	0	2 (1.0%)	0	3 (0.9%)
代謝性アシドーシス	0	1 (2.0%)	0	1 (0.5%)	0	0
低血糖症	0	0	0	1 (0.5%)	0	1 (0.3%)
高ナトリウム血症	0	1 (2.0%)	0	0	0	0
低カリウム血症	0	0	0	1 (0.5%)	0	0
過小食	0	1 (2.0%)	0	0	0	0
高カリウム血症	0	0	0	0	0	1 (0.3%)
低ナトリウム血症	0	0	0	0	0	1 (0.3%)
栄養障害	0	0	0	0	0	1 (0.3%)
眼障害	0	0	2 (1.0%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
片側失明	0	0	1 (0.5%)	0	0	1 (0.3%)
視神経症	0	0	1 (0.5%)	0	0	1 (0.3%)
眼瞼浮腫	0	0	0	1 (0.5%)	0	0
網膜動脈閉塞	0	0	0	0	1 (1.3%)	0
網膜出血	0	0	0	0	0	1 (0.3%)
硝子体出血	0	0	0	0	0	1 (0.3%)
精神障害	0	1 (2.0%)	1 (0.5%)	5 (2.4%)	0	3 (0.9%)
うつ病	0	0	1 (0.5%)	0	0	1 (0.3%)
幻視	0	0	0	2 (1.0%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-156 重篤な有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
精神状態変化	0	1 (2.0%)	0	1 (0.5%)	0	0
錯乱状態	0	0	0	1 (0.5%)	0	1 (0.3%)
幻覚	0	0	0	1 (0.5%)	0	1 (0.3%)
抑うつ気分	0	0	0	1 (0.5%)	0	0
自殺企図	0	0	0	1 (0.5%)	0	0
異常行動	0	0	0	0	0	1 (0.3%)
攻撃性	0	0	0	0	0	1 (0.3%)
激越	0	0	0	0	0	1 (0.3%)
生殖系および乳房障害	0	0	0	0	0	1 (0.3%)
良性前立腺肥大症	0	0	0	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_mye_ser_1.sas
Program Run: 04JUN21:14:54:55

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
Overall	8 (14.8%)	15 (29.4%)	29 (14.3%)	44 (21.2%)	14 (17.5%)	42 (13.0%)
感染症および寄生虫症	2 (3.7%)	6 (11.8%)	9 (4.4%)	9 (4.3%)	5 (6.3%)	13 (4.0%)
真菌感染	0	1 (2.0%)	2 (1.0%)	0	0	3 (0.9%)
敗血症性ショック	1 (1.9%)	0	1 (0.5%)	0	3 (3.8%)	1 (0.3%)
敗血症	0	1 (2.0%)	1 (0.5%)	2 (1.0%)	0	1 (0.3%)
アスペルギルス症	0	1 (2.0%)	1 (0.5%)	0	0	3 (0.9%)
肺炎	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
気管支肺炎	0	0	1 (0.5%)	0	0	1 (0.3%)
気管支肺アスペルギルス症	1 (1.9%)	0	0	0	1 (1.3%)	0
心内膜炎	0	0	1 (0.5%)	0	0	1 (0.3%)
感染	0	0	1 (0.5%)	0	0	1 (0.3%)
細菌性敗血症	0	0	0	3 (1.4%)	0	0
肺感染	0	1 (2.0%)	0	1 (0.5%)	0	0
髄膜炎	0	1 (2.0%)	0	0	0	0
ムコール症	0	0	0	1 (0.5%)	0	0
シュードモナス性敗血症	0	1 (2.0%)	0	0	0	0
ブドウ球菌感染	0	0	0	1 (0.5%)	0	0
全身性カンジダ	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
脳膿瘍	0	0	0	0	1 (1.3%)	0
大腸菌性菌血症	0	0	0	0	0	1 (0.3%)
呼吸器、胸郭および縦隔障害	1 (1.9%)	0	5 (2.5%)	5 (2.4%)	1 (1.3%)	5 (1.5%)
呼吸不全	0	0	2 (1.0%)	4 (1.9%)	0	2 (0.6%)
呼吸困難	0	0	2 (1.0%)	0	0	2 (0.6%)
呼吸窮迫	1 (1.9%)	0	0	1 (0.5%)	1 (1.3%)	0
急性呼吸不全	0	0	1 (0.5%)	0	0	1 (0.3%)
神経系障害	0	1 (2.0%)	5 (2.5%)	3 (1.4%)	0	7 (2.2%)
痙攣	0	0	2 (1.0%)	0	0	2 (0.6%)
てんかん	0	0	2 (1.0%)	0	0	2 (0.6%)
脳症	0	0	1 (0.5%)	0	0	1 (0.3%)
大発作痙攣	0	0	0	1 (0.5%)	0	0
昏迷	0	1 (2.0%)	0	0	0	0
くも膜下出血	0	0	0	1 (0.5%)	0	0
振戦	0	0	0	1 (0.5%)	0	0
脳血管発作	0	0	0	0	0	1 (0.3%)
卒中の出血性変化	0	0	0	0	0	1 (0.3%)
臨床検査	2 (3.7%)	1 (2.0%)	2 (1.0%)	5 (2.4%)	3 (3.8%)	3 (0.9%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
血中ビリルビン増加	1 (1.9%)	0	1 (0.5%)	0	1 (1.3%)	1 (0.3%)
血中ナトリウム減少	0	0	1 (0.5%)	0	0	1 (0.3%)
トランスアミナーゼ上昇	1 (1.9%)	0	0	0	1 (1.3%)	0
肝機能検査異常	0	0	0	2 (1.0%)	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (2.0%)	0	0	0	1 (0.3%)
血中アルカリホスファターゼ増加	0	0	0	1 (0.5%)	0	1 (0.3%)
肝酵素上昇	0	0	0	1 (0.5%)	1 (1.3%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (2.0%)	0	0	0	0
心電図ＱＴ延長	0	0	0	1 (0.5%)	0	0
血中乳酸脱水素酵素増加	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	1 (0.3%)
心臓障害	1 (1.9%)	0	3 (1.5%)	3 (1.4%)	1 (1.3%)	3 (0.9%)
心停止	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
心肺停止	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
うっ血性心筋症	1 (1.9%)	0	0	0	1 (1.3%)	0
上室性頻脈	0	0	1 (0.5%)	0	0	1 (0.3%)
心室性頻脈	0	0	0	1 (0.5%)	0	0
腎および尿路障害	1 (1.9%)	1 (2.0%)	2 (1.0%)	2 (1.0%)	2 (2.5%)	3 (0.9%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
腎不全	1 (1.9%)	0	1 (0.5%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
急性腎不全	0	1 (2.0%)	1 (0.5%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
精神障害	1 (1.9%)	0	1 (0.5%)	6 (2.9%)	1 (1.3%)	2 (0.6%)
錯乱状態	1 (1.9%)	0	1 (0.5%)	2 (1.0%)	1 (1.3%)	2 (0.6%)
幻視	0	0	0	3 (1.4%)	0	0
幻覚	0	0	0	1 (0.5%)	0	1 (0.3%)
抑うつ気分	0	0	0	1 (0.5%)	0	0
不快気分	0	0	0	1 (0.5%)	0	0
皮膚および皮下組織障害	1 (1.9%)	2 (3.9%)	1 (0.5%)	3 (1.4%)	1 (1.3%)	1 (0.3%)
皮膚炎	1 (1.9%)	0	0	0	1 (1.3%)	0
アレルギー性皮膚炎	0	0	1 (0.5%)	0	0	1 (0.3%)
発疹	0	2 (3.9%)	0	2 (1.0%)	0	0
薬疹	0	0	0	1 (0.5%)	0	0
胃腸障害	0	1 (2.0%)	2 (1.0%)	2 (1.0%)	0	4 (1.2%)
嘔吐	0	1 (2.0%)	1 (0.5%)	1 (0.5%)	0	2 (0.6%)
嚥下障害	0	0	1 (0.5%)	0	0	1 (0.3%)
小腸閉塞	0	0	1 (0.5%)	0	0	1 (0.3%)
悪心	0	1 (2.0%)	0	1 (0.5%)	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
肝胆道系障害	0	3 (5.9%)	1 (0.5%)	3 (1.4%)	1 (1.3%)	1 (0.3%)
急性肝炎	0	0	1 (0.5%)	0	0	1 (0.3%)
肝不全	0	2 (3.9%)	0	0	0	0
高ビリルビン血症	0	1 (2.0%)	0	1 (0.5%)	0	0
肝機能異常	0	0	0	1 (0.5%)	0	0
肝病変	0	0	0	1 (0.5%)	0	0
肝炎	0	1 (2.0%)	0	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (0.5%)	0	0
急性肝不全	0	0	0	0	1 (1.3%)	0
血液およびリンパ系障害	0	1 (2.0%)	1 (0.5%)	2 (1.0%)	0	1 (0.3%)
汎血球減少症	0	1 (2.0%)	1 (0.5%)	0	0	1 (0.3%)
微小血管症性溶血性貧血	0	0	0	1 (0.5%)	0	0
脾臓病変	0	0	0	1 (0.5%)	0	0
眼障害	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
視神経症	0	0	1 (0.5%)	0	0	1 (0.3%)
眼瞼浮腫	0	0	0	1 (0.5%)	0	0
全身障害および投与局所様態	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)
悪寒	0	0	1 (0.5%)	1 (0.5%)	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-157 投与中止に至った有害事象（同種骨髄／造血幹細胞移植の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Allogeneic BMT/HSCT Status Yes		Allogeneic BMT/HSCT Status No		Allogeneic BMT/HSCT Status Yes	Allogeneic BMT/HSCT Status No
System Organ Class Preferred Term	ISA (N = 54)	VRC (N = 51)	ISA (N = 203)	VRC (N = 208)	ISA (N = 80)	ISA (N = 323)
傷害、中毒および処置合併症	0	0	1 (0.5%)	0	0	1 (0.3%)
過量投与	0	0	1 (0.5%)	0	0	1 (0.3%)
筋骨格系および結合組織障害	1 (1.9%)	0	0	0	1 (1.3%)	0
筋炎	1 (1.9%)	0	0	0	1 (1.3%)	0
血管障害	0	0	1 (0.5%)	0	0	1 (0.3%)
低血圧	0	0	1 (0.5%)	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)	0	2 (3.9%)	0	5 (2.4%)	0	3 (0.9%)
急性骨髄性白血病	0	1 (2.0%)	0	3 (1.4%)	0	0
再発急性骨髄性白血病	0	1 (2.0%)	0	0	0	1 (0.3%)
慢性リンパ性白血病	0	0	0	1 (0.5%)	0	0
肺の悪性新生物	0	0	0	1 (0.5%)	0	0
白血病再発	0	0	0	0	0	1 (0.3%)
悪性新生物進行	0	0	0	0	0	1 (0.3%)
免疫系障害	0	1 (2.0%)	0	0	0	0
急性肝移植片対宿主病	0	1 (2.0%)	0	0	0	0
代謝および栄養障害	0	0	0	1 (0.5%)	0	0
代謝性アシドーシス	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
BMT: bone marrow transplant; HSCT: hematopoietic stem cell transplantation

Program Name: t_ae_mye_discon_1.sas
Program Run: 04JUN21:14:55:00

表 8-158 SOC別の有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
Overall	168 (97.1%)	184 (98.4%)	79 (94.0%)	71 (98.6%)	213 (97.3%)	173 (94.0%)
胃腸障害	121 (69.9%)	135 (72.2%)	53 (63.1%)	45 (62.5%)	150 (68.5%)	107 (58.2%)
感染症および寄生虫症	108 (62.4%)	114 (61.0%)	44 (52.4%)	44 (61.1%)	138 (63.0%)	105 (57.1%)
全身障害および投与局所様態	110 (63.6%)	114 (61.0%)	38 (45.2%)	30 (41.7%)	134 (61.2%)	82 (44.6%)
呼吸器、胸郭および縦隔障害	101 (58.4%)	107 (57.2%)	42 (50.0%)	40 (55.6%)	129 (58.9%)	77 (41.8%)
代謝および栄養障害	80 (46.2%)	92 (49.2%)	28 (33.3%)	29 (40.3%)	106 (48.4%)	64 (34.8%)
神経系障害	70 (40.5%)	71 (38.0%)	25 (29.8%)	18 (25.0%)	84 (38.4%)	61 (33.2%)
皮膚および皮下組織障害	66 (38.2%)	82 (43.9%)	20 (23.8%)	28 (38.9%)	82 (37.4%)	43 (23.4%)
臨床検査	55 (31.8%)	71 (38.0%)	30 (35.7%)	25 (34.7%)	72 (32.9%)	47 (25.5%)
血液およびリンパ系障害	56 (32.4%)	65 (34.8%)	21 (25.0%)	17 (23.6%)	68 (31.1%)	38 (20.7%)
精神障害	51 (29.5%)	67 (35.8%)	19 (22.6%)	19 (26.4%)	65 (29.7%)	40 (21.7%)
筋骨格系および結合組織障害	54 (31.2%)	59 (31.6%)	15 (17.9%)	18 (25.0%)	66 (30.1%)	43 (23.4%)
血管障害	46 (26.6%)	61 (32.6%)	21 (25.0%)	16 (22.2%)	60 (27.4%)	41 (22.3%)
腎および尿路障害	39 (22.5%)	44 (23.5%)	16 (19.0%)	14 (19.4%)	52 (23.7%)	29 (15.8%)
心臓障害	31 (17.9%)	43 (23.0%)	12 (14.3%)	14 (19.4%)	44 (20.1%)	24 (13.0%)
眼障害	26 (15.0%)	44 (23.5%)	13 (15.5%)	25 (34.7%)	33 (15.1%)	25 (13.6%)
傷害、中毒および処置合併症	27 (15.6%)	29 (15.5%)	6 (7.1%)	10 (13.9%)	35 (16.0%)	20 (10.9%)
肝胆道系障害	19 (11.0%)	28 (15.0%)	4 (4.8%)	14 (19.4%)	27 (12.3%)	12 (6.5%)
免疫系障害	9 (5.2%)	19 (10.2%)	11 (13.1%)	6 (8.3%)	12 (5.5%)	17 (9.2%)
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）	15 (8.7%)	24 (12.8%)	4 (4.8%)	7 (9.7%)	23 (10.5%)	6 (3.3%)
耳および迷路障害	11 (6.4%)	7 (3.7%)	3 (3.6%)	6 (8.3%)	14 (6.4%)	7 (3.8%)
生殖系および乳房障害	6 (3.5%)	11 (5.9%)	2 (2.4%)	2 (2.8%)	10 (4.6%)	7 (3.8%)
内分泌障害	3 (1.7%)	1 (0.5%)	2 (2.4%)	2 (2.8%)	4 (1.8%)	6 (3.3%)
先天性、家族性および遺伝性障害	3 (1.7%)	2 (1.1%)	0	0	3 (1.4%)	0
社会環境	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_soc_1.sas
Program Run: 04JUN21:15:20:14

表 8-159 注目すべき有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
肝機能異常・肝炎	33 (19.1%)	62 (33.2%)	20 (23.8%)	20 (27.8%)	48 (21.9%)	34 (18.5%)
アナフィラキシー	2 (1.2%)	3 (1.6%)	0	0	2 (0.9%)	0
重度皮膚障害	3 (1.7%)	2 (1.1%)	0	0	3 (1.4%)	0
心電図QT短縮	1 (0.6%)	0	0	0	1 (0.5%)	0
トルサード ド ポアント	11 (6.4%)	13 (7.0%)	4 (4.8%)	6 (8.3%)	14 (6.4%)	4 (2.2%)
急性膵炎	0	0	0	0	0	1 (0.5%)
精神神経症状	54 (31.2%)	60 (32.1%)	19 (22.6%)	19 (26.4%)	68 (31.1%)	42 (22.8%)
視覚障害	16 (9.2%)	28 (15.0%)	7 (8.3%)	19 (26.4%)	20 (9.1%)	11 (6.0%)
皮膚または子宮の悪性腫瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
静脈内投与例	(N = 173)	(N = 187)	(N = 84)	(N = 72)	(N = 213)	(N = 144)
注入部位／注射部位反応	7 (4.0%)	2 (1.1%)	4 (4.8%)	2 (2.8%)	7 (3.3%)	9 (6.3%)
IRR	53 (30.6%)	57 (30.5%)	17 (20.2%)	19 (26.4%)	67 (31.5%)	35 (24.3%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_tumor_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-160 死亡に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
Overall	46 (26.6%)	56 (29.9%)	16 (19.0%)	16 (22.2%)	71 (32.4%)	35 (19.0%)
感染症および寄生虫症	21 (12.1%)	12 (6.4%)	7 (8.3%)	6 (8.3%)	31 (14.2%)	18 (9.8%)
敗血症性ショック	5 (2.9%)	3 (1.6%)	3 (3.6%)	1 (1.4%)	6 (2.7%)	6 (3.3%)
敗血症	7 (4.0%)	3 (1.6%)	0	2 (2.8%)	8 (3.7%)	0
アスペルギルス症	1 (0.6%)	2 (1.1%)	2 (2.4%)	0	2 (0.9%)	2 (1.1%)
真菌感染	2 (1.2%)	0	1 (1.2%)	2 (2.8%)	2 (0.9%)	1 (0.5%)
肺炎	1 (0.6%)	0	0	2 (2.8%)	3 (1.4%)	0
ムコール症	1 (0.6%)	0	0	0	2 (0.9%)	0
アシネトバクター性菌血症	1 (0.6%)	0	0	0	1 (0.5%)	0
気管支肺アスペルギルス症	1 (0.6%)	0	0	0	1 (0.5%)	0
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (1.2%)	0	0	1 (0.5%)
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	1 (0.5%)	0
クレブシエラ性敗血症	0	1 (0.5%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
真菌性肺炎	0	0	0	0	2 (0.9%)	0
細菌性敗血症	0	0	0	0	0	1 (0.5%)
蓄膿	0	0	0	0	0	1 (0.5%)
真菌性敗血症	0	0	0	0	1 (0.5%)	0
肺感染	0	0	0	0	0	1 (0.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_death_1.sas
Program Run: 04JUN21:14:55:16

表 8-160 死亡に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
シュードモナス菌性肺感染	0	0	0	0	0	1 (0.5%)
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.5%)
原発性異型肺炎	0	0	0	0	0	1 (0.5%)
真菌性副鼻腔炎	0	0	0	0	0	1 (0.5%)
ブドウ球菌性敗血症	0	0	0	0	0	1 (0.5%)
呼吸器、胸郭および縦隔障害	9 (5.2%)	9 (4.8%)	5 (6.0%)	3 (4.2%)	11 (5.0%)	7 (3.8%)
呼吸不全	5 (2.9%)	4 (2.1%)	1 (1.2%)	2 (2.8%)	5 (2.3%)	2 (1.1%)
急性呼吸不全	2 (1.2%)	1 (0.5%)	1 (1.2%)	0	2 (0.9%)	2 (1.1%)
喀血	1 (0.6%)	1 (0.5%)	1 (1.2%)	0	2 (0.9%)	1 (0.5%)
肺出血	1 (0.6%)	0	1 (1.2%)	1 (1.4%)	1 (0.5%)	1 (0.5%)
呼吸窮迫	0	0	1 (1.2%)	0	0	1 (0.5%)
急性呼吸窮迫症候群	0	1 (0.5%)	0	0	0	0
肺塞栓症	0	1 (0.5%)	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸困難	0	0	0	0	1 (0.5%)	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)	9 (5.2%)	18 (9.6%)	1 (1.2%)	3 (4.2%)	16 (7.3%)	1 (0.5%)
急性骨髄性白血病	3 (1.7%)	6 (3.2%)	0	1 (1.4%)	4 (1.8%)	0
多発性骨髄腫	2 (1.2%)	0	0	0	2 (0.9%)	0
悪性新生物進行	0	1 (0.5%)	1 (1.2%)	0	2 (0.9%)	1 (0.5%)
芽球発症	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
骨髄性白血病	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_death_1.sas
Program Run: 04JUN21:14:55:16

表 8-160 死亡に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
骨髄異形成症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	3 (1.6%)	0	1 (1.4%)	1 (0.5%)	0
慢性リンパ性白血病	0	1 (0.5%)	0	1 (1.4%)	1 (0.5%)	0
再発急性リンパ性白血病	0	1 (0.5%)	0	0	1 (0.5%)	0
Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
リンパ腫	0	1 (0.5%)	0	0	0	0
新生物進行	0	1 (0.5%)	0	0	0	0
白血病再発	0	0	0	0	1 (0.5%)	0
心臓障害	3 (1.7%)	4 (2.1%)	1 (1.2%)	1 (1.4%)	5 (2.3%)	2 (1.1%)
心停止	1 (0.6%)	3 (1.6%)	0	0	1 (0.5%)	0
心肺停止	1 (0.6%)	1 (0.5%)	0	0	3 (1.4%)	0
うっ血性心筋症	0	0	1 (1.2%)	0	0	1 (0.5%)
心膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
急性心筋梗塞	0	0	0	1 (1.4%)	0	0
急性心不全	0	0	0	0	0	1 (0.5%)
神経系障害	2 (1.2%)	6 (3.2%)	1 (1.2%)	1 (1.4%)	2 (0.9%)	3 (1.6%)
頭蓋内出血	2 (1.2%)	3 (1.6%)	0	0	2 (0.9%)	0
神経毒性	0	0	1 (1.2%)	0	0	1 (0.5%)
脳出血	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
昏迷	0	0	0	1 (1.4%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_death_1.sas
Program Run: 04JUN21:14:55:16

表 8-160 死亡に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
くも膜下出血	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	0	2 (1.1%)
全身障害および投与局所様態	2 (1.2%)	6 (3.2%)	0	2 (2.8%)	6 (2.7%)	1 (0.5%)
多臓器不全	1 (0.6%)	5 (2.7%)	0	1 (1.4%)	2 (0.9%)	0
死亡	1 (0.6%)	0	0	1 (1.4%)	4 (1.8%)	0
心突然死	0	1 (0.5%)	0	0	0	0
全身健康状態低下	0	0	0	0	0	1 (0.5%)
血管障害	2 (1.2%)	1 (0.5%)	0	0	2 (0.9%)	1 (0.5%)
出血	1 (0.6%)	0	0	0	1 (0.5%)	0
血液量減少性ショック	1 (0.6%)	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	1 (0.5%)	0	0	0	0
動脈炎	0	0	0	0	0	1 (0.5%)
血液およびリンパ系障害	1 (0.6%)	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
出血性障害	0	0	1 (1.2%)	0	0	1 (0.5%)
血小板減少症	1 (0.6%)	0	0	0	1 (0.5%)	0
汎血球減少症	0	1 (0.5%)	0	0	0	0
免疫系障害	0	0	1 (1.2%)	0	0	2 (1.1%)
急性移植片対宿主病	0	0	1 (1.2%)	0	0	1 (0.5%)
移植片対宿主病	0	0	0	0	0	1 (0.5%)
腎および尿路障害	1 (0.6%)	0	0	0	2 (0.9%)	0
腎不全	1 (0.6%)	0	0	0	1 (0.5%)	0
急性腎不全	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_death_1.sas
Program Run: 04JUN21:14:55:16

表 8-160 死亡に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
肝胆道系障害	1 (0.6%)	0	0	0	1 (0.5%)	0
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0
代謝および栄養障害	0	1 (0.5%)	0	1 (1.4%)	0	0
低血糖症	0	1 (0.5%)	0	0	0	0
代謝性アシドーシス	0	0	0	1 (1.4%)	0	0
胃腸障害	0	1 (0.5%)	0	0	0	0
直腸出血	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_death_1.sas
Program Run: 04JUN21:14:55:16

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
Overall	102 (59.0%)	113 (60.4%)	32 (38.1%)	36 (50.0%)	139 (63.5%)	84 (45.7%)
感染症および寄生虫症	37 (21.4%)	42 (22.5%)	14 (16.7%)	19 (26.4%)	56 (25.6%)	50 (27.2%)
敗血症性ショック	9 (5.2%)	7 (3.7%)	5 (6.0%)	3 (4.2%)	10 (4.6%)	10 (5.4%)
敗血症	7 (4.0%)	5 (2.7%)	0	3 (4.2%)	8 (3.7%)	2 (1.1%)
肺炎	3 (1.7%)	6 (3.2%)	2 (2.4%)	4 (5.6%)	5 (2.3%)	7 (3.8%)
アスペルギルス症	2 (1.2%)	3 (1.6%)	2 (2.4%)	0	4 (1.8%)	3 (1.6%)
真菌感染	2 (1.2%)	1 (0.5%)	1 (1.2%)	2 (2.8%)	3 (1.4%)	1 (0.5%)
サイトメガロウイルス感染	0	1 (0.5%)	2 (2.4%)	1 (1.4%)	0	4 (2.2%)
気管支肺アスペルギルス症	2 (1.2%)	1 (0.5%)	0	0	2 (0.9%)	0
シュードモナス性敗血症	1 (0.6%)	1 (0.5%)	0	0	3 (1.4%)	0
大腸菌性敗血症	0	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
尿路感染	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	1 (0.5%)
蜂巣炎	0	0	1 (1.2%)	1 (1.4%)	0	1 (0.5%)
クレブシエラ性菌血症	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
クレブシエラ性敗血症	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
ムコール症	1 (0.6%)	0	0	0	2 (0.9%)	1 (0.5%)
クロストリジウム・ディフィシレ大腸炎	1 (0.6%)	0	0	0	1 (0.5%)	1 (0.5%)
腸球菌性菌血症	1 (0.6%)	0	0	0	2 (0.9%)	0
ブドウ球菌感染	1 (0.6%)	0	0	0	2 (0.9%)	0
アシネトバクター性菌血症	1 (0.6%)	0	0	0	1 (0.5%)	0
肺炎球菌性気管支炎	0	0	1 (1.2%)	0	0	1 (0.5%)
気管支肺炎	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
脳アスペルギルス症	0	0	1 (1.2%)	0	0	1 (0.5%)
サイトメガロウイルス血症	0	0	1 (1.2%)	0	0	1 (0.5%)
ヘルペス脳炎	1 (0.6%)	0	0	0	1 (0.5%)	0
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (1.2%)	0	0	1 (0.5%)
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
注入部位感染	1 (0.6%)	0	0	0	1 (0.5%)	0
筋膿瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
モラクセラ菌性肺炎	1 (0.6%)	0	0	0	1 (0.5%)	0
気道感染	1 (0.6%)	0	0	0	1 (0.5%)	0
敗血症症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
皮膚感染	1 (0.6%)	0	0	0	1 (0.5%)	0
細菌性敗血症	0	4 (2.1%)	0	0	0	1 (0.5%)
ブドウ球菌性菌血症	0	2 (1.1%)	0	1 (1.4%)	1 (0.5%)	0
菌血症	0	0	0	2 (2.8%)	0	3 (1.6%)
ブドウ球菌性敗血症	0	2 (1.1%)	0	0	0	1 (0.5%)
クロストリジウム性菌血症	0	1 (0.5%)	0	1 (1.4%)	0	0
髄膜炎	0	2 (1.1%)	0	0	0	0
細菌性肺炎	0	0	0	1 (1.4%)	1 (0.5%)	2 (1.1%)
帯状疱疹	0	1 (0.5%)	0	0	0	2 (1.1%)
蓄膿	0	0	0	1 (1.4%)	0	1 (0.5%)
カンピロバクター胃腸炎	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
カテーテル関連感染	0	1 (0.5%)	0	0	0	0
感染性下痢	0	0	0	1 (1.4%)	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (1.4%)	0	0
単純ヘルペス	0	0	0	1 (1.4%)	0	0
肺膿瘍	0	1 (0.5%)	0	0	0	0
壊死性筋膜炎	0	1 (0.5%)	0	0	0	0
肺炎球菌性肺炎	0	1 (0.5%)	0	0	0	0
ブドウ球菌性肺炎	0	0	0	1 (1.4%)	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
シュードモナス感染	0	1 (0.5%)	0	0	0	0
膿胸	0	1 (0.5%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0
トキソプラズマ症	0	1 (0.5%)	0	0	0	0
結核	0	1 (0.5%)	0	0	0	0
細菌性尿路感染	0	0	0	1 (1.4%)	0	0
真菌性肺炎	0	0	0	0	2 (0.9%)	0
接合真菌症	0	0	0	0	1 (0.5%)	1 (0.5%)
腹部膿瘍	0	0	0	0	1 (0.5%)	0
虫垂炎	0	0	0	0	0	1 (0.5%)
ＢＫウイルス感染	0	0	0	0	1 (0.5%)	0
脳膿瘍	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
気管支拡張症	0	0	0	0	0	1 (0.5%)
細気管支炎	0	0	0	0	0	1 (0.5%)
カテーテル留置部位感染	0	0	0	0	0	1 (0.5%)
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.5%)
大腸菌性菌血症	0	0	0	0	1 (0.5%)	0
真菌性敗血症	0	0	0	0	1 (0.5%)	0
ノロウイルス性胃腸炎	0	0	0	0	0	1 (0.5%)
ウイルス性胃腸炎	0	0	0	0	0	1 (0.5%)
インフルエンザ	0	0	0	0	0	1 (0.5%)
肺感染	0	0	0	0	0	1 (0.5%)
シュードモナス菌性肺感染	0	0	0	0	0	1 (0.5%)
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	1 (0.5%)
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.5%)
インフルエンザ性肺炎	0	0	0	0	0	1 (0.5%)
原発性異型肺炎	0	0	0	0	0	1 (0.5%)
シュードモナス性気管支炎	0	0	0	0	0	1 (0.5%)
副鼻腔炎	0	0	0	0	0	1 (0.5%)
真菌性副鼻腔炎	0	0	0	0	0	1 (0.5%)
レンサ球菌性菌血症	0	0	0	0	1 (0.5%)	0
皮下組織膿瘍	0	0	0	0	0	1 (0.5%)
尿路性敗血症	0	0	0	0	0	1 (0.5%)
ウイルス性下痢	0	0	0	0	0	1 (0.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
呼吸器、胸郭および縦隔障害	30 (17.3%)	29 (15.5%)	11 (13.1%)	14 (19.4%)	40 (18.3%)	21 (11.4%)
呼吸不全	13 (7.5%)	8 (4.3%)	1 (1.2%)	4 (5.6%)	16 (7.3%)	3 (1.6%)
急性呼吸不全	4 (2.3%)	3 (1.6%)	1 (1.2%)	2 (2.8%)	5 (2.3%)	3 (1.6%)
呼吸困難	3 (1.7%)	1 (0.5%)	2 (2.4%)	0	4 (1.8%)	2 (1.1%)
呼吸窮迫	3 (1.7%)	2 (1.1%)	1 (1.2%)	1 (1.4%)	3 (1.4%)	1 (0.5%)
喀血	1 (0.6%)	1 (0.5%)	1 (1.2%)	1 (1.4%)	2 (0.9%)	2 (1.1%)
低酸素症	1 (0.6%)	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	2 (1.1%)
肺出血	1 (0.6%)	0	1 (1.2%)	1 (1.4%)	1 (0.5%)	1 (0.5%)
胸水	1 (0.6%)	1 (0.5%)	0	0	2 (0.9%)	0
肺水腫	1 (0.6%)	0	0	1 (1.4%)	2 (0.9%)	0
肺障害	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0
呼吸抑制	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
嚥下性肺炎	0	0	1 (1.2%)	0	1 (0.5%)	2 (1.1%)
頻呼吸	0	0	1 (1.2%)	0	0	2 (1.1%)
気管支胸膜瘻	0	0	1 (1.2%)	0	0	1 (0.5%)
気管支痙攣	0	0	1 (1.2%)	0	0	1 (0.5%)
水気胸	0	0	1 (1.2%)	0	0	1 (0.5%)
胸膜痛	1 (0.6%)	0	0	0	1 (0.5%)	0
呼吸性アシドーシス	0	0	1 (1.2%)	0	0	1 (0.5%)
鼻出血	0	3 (1.6%)	0	1 (1.4%)	0	0
肺塞栓症	0	2 (1.1%)	0	1 (1.4%)	1 (0.5%)	0
肺浸潤	0	1 (0.5%)	0	2 (2.8%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
急性呼吸窮迫症候群	0	2 (1.1%)	0	0	0	1 (0.5%)
急性肺損傷	0	1 (0.5%)	0	0	0	0
慢性閉塞性肺疾患	0	0	0	1 (1.4%)	0	0
咳嗽	0	1 (0.5%)	0	0	0	0
血胸	0	0	0	1 (1.4%)	0	0
気胸	0	0	0	1 (1.4%)	0	0
湿性咳嗽	0	1 (0.5%)	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸停止	0	1 (0.5%)	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.5%)
肺胞出血	0	0	0	0	1 (0.5%)	0
肺梗塞	0	0	0	0	0	1 (0.5%)
副鼻腔障害	0	0	0	0	1 (0.5%)	0
喘鳴	0	0	0	0	0	1 (0.5%)
血液およびリンパ系障害	23 (13.3%)	14 (7.5%)	5 (6.0%)	3 (4.2%)	26 (11.9%)	7 (3.8%)
発熱性好中球減少症	13 (7.5%)	5 (2.7%)	1 (1.2%)	0	15 (6.8%)	1 (0.5%)
汎血球減少症	4 (2.3%)	3 (1.6%)	0	0	4 (1.8%)	1 (0.5%)
好中球減少症	3 (1.7%)	3 (1.6%)	1 (1.2%)	0	3 (1.4%)	1 (0.5%)
血小板減少症	3 (1.7%)	4 (2.1%)	0	0	3 (1.4%)	0
無顆粒球症	0	0	2 (2.4%)	0	0	2 (1.1%)
貧血	1 (0.6%)	0	0	2 (2.8%)	2 (0.9%)	1 (0.5%)
出血性障害	0	0	1 (1.2%)	0	0	1 (0.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
白血球増加症	1 (0.6%)	0	0	0	1 (0.5%)	0
脾臓梗塞	1 (0.6%)	0	0	0	1 (0.5%)	0
出血性貧血	0	0	0	1 (1.4%)	0	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
血小板減少性紫斑病	0	1 (0.5%)	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)	14 (8.1%)	23 (12.3%)	4 (4.8%)	6 (8.3%)	22 (10.0%)	4 (2.2%)
急性骨髄性白血病	3 (1.7%)	7 (3.7%)	0	1 (1.4%)	5 (2.3%)	0
リンパ腫	1 (0.6%)	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
多発性骨髄腫	2 (1.2%)	0	0	0	2 (0.9%)	0
悪性新生物進行	0	1 (0.5%)	1 (1.2%)	0	2 (0.9%)	1 (0.5%)
再発急性リンパ性白血病	1 (0.6%)	1 (0.5%)	0	0	2 (0.9%)	0
芽球発症	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
骨髄性白血病	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
新生物進行	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	1 (0.6%)	0	0	0	1 (0.5%)	0
子宮内膜癌	1 (0.6%)	0	0	0	1 (0.5%)	0
髄膜転移	0	0	1 (1.2%)	0	0	1 (0.5%)
骨髄異形成症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
非ホジキンリンパ腫	0	0	1 (1.2%)	0	0	1 (0.5%)
原発性体腔性リンパ腫	1 (0.6%)	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	3 (1.6%)	0	2 (2.8%)	2 (0.9%)	0
慢性リンパ性白血病	0	1 (0.5%)	0	1 (1.4%)	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
急性白血病	0	1 (0.5%)	0	0	0	0
急性リンパ性白血病	0	1 (0.5%)	0	0	0	0
Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
再発Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	0	0	1 (1.4%)	0	0
白血病	0	1 (0.5%)	0	0	0	0
肺の悪性新生物	0	0	0	1 (1.4%)	0	0
骨転移	0	1 (0.5%)	0	0	0	0
転移部痛	0	1 (0.5%)	0	0	0	0
白血病再発	0	0	0	0	1 (0.5%)	0
白血病浸潤	0	0	0	0	1 (0.5%)	0
神経系障害	14 (8.1%)	13 (7.0%)	3 (3.6%)	3 (4.2%)	17 (7.8%)	9 (4.9%)
痙攣	3 (1.7%)	0	0	1 (1.4%)	4 (1.8%)	1 (0.5%)
頭蓋内出血	2 (1.2%)	3 (1.6%)	0	0	2 (0.9%)	0
てんかん	1 (0.6%)	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
多発ニューロパチー	2 (1.2%)	0	0	0	2 (0.9%)	0
中枢神経系病変	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
脳症	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0
虚血性脳卒中	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
対麻痺	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
頭痛	0	0	1 (1.2%)	0	0	2 (1.1%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
脳幹卒中	1 (0.6%)	0	0	0	1 (0.5%)	0
脳虚血	1 (0.6%)	0	0	0	1 (0.5%)	0
熱性痙攣	1 (0.6%)	0	0	0	1 (0.5%)	0
神経毒性	0	0	1 (1.2%)	0	0	1 (0.5%)
失語症	0	1 (0.5%)	0	0	0	1 (0.5%)
脳出血	0	1 (0.5%)	0	0	0	0
浮動性めまい	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
片麻痺	0	1 (0.5%)	0	0	0	0
昏迷	0	0	0	1 (1.4%)	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0
第７脳神経麻痺	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	1 (0.5%)	2 (1.1%)
脳血管発作	0	0	0	0	0	1 (0.5%)
卒中の出血性変化	0	0	0	0	0	1 (0.5%)
不全片麻痺	0	0	0	0	0	1 (0.5%)
一過性脳虚血発作	0	0	0	0	1 (0.5%)	0
全身障害および投与局所様態	8 (4.6%)	15 (8.0%)	3 (3.6%)	4 (5.6%)	15 (6.8%)	5 (2.7%)
発熱	5 (2.9%)	8 (4.3%)	3 (3.6%)	2 (2.8%)	7 (3.2%)	3 (1.6%)
多臓器不全	1 (0.6%)	6 (3.2%)	0	1 (1.4%)	2 (0.9%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
死亡	1 (0.6%)	0	0	1 (1.4%)	4 (1.8%)	0
悪寒	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
全身健康状態低下	0	0	1 (1.2%)	0	0	2 (1.1%)
無力症	1 (0.6%)	0	0	0	1 (0.5%)	0
胸痛	1 (0.6%)	0	0	0	1 (0.5%)	0
心突然死	0	1 (0.5%)	0	0	0	0
非心臓性胸痛	0	0	0	0	1 (0.5%)	1 (0.5%)
末梢性浮腫	0	0	0	0	1 (0.5%)	0
心臓障害	8 (4.6%)	10 (5.3%)	3 (3.6%)	2 (2.8%)	13 (5.9%)	6 (3.3%)
心肺停止	1 (0.6%)	2 (1.1%)	1 (1.2%)	0	3 (1.4%)	1 (0.5%)
心停止	1 (0.6%)	4 (2.1%)	0	1 (1.4%)	1 (0.5%)	0
心房細動	1 (0.6%)	1 (0.5%)	0	0	2 (0.9%)	1 (0.5%)
急性心筋梗塞	1 (0.6%)	0	0	1 (1.4%)	2 (0.9%)	0
不整脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心原性ショック	1 (0.6%)	0	0	0	1 (0.5%)	0
うっ血性心筋症	0	0	1 (1.2%)	0	0	1 (0.5%)
心膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
洞性徐脈	0	0	1 (1.2%)	0	0	1 (0.5%)
上室性頻脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心室性頻脈	0	2 (1.1%)	0	0	0	0
狭心症	0	1 (0.5%)	0	0	0	0
完全房室ブロック	0	0	0	0	0	1 (0.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
急性心不全	0	0	0	0	0	1 (0.5%)
電気収縮解離	0	0	0	0	1 (0.5%)	0
腎および尿路障害	6 (3.5%)	7 (3.7%)	4 (4.8%)	3 (4.2%)	11 (5.0%)	8 (4.3%)
急性腎不全	2 (1.2%)	5 (2.7%)	4 (4.8%)	3 (4.2%)	7 (3.2%)	7 (3.8%)
腎不全	3 (1.7%)	2 (1.1%)	0	0	3 (1.4%)	1 (0.5%)
血尿	1 (0.6%)	0	0	0	1 (0.5%)	0
胃腸障害	6 (3.5%)	8 (4.3%)	3 (3.6%)	4 (5.6%)	14 (6.4%)	13 (7.1%)
下痢	2 (1.2%)	1 (0.5%)	0	0	3 (1.4%)	1 (0.5%)
小腸閉塞	1 (0.6%)	0	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
悪心	1 (0.6%)	0	0	1 (1.4%)	3 (1.4%)	0
腸出血	0	0	1 (1.2%)	1 (1.4%)	0	1 (0.5%)
腹膜炎	0	1 (0.5%)	1 (1.2%)	0	0	1 (0.5%)
腹痛	1 (0.6%)	0	0	0	4 (1.8%)	2 (1.1%)
大腸炎	1 (0.6%)	0	0	0	2 (0.9%)	0
便秘	1 (0.6%)	0	0	0	2 (0.9%)	0
胃穿孔	0	0	1 (1.2%)	0	0	1 (0.5%)
食道潰瘍	0	0	1 (1.2%)	0	0	1 (0.5%)
胃腸出血	0	2 (1.1%)	0	1 (1.4%)	0	3 (1.6%)
食中毒	0	0	0	1 (1.4%)	0	0
胃腸の炎症	0	1 (0.5%)	0	0	0	0
麻痺性イレウス	0	1 (0.5%)	0	0	0	0
肛門周囲痛	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
直腸出血	0	1 (0.5%)	0	0	0	0
嘔吐	0	0	0	0	3 (1.4%)	1 (0.5%)
嚥下障害	0	0	0	0	1 (0.5%)	1 (0.5%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.5%)
限局性腹腔内液貯留	0	0	0	0	1 (0.5%)	0
食道炎	0	0	0	0	0	1 (0.5%)
膵炎	0	0	0	0	0	1 (0.5%)
慢性膵炎	0	0	0	0	0	1 (0.5%)
再発性膵炎	0	0	0	0	0	1 (0.5%)
免疫系障害	2 (1.2%)	6 (3.2%)	2 (2.4%)	0	3 (1.4%)	6 (3.3%)
急性腸管移植片対宿主病	0	2 (1.1%)	1 (1.2%)	0	0	1 (0.5%)
急性移植片対宿主病	0	1 (0.5%)	1 (1.2%)	0	1 (0.5%)	2 (1.1%)
アナフィラキシーショック	1 (0.6%)	0	0	0	1 (0.5%)	0
過敏症	1 (0.6%)	0	0	0	1 (0.5%)	0
アナフィラキシー反応	0	2 (1.1%)	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0
移植片対宿主病	0	0	0	0	0	2 (1.1%)
肺移植拒絶反応	0	0	0	0	0	1 (0.5%)
血管障害	4 (2.3%)	4 (2.1%)	0	2 (2.8%)	5 (2.3%)	4 (2.2%)
低血圧	1 (0.6%)	2 (1.1%)	0	0	1 (0.5%)	2 (1.1%)
出血	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0
血液量減少性ショック	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
血管炎	1 (0.6%)	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	1 (0.5%)	0	0	1 (0.5%)	1 (0.5%)
ショック	0	1 (0.5%)	0	0	0	0
動脈炎	0	0	0	0	0	1 (0.5%)
肝胆道系障害	2 (1.2%)	3 (1.6%)	1 (1.2%)	3 (4.2%)	3 (1.4%)	5 (2.7%)
胆嚢炎	1 (0.6%)	0	0	0	1 (0.5%)	1 (0.5%)
肝炎	0	0	1 (1.2%)	0	0	1 (0.5%)
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0
肝不全	0	1 (0.5%)	0	1 (1.4%)	0	0
肝機能異常	0	0	0	2 (2.8%)	0	0
高ビリルビン血症	0	2 (1.1%)	0	0	0	0
急性胆嚢炎	0	1 (0.5%)	0	0	0	0
急性肝不全	0	0	0	0	1 (0.5%)	0
細胆管炎	0	0	0	0	0	1 (0.5%)
胆石症	0	0	0	0	0	1 (0.5%)
肝障害	0	0	0	0	0	1 (0.5%)
臨床検査	2 (1.2%)	5 (2.7%)	1 (1.2%)	1 (1.4%)	2 (0.9%)	1 (0.5%)
肝機能検査異常	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
血中ナトリウム減少	0	0	1 (1.2%)	0	0	1 (0.5%)
ヘモグロビン減少	1 (0.6%)	0	0	0	1 (0.5%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
血中アルカリホスファターゼ増加	0	0	0	1 (1.4%)	0	0
血中ビリルビン増加	0	1 (0.5%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
肝酵素上昇	0	1 (0.5%)	0	0	0	0
傷害、中毒および処置合併症	3 (1.7%)	3 (1.6%)	0	0	3 (1.4%)	0
薬物毒性	2 (1.2%)	0	0	0	2 (0.9%)	0
転倒・転落	1 (0.6%)	0	0	0	1 (0.5%)	0
家庭内事故	0	1 (0.5%)	0	0	0	0
大腿骨頚部骨折	0	1 (0.5%)	0	0	0	0
橈骨骨折	0	1 (0.5%)	0	0	0	0
皮膚および皮下組織障害	3 (1.7%)	1 (0.5%)	0	1 (1.4%)	3 (1.4%)	0
褥瘡性潰瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0
脂肪織炎	1 (0.6%)	0	0	0	1 (0.5%)	0
発疹	0	1 (0.5%)	0	1 (1.4%)	0	0
筋骨格系および結合組織障害	2 (1.2%)	0	1 (1.2%)	0	3 (1.4%)	4 (2.2%)
筋骨格系胸痛	1 (0.6%)	0	0	0	2 (0.9%)	1 (0.5%)
筋肉内出血	0	0	1 (1.2%)	0	0	1 (0.5%)
筋炎	1 (0.6%)	0	0	0	1 (0.5%)	0
関節炎	0	0	0	0	0	1 (0.5%)
四肢痛	0	0	0	0	1 (0.5%)	0
全身性エリテマトーデス	0	0	0	0	0	1 (0.5%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
代謝および栄養障害	2 (1.2%)	5 (2.7%)	0	2 (2.8%)	5 (2.3%)	4 (2.2%)
コントロール不良の糖尿病	1 (0.6%)	0	0	0	1 (0.5%)	0
成長障害	1 (0.6%)	0	0	0	1 (0.5%)	0
脱水	0	2 (1.1%)	0	0	1 (0.5%)	2 (1.1%)
代謝性アシドーシス	0	1 (0.5%)	0	1 (1.4%)	0	0
低血糖症	0	1 (0.5%)	0	0	0	1 (0.5%)
高ナトリウム血症	0	0	0	1 (1.4%)	0	0
低カリウム血症	0	1 (0.5%)	0	0	0	0
過小食	0	1 (0.5%)	0	0	0	0
高カリウム血症	0	0	0	0	1 (0.5%)	0
低ナトリウム血症	0	0	0	0	0	1 (0.5%)
栄養障害	0	0	0	0	1 (0.5%)	0
眼障害	2 (1.2%)	1 (0.5%)	0	0	2 (0.9%)	2 (1.1%)
片側失明	1 (0.6%)	0	0	0	1 (0.5%)	0
視神経症	1 (0.6%)	0	0	0	1 (0.5%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0
網膜動脈閉塞	0	0	0	0	0	1 (0.5%)
網膜出血	0	0	0	0	0	1 (0.5%)
硝子体出血	0	0	0	0	0	1 (0.5%)
精神障害	1 (0.6%)	6 (3.2%)	0	0	2 (0.9%)	1 (0.5%)
うつ病	1 (0.6%)	0	0	0	1 (0.5%)	0
幻視	0	2 (1.1%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-161 重篤な有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
精神状態変化	0	2 (1.1%)	0	0	0	0
錯乱状態	0	1 (0.5%)	0	0	0	1 (0.5%)
幻覚	0	1 (0.5%)	0	0	0	1 (0.5%)
抑うつ気分	0	1 (0.5%)	0	0	0	0
自殺企図	0	1 (0.5%)	0	0	0	0
異常行動	0	0	0	0	1 (0.5%)	0
攻撃性	0	0	0	0	1 (0.5%)	0
激越	0	0	0	0	1 (0.5%)	0
生殖系および乳房障害	0	0	0	0	1 (0.5%)	0
良性前立腺肥大症	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_tumor_ser_1.sas
Program Run: 04JUN21:14:55:21

表 8-162 投与中止に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
Overall	30 (17.3%)	42 (22.5%)	7 (8.3%)	17 (23.6%)	41 (18.7%)	15 (8.2%)
感染症および寄生虫症	11 (6.4%)	11 (5.9%)	0	4 (5.6%)	17 (7.8%)	1 (0.5%)
真菌感染	2 (1.2%)	0	0	1 (1.4%)	3 (1.4%)	0
敗血症性ショック	2 (1.2%)	0	0	0	3 (1.4%)	1 (0.5%)
敗血症	1 (0.6%)	1 (0.5%)	0	2 (2.8%)	1 (0.5%)	0
アスペルギルス症	1 (0.6%)	1 (0.5%)	0	0	3 (1.4%)	0
肺炎	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0
気管支肺炎	1 (0.6%)	0	0	0	1 (0.5%)	0
気管支肺アスペルギルス症	1 (0.6%)	0	0	0	1 (0.5%)	0
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
細菌性敗血症	0	3 (1.6%)	0	0	0	0
肺感染	0	1 (0.5%)	0	1 (1.4%)	0	0
髄膜炎	0	1 (0.5%)	0	0	0	0
ムコール症	0	1 (0.5%)	0	0	0	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	0	0
ブドウ球菌感染	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0
脳膿瘍	0	0	0	0	1 (0.5%)	0
大腸菌性菌血症	0	0	0	0	1 (0.5%)	0
呼吸器、胸郭および縦隔障害	5 (2.9%)	4 (2.1%)	1 (1.2%)	1 (1.4%)	5 (2.3%)	1 (0.5%)
呼吸不全	2 (1.2%)	3 (1.6%)	0	1 (1.4%)	2 (0.9%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_discon_1.sas
Program Run: 04JUN21:14:55:26

表 8-162 投与中止に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
呼吸困難	2 (1.2%)	0	0	0	2 (0.9%)	0
呼吸窮迫	0	1 (0.5%)	1 (1.2%)	0	0	1 (0.5%)
急性呼吸不全	1 (0.6%)	0	0	0	1 (0.5%)	0
神経系障害	4 (2.3%)	3 (1.6%)	1 (1.2%)	1 (1.4%)	4 (1.8%)	3 (1.6%)
痙攣	2 (1.2%)	0	0	0	2 (0.9%)	0
てんかん	1 (0.6%)	0	1 (1.2%)	0	1 (0.5%)	1 (0.5%)
脳症	1 (0.6%)	0	0	0	1 (0.5%)	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
昏迷	0	0	0	1 (1.4%)	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0
脳血管発作	0	0	0	0	0	1 (0.5%)
卒中の出血性変化	0	0	0	0	0	1 (0.5%)
臨床検査	2 (1.2%)	5 (2.7%)	2 (2.4%)	1 (1.4%)	2 (0.9%)	4 (2.2%)
血中ビリルビン増加	2 (1.2%)	0	0	0	2 (0.9%)	0
血中ナトリウム減少	0	0	1 (1.2%)	0	0	1 (0.5%)
トランスアミナーゼ上昇	0	0	1 (1.2%)	0	0	1 (0.5%)
肝機能検査異常	0	2 (1.1%)	0	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	1 (0.5%)
血中アルカリホスファターゼ増加	0	0	0	1 (1.4%)	0	1 (0.5%)
肝酵素上昇	0	1 (0.5%)	0	0	0	1 (0.5%)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_discon_1.sas
Program Run: 04JUN21:14:55:26

表 8-162 投与中止に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	1 (0.5%)
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	1 (0.5%)
心臓障害	3 (1.7%)	3 (1.6%)	1 (1.2%)	0	3 (1.4%)	1 (0.5%)
心停止	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
心肺停止	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
うっ血性心筋症	0	0	1 (1.2%)	0	0	1 (0.5%)
上室性頻脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心室性頻脈	0	1 (0.5%)	0	0	0	0
腎および尿路障害	3 (1.7%)	2 (1.1%)	0	1 (1.4%)	4 (1.8%)	1 (0.5%)
腎不全	2 (1.2%)	1 (0.5%)	0	0	2 (0.9%)	0
急性腎不全	1 (0.6%)	1 (0.5%)	0	1 (1.4%)	2 (0.9%)	1 (0.5%)
精神障害	1 (0.6%)	5 (2.7%)	1 (1.2%)	1 (1.4%)	1 (0.5%)	2 (1.1%)
錯乱状態	1 (0.6%)	2 (1.1%)	1 (1.2%)	0	1 (0.5%)	2 (1.1%)
幻視	0	3 (1.6%)	0	0	0	0
幻覚	0	1 (0.5%)	0	0	0	1 (0.5%)
抑うつ気分	0	1 (0.5%)	0	0	0	0
不快気分	0	0	0	1 (1.4%)	0	0
皮膚および皮下組織障害	2 (1.2%)	3 (1.6%)	0	2 (2.8%)	2 (0.9%)	0
皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0
アレルギー性皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0
発疹	0	2 (1.1%)	0	2 (2.8%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_discon_1.sas
Program Run: 04JUN21:14:55:26

表 8-162 投与中止に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
薬疹	0	1 (0.5%)	0	0	0	0
胃腸障害	0	3 (1.6%)	2 (2.4%)	0	0	4 (2.2%)
嘔吐	0	2 (1.1%)	1 (1.2%)	0	0	2 (1.1%)
嚥下障害	0	0	1 (1.2%)	0	0	1 (0.5%)
小腸閉塞	0	0	1 (1.2%)	0	0	1 (0.5%)
悪心	0	2 (1.1%)	0	0	0	1 (0.5%)
肝胆道系障害	1 (0.6%)	3 (1.6%)	0	3 (4.2%)	2 (0.9%)	0
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0
肝不全	0	1 (0.5%)	0	1 (1.4%)	0	0
高ビリルビン血症	0	1 (0.5%)	0	1 (1.4%)	0	0
肝機能異常	0	1 (0.5%)	0	0	0	0
肝病変	0	0	0	1 (1.4%)	0	0
肝炎	0	1 (0.5%)	0	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (1.4%)	0	0
急性肝不全	0	0	0	0	1 (0.5%)	0
血液およびリンパ系障害	1 (0.6%)	1 (0.5%)	0	2 (2.8%)	1 (0.5%)	0
汎血球減少症	1 (0.6%)	0	0	1 (1.4%)	1 (0.5%)	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
脾臓病変	0	0	0	1 (1.4%)	0	0
眼障害	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
視神経症	1 (0.6%)	0	0	0	1 (0.5%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_discon_1.sas
Program Run: 04JUN21:14:55:26

表 8-162 投与中止に至った有害事象（コントロール不良な悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Uncontrolled Malignancy Status Yes		Uncontrolled Malignancy Status No		Uncontrolled Malignancy Status Yes	Uncontrolled Malignancy Status No
System Organ Class Preferred Term	ISA (N = 173)	VRC (N = 187)	ISA (N = 84)	VRC (N = 72)	ISA (N = 219)	ISA (N = 184)
全身障害および投与局所様態	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
悪寒	1 (0.6%)	1 (0.5%)	0	0	1 (0.5%)	0
傷害、中毒および処置合併症	1 (0.6%)	0	0	0	1 (0.5%)	0
過量投与	1 (0.6%)	0	0	0	1 (0.5%)	0
筋骨格系および結合組織障害	1 (0.6%)	0	0	0	1 (0.5%)	0
筋炎	1 (0.6%)	0	0	0	1 (0.5%)	0
血管障害	1 (0.6%)	0	0	0	1 (0.5%)	0
低血圧	1 (0.6%)	0	0	0	1 (0.5%)	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	4 (2.1%)	0	3 (4.2%)	3 (1.4%)	0
急性骨髄性白血病	0	3 (1.6%)	0	1 (1.4%)	0	0
再発急性骨髄性白血病	0	1 (0.5%)	0	0	1 (0.5%)	0
慢性リンパ性白血病	0	0	0	1 (1.4%)	0	0
肺の悪性新生物	0	0	0	1 (1.4%)	0	0
白血病再発	0	0	0	0	1 (0.5%)	0
悪性新生物進行	0	0	0	0	1 (0.5%)	0
免疫系障害	0	0	0	1 (1.4%)	0	0
急性肝移植片対宿主病	0	0	0	1 (1.4%)	0	0
代謝および栄養障害	0	1 (0.5%)	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_tumor_discon_1.sas
Program Run: 04JUN21:14:55:26

表 8-163 SOC別の有害事象（血液悪性腫瘍の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
Overall	5 (100.0%)	2 (100.0%)	50 (90.9%)	26 (92.9%)	6 (100.0%)	61 (91.0%)
感染症および寄生虫症	2 (40.0%)	2 (100.0%)	20 (36.4%)	8 (28.6%)	3 (50.0%)	22 (32.8%)
胃腸障害	2 (40.0%)	1 (50.0%)	15 (27.3%)	11 (39.3%)	3 (50.0%)	18 (26.9%)
臨床検査	1 (20.0%)	0	15 (27.3%)	7 (25.0%)	1 (16.7%)	20 (29.9%)
肝胆道系障害	2 (40.0%)	0	9 (16.4%)	10 (35.7%)	2 (33.3%)	10 (14.9%)
神経系障害	1 (20.0%)	0	9 (16.4%)	6 (21.4%)	2 (33.3%)	13 (19.4%)
皮膚および皮下組織障害	0	0	9 (16.4%)	4 (14.3%)	1 (16.7%)	10 (14.9%)
眼障害	1 (20.0%)	0	7 (12.7%)	13 (46.4%)	2 (33.3%)	8 (11.9%)
代謝および栄養障害	1 (20.0%)	1 (50.0%)	7 (12.7%)	1 (3.6%)	2 (33.3%)	9 (13.4%)
一般・全身障害および投与部位の状態	0	1 (50.0%)	8 (14.5%)	0	0	9 (13.4%)
呼吸器、胸郭および縦隔障害	1 (20.0%)	1 (50.0%)	6 (10.9%)	2 (7.1%)	2 (33.3%)	7 (10.4%)
腎および尿路障害	0	0	5 (9.1%)	2 (7.1%)	1 (16.7%)	6 (9.0%)
血管障害	1 (20.0%)	0	4 (7.3%)	1 (3.6%)	2 (33.3%)	4 (6.0%)
精神障害	2 (40.0%)	1 (50.0%)	1 (1.8%)	6 (21.4%)	2 (33.3%)	2 (3.0%)
筋骨格系および結合組織障害	0	0	3 (5.5%)	4 (14.3%)	1 (16.7%)	3 (4.5%)
傷害、中毒および処置合併症	0	0	3 (5.5%)	2 (7.1%)	0	4 (6.0%)
心臓障害	1 (20.0%)	0	2 (3.6%)	1 (3.6%)	2 (33.3%)	4 (6.0%)
耳および迷路障害	0	0	2 (3.6%)	1 (3.6%)	0	2 (3.0%)
免疫系障害	1 (20.0%)	1 (50.0%)	0	0	1 (16.7%)	0
内分泌障害	0	0	1 (1.8%)	0	0	2 (3.0%)
先天性、家族性および遺伝性障害	0	1 (50.0%)	0	2 (7.1%)	0	1 (1.5%)
血液およびリンパ系障害	0	0	0	1 (3.6%)	1 (16.7%)	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_soc_2.sas
Program Run: 16JUN21:13:32:39

表 8-164 注目すべき有害事象（血液悪性腫瘍の有無別） - AK1820-301試験のCohort Aおよび Cohort A/B併合

	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
肝機能異常・肝炎	3 (60.0%)	0	19 (34.5%)	14 (50.0%)	3 (50.0%)	21 (31.3%)
アナフィラキシー	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0
トルサード ド ポアント	0	0	1 (1.8%)	0	0	2 (3.0%)
急性膵炎	0	0	0	0	0	0
精神神経症状	2 (40.0%)	1 (50.0%)	1 (1.8%)	6 (21.4%)	2 (33.3%)	3 (4.5%)
視覚障害	0	1 (50.0%)	7 (12.7%)	14 (50.0%)	0	8 (11.9%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0
静脈内投与例	(N = 3)	(N = 1)	(N = 5)	(N = 1)	(N = 3)	(N = 6)
注入部位／注射部位反応	0	0	3 (60.0%)	0	0	3 (50.0%)
IRR	0	1 (100.0%)	0	0	0	1 (16.7%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_blood_eoi_2.sas
Program Run: 16JUN21:13:32:44

表 8-165 死亡に至った有害事象（血液悪性腫瘍の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
Overall	2 (40.0%)	0	2 (3.6%)	0	2 (33.3%)	4 (6.0%)
呼吸器、胸郭および縦隔障害	1 (20.0%)	0	1 (1.8%)	0	1 (16.7%)	2 (3.0%)
特発性肺炎症候群	1 (20.0%)	0	0	0	1 (16.7%)	0
肺臓炎	0	0	1 (1.8%)	0	0	1 (1.5%)
誤嚥性肺炎	0	0	0	0	0	1 (1.5%)
感染症および寄生虫症	1 (20.0%)	0	1 (1.8%)	0	1 (16.7%)	1 (1.5%)
肺炎球菌感染	0	0	1 (1.8%)	0	0	1 (1.5%)
副鼻腔炎	1 (20.0%)	0	0	0	1 (16.7%)	0
神経系障害	1 (20.0%)	0	0	0	1 (16.7%)	0
大脳基底核梗塞	1 (20.0%)	0	0	0	1 (16.7%)	0
心臓障害	0	0	0	0	0	1 (1.5%)
急性心筋梗塞	0	0	0	0	0	1 (1.5%)
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (1.5%)
死亡	0	0	0	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_2.sas
Program Run: 16JUN21:13:32:50

表 8-166 重篤な有害事象（血液悪性腫瘍の有無別）－AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
Overall	2 (40.0%)	0	11 (20.0%)	3 (10.7%)	3 (50.0%)	14 (20.9%)
感染症および寄生虫症	1 (20.0%)	0	5 (9.1%)	2 (7.1%)	2 (33.3%)	6 (9.0%)
肺炎	0	0	2 (3.6%)	1 (3.6%)	0	2 (3.0%)
感染性胸水	0	0	2 (3.6%)	0	0	2 (3.0%)
気管支炎	0	0	1 (1.8%)	0	0	1 (1.5%)
肺炎球菌感染	0	0	1 (1.8%)	0	0	1 (1.5%)
副鼻腔炎	1 (20.0%)	0	0	0	1 (16.7%)	0
アスペルギルス感染	0	0	0	1 (3.6%)	0	0
菌血症	0	0	0	0	1 (16.7%)	0
蜂巣炎	0	0	0	0	0	1 (1.5%)
呼吸器、胸郭および縦隔障害	1 (20.0%)	0	3 (5.5%)	0	1 (16.7%)	4 (6.0%)
喀血	0	0	1 (1.8%)	0	0	1 (1.5%)
特発性肺炎症候群	1 (20.0%)	0	0	0	1 (16.7%)	0
肺臓炎	0	0	1 (1.8%)	0	0	1 (1.5%)
気胸	0	0	1 (1.8%)	0	0	1 (1.5%)
誤嚥性肺炎	0	0	0	0	0	1 (1.5%)
肝胆道系障害	0	0	1 (1.8%)	1 (3.6%)	0	1 (1.5%)
胆嚢炎	0	0	1 (1.8%)	0	0	1 (1.5%)
薬物性肝障害	0	0	0	1 (3.6%)	0	0
筋骨格系および結合組織障害	0	0	1 (1.8%)	1 (3.6%)	0	1 (1.5%)
筋力低下	0	0	1 (1.8%)	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_ser_2.sas
Program Run: 16JUN21:13:32:57

表 8-166 重篤な有害事象（血液悪性腫瘍の有無別）－AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
横紋筋融解症	0	0	0	1 (3.6%)	0	0
内分泌障害	0	0	1 (1.8%)	0	0	1 (1.5%)
抗利尿ホルモン不適合分泌	0	0	1 (1.8%)	0	0	1 (1.5%)
代謝および栄養障害	0	0	1 (1.8%)	0	0	1 (1.5%)
低ナトリウム血症	0	0	1 (1.8%)	0	0	1 (1.5%)
神経系障害	1 (20.0%)	0	0	0	1 (16.7%)	0
大脳基底核梗塞	1 (20.0%)	0	0	0	1 (16.7%)	0
腎および尿路障害	0	0	1 (1.8%)	0	0	1 (1.5%)
腎機能障害	0	0	1 (1.8%)	0	0	1 (1.5%)
心臓障害	0	0	0	0	0	2 (3.0%)
急性心筋梗塞	0	0	0	0	0	1 (1.5%)
急性心不全	0	0	0	0	0	1 (1.5%)
血液およびリンパ系障害	0	0	0	0	1 (16.7%)	0
好中球減少症	0	0	0	0	1 (16.7%)	0
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (1.5%)
死亡	0	0	0	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_ser_2.sas
Program Run: 16JUN21:13:32:57

表 8-167 投与中止に至った有害事象（血液悪性腫瘍の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
Overall	2 (40.0%)	0	8 (14.5%)	4 (14.3%)	2 (33.3%)	9 (13.4%)
肝胆道系障害	1 (20.0%)	0	1 (1.8%)	2 (7.1%)	1 (16.7%)	1 (1.5%)
肝機能異常	1 (20.0%)	0	1 (1.8%)	1 (3.6%)	1 (16.7%)	1 (1.5%)
薬物性肝障害	0	0	0	1 (3.6%)	0	0
感染症および寄生虫症	0	0	2 (3.6%)	0	0	2 (3.0%)
感染性胸水	0	0	1 (1.8%)	0	0	1 (1.5%)
肺炎球菌感染	0	0	1 (1.8%)	0	0	1 (1.5%)
代謝および栄養障害	0	0	2 (3.6%)	0	0	2 (3.0%)
高カリウム血症	0	0	1 (1.8%)	0	0	1 (1.5%)
低ナトリウム血症	0	0	1 (1.8%)	0	0	1 (1.5%)
神経系障害	0	0	1 (1.8%)	1 (3.6%)	0	1 (1.5%)
感覚鈍麻	0	0	1 (1.8%)	0	0	1 (1.5%)
多発ニューロパチー	0	0	0	1 (3.6%)	0	0
臨床検査	1 (20.0%)	0	0	0	1 (16.7%)	1 (1.5%)
肝機能検査値上昇	1 (20.0%)	0	0	0	1 (16.7%)	0
心電図異常	0	0	0	0	0	1 (1.5%)
耳および迷路障害	0	0	1 (1.8%)	0	0	1 (1.5%)
耳管開放	0	0	1 (1.8%)	0	0	1 (1.5%)
胃腸障害	0	0	1 (1.8%)	0	0	1 (1.5%)
悪心	0	0	1 (1.8%)	0	0	1 (1.5%)
一般・全身障害および投与部位の状態	0	0	1 (1.8%)	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_2.sas
Program Run: 16JUN21:13:33:02

表 8-167 投与中止に至った有害事象（血液悪性腫瘍の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 5)	VRC (N = 2)	ISA (N = 55)	VRC (N = 28)	ISA (N = 6)	ISA (N = 67)
注射部位蕁麻疹	0	0	1 (1.8%)	0	0	1 (1.5%)
腎および尿路障害	0	0	1 (1.8%)	0	0	1 (1.5%)
腎機能障害	0	0	1 (1.8%)	0	0	1 (1.5%)
呼吸器、胸郭および縦隔障害	0	0	1 (1.8%)	0	0	1 (1.5%)
呼吸困難	0	0	1 (1.8%)	0	0	1 (1.5%)
口腔咽頭不快感	0	0	1 (1.8%)	0	0	1 (1.5%)
皮膚および皮下組織障害	0	0	1 (1.8%)	0	0	1 (1.5%)
冷汗	0	0	1 (1.8%)	0	0	1 (1.5%)
眼障害	0	0	0	1 (3.6%)	0	0
視力障害	0	0	0	1 (3.6%)	0	0
筋骨格系および結合組織障害	0	0	0	1 (3.6%)	0	0
横紋筋融解症	0	0	0	1 (3.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_2.sas
Program Run: 16JUN21:13:33:02

表 8-168 SOC別の有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
Overall	205 (97.2%)	219 (98.6%)	42 (91.3%)	36 (97.3%)	267 (97.4%)	119 (92.2%)
胃腸障害	150 (71.1%)	158 (71.2%)	24 (52.2%)	22 (59.5%)	189 (69.0%)	68 (52.7%)
感染症および寄生虫症	127 (60.2%)	140 (63.1%)	25 (54.3%)	18 (48.6%)	173 (63.1%)	70 (54.3%)
全身障害および投与局所様態	131 (62.1%)	132 (59.5%)	17 (37.0%)	12 (32.4%)	167 (60.9%)	49 (38.0%)
呼吸器、胸郭および縦隔障害	123 (58.3%)	128 (57.7%)	20 (43.5%)	19 (51.4%)	158 (57.7%)	48 (37.2%)
代謝および栄養障害	91 (43.1%)	106 (47.7%)	17 (37.0%)	15 (40.5%)	127 (46.4%)	43 (33.3%)
神経系障害	81 (38.4%)	81 (36.5%)	14 (30.4%)	8 (21.6%)	100 (36.5%)	45 (34.9%)
皮膚および皮下組織障害	73 (34.6%)	104 (46.8%)	13 (28.3%)	6 (16.2%)	92 (33.6%)	33 (25.6%)
臨床検査	75 (35.5%)	82 (36.9%)	10 (21.7%)	14 (37.8%)	94 (34.3%)	25 (19.4%)
血液およびリンパ系障害	63 (29.9%)	79 (35.6%)	14 (30.4%)	3 (8.1%)	81 (29.6%)	25 (19.4%)
精神障害	58 (27.5%)	78 (35.1%)	12 (26.1%)	8 (21.6%)	78 (28.5%)	27 (20.9%)
筋骨格系および結合組織障害	61 (28.9%)	70 (31.5%)	8 (17.4%)	7 (18.9%)	76 (27.7%)	33 (25.6%)
血管障害	52 (24.6%)	69 (31.1%)	15 (32.6%)	8 (21.6%)	73 (26.6%)	28 (21.7%)
腎および尿路障害	48 (22.7%)	54 (24.3%)	7 (15.2%)	4 (10.8%)	63 (23.0%)	18 (14.0%)
心臓障害	37 (17.5%)	53 (23.9%)	6 (13.0%)	4 (10.8%)	55 (20.1%)	13 (10.1%)
眼障害	31 (14.7%)	56 (25.2%)	8 (17.4%)	13 (35.1%)	42 (15.3%)	16 (12.4%)
傷害、中毒および処置合併症	29 (13.7%)	34 (15.3%)	4 (8.7%)	5 (13.5%)	41 (15.0%)	14 (10.9%)
肝胆道系障害	20 (9.5%)	38 (17.1%)	3 (6.5%)	4 (10.8%)	30 (10.9%)	9 (7.0%)
免疫系障害	17 (8.1%)	25 (11.3%)	3 (6.5%)	0	25 (9.1%)	4 (3.1%)
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）	17 (8.1%)	28 (12.6%)	2 (4.3%)	3 (8.1%)	26 (9.5%)	3 (2.3%)
耳および迷路障害	11 (5.2%)	13 (5.9%)	3 (6.5%)	0	14 (5.1%)	7 (5.4%)
生殖系および乳房障害	6 (2.8%)	12 (5.4%)	2 (4.3%)	1 (2.7%)	11 (4.0%)	6 (4.7%)
内分泌障害	3 (1.4%)	3 (1.4%)	2 (4.3%)	0	6 (2.2%)	4 (3.1%)
先天性、家族性および遺伝性障害	3 (1.4%)	2 (0.9%)	0	0	3 (1.1%)	0
社会環境	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_soc_1.sas
Program Run: 04JUN21:15:20:14

表 8-169 注目すべき有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
肝機能異常・肝炎	47 (22.3%)	74 (33.3%)	6 (13.0%)	8 (21.6%)	64 (23.4%)	18 (14.0%)
アナフィラキシー	2 (0.9%)	3 (1.4%)	0	0	2 (0.7%)	0
重度皮膚障害	3 (1.4%)	2 (0.9%)	0	0	3 (1.1%)	0
心電図QT短縮	1 (0.5%)	0	0	0	1 (0.4%)	0
トルサード ド ポアント	11 (5.2%)	15 (6.8%)	4 (8.7%)	4 (10.8%)	14 (5.1%)	4 (3.1%)
急性膵炎	0	0	0	0	0	1 (0.8%)
精神神経症状	61 (28.9%)	72 (32.4%)	12 (26.1%)	7 (18.9%)	80 (29.2%)	30 (23.3%)
視覚障害	20 (9.5%)	36 (16.2%)	3 (6.5%)	11 (29.7%)	26 (9.5%)	5 (3.9%)
皮膚または子宮の悪性腫瘍	1 (0.5%)	0	0	0	1 (0.4%)	0
静脈内投与例	(N = 211)	(N = 222)	(N = 46)	(N = 37)	(N = 265)	(N = 92)
注入部位／注射部位反応	9 (4.3%)	4 (1.8%)	2 (4.3%)	0	11 (4.2%)	5 (5.4%)
IRR	59 (28.0%)	66 (29.7%)	11 (23.9%)	10 (27.0%)	78 (29.4%)	24 (26.1%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_blood_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-170 死亡に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
Overall	54 (25.6%)	65 (29.3%)	8 (17.4%)	7 (18.9%)	86 (31.4%)	20 (15.5%)
感染症および寄生虫症	24 (11.4%)	15 (6.8%)	4 (8.7%)	3 (8.1%)	39 (14.2%)	10 (7.8%)
敗血症性ショック	6 (2.8%)	4 (1.8%)	2 (4.3%)	0	9 (3.3%)	3 (2.3%)
敗血症	7 (3.3%)	3 (1.4%)	0	2 (5.4%)	8 (2.9%)	0
アスペルギルス症	3 (1.4%)	2 (0.9%)	0	0	4 (1.5%)	0
真菌感染	2 (0.9%)	1 (0.5%)	1 (2.2%)	1 (2.7%)	2 (0.7%)	1 (0.8%)
肺炎	1 (0.5%)	1 (0.5%)	0	1 (2.7%)	2 (0.7%)	1 (0.8%)
ムコール症	0	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
アシネトバクター性菌血症	1 (0.5%)	0	0	0	1 (0.4%)	0
気管支肺アスペルギルス症	1 (0.5%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.5%)	0	0	0	1 (0.4%)	0
フサリウム感染	1 (0.5%)	0	0	0	1 (0.4%)	0
感染	1 (0.5%)	0	0	0	1 (0.4%)	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	1 (0.4%)	0
クレブシエラ性敗血症	0	1 (0.5%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
真菌性肺炎	0	0	0	0	2 (0.7%)	0
細菌性敗血症	0	0	0	0	0	1 (0.8%)
蓄膿	0	0	0	0	1 (0.4%)	0
真菌性敗血症	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_1.sas
Program Run: 04JUN21:14:56:25

表 8-170 死亡に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
肺感染	0	0	0	0	0	1 (0.8%)
シュードモナス菌性肺感染	0	0	0	0	1 (0.4%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.8%)
原発性異型肺炎	0	0	0	0	0	1 (0.8%)
真菌性副鼻腔炎	0	0	0	0	1 (0.4%)	0
ブドウ球菌性敗血症	0	0	0	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害	11 (5.2%)	10 (4.5%)	3 (6.5%)	2 (5.4%)	12 (4.4%)	6 (4.7%)
呼吸不全	5 (2.4%)	5 (2.3%)	1 (2.2%)	1 (2.7%)	5 (1.8%)	2 (1.6%)
急性呼吸不全	2 (0.9%)	1 (0.5%)	1 (2.2%)	0	2 (0.7%)	2 (1.6%)
喀血	1 (0.5%)	1 (0.5%)	1 (2.2%)	0	1 (0.4%)	2 (1.6%)
肺出血	2 (0.9%)	0	0	1 (2.7%)	2 (0.7%)	0
呼吸窮迫	1 (0.5%)	0	0	0	1 (0.4%)	0
急性呼吸窮迫症候群	0	1 (0.5%)	0	0	0	0
肺塞栓症	0	1 (0.5%)	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸困難	0	0	0	0	1 (0.4%)	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)	10 (4.7%)	21 (9.5%)	0	0	16 (5.8%)	1 (0.8%)
急性骨髄性白血病	3 (1.4%)	7 (3.2%)	0	0	4 (1.5%)	0
多発性骨髄腫	2 (0.9%)	0	0	0	2 (0.7%)	0
悪性新生物進行	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	1 (0.8%)
芽球発症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_1.sas
Program Run: 04JUN21:14:56:25

表 8-170 死亡に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
再発慢性リンパ性白血病	1 (0.5%)	0	0	0	1 (0.4%)	0
骨髄異形成症候群	1 (0.5%)	0	0	0	1 (0.4%)	0
再発急性骨髄性白血病	0	4 (1.8%)	0	0	1 (0.4%)	0
慢性リンパ性白血病	0	2 (0.9%)	0	0	1 (0.4%)	0
再発急性リンパ性白血病	0	1 (0.5%)	0	0	1 (0.4%)	0
Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
リンパ腫	0	1 (0.5%)	0	0	0	0
新生物進行	0	1 (0.5%)	0	0	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
心臓障害	4 (1.9%)	4 (1.8%)	0	1 (2.7%)	7 (2.6%)	0
心停止	1 (0.5%)	3 (1.4%)	0	0	1 (0.4%)	0
心肺停止	1 (0.5%)	1 (0.5%)	0	0	3 (1.1%)	0
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.4%)	0
心膜炎	1 (0.5%)	0	0	0	1 (0.4%)	0
急性心筋梗塞	0	0	0	1 (2.7%)	0	0
急性心不全	0	0	0	0	1 (0.4%)	0
神経系障害	3 (1.4%)	7 (3.2%)	0	0	4 (1.5%)	1 (0.8%)
頭蓋内出血	2 (0.9%)	3 (1.4%)	0	0	2 (0.7%)	0
神経毒性	1 (0.5%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_1.sas
Program Run: 04JUN21:14:56:25

表 8-170 死亡に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
脳出血	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	1 (0.4%)	1 (0.8%)
全身障害および投与局所様態	2 (0.9%)	7 (3.2%)	0	1 (2.7%)	6 (2.2%)	1 (0.8%)
多臓器不全	1 (0.5%)	6 (2.7%)	0	0	2 (0.7%)	0
死亡	1 (0.5%)	0	0	1 (2.7%)	4 (1.5%)	0
心突然死	0	1 (0.5%)	0	0	0	0
全身健康状態低下	0	0	0	0	0	1 (0.8%)
血管障害	2 (0.9%)	1 (0.5%)	0	0	3 (1.1%)	0
出血	1 (0.5%)	0	0	0	1 (0.4%)	0
血液量減少性ショック	1 (0.5%)	0	0	0	1 (0.4%)	0
深部静脈血栓症	0	1 (0.5%)	0	0	0	0
動脈炎	0	0	0	0	1 (0.4%)	0
血液およびリンパ系障害	1 (0.5%)	1 (0.5%)	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
出血性障害	0	0	1 (2.2%)	0	0	1 (0.8%)
血小板減少症	1 (0.5%)	0	0	0	1 (0.4%)	0
汎血球減少症	0	1 (0.5%)	0	0	0	0
免疫系障害	0	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
急性移植片対宿主病	0	0	1 (2.2%)	0	0	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_1.sas
Program Run: 04JUN21:14:56:25

表 8-170 死亡に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
移植片対宿主病	0	0	0	0	1 (0.4%)	0
腎および尿路障害	1 (0.5%)	0	0	0	2 (0.7%)	0
腎不全	1 (0.5%)	0	0	0	1 (0.4%)	0
急性腎不全	0	0	0	0	1 (0.4%)	0
肝胆道系障害	1 (0.5%)	0	0	0	1 (0.4%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.4%)	0
代謝および栄養障害	0	2 (0.9%)	0	0	0	0
低血糖症	0	1 (0.5%)	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0
胃腸障害	0	1 (0.5%)	0	0	0	0
直腸出血	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_death_1.sas
Program Run: 04JUN21:14:56:25

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
Overall	115 (54.5%)	132 (59.5%)	19 (41.3%)	17 (45.9%)	165 (60.2%)	58 (45.0%)
感染症および寄生虫症	45 (21.3%)	53 (23.9%)	6 (13.0%)	8 (21.6%)	77 (28.1%)	29 (22.5%)
敗血症性ショック	11 (5.2%)	9 (4.1%)	3 (6.5%)	1 (2.7%)	15 (5.5%)	5 (3.9%)
敗血症	7 (3.3%)	6 (2.7%)	0	2 (5.4%)	9 (3.3%)	1 (0.8%)
肺炎	5 (2.4%)	9 (4.1%)	0	1 (2.7%)	8 (2.9%)	4 (3.1%)
アスペルギルス症	4 (1.9%)	3 (1.4%)	0	0	7 (2.6%)	0
真菌感染	2 (0.9%)	2 (0.9%)	1 (2.2%)	1 (2.7%)	3 (1.1%)	1 (0.8%)
サイトメガロウイルス感染	1 (0.5%)	2 (0.9%)	1 (2.2%)	0	1 (0.4%)	3 (2.3%)
気管支肺アスペルギルス症	2 (0.9%)	1 (0.5%)	0	0	2 (0.7%)	0
シュードモナス性敗血症	1 (0.5%)	1 (0.5%)	0	0	3 (1.1%)	0
大腸菌性敗血症	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	0
尿路感染	1 (0.5%)	0	0	1 (2.7%)	1 (0.4%)	1 (0.8%)
蜂巣炎	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
クレブシエラ性菌血症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
クレブシエラ性敗血症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
ムコール症	0	0	1 (2.2%)	0	1 (0.4%)	2 (1.6%)
クロストリジウム・ディフィシレ大腸炎	1 (0.5%)	0	0	0	2 (0.7%)	0
腸球菌性菌血症	1 (0.5%)	0	0	0	2 (0.7%)	0
ブドウ球菌感染	1 (0.5%)	0	0	0	1 (0.4%)	1 (0.8%)
アシネトバクター性菌血症	1 (0.5%)	0	0	0	1 (0.4%)	0
肺炎球菌性気管支炎	0	0	1 (2.2%)	0	0	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
気管支肺炎	1 (0.5%)	0	0	0	1 (0.4%)	0
脳アスペルギルス症	1 (0.5%)	0	0	0	1 (0.4%)	0
サイトメガロウイルス血症	1 (0.5%)	0	0	0	1 (0.4%)	0
ヘルペス脳炎	1 (0.5%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.5%)	0	0	0	1 (0.4%)	0
フサリウム感染	1 (0.5%)	0	0	0	1 (0.4%)	0
感染	1 (0.5%)	0	0	0	1 (0.4%)	0
注入部位感染	1 (0.5%)	0	0	0	1 (0.4%)	0
筋膿瘍	1 (0.5%)	0	0	0	1 (0.4%)	0
モラクセラ菌性肺炎	1 (0.5%)	0	0	0	1 (0.4%)	0
気道感染	1 (0.5%)	0	0	0	1 (0.4%)	0
敗血症症候群	0	0	1 (2.2%)	0	0	1 (0.8%)
皮膚感染	1 (0.5%)	0	0	0	1 (0.4%)	0
細菌性敗血症	0	4 (1.8%)	0	0	0	1 (0.8%)
ブドウ球菌性菌血症	0	3 (1.4%)	0	0	1 (0.4%)	0
菌血症	0	1 (0.5%)	0	1 (2.7%)	2 (0.7%)	1 (0.8%)
ブドウ球菌性敗血症	0	2 (0.9%)	0	0	1 (0.4%)	0
クロストリジウム性菌血症	0	2 (0.9%)	0	0	0	0
髄膜炎	0	2 (0.9%)	0	0	0	0
細菌性肺炎	0	1 (0.5%)	0	0	2 (0.7%)	1 (0.8%)
帯状疱疹	0	1 (0.5%)	0	0	1 (0.4%)	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
蓄膿	0	0	0	1 (2.7%)	1 (0.4%)	0
カンピロバクター胃腸炎	0	1 (0.5%)	0	0	0	0
カテーテル関連感染	0	1 (0.5%)	0	0	0	0
感染性下痢	0	1 (0.5%)	0	0	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (2.7%)	0	0
単純ヘルペス	0	1 (0.5%)	0	0	0	0
肺膿瘍	0	1 (0.5%)	0	0	0	0
壊死性筋膜炎	0	1 (0.5%)	0	0	0	0
肺炎球菌性肺炎	0	1 (0.5%)	0	0	0	0
ブドウ球菌性肺炎	0	1 (0.5%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.5%)	0	0	0	0
シュードモナス感染	0	1 (0.5%)	0	0	0	0
膿胸	0	0	0	1 (2.7%)	0	0
ステノトロフォモナス性敗血症	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0
トキソプラズマ症	0	1 (0.5%)	0	0	0	0
結核	0	1 (0.5%)	0	0	0	0
細菌性尿路感染	0	0	0	1 (2.7%)	0	0
真菌性肺炎	0	0	0	0	2 (0.7%)	0
接合真菌症	0	0	0	0	2 (0.7%)	0
腹部膿瘍	0	0	0	0	1 (0.4%)	0

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A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
虫垂炎	0	0	0	0	0	1 (0.8%)
ＢＫウイルス感染	0	0	0	0	1 (0.4%)	0
脳膿瘍	0	0	0	0	1 (0.4%)	0
気管支拡張症	0	0	0	0	0	1 (0.8%)
細気管支炎	0	0	0	0	0	1 (0.8%)
カテーテル留置部位感染	0	0	0	0	1 (0.4%)	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.8%)
大腸菌性菌血症	0	0	0	0	0	1 (0.8%)
真菌性敗血症	0	0	0	0	1 (0.4%)	0
ノロウイルス性胃腸炎	0	0	0	0	1 (0.4%)	0
ウイルス性胃腸炎	0	0	0	0	1 (0.4%)	0
インフルエンザ	0	0	0	0	1 (0.4%)	0
肺感染	0	0	0	0	0	1 (0.8%)
シュードモナス菌性肺感染	0	0	0	0	1 (0.4%)	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	1 (0.4%)	0
ブラストミセス菌性肺炎	0	0	0	0	0	1 (0.8%)
インフルエンザ性肺炎	0	0	0	0	1 (0.4%)	0
原発性異型肺炎	0	0	0	0	0	1 (0.8%)
シュードモナス性気管支炎	0	0	0	0	0	1 (0.8%)
副鼻腔炎	0	0	0	0	1 (0.4%)	0
真菌性副鼻腔炎	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
レンサ球菌性菌血症	0	0	0	0	1 (0.4%)	0
皮下組織膿瘍	0	0	0	0	0	1 (0.8%)
尿路性敗血症	0	0	0	0	0	1 (0.8%)
ウイルス性下痢	0	0	0	0	1 (0.4%)	0
呼吸器、胸郭および縦隔障害	34 (16.1%)	37 (16.7%)	7 (15.2%)	6 (16.2%)	46 (16.8%)	15 (11.6%)
呼吸不全	13 (6.2%)	10 (4.5%)	1 (2.2%)	2 (5.4%)	16 (5.8%)	3 (2.3%)
急性呼吸不全	4 (1.9%)	4 (1.8%)	1 (2.2%)	1 (2.7%)	6 (2.2%)	2 (1.6%)
呼吸困難	4 (1.9%)	1 (0.5%)	1 (2.2%)	0	5 (1.8%)	1 (0.8%)
呼吸窮迫	3 (1.4%)	3 (1.4%)	1 (2.2%)	0	3 (1.1%)	1 (0.8%)
喀血	1 (0.5%)	2 (0.9%)	1 (2.2%)	0	1 (0.4%)	3 (2.3%)
低酸素症	2 (0.9%)	1 (0.5%)	0	0	3 (1.1%)	0
肺出血	2 (0.9%)	0	0	1 (2.7%)	2 (0.7%)	0
胸水	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	0
肺水腫	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	0
肺障害	1 (0.5%)	0	0	1 (2.7%)	1 (0.4%)	0
呼吸抑制	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
嚥下性肺炎	0	0	1 (2.2%)	0	2 (0.7%)	1 (0.8%)
頻呼吸	0	0	1 (2.2%)	0	0	2 (1.6%)
気管支胸膜瘻	0	0	1 (2.2%)	0	0	1 (0.8%)
気管支痙攣	0	0	1 (2.2%)	0	0	1 (0.8%)
水気胸	1 (0.5%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
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表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
胸膜痛	1 (0.5%)	0	0	0	1 (0.4%)	0
呼吸性アシドーシス	1 (0.5%)	0	0	0	1 (0.4%)	0
鼻出血	0	4 (1.8%)	0	0	0	0
肺塞栓症	0	2 (0.9%)	0	1 (2.7%)	0	1 (0.8%)
肺浸潤	0	3 (1.4%)	0	0	0	0
急性呼吸窮迫症候群	0	2 (0.9%)	0	0	0	1 (0.8%)
急性肺損傷	0	1 (0.5%)	0	0	0	0
慢性閉塞性肺疾患	0	0	0	1 (2.7%)	0	0
咳嗽	0	1 (0.5%)	0	0	0	0
血胸	0	0	0	1 (2.7%)	0	0
気胸	0	1 (0.5%)	0	0	0	0
湿性咳嗽	0	1 (0.5%)	0	0	0	0
肺高血圧症	0	1 (0.5%)	0	0	0	0
呼吸停止	0	1 (0.5%)	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.8%)
肺胞出血	0	0	0	0	1 (0.4%)	0
肺梗塞	0	0	0	0	1 (0.4%)	0
副鼻腔障害	0	0	0	0	1 (0.4%)	0
喘鳴	0	0	0	0	0	1 (0.8%)
血液およびリンパ系障害	24 (11.4%)	16 (7.2%)	4 (8.7%)	1 (2.7%)	29 (10.6%)	4 (3.1%)
発熱性好中球減少症	12 (5.7%)	5 (2.3%)	2 (4.3%)	0	14 (5.1%)	2 (1.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
汎血球減少症	4 (1.9%)	3 (1.4%)	0	0	5 (1.8%)	0
好中球減少症	4 (1.9%)	3 (1.4%)	0	0	4 (1.5%)	0
血小板減少症	3 (1.4%)	4 (1.8%)	0	0	3 (1.1%)	0
無顆粒球症	1 (0.5%)	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
貧血	1 (0.5%)	2 (0.9%)	0	0	3 (1.1%)	0
出血性障害	0	0	1 (2.2%)	0	0	1 (0.8%)
白血球増加症	1 (0.5%)	0	0	0	1 (0.4%)	0
脾臓梗塞	1 (0.5%)	0	0	0	1 (0.4%)	0
出血性貧血	0	0	0	1 (2.7%)	0	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
血小板減少性紫斑病	0	1 (0.5%)	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)	16 (7.6%)	27 (12.2%)	2 (4.3%)	2 (5.4%)	23 (8.4%)	3 (2.3%)
急性骨髄性白血病	3 (1.4%)	8 (3.6%)	0	0	5 (1.8%)	0
リンパ腫	1 (0.5%)	1 (0.5%)	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
多発性骨髄腫	2 (0.9%)	0	0	0	2 (0.7%)	0
悪性新生物進行	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	1 (0.8%)
再発急性リンパ性白血病	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	0
芽球発症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
骨髄性白血病	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
新生物進行	0	1 (0.5%)	1 (2.2%)	0	0	1 (0.8%)
再発慢性リンパ性白血病	1 (0.5%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
子宮内膜癌	1 (0.5%)	0	0	0	1 (0.4%)	0
髄膜転移	1 (0.5%)	0	0	0	1 (0.4%)	0
骨髄異形成症候群	1 (0.5%)	0	0	0	1 (0.4%)	0
非ホジキンリンパ腫	1 (0.5%)	0	0	0	1 (0.4%)	0
原発性体腔性リンパ腫	1 (0.5%)	0	0	0	1 (0.4%)	0
再発急性骨髄性白血病	0	5 (2.3%)	0	0	2 (0.7%)	0
慢性リンパ性白血病	0	2 (0.9%)	0	0	1 (0.4%)	0
急性白血病	0	1 (0.5%)	0	0	0	0
急性リンパ性白血病	0	1 (0.5%)	0	0	0	0
Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
再発Ｂ細胞性リンパ腫	0	1 (0.5%)	0	0	0	0
バーキット白血病	0	1 (0.5%)	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.5%)	0	0	0	0
白血病	0	1 (0.5%)	0	0	0	0
肺の悪性新生物	0	0	0	1 (2.7%)	0	0
骨転移	0	1 (0.5%)	0	0	0	0
転移部痛	0	0	0	1 (2.7%)	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
白血病浸潤	0	0	0	0	1 (0.4%)	0
神経系障害	15 (7.1%)	16 (7.2%)	2 (4.3%)	0	19 (6.9%)	7 (5.4%)
痙攣	3 (1.4%)	1 (0.5%)	0	0	4 (1.5%)	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
頭蓋内出血	2 (0.9%)	3 (1.4%)	0	0	2 (0.7%)	0
てんかん	1 (0.5%)	1 (0.5%)	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
多発ニューロパチー	2 (0.9%)	0	0	0	2 (0.7%)	0
中枢神経系病変	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
脳症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
虚血性脳卒中	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
対麻痺	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
頭痛	0	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
脳幹卒中	1 (0.5%)	0	0	0	1 (0.4%)	0
脳虚血	1 (0.5%)	0	0	0	1 (0.4%)	0
熱性痙攣	1 (0.5%)	0	0	0	1 (0.4%)	0
神経毒性	1 (0.5%)	0	0	0	1 (0.4%)	0
失語症	0	1 (0.5%)	0	0	1 (0.4%)	0
脳出血	0	1 (0.5%)	0	0	0	0
浮動性めまい	0	1 (0.5%)	0	0	0	0
脳炎	0	1 (0.5%)	0	0	0	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
片麻痺	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
第 7 脳神経麻痺	0	1 (0.5%)	0	0	0	0
脳梗塞	0	0	0	0	2 (0.7%)	1 (0.8%)
脳血管発作	0	0	0	0	0	1 (0.8%)
卒中の出血性変化	0	0	0	0	0	1 (0.8%)
不全片麻痺	0	0	0	0	0	1 (0.8%)
一過性脳虚血発作	0	0	0	0	0	1 (0.8%)
全身障害および投与局所様態	10 (4.7%)	17 (7.7%)	1 (2.2%)	2 (5.4%)	16 (5.8%)	4 (3.1%)
発熱	7 (3.3%)	9 (4.1%)	1 (2.2%)	1 (2.7%)	9 (3.3%)	1 (0.8%)
多臓器不全	1 (0.5%)	7 (3.2%)	0	0	2 (0.7%)	0
死亡	1 (0.5%)	0	0	1 (2.7%)	4 (1.5%)	0
悪寒	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
全身健康状態低下	1 (0.5%)	0	0	0	1 (0.4%)	1 (0.8%)
無力症	1 (0.5%)	0	0	0	1 (0.4%)	0
胸痛	1 (0.5%)	0	0	0	1 (0.4%)	0
心突然死	0	1 (0.5%)	0	0	0	0
非心臓性胸痛	0	0	0	0	0	2 (1.6%)
末梢性浮腫	0	0	0	0	1 (0.4%)	0
心臓障害	8 (3.8%)	10 (4.5%)	3 (6.5%)	2 (5.4%)	15 (5.5%)	4 (3.1%)
心肺停止	1 (0.5%)	2 (0.9%)	1 (2.2%)	0	3 (1.1%)	1 (0.8%)
心停止	1 (0.5%)	4 (1.8%)	0	1 (2.7%)	1 (0.4%)	0
心房細動	1 (0.5%)	1 (0.5%)	0	0	2 (0.7%)	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
急性心筋梗塞	1 (0.5%)	0	0	1 (2.7%)	2 (0.7%)	0
不整脈	1 (0.5%)	0	0	0	1 (0.4%)	0
心原性ショック	1 (0.5%)	0	0	0	1 (0.4%)	0
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.4%)	0
心膜炎	1 (0.5%)	0	0	0	1 (0.4%)	0
洞性徐脈	0	0	1 (2.2%)	0	0	1 (0.8%)
上室性頻脈	0	0	1 (2.2%)	0	0	1 (0.8%)
心室性頻脈	0	2 (0.9%)	0	0	0	0
狭心症	0	1 (0.5%)	0	0	0	0
完全房室ブロック	0	0	0	0	1 (0.4%)	0
急性心不全	0	0	0	0	1 (0.4%)	0
電気収縮解離	0	0	0	0	1 (0.4%)	0
腎および尿路障害	8 (3.8%)	9 (4.1%)	2 (4.3%)	1 (2.7%)	14 (5.1%)	5 (3.9%)
急性腎不全	4 (1.9%)	7 (3.2%)	2 (4.3%)	1 (2.7%)	10 (3.6%)	4 (3.1%)
腎不全	3 (1.4%)	2 (0.9%)	0	0	3 (1.1%)	1 (0.8%)
血尿	1 (0.5%)	0	0	0	1 (0.4%)	0
胃腸障害	6 (2.8%)	11 (5.0%)	3 (6.5%)	1 (2.7%)	15 (5.5%)	12 (9.3%)
下痢	2 (0.9%)	1 (0.5%)	0	0	3 (1.1%)	1 (0.8%)
小腸閉塞	0	0	2 (4.3%)	0	0	2 (1.6%)
悪心	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	2 (1.6%)
腸出血	0	1 (0.5%)	1 (2.2%)	0	0	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
腹膜炎	0	1 (0.5%)	1 (2.2%)	0	0	1 (0.8%)
腹痛	1 (0.5%)	0	0	0	3 (1.1%)	3 (2.3%)
大腸炎	0	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
便秘	1 (0.5%)	0	0	0	2 (0.7%)	0
胃穿孔	0	0	1 (2.2%)	0	0	1 (0.8%)
食道潰瘍	1 (0.5%)	0	0	0	1 (0.4%)	0
胃腸出血	0	3 (1.4%)	0	0	1 (0.4%)	2 (1.6%)
食中毒	0	0	0	1 (2.7%)	0	0
胃腸の炎症	0	1 (0.5%)	0	0	0	0
麻痺性イレウス	0	1 (0.5%)	0	0	0	0
肛門周囲痛	0	1 (0.5%)	0	0	0	0
直腸出血	0	1 (0.5%)	0	0	0	0
嘔吐	0	0	0	0	1 (0.4%)	3 (2.3%)
嚥下障害	0	0	0	0	0	2 (1.6%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.8%)
限局性腹腔内液貯留	0	0	0	0	1 (0.4%)	0
食道炎	0	0	0	0	1 (0.4%)	0
膵炎	0	0	0	0	0	1 (0.8%)
慢性膵炎	0	0	0	0	0	1 (0.8%)
再発性膵炎	0	0	0	0	0	1 (0.8%)
免疫系障害	3 (1.4%)	6 (2.7%)	1 (2.2%)	0	7 (2.6%)	2 (1.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
急性腸管移植片対宿主病	1 (0.5%)	2 (0.9%)	0	0	1 (0.4%)	0
急性移植片対宿主病	0	1 (0.5%)	1 (2.2%)	0	2 (0.7%)	1 (0.8%)
アナフィラキシーショック	1 (0.5%)	0	0	0	1 (0.4%)	0
過敏症	1 (0.5%)	0	0	0	1 (0.4%)	0
アナフィラキシー反応	0	2 (0.9%)	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0
移植片対宿主病	0	0	0	0	2 (0.7%)	0
肺移植拒絶反応	0	0	0	0	0	1 (0.8%)
血管障害	4 (1.9%)	4 (1.8%)	0	2 (5.4%)	8 (2.9%)	1 (0.8%)
低血圧	1 (0.5%)	2 (0.9%)	0	0	3 (1.1%)	0
出血	1 (0.5%)	0	0	1 (2.7%)	1 (0.4%)	0
血液量減少性ショック	1 (0.5%)	0	0	1 (2.7%)	1 (0.4%)	0
血管炎	1 (0.5%)	0	0	0	1 (0.4%)	0
深部静脈血栓症	0	1 (0.5%)	0	0	1 (0.4%)	1 (0.8%)
ショック	0	1 (0.5%)	0	0	0	0
動脈炎	0	0	0	0	1 (0.4%)	0
肝胆道系障害	2 (0.9%)	6 (2.7%)	1 (2.2%)	0	4 (1.5%)	4 (3.1%)
胆嚢炎	0	0	1 (2.2%)	0	0	2 (1.6%)
肝炎	1 (0.5%)	0	0	0	1 (0.4%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.4%)	0
肝不全	0	2 (0.9%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
肝機能異常	0	2 (0.9%)	0	0	0	0
高ビリルビン血症	0	2 (0.9%)	0	0	0	0
急性胆嚢炎	0	1 (0.5%)	0	0	0	0
急性肝不全	0	0	0	0	1 (0.4%)	0
細胆管炎	0	0	0	0	0	1 (0.8%)
胆石症	0	0	0	0	1 (0.4%)	0
肝障害	0	0	0	0	0	1 (0.8%)
臨床検査	3 (1.4%)	5 (2.3%)	0	1 (2.7%)	3 (1.1%)	0
肝機能検査異常	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
血中ナトリウム減少	1 (0.5%)	0	0	0	1 (0.4%)	0
ヘモグロビン減少	1 (0.5%)	0	0	0	1 (0.4%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	1 (2.7%)	0	0
血中ビリルビン増加	0	1 (0.5%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
肝酵素上昇	0	1 (0.5%)	0	0	0	0
傷害、中毒および処置合併症	3 (1.4%)	3 (1.4%)	0	0	3 (1.1%)	0
薬物毒性	2 (0.9%)	0	0	0	2 (0.7%)	0
転倒・転落	1 (0.5%)	0	0	0	1 (0.4%)	0
家庭内事故	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
大腿骨頚部骨折	0	1 (0.5%)	0	0	0	0
橈骨骨折	0	1 (0.5%)	0	0	0	0
皮膚および皮下組織障害	3 (1.4%)	2 (0.9%)	0	0	3 (1.1%)	0
褥瘡性潰瘍	1 (0.5%)	0	0	0	1 (0.4%)	0
皮膚炎	1 (0.5%)	0	0	0	1 (0.4%)	0
脂肪織炎	1 (0.5%)	0	0	0	1 (0.4%)	0
発疹	0	2 (0.9%)	0	0	0	0
筋骨格系および結合組織障害	2 (0.9%)	0	1 (2.2%)	0	4 (1.5%)	3 (2.3%)
筋骨格系胸痛	1 (0.5%)	0	0	0	3 (1.1%)	0
筋肉内出血	0	0	1 (2.2%)	0	0	1 (0.8%)
筋炎	1 (0.5%)	0	0	0	1 (0.4%)	0
関節炎	0	0	0	0	0	1 (0.8%)
四肢痛	0	0	0	0	1 (0.4%)	0
全身性エリテマトーデス	0	0	0	0	0	1 (0.8%)
代謝および栄養障害	2 (0.9%)	6 (2.7%)	0	1 (2.7%)	3 (1.1%)	6 (4.7%)
コントロール不良の糖尿病	1 (0.5%)	0	0	0	1 (0.4%)	0
成長障害	1 (0.5%)	0	0	0	1 (0.4%)	0
脱水	0	1 (0.5%)	0	1 (2.7%)	0	3 (2.3%)
代謝性アシドーシス	0	2 (0.9%)	0	0	0	0
低血糖症	0	1 (0.5%)	0	0	0	1 (0.8%)
高ナトリウム血症	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
低カリウム血症	0	1 (0.5%)	0	0	0	0
過小食	0	1 (0.5%)	0	0	0	0
高カリウム血症	0	0	0	0	1 (0.4%)	0
低ナトリウム血症	0	0	0	0	0	1 (0.8%)
栄養障害	0	0	0	0	0	1 (0.8%)
眼障害	2 (0.9%)	1 (0.5%)	0	0	3 (1.1%)	1 (0.8%)
片側失明	1 (0.5%)	0	0	0	1 (0.4%)	0
視神経症	1 (0.5%)	0	0	0	1 (0.4%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0
網膜動脈閉塞	0	0	0	0	1 (0.4%)	0
網膜出血	0	0	0	0	0	1 (0.8%)
硝子体出血	0	0	0	0	0	1 (0.8%)
精神障害	1 (0.5%)	6 (2.7%)	0	0	2 (0.7%)	1 (0.8%)
うつ病	1 (0.5%)	0	0	0	1 (0.4%)	0
幻視	0	2 (0.9%)	0	0	0	0
精神状態変化	0	2 (0.9%)	0	0	0	0
錯乱状態	0	1 (0.5%)	0	0	0	1 (0.8%)
幻覚	0	1 (0.5%)	0	0	0	1 (0.8%)
抑うつ気分	0	1 (0.5%)	0	0	0	0
自殺企図	0	1 (0.5%)	0	0	0	0
異常行動	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-171 重篤な有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
攻撃性	0	0	0	0	1 (0.4%)	0
激越	0	0	0	0	1 (0.4%)	0
生殖系および乳房障害	0	0	0	0	1 (0.4%)	0
良性前立腺肥大症	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_blood_ser_1.sas
Program Run: 04JUN21:14:56:29

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
Overall	34 (16.1%)	53 (23.9%)	3 (6.5%)	6 (16.2%)	46 (16.8%)	10 (7.8%)
感染症および寄生虫症	11 (5.2%)	13 (5.9%)	0	2 (5.4%)	17 (6.2%)	1 (0.8%)
真菌感染	2 (0.9%)	1 (0.5%)	0	0	3 (1.1%)	0
敗血症性ショック	2 (0.9%)	0	0	0	4 (1.5%)	0
敗血症	1 (0.5%)	1 (0.5%)	0	2 (5.4%)	1 (0.4%)	0
アスペルギルス症	1 (0.5%)	1 (0.5%)	0	0	3 (1.1%)	0
肺炎	1 (0.5%)	0	0	1 (2.7%)	1 (0.4%)	0
気管支肺炎	1 (0.5%)	0	0	0	1 (0.4%)	0
気管支肺アスペルギルス症	1 (0.5%)	0	0	0	1 (0.4%)	0
心内膜炎	1 (0.5%)	0	0	0	1 (0.4%)	0
感染	1 (0.5%)	0	0	0	1 (0.4%)	0
細菌性敗血症	0	3 (1.4%)	0	0	0	0
肺感染	0	2 (0.9%)	0	0	0	0
髄膜炎	0	1 (0.5%)	0	0	0	0
ムコール症	0	1 (0.5%)	0	0	0	0
シュードモナス性敗血症	0	1 (0.5%)	0	0	0	0
ブドウ球菌感染	0	1 (0.5%)	0	0	0	0
全身性カンジダ	0	1 (0.5%)	0	0	0	0
脳膿瘍	0	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
大腸菌性菌血症	0	0	0	0	0	1 (0.8%)
呼吸器、胸郭および縦隔障害	6 (2.8%)	5 (2.3%)	0	0	6 (2.2%)	0
呼吸不全	2 (0.9%)	4 (1.8%)	0	0	2 (0.7%)	0
呼吸困難	2 (0.9%)	0	0	0	2 (0.7%)	0
呼吸窮迫	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
急性呼吸不全	1 (0.5%)	0	0	0	1 (0.4%)	0
神経系障害	4 (1.9%)	4 (1.8%)	1 (2.2%)	0	4 (1.5%)	3 (2.3%)
痙攣	2 (0.9%)	0	0	0	2 (0.7%)	0
てんかん	1 (0.5%)	0	1 (2.2%)	0	1 (0.4%)	1 (0.8%)
脳症	1 (0.5%)	0	0	0	1 (0.4%)	0
大発作痙攣	0	1 (0.5%)	0	0	0	0
昏迷	0	1 (0.5%)	0	0	0	0
くも膜下出血	0	1 (0.5%)	0	0	0	0
振戦	0	1 (0.5%)	0	0	0	0
脳血管発作	0	0	0	0	0	1 (0.8%)
卒中の出血性変化	0	0	0	0	0	1 (0.8%)
臨床検査	4 (1.9%)	5 (2.3%)	0	1 (2.7%)	5 (1.8%)	1 (0.8%)
血中ビリルビン増加	2 (0.9%)	0	0	0	2 (0.7%)	0
血中ナトリウム減少	1 (0.5%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
トランスアミナーゼ上昇	1 (0.5%)	0	0	0	1 (0.4%)	0
肝機能検査異常	0	2 (0.9%)	0	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	1 (0.8%)
血中アルカリホスファターゼ増加	0	0	0	1 (2.7%)	0	1 (0.8%)
肝酵素上昇	0	1 (0.5%)	0	0	1 (0.4%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.5%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.5%)	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	1 (0.8%)
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	1 (0.8%)
心臓障害	3 (1.4%)	3 (1.4%)	1 (2.2%)	0	3 (1.1%)	1 (0.8%)
心停止	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
心肺停止	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
うっ血性心筋症	1 (0.5%)	0	0	0	1 (0.4%)	0
上室性頻脈	0	0	1 (2.2%)	0	0	1 (0.8%)
心室性頻脈	0	1 (0.5%)	0	0	0	0
腎および尿路障害	3 (1.4%)	3 (1.4%)	0	0	4 (1.5%)	1 (0.8%)
腎不全	2 (0.9%)	1 (0.5%)	0	0	2 (0.7%)	0
急性腎不全	1 (0.5%)	2 (0.9%)	0	0	2 (0.7%)	1 (0.8%)
精神障害	2 (0.9%)	5 (2.3%)	0	1 (2.7%)	2 (0.7%)	1 (0.8%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
錯乱状態	2 (0.9%)	2 (0.9%)	0	0	2 (0.7%)	1 (0.8%)
幻視	0	3 (1.4%)	0	0	0	0
幻覚	0	1 (0.5%)	0	0	0	1 (0.8%)
抑うつ気分	0	1 (0.5%)	0	0	0	0
不快気分	0	0	0	1 (2.7%)	0	0
皮膚および皮下組織障害	2 (0.9%)	5 (2.3%)	0	0	2 (0.7%)	0
皮膚炎	1 (0.5%)	0	0	0	1 (0.4%)	0
アレルギー性皮膚炎	1 (0.5%)	0	0	0	1 (0.4%)	0
発疹	0	4 (1.8%)	0	0	0	0
薬疹	0	1 (0.5%)	0	0	0	0
胃腸障害	1 (0.5%)	3 (1.4%)	1 (2.2%)	0	1 (0.4%)	3 (2.3%)
嘔吐	0	2 (0.9%)	1 (2.2%)	0	0	2 (1.6%)
嚥下障害	1 (0.5%)	0	0	0	1 (0.4%)	0
小腸閉塞	0	0	1 (2.2%)	0	0	1 (0.8%)
悪心	0	2 (0.9%)	0	0	0	1 (0.8%)
肝胆道系障害	1 (0.5%)	5 (2.3%)	0	1 (2.7%)	2 (0.7%)	0
急性肝炎	1 (0.5%)	0	0	0	1 (0.4%)	0
肝不全	0	2 (0.9%)	0	0	0	0
高ビリルビン血症	0	1 (0.5%)	0	1 (2.7%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
肝機能異常	0	1 (0.5%)	0	0	0	0
肝病変	0	1 (0.5%)	0	0	0	0
肝炎	0	1 (0.5%)	0	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (2.7%)	0	0
急性肝不全	0	0	0	0	1 (0.4%)	0
血液およびリンパ系障害	1 (0.5%)	3 (1.4%)	0	0	1 (0.4%)	0
汎血球減少症	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
微小血管症性溶血性貧血	0	1 (0.5%)	0	0	0	0
脾臓病変	0	1 (0.5%)	0	0	0	0
眼障害	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
視神経症	1 (0.5%)	0	0	0	1 (0.4%)	0
眼瞼浮腫	0	1 (0.5%)	0	0	0	0
全身障害および投与局所様態	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
悪寒	1 (0.5%)	1 (0.5%)	0	0	1 (0.4%)	0
傷害、中毒および処置合併症	1 (0.5%)	0	0	0	1 (0.4%)	0
過量投与	1 (0.5%)	0	0	0	1 (0.4%)	0
筋骨格系および結合組織障害	1 (0.5%)	0	0	0	1 (0.4%)	0
筋炎	1 (0.5%)	0	0	0	1 (0.4%)	0
血管障害	1 (0.5%)	0	0	0	1 (0.4%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-172 投与中止に至った有害事象（血液悪性腫瘍の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Hematologic Malignancy Status Yes		Hematologic Malignancy Status No		Hematologic Malignancy Status Yes	Hematologic Malignancy Status No
System Organ Class Preferred Term	ISA (N = 211)	VRC (N = 222)	ISA (N = 46)	VRC (N = 37)	ISA (N = 274)	ISA (N = 129)
低血圧	1 (0.5%)	0	0	0	1 (0.4%)	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	6 (2.7%)	0	1 (2.7%)	3 (1.1%)	0
急性骨髄性白血病	0	4 (1.8%)	0	0	0	0
再発急性骨髄性白血病	0	1 (0.5%)	0	0	1 (0.4%)	0
慢性リンパ性白血病	0	1 (0.5%)	0	0	0	0
肺の悪性新生物	0	0	0	1 (2.7%)	0	0
白血病再発	0	0	0	0	1 (0.4%)	0
悪性新生物進行	0	0	0	0	1 (0.4%)	0
免疫系障害	0	1 (0.5%)	0	0	0	0
急性肝移植片対宿主病	0	1 (0.5%)	0	0	0	0
代謝および栄養障害	0	1 (0.5%)	0	0	0	0
代謝性アシドーシス	0	1 (0.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_blood_discon_1.sas
Program Run: 04JUN21:14:56:34

表 8-173 SOC別の有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
Overall	158 (96.9%)	172 (98.3%)	89 (94.7%)	83 (98.8%)	195 (97.0%)	154 (96.3%)
胃腸障害	118 (72.4%)	127 (72.6%)	56 (59.6%)	53 (63.1%)	144 (71.6%)	96 (60.0%)
感染症および寄生虫症	98 (60.1%)	107 (61.1%)	54 (57.4%)	51 (60.7%)	128 (63.7%)	95 (59.4%)
全身障害および投与局所様態	95 (58.3%)	104 (59.4%)	53 (56.4%)	40 (47.6%)	115 (57.2%)	90 (56.3%)
呼吸器、胸郭および縦隔障害	98 (60.1%)	98 (56.0%)	45 (47.9%)	49 (58.3%)	124 (61.7%)	73 (45.6%)
代謝および栄養障害	76 (46.6%)	82 (46.9%)	32 (34.0%)	39 (46.4%)	97 (48.3%)	63 (39.4%)
神経系障害	59 (36.2%)	65 (37.1%)	36 (38.3%)	24 (28.6%)	69 (34.3%)	64 (40.0%)
皮膚および皮下組織障害	61 (37.4%)	82 (46.9%)	25 (26.6%)	28 (33.3%)	76 (37.8%)	40 (25.0%)
臨床検査	57 (35.0%)	62 (35.4%)	28 (29.8%)	34 (40.5%)	70 (34.8%)	44 (27.5%)
血液およびリンパ系障害	50 (30.7%)	62 (35.4%)	27 (28.7%)	20 (23.8%)	62 (30.8%)	39 (24.4%)
精神障害	48 (29.4%)	64 (36.6%)	22 (23.4%)	22 (26.2%)	56 (27.9%)	42 (26.3%)
筋骨格系および結合組織障害	47 (28.8%)	57 (32.6%)	22 (23.4%)	20 (23.8%)	54 (26.9%)	43 (26.9%)
血管障害	47 (28.8%)	54 (30.9%)	20 (21.3%)	23 (27.4%)	62 (30.8%)	32 (20.0%)
腎および尿路障害	36 (22.1%)	35 (20.0%)	19 (20.2%)	23 (27.4%)	46 (22.9%)	30 (18.8%)
心臓障害	27 (16.6%)	36 (20.6%)	16 (17.0%)	21 (25.0%)	41 (20.4%)	25 (15.6%)
眼障害	27 (16.6%)	44 (25.1%)	12 (12.8%)	25 (29.8%)	33 (16.4%)	24 (15.0%)
傷害、中毒および処置合併症	23 (14.1%)	28 (16.0%)	10 (10.6%)	11 (13.1%)	28 (13.9%)	22 (13.8%)
肝胆道系障害	15 (9.2%)	29 (16.6%)	8 (8.5%)	13 (15.5%)	23 (11.4%)	13 (8.1%)
免疫系障害	13 (8.0%)	15 (8.6%)	7 (7.4%)	10 (11.9%)	16 (8.0%)	13 (8.1%)
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）	14 (8.6%)	20 (11.4%)	5 (5.3%)	11 (13.1%)	19 (9.5%)	10 (6.3%)
耳および迷路障害	11 (6.7%)	9 (5.1%)	3 (3.2%)	4 (4.8%)	12 (6.0%)	8 (5.0%)
生殖系および乳房障害	4 (2.5%)	9 (5.1%)	4 (4.3%)	4 (4.8%)	5 (2.5%)	9 (5.6%)
内分泌障害	3 (1.8%)	1 (0.6%)	2 (2.1%)	2 (2.4%)	3 (1.5%)	7 (4.4%)
先天性、家族性および遺伝性障害	3 (1.8%)	2 (1.1%)	0	0	3 (1.5%)	0
社会環境	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_soc_1.sas
Program Run: 04JUN21:15:20:14

表 8-174 注目すべき有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
肝機能異常・肝炎	35 (21.5%)	57 (32.6%)	18 (19.1%)	25 (29.8%)	48 (23.9%)	29 (18.1%)
アナフィラキシー	2 (1.2%)	2 (1.1%)	0	1 (1.2%)	2 (1.0%)	0
重度皮膚障害	3 (1.8%)	2 (1.1%)	0	0	3 (1.5%)	0
心電図QT短縮	1 (0.6%)	0	0	0	1 (0.5%)	0
トルサード ド ポアント	11 (6.7%)	12 (6.9%)	4 (4.3%)	7 (8.3%)	13 (6.5%)	5 (3.1%)
急性膵炎	0	0	0	0	0	1 (0.6%)
精神神経症状	48 (29.4%)	58 (33.1%)	25 (26.6%)	21 (25.0%)	56 (27.9%)	45 (28.1%)
視覚障害	18 (11.0%)	31 (17.7%)	5 (5.3%)	16 (19.0%)	21 (10.4%)	10 (6.3%)
皮膚または子宮の悪性腫瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
静脈内投与例	(N = 163)	(N = 175)	(N = 94)	(N = 84)	(N = 198)	(N = 140)
注入部位／注射部位反応	7 (4.3%)	2 (1.1%)	4 (4.3%)	2 (2.4%)	7 (3.5%)	7 (5.0%)
IRR	49 (30.1%)	54 (30.9%)	21 (22.3%)	22 (26.2%)	63 (31.8%)	35 (25.0%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_neut_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-175 死亡に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
Overall	42 (25.8%)	49 (28.0%)	20 (21.3%)	23 (27.4%)	60 (29.9%)	42 (26.3%)
感染症および寄生虫症	20 (12.3%)	11 (6.3%)	8 (8.5%)	7 (8.3%)	29 (14.4%)	17 (10.6%)
敗血症性ショック	5 (3.1%)	3 (1.7%)	3 (3.2%)	1 (1.2%)	6 (3.0%)	5 (3.1%)
敗血症	6 (3.7%)	1 (0.6%)	1 (1.1%)	4 (4.8%)	7 (3.5%)	1 (0.6%)
アスペルギルス症	2 (1.2%)	1 (0.6%)	1 (1.1%)	1 (1.2%)	3 (1.5%)	1 (0.6%)
真菌感染	3 (1.8%)	1 (0.6%)	0	1 (1.2%)	3 (1.5%)	0
肺炎	0	1 (0.6%)	1 (1.1%)	1 (1.2%)	1 (0.5%)	2 (1.3%)
ムコール症	1 (0.6%)	0	0	0	2 (1.0%)	0
アシネトバクター性菌血症	1 (0.6%)	0	0	0	1 (0.5%)	0
気管支肺アスペルギルス症	0	0	1 (1.1%)	0	0	1 (0.6%)
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (1.1%)	0	0	1 (0.6%)
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
シュードモナス性敗血症	0	1 (0.6%)	0	0	0	1 (0.6%)
クレブシエラ性敗血症	0	1 (0.6%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.6%)	0	0	0	0
真菌性肺炎	0	0	0	0	2 (1.0%)	0
細菌性敗血症	0	0	0	0	0	1 (0.6%)
蓄膿	0	0	0	0	0	1 (0.6%)
真菌性敗血症	0	0	0	0	1 (0.5%)	0
シュードモナス菌性肺感染	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_death_1.sas
Program Run: 04JUN21:14:56:51

表 8-175 死亡に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
原発性異型肺炎	0	0	0	0	0	1 (0.6%)
真菌性副鼻腔炎	0	0	0	0	0	1 (0.6%)
ブドウ球菌性敗血症	0	0	0	0	1 (0.5%)	0
呼吸器、胸郭および縦隔障害	10 (6.1%)	10 (5.7%)	4 (4.3%)	2 (2.4%)	11 (5.5%)	6 (3.8%)
呼吸不全	5 (3.1%)	5 (2.9%)	1 (1.1%)	1 (1.2%)	5 (2.5%)	2 (1.3%)
急性呼吸不全	2 (1.2%)	0	1 (1.1%)	1 (1.2%)	2 (1.0%)	1 (0.6%)
喀血	2 (1.2%)	1 (0.6%)	0	0	2 (1.0%)	1 (0.6%)
肺出血	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
呼吸窮迫	0	0	1 (1.1%)	0	0	1 (0.6%)
急性呼吸窮迫症候群	0	1 (0.6%)	0	0	0	0
肺塞栓症	0	1 (0.6%)	0	0	0	0
肺高血圧症	0	1 (0.6%)	0	0	0	0
呼吸困難	0	0	0	0	1 (0.5%)	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)	7 (4.3%)	15 (8.6%)	3 (3.2%)	6 (7.1%)	11 (5.5%)	6 (3.8%)
急性骨髄性白血病	3 (1.8%)	6 (3.4%)	0	1 (1.2%)	3 (1.5%)	1 (0.6%)
多発性骨髄腫	1 (0.6%)	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
悪性新生物進行	0	0	1 (1.1%)	1 (1.2%)	1 (0.5%)	2 (1.3%)
芽球発症	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
骨髄性白血病	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	0	0	1 (1.1%)	0	0	1 (0.6%)
骨髄異形成症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	2 (1.1%)	0	2 (2.4%)	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_death_1.sas
Program Run: 04JUN21:14:56:51

表 8-175 死亡に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
慢性リンパ性白血病	0	1 (0.6%)	0	1 (1.2%)	1 (0.5%)	0
再発急性リンパ性白血病	0	1 (0.6%)	0	0	1 (0.5%)	0
Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0
バーキット白血病	0	1 (0.6%)	0	0	0	0
リンパ腫	0	1 (0.6%)	0	0	0	0
新生物進行	0	1 (0.6%)	0	0	0	0
白血病再発	0	0	0	0	0	1 (0.6%)
心臓障害	3 (1.8%)	2 (1.1%)	1 (1.1%)	3 (3.6%)	5 (2.5%)	2 (1.3%)
心停止	1 (0.6%)	1 (0.6%)	0	2 (2.4%)	1 (0.5%)	0
心肺停止	1 (0.6%)	1 (0.6%)	0	0	2 (1.0%)	1 (0.6%)
うっ血性心筋症	0	0	1 (1.1%)	0	0	1 (0.6%)
心膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
急性心筋梗塞	0	0	0	1 (1.2%)	0	0
急性心不全	0	0	0	0	1 (0.5%)	0
神経系障害	0	4 (2.3%)	3 (3.2%)	3 (3.6%)	0	5 (3.1%)
頭蓋内出血	0	1 (0.6%)	2 (2.1%)	2 (2.4%)	0	2 (1.3%)
神経毒性	0	0	1 (1.1%)	0	0	1 (0.6%)
脳出血	0	1 (0.6%)	0	0	0	0
脳炎	0	1 (0.6%)	0	0	0	0
昏迷	0	0	0	1 (1.2%)	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0
脳梗塞	0	0	0	0	0	2 (1.3%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_death_1.sas
Program Run: 04JUN21:14:56:51

表 8-175 死亡に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
全身障害および投与局所様態	1 (0.6%)	6 (3.4%)	1 (1.1%)	2 (2.4%)	3 (1.5%)	4 (2.5%)
多臓器不全	1 (0.6%)	5 (2.9%)	0	1 (1.2%)	2 (1.0%)	0
死亡	0	0	1 (1.1%)	1 (1.2%)	1 (0.5%)	3 (1.9%)
心突然死	0	1 (0.6%)	0	0	0	0
全身健康状態低下	0	0	0	0	0	1 (0.6%)
血管障害	2 (1.2%)	1 (0.6%)	0	0	2 (1.0%)	1 (0.6%)
出血	1 (0.6%)	0	0	0	1 (0.5%)	0
血液量減少性ショック	1 (0.6%)	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	1 (0.6%)	0	0	0	0
動脈炎	0	0	0	0	0	1 (0.6%)
血液およびリンパ系障害	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
出血性障害	1 (0.6%)	0	0	0	1 (0.5%)	0
血小板減少症	0	0	1 (1.1%)	0	0	1 (0.6%)
汎血球減少症	0	1 (0.6%)	0	0	0	0
免疫系障害	0	0	1 (1.1%)	0	0	2 (1.3%)
急性移植片対宿主病	0	0	1 (1.1%)	0	0	1 (0.6%)
移植片対宿主病	0	0	0	0	0	1 (0.6%)
腎および尿路障害	1 (0.6%)	0	0	0	2 (1.0%)	0
腎不全	1 (0.6%)	0	0	0	1 (0.5%)	0
急性腎不全	0	0	0	0	1 (0.5%)	0
肝胆道系障害	1 (0.6%)	0	0	0	1 (0.5%)	0
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_death_1.sas
Program Run: 04JUN21:14:56:51

表 8-175 死亡に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
代謝および栄養障害	0	1 (0.6%)	0	1 (1.2%)	0	0
低血糖症	0	1 (0.6%)	0	0	0	0
代謝性アシドーシス	0	0	0	1 (1.2%)	0	0
胃腸障害	0	1 (0.6%)	0	0	0	0
直腸出血	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_death_1.sas
Program Run: 04JUN21:14:56:51

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
Overall	94 (57.7%)	97 (55.4%)	40 (42.6%)	52 (61.9%)	125 (62.2%)	86 (53.8%)
感染症および寄生虫症	37 (22.7%)	37 (21.1%)	14 (14.9%)	24 (28.6%)	58 (28.9%)	41 (25.6%)
敗血症性ショック	10 (6.1%)	8 (4.6%)	4 (4.3%)	2 (2.4%)	11 (5.5%)	7 (4.4%)
敗血症	6 (3.7%)	2 (1.1%)	1 (1.1%)	6 (7.1%)	8 (4.0%)	1 (0.6%)
肺炎	2 (1.2%)	5 (2.9%)	3 (3.2%)	5 (6.0%)	3 (1.5%)	7 (4.4%)
アスペルギルス症	3 (1.8%)	2 (1.1%)	1 (1.1%)	1 (1.2%)	5 (2.5%)	2 (1.3%)
真菌感染	3 (1.8%)	2 (1.1%)	0	1 (1.2%)	4 (2.0%)	0
サイトメガロウイルス感染	2 (1.2%)	1 (0.6%)	0	1 (1.2%)	2 (1.0%)	2 (1.3%)
気管支肺アスペルギルス症	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
シュードモナス性敗血症	1 (0.6%)	1 (0.6%)	0	0	2 (1.0%)	1 (0.6%)
大腸菌性敗血症	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	1 (0.6%)
尿路感染	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	1 (0.6%)
蜂巣炎	0	0	1 (1.1%)	1 (1.2%)	0	1 (0.6%)
クレブシエラ性菌血症	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
クレブシエラ性敗血症	0	1 (0.6%)	1 (1.1%)	0	0	1 (0.6%)
ムコール症	1 (0.6%)	0	0	0	2 (1.0%)	1 (0.6%)
クロストリジウム・ディフィシレ大腸炎	0	0	1 (1.1%)	0	0	2 (1.3%)
腸球菌性菌血症	0	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
ブドウ球菌感染	1 (0.6%)	0	0	0	1 (0.5%)	1 (0.6%)
アシネトバクター性菌血症	1 (0.6%)	0	0	0	1 (0.5%)	0
肺炎球菌性気管支炎	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
気管支肺炎	1 (0.6%)	0	0	0	1 (0.5%)	0
脳アスペルギルス症	1 (0.6%)	0	0	0	1 (0.5%)	0
サイトメガロウイルス血症	0	0	1 (1.1%)	0	0	1 (0.6%)
ヘルペス脳炎	1 (0.6%)	0	0	0	1 (0.5%)	0
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
フサリウム感染	0	0	1 (1.1%)	0	0	1 (0.6%)
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
注入部位感染	1 (0.6%)	0	0	0	1 (0.5%)	0
筋膿瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
モラクセラ菌性肺炎	0	0	1 (1.1%)	0	0	1 (0.6%)
気道感染	0	0	1 (1.1%)	0	0	1 (0.6%)
敗血症症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
皮膚感染	1 (0.6%)	0	0	0	1 (0.5%)	0
細菌性敗血症	0	4 (2.3%)	0	0	0	1 (0.6%)
ブドウ球菌性菌血症	0	3 (1.7%)	0	0	1 (0.5%)	0
菌血症	0	1 (0.6%)	0	1 (1.2%)	2 (1.0%)	1 (0.6%)
ブドウ球菌性敗血症	0	2 (1.1%)	0	0	1 (0.5%)	0
クロストリジウム性菌血症	0	0	0	2 (2.4%)	0	0
髄膜炎	0	1 (0.6%)	0	1 (1.2%)	0	0
帯状疱疹	0	1 (0.6%)	0	0	1 (0.5%)	1 (0.6%)
細菌性肺炎	0	0	0	1 (1.2%)	1 (0.5%)	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
蓄膿	0	0	0	1 (1.2%)	0	1 (0.6%)
カンピロバクター胃腸炎	0	1 (0.6%)	0	0	0	0
カテーテル関連感染	0	1 (0.6%)	0	0	0	0
感染性下痢	0	1 (0.6%)	0	0	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (1.2%)	0	0
単純ヘルペス	0	0	0	1 (1.2%)	0	0
肺膿瘍	0	0	0	1 (1.2%)	0	0
壊死性筋膜炎	0	1 (0.6%)	0	0	0	0
肺炎球菌性肺炎	0	1 (0.6%)	0	0	0	0
ブドウ球菌性肺炎	0	1 (0.6%)	0	0	0	0
シュードモナス性菌血症	0	1 (0.6%)	0	0	0	0
シュードモナス感染	0	1 (0.6%)	0	0	0	0
膿胸	0	0	0	1 (1.2%)	0	0
ステノトロフォモナス性敗血症	0	1 (0.6%)	0	0	0	0
全身性カンジダ	0	1 (0.6%)	0	0	0	0
トキソプラズマ症	0	1 (0.6%)	0	0	0	0
結核	0	1 (0.6%)	0	0	0	0
細菌性尿路感染	0	0	0	1 (1.2%)	0	0
真菌性肺炎	0	0	0	0	2 (1.0%)	0
接合真菌症	0	0	0	0	2 (1.0%)	0
腹部膿瘍	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
虫垂炎	0	0	0	0	1 (0.5%)	0
ＢＫウイルス感染	0	0	0	0	1 (0.5%)	0
脳膿瘍	0	0	0	0	0	1 (0.6%)
細気管支炎	0	0	0	0	0	1 (0.6%)
カテーテル留置部位感染	0	0	0	0	1 (0.5%)	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.6%)
大腸菌性菌血症	0	0	0	0	0	1 (0.6%)
真菌性敗血症	0	0	0	0	1 (0.5%)	0
ノロウイルス性胃腸炎	0	0	0	0	0	1 (0.6%)
ウイルス性胃腸炎	0	0	0	0	0	1 (0.6%)
インフルエンザ	0	0	0	0	0	1 (0.6%)
シュードモナス菌性肺感染	0	0	0	0	0	1 (0.6%)
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	1 (0.6%)
インフルエンザ性肺炎	0	0	0	0	1 (0.5%)	0
原発性異型肺炎	0	0	0	0	0	1 (0.6%)
シュードモナス性気管支炎	0	0	0	0	0	1 (0.6%)
副鼻腔炎	0	0	0	0	0	1 (0.6%)
真菌性副鼻腔炎	0	0	0	0	0	1 (0.6%)
レンサ球菌性菌血症	0	0	0	0	1 (0.5%)	0
皮下組織膿瘍	0	0	0	0	1 (0.5%)	0
尿路性敗血症	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
ウイルス性下痢	0	0	0	0	1 (0.5%)	0
呼吸器、胸郭および縦隔障害	30 (18.4%)	27 (15.4%)	11 (11.7%)	16 (19.0%)	41 (20.4%)	17 (10.6%)
呼吸不全	13 (8.0%)	9 (5.1%)	1 (1.1%)	3 (3.6%)	15 (7.5%)	4 (2.5%)
急性呼吸不全	4 (2.5%)	2 (1.1%)	1 (1.1%)	3 (3.6%)	6 (3.0%)	1 (0.6%)
呼吸困難	3 (1.8%)	0	2 (2.1%)	1 (1.2%)	4 (2.0%)	2 (1.3%)
呼吸窮迫	3 (1.8%)	2 (1.1%)	1 (1.1%)	1 (1.2%)	3 (1.5%)	1 (0.6%)
喀血	2 (1.2%)	1 (0.6%)	0	1 (1.2%)	3 (1.5%)	1 (0.6%)
低酸素症	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	2 (1.0%)	1 (0.6%)
肺出血	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
胸水	1 (0.6%)	0	0	1 (1.2%)	2 (1.0%)	0
肺水腫	0	0	1 (1.1%)	1 (1.2%)	1 (0.5%)	1 (0.6%)
肺障害	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
呼吸抑制	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
嚥下性肺炎	0	0	1 (1.1%)	0	1 (0.5%)	2 (1.3%)
気管支胸膜瘻	0	0	1 (1.1%)	0	0	1 (0.6%)
気管支痙攣	0	0	1 (1.1%)	0	0	1 (0.6%)
水気胸	0	0	1 (1.1%)	0	0	1 (0.6%)
胸膜痛	1 (0.6%)	0	0	0	1 (0.5%)	0
呼吸性アシドーシス	0	0	1 (1.1%)	0	0	1 (0.6%)
頻呼吸	0	0	1 (1.1%)	0	0	1 (0.6%)
鼻出血	0	3 (1.7%)	0	1 (1.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
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表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
肺浸潤	0	2 (1.1%)	0	1 (1.2%)	0	0
肺塞栓症	0	1 (0.6%)	0	2 (2.4%)	0	0
急性呼吸窮迫症候群	0	2 (1.1%)	0	0	1 (0.5%)	0
急性肺損傷	0	1 (0.6%)	0	0	0	0
慢性閉塞性肺疾患	0	0	0	1 (1.2%)	0	0
咳嗽	0	1 (0.6%)	0	0	0	0
血胸	0	0	0	1 (1.2%)	0	0
気胸	0	0	0	1 (1.2%)	0	0
湿性咳嗽	0	0	0	1 (1.2%)	0	0
肺高血圧症	0	1 (0.6%)	0	0	0	0
呼吸停止	0	1 (0.6%)	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.6%)
肺胞出血	0	0	0	0	1 (0.5%)	0
肺梗塞	0	0	0	0	0	1 (0.6%)
副鼻腔障害	0	0	0	0	1 (0.5%)	0
血液およびリンパ系障害	22 (13.5%)	14 (8.0%)	6 (6.4%)	3 (3.6%)	26 (12.9%)	7 (4.4%)
発熱性好中球減少症	12 (7.4%)	5 (2.9%)	2 (2.1%)	0	14 (7.0%)	2 (1.3%)
汎血球減少症	3 (1.8%)	3 (1.7%)	1 (1.1%)	0	3 (1.5%)	2 (1.3%)
好中球減少症	3 (1.8%)	3 (1.7%)	1 (1.1%)	0	3 (1.5%)	1 (0.6%)
血小板減少症	2 (1.2%)	4 (2.3%)	1 (1.1%)	0	2 (1.0%)	1 (0.6%)
無顆粒球症	0	0	2 (2.1%)	0	0	2 (1.3%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
貧血	1 (0.6%)	0	0	2 (2.4%)	3 (1.5%)	0
出血性障害	1 (0.6%)	0	0	0	1 (0.5%)	0
白血球増加症	1 (0.6%)	0	0	0	1 (0.5%)	0
脾臓梗塞	1 (0.6%)	0	0	0	1 (0.5%)	0
出血性貧血	0	0	0	1 (1.2%)	0	0
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0
血小板減少性紫斑病	0	1 (0.6%)	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)	13 (8.0%)	19 (10.9%)	5 (5.3%)	10 (11.9%)	18 (9.0%)	8 (5.0%)
急性骨髄性白血病	3 (1.8%)	7 (4.0%)	0	1 (1.2%)	3 (1.5%)	2 (1.3%)
リンパ腫	2 (1.2%)	1 (0.6%)	0	0	2 (1.0%)	0
多発性骨髄腫	1 (0.6%)	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
悪性新生物進行	0	0	1 (1.1%)	1 (1.2%)	1 (0.5%)	2 (1.3%)
再発急性リンパ性白血病	1 (0.6%)	1 (0.6%)	0	0	2 (1.0%)	0
芽球発症	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
骨髄性白血病	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
新生物進行	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
再発慢性リンパ性白血病	0	0	1 (1.1%)	0	0	1 (0.6%)
子宮内膜癌	1 (0.6%)	0	0	0	1 (0.5%)	0
髄膜転移	0	0	1 (1.1%)	0	0	1 (0.6%)
骨髄異形成症候群	1 (0.6%)	0	0	0	1 (0.5%)	0
非ホジキンリンパ腫	0	0	1 (1.1%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
原発性体腔性リンパ腫	1 (0.6%)	0	0	0	1 (0.5%)	0
再発急性骨髄性白血病	0	3 (1.7%)	0	2 (2.4%)	2 (1.0%)	0
慢性リンパ性白血病	0	1 (0.6%)	0	1 (1.2%)	1 (0.5%)	0
急性白血病	0	1 (0.6%)	0	0	0	0
急性リンパ性白血病	0	0	0	1 (1.2%)	0	0
Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0
再発Ｂ細胞性リンパ腫	0	1 (0.6%)	0	0	0	0
バーキット白血病	0	1 (0.6%)	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.6%)	0	0	0	0
白血病	0	1 (0.6%)	0	0	0	0
肺の悪性新生物	0	0	0	1 (1.2%)	0	0
骨転移	0	0	0	1 (1.2%)	0	0
転移部痛	0	0	0	1 (1.2%)	0	0
白血病再発	0	0	0	0	0	1 (0.6%)
白血病浸潤	0	0	0	0	0	1 (0.6%)
神経系障害	9 (5.5%)	9 (5.1%)	8 (8.5%)	7 (8.3%)	9 (4.5%)	15 (9.4%)
痙攣	1 (0.6%)	0	2 (2.1%)	1 (1.2%)	1 (0.5%)	3 (1.9%)
頭蓋内出血	0	1 (0.6%)	2 (2.1%)	2 (2.4%)	0	2 (1.3%)
てんかん	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
多発ニューロパチー	2 (1.2%)	0	0	0	2 (1.0%)	0
中枢神経系病変	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
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表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
脳症	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
虚血性脳卒中	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
対麻痺	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
頭痛	0	0	1 (1.1%)	0	0	2 (1.3%)
脳幹卒中	0	0	1 (1.1%)	0	0	1 (0.6%)
脳虚血	1 (0.6%)	0	0	0	1 (0.5%)	0
熱性痙攣	1 (0.6%)	0	0	0	1 (0.5%)	0
神経毒性	0	0	1 (1.1%)	0	0	1 (0.6%)
失語症	0	1 (0.6%)	0	0	0	1 (0.6%)
脳出血	0	1 (0.6%)	0	0	0	0
浮動性めまい	0	1 (0.6%)	0	0	0	0
脳炎	0	1 (0.6%)	0	0	0	0
大発作痙攣	0	0	0	1 (1.2%)	0	0
片麻痺	0	1 (0.6%)	0	0	0	0
昏迷	0	0	0	1 (1.2%)	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0
振戦	0	1 (0.6%)	0	0	0	0
第 7 脳神経麻痺	0	1 (0.6%)	0	0	0	0
脳梗塞	0	0	0	0	0	2 (1.3%)
脳血管発作	0	0	0	0	0	1 (0.6%)
卒中の出血性変化	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
不全片麻痺	0	0	0	0	0	1 (0.6%)
一過性脳虚血発作	0	0	0	0	0	1 (0.6%)
全身障害および投与局所様態	9 (5.5%)	14 (8.0%)	2 (2.1%)	5 (6.0%)	12 (6.0%)	7 (4.4%)
発熱	7 (4.3%)	7 (4.0%)	1 (1.1%)	3 (3.6%)	8 (4.0%)	2 (1.3%)
多臓器不全	1 (0.6%)	6 (3.4%)	0	1 (1.2%)	2 (1.0%)	0
死亡	0	0	1 (1.1%)	1 (1.2%)	1 (0.5%)	3 (1.9%)
悪寒	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
全身健康状態低下	1 (0.6%)	0	0	0	1 (0.5%)	1 (0.6%)
無力症	1 (0.6%)	0	0	0	1 (0.5%)	0
胸痛	1 (0.6%)	0	0	0	1 (0.5%)	0
心突然死	0	1 (0.6%)	0	0	0	0
非心臓性胸痛	0	0	0	0	0	1 (0.6%)
末梢性浮腫	0	0	0	0	0	1 (0.6%)
心臓障害	8 (4.9%)	8 (4.6%)	3 (3.2%)	4 (4.8%)	13 (6.5%)	6 (3.8%)
心肺停止	1 (0.6%)	2 (1.1%)	1 (1.1%)	0	2 (1.0%)	2 (1.3%)
心停止	1 (0.6%)	3 (1.7%)	0	2 (2.4%)	1 (0.5%)	0
心房細動	1 (0.6%)	1 (0.6%)	0	0	2 (1.0%)	1 (0.6%)
急性心筋梗塞	1 (0.6%)	0	0	1 (1.2%)	2 (1.0%)	0
不整脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心原性ショック	1 (0.6%)	0	0	0	1 (0.5%)	0
うっ血性心筋症	0	0	1 (1.1%)	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
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表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
心膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
洞性徐脈	0	0	1 (1.1%)	0	0	1 (0.6%)
上室性頻脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心室性頻脈	0	1 (0.6%)	0	1 (1.2%)	0	0
狭心症	0	1 (0.6%)	0	0	0	0
完全房室ブロック	0	0	0	0	0	1 (0.6%)
急性心不全	0	0	0	0	1 (0.5%)	0
電気収縮解離	0	0	0	0	1 (0.5%)	0
腎および尿路障害	7 (4.3%)	7 (4.0%)	3 (3.2%)	3 (3.6%)	11 (5.5%)	7 (4.4%)
急性腎不全	4 (2.5%)	5 (2.9%)	2 (2.1%)	3 (3.6%)	8 (4.0%)	5 (3.1%)
腎不全	2 (1.2%)	2 (1.1%)	1 (1.1%)	0	2 (1.0%)	2 (1.3%)
血尿	1 (0.6%)	0	0	0	1 (0.5%)	0
胃腸障害	7 (4.3%)	8 (4.6%)	2 (2.1%)	4 (4.8%)	11 (5.5%)	13 (8.1%)
下痢	2 (1.2%)	1 (0.6%)	0	0	2 (1.0%)	2 (1.3%)
小腸閉塞	0	0	2 (2.1%)	0	0	2 (1.3%)
悪心	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	1 (0.6%)
腸出血	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
腹膜炎	0	0	1 (1.1%)	1 (1.2%)	0	1 (0.6%)
腹痛	1 (0.6%)	0	0	0	2 (1.0%)	3 (1.9%)
大腸炎	0	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
便秘	1 (0.6%)	0	0	0	1 (0.5%)	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
胃穿孔	0	0	1 (1.1%)	0	0	1 (0.6%)
食道潰瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
胃腸出血	0	2 (1.1%)	0	1 (1.2%)	0	2 (1.3%)
食中毒	0	0	0	1 (1.2%)	0	0
胃腸の炎症	0	1 (0.6%)	0	0	0	0
麻痺性イレウス	0	1 (0.6%)	0	0	0	0
肛門周囲痛	0	1 (0.6%)	0	0	0	0
直腸出血	0	1 (0.6%)	0	0	0	0
嚥下障害	0	0	0	0	0	2 (1.3%)
嘔吐	0	0	0	0	1 (0.5%)	1 (0.6%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.6%)
限局性腹腔内液貯留	0	0	0	0	1 (0.5%)	0
食道炎	0	0	0	0	0	1 (0.6%)
膵炎	0	0	0	0	0	1 (0.6%)
慢性膵炎	0	0	0	0	0	1 (0.6%)
再発性膵炎	0	0	0	0	0	1 (0.6%)
免疫系障害	3 (1.8%)	4 (2.3%)	1 (1.1%)	2 (2.4%)	4 (2.0%)	5 (3.1%)
急性腸管移植片対宿主病	1 (0.6%)	2 (1.1%)	0	0	1 (0.5%)	0
急性移植片対宿主病	0	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	2 (1.3%)
アナフィラキシーショック	1 (0.6%)	0	0	0	1 (0.5%)	0
過敏症	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
アナフィラキシー反応	0	1 (0.6%)	0	1 (1.2%)	0	0
急性肝移植片対宿主病	0	0	0	1 (1.2%)	0	0
移植片対宿主病	0	0	0	0	0	2 (1.3%)
肺移植拒絶反応	0	0	0	0	0	1 (0.6%)
血管障害	4 (2.5%)	4 (2.3%)	0	2 (2.4%)	6 (3.0%)	2 (1.3%)
低血圧	1 (0.6%)	1 (0.6%)	0	1 (1.2%)	3 (1.5%)	0
出血	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
血液量減少性ショック	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
血管炎	1 (0.6%)	0	0	0	1 (0.5%)	0
深部静脈血栓症	0	1 (0.6%)	0	0	0	1 (0.6%)
ショック	0	1 (0.6%)	0	0	0	0
動脈炎	0	0	0	0	0	1 (0.6%)
肝胆道系障害	1 (0.6%)	4 (2.3%)	2 (2.1%)	2 (2.4%)	3 (1.5%)	4 (2.5%)
胆嚢炎	0	0	1 (1.1%)	0	0	2 (1.3%)
肝炎	0	0	1 (1.1%)	0	0	1 (0.6%)
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0
肝不全	0	1 (0.6%)	0	1 (1.2%)	0	0
肝機能異常	0	1 (0.6%)	0	1 (1.2%)	0	0
高ビリルビン血症	0	2 (1.1%)	0	0	0	0
急性胆嚢炎	0	1 (0.6%)	0	0	0	0
急性肝不全	0	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
細胆管炎	0	0	0	0	0	1 (0.6%)
胆石症	0	0	0	0	1 (0.5%)	0
臨床検査	2 (1.2%)	5 (2.9%)	1 (1.1%)	1 (1.2%)	2 (1.0%)	1 (0.6%)
肝機能検査異常	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
血中ナトリウム減少	0	0	1 (1.1%)	0	0	1 (0.6%)
ヘモグロビン減少	1 (0.6%)	0	0	0	1 (0.5%)	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0
血中アルカリホスファターゼ増加	0	1 (0.6%)	0	0	0	0
血中ビリルビン増加	0	1 (0.6%)	0	0	0	0
心電図ＱＴ延長	0	1 (0.6%)	0	0	0	0
肝酵素上昇	0	1 (0.6%)	0	0	0	0
傷害、中毒および処置合併症	3 (1.8%)	2 (1.1%)	0	1 (1.2%)	3 (1.5%)	0
薬物毒性	2 (1.2%)	0	0	0	2 (1.0%)	0
転倒・転落	1 (0.6%)	0	0	0	1 (0.5%)	0
家庭内事故	0	1 (0.6%)	0	0	0	0
大腿骨頚部骨折	0	1 (0.6%)	0	0	0	0
橈骨骨折	0	0	0	1 (1.2%)	0	0
皮膚および皮下組織障害	3 (1.8%)	0	0	2 (2.4%)	3 (1.5%)	0
褥瘡性潰瘍	1 (0.6%)	0	0	0	1 (0.5%)	0
皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
脂肪織炎	1 (0.6%)	0	0	0	1 (0.5%)	0
発疹	0	0	0	2 (2.4%)	0	0
筋骨格系および結合組織障害	2 (1.2%)	0	1 (1.1%)	0	3 (1.5%)	2 (1.3%)
筋骨格系胸痛	1 (0.6%)	0	0	0	2 (1.0%)	1 (0.6%)
筋肉内出血	0	0	1 (1.1%)	0	0	1 (0.6%)
筋炎	1 (0.6%)	0	0	0	1 (0.5%)	0
四肢痛	0	0	0	0	0	1 (0.6%)
代謝および栄養障害	2 (1.2%)	3 (1.7%)	0	4 (4.8%)	3 (1.5%)	4 (2.5%)
コントロール不良の糖尿病	1 (0.6%)	0	0	0	1 (0.5%)	0
成長障害	1 (0.6%)	0	0	0	1 (0.5%)	0
脱水	0	1 (0.6%)	0	1 (1.2%)	1 (0.5%)	1 (0.6%)
代謝性アシドーシス	0	1 (0.6%)	0	1 (1.2%)	0	0
低血糖症	0	1 (0.6%)	0	0	0	1 (0.6%)
高ナトリウム血症	0	0	0	1 (1.2%)	0	0
低カリウム血症	0	1 (0.6%)	0	0	0	0
過小食	0	0	0	1 (1.2%)	0	0
高カリウム血症	0	0	0	0	0	1 (0.6%)
栄養障害	0	0	0	0	0	1 (0.6%)
眼障害	2 (1.2%)	0	0	1 (1.2%)	2 (1.0%)	2 (1.3%)
片側失明	1 (0.6%)	0	0	0	1 (0.5%)	0
視神経症	1 (0.6%)	0	0	0	1 (0.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-176 重篤な有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
眼瞼浮腫	0	0	0	1 (1.2%)	0	0
網膜動脈閉塞	0	0	0	0	0	1 (0.6%)
網膜出血	0	0	0	0	0	1 (0.6%)
硝子体出血	0	0	0	0	0	1 (0.6%)
精神障害	1 (0.6%)	5 (2.9%)	0	1 (1.2%)	1 (0.5%)	2 (1.3%)
うつ病	1 (0.6%)	0	0	0	1 (0.5%)	0
幻視	0	1 (0.6%)	0	1 (1.2%)	0	0
精神状態変化	0	1 (0.6%)	0	1 (1.2%)	0	0
錯乱状態	0	0	0	1 (1.2%)	0	1 (0.6%)
幻覚	0	1 (0.6%)	0	0	0	1 (0.6%)
抑うつ気分	0	1 (0.6%)	0	0	0	0
自殺企図	0	1 (0.6%)	0	0	0	0
異常行動	0	0	0	0	0	1 (0.6%)
攻撃性	0	0	0	0	0	1 (0.6%)
激越	0	0	0	0	0	1 (0.6%)
生殖系および乳房障害	0	0	0	0	0	1 (0.6%)
良性前立腺肥大症	0	0	0	0	0	1 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_neut_ser_1.sas
Program Run: 04JUN21:14:56:55

表 8-177 投与中止に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
Overall	25 (15.3%)	37 (21.1%)	12 (12.8%)	22 (26.2%)	33 (16.4%)	23 (14.4%)
感染症および寄生虫症	10 (6.1%)	10 (5.7%)	1 (1.1%)	5 (6.0%)	14 (7.0%)	4 (2.5%)
真菌感染	2 (1.2%)	0	0	1 (1.2%)	3 (1.5%)	0
敗血症性ショック	2 (1.2%)	0	0	0	3 (1.5%)	1 (0.6%)
敗血症	1 (0.6%)	1 (0.6%)	0	2 (2.4%)	1 (0.5%)	0
アスペルギルス症	1 (0.6%)	1 (0.6%)	0	0	3 (1.5%)	0
肺炎	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
気管支肺炎	1 (0.6%)	0	0	0	1 (0.5%)	0
気管支肺アスペルギルス症	0	0	1 (1.1%)	0	0	1 (0.6%)
心内膜炎	1 (0.6%)	0	0	0	1 (0.5%)	0
感染	1 (0.6%)	0	0	0	1 (0.5%)	0
細菌性敗血症	0	3 (1.7%)	0	0	0	0
肺感染	0	1 (0.6%)	0	1 (1.2%)	0	0
髄膜炎	0	1 (0.6%)	0	0	0	0
ムコール症	0	1 (0.6%)	0	0	0	0
シュードモナス性敗血症	0	1 (0.6%)	0	0	0	0
ブドウ球菌感染	0	1 (0.6%)	0	0	0	0
全身性カンジダ	0	0	0	1 (1.2%)	0	0
脳膿瘍	0	0	0	0	0	1 (0.6%)
大腸菌性菌血症	0	0	0	0	0	1 (0.6%)
呼吸器、胸郭および縦隔障害	3 (1.8%)	5 (2.9%)	3 (3.2%)	0	3 (1.5%)	3 (1.9%)
呼吸不全	2 (1.2%)	4 (2.3%)	0	0	2 (1.0%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_discon_1.sas
Program Run: 04JUN21:14:57:01

表 8-177 投与中止に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
呼吸困難	1 (0.6%)	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
呼吸窮迫	0	1 (0.6%)	1 (1.1%)	0	0	1 (0.6%)
急性呼吸不全	0	0	1 (1.1%)	0	0	1 (0.6%)
神経系障害	3 (1.8%)	2 (1.1%)	2 (2.1%)	2 (2.4%)	3 (1.5%)	4 (2.5%)
痙攣	1 (0.6%)	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
てんかん	1 (0.6%)	0	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
脳症	1 (0.6%)	0	0	0	1 (0.5%)	0
大発作痙攣	0	0	0	1 (1.2%)	0	0
昏迷	0	0	0	1 (1.2%)	0	0
くも膜下出血	0	1 (0.6%)	0	0	0	0
振戦	0	1 (0.6%)	0	0	0	0
脳血管発作	0	0	0	0	0	1 (0.6%)
卒中の出血性変化	0	0	0	0	0	1 (0.6%)
臨床検査	2 (1.2%)	4 (2.3%)	2 (2.1%)	2 (2.4%)	2 (1.0%)	4 (2.5%)
血中ビリルビン増加	2 (1.2%)	0	0	0	2 (1.0%)	0
血中ナトリウム減少	0	0	1 (1.1%)	0	0	1 (0.6%)
トランスアミナーゼ上昇	0	0	1 (1.1%)	0	0	1 (0.6%)
肝機能検査異常	0	0	0	2 (2.4%)	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	1 (0.6%)
血中アルカリホスファターゼ増加	0	1 (0.6%)	0	0	0	1 (0.6%)
肝酵素上昇	0	1 (0.6%)	0	0	0	1 (0.6%)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_discon_1.sas
Program Run: 04JUN21:14:57:01

表 8-177 投与中止に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
心電図ＱＴ延長	0	1 (0.6%)	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	1 (0.6%)
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	1 (0.6%)
心臓障害	3 (1.8%)	1 (0.6%)	1 (1.1%)	2 (2.4%)	3 (1.5%)	1 (0.6%)
心停止	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
心肺停止	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
うっ血性心筋症	0	0	1 (1.1%)	0	0	1 (0.6%)
上室性頻脈	1 (0.6%)	0	0	0	1 (0.5%)	0
心室性頻脈	0	0	0	1 (1.2%)	0	0
腎および尿路障害	2 (1.2%)	2 (1.1%)	1 (1.1%)	1 (1.2%)	3 (1.5%)	2 (1.3%)
腎不全	1 (0.6%)	1 (0.6%)	1 (1.1%)	0	1 (0.5%)	1 (0.6%)
急性腎不全	1 (0.6%)	1 (0.6%)	0	1 (1.2%)	2 (1.0%)	1 (0.6%)
精神障害	1 (0.6%)	4 (2.3%)	1 (1.1%)	2 (2.4%)	1 (0.5%)	2 (1.3%)
錯乱状態	1 (0.6%)	1 (0.6%)	1 (1.1%)	1 (1.2%)	1 (0.5%)	2 (1.3%)
幻視	0	2 (1.1%)	0	1 (1.2%)	0	0
幻覚	0	1 (0.6%)	0	0	0	1 (0.6%)
抑うつ気分	0	1 (0.6%)	0	0	0	0
不快気分	0	0	0	1 (1.2%)	0	0
皮膚および皮下組織障害	2 (1.2%)	2 (1.1%)	0	3 (3.6%)	2 (1.0%)	0
皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0
アレルギー性皮膚炎	1 (0.6%)	0	0	0	1 (0.5%)	0
発疹	0	1 (0.6%)	0	3 (3.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_discon_1.sas
Program Run: 04JUN21:14:57:01

表 8-177 投与中止に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
薬疹	0	1 (0.6%)	0	0	0	0
胃腸障害	0	3 (1.7%)	2 (2.1%)	0	0	4 (2.5%)
嘔吐	0	2 (1.1%)	1 (1.1%)	0	0	2 (1.3%)
嚥下障害	0	0	1 (1.1%)	0	0	1 (0.6%)
小腸閉塞	0	0	1 (1.1%)	0	0	1 (0.6%)
悪心	0	2 (1.1%)	0	0	0	1 (0.6%)
肝胆道系障害	1 (0.6%)	4 (2.3%)	0	2 (2.4%)	2 (1.0%)	0
急性肝炎	1 (0.6%)	0	0	0	1 (0.5%)	0
肝不全	0	1 (0.6%)	0	1 (1.2%)	0	0
高ビリルビン血症	0	1 (0.6%)	0	1 (1.2%)	0	0
肝機能異常	0	1 (0.6%)	0	0	0	0
肝病変	0	1 (0.6%)	0	0	0	0
肝炎	0	1 (0.6%)	0	0	0	0
高トランスアミナーゼ血症	0	0	0	1 (1.2%)	0	0
急性肝不全	0	0	0	0	1 (0.5%)	0
血液およびリンパ系障害	0	2 (1.1%)	1 (1.1%)	1 (1.2%)	0	1 (0.6%)
汎血球減少症	0	0	1 (1.1%)	1 (1.2%)	0	1 (0.6%)
微小血管症性溶血性貧血	0	1 (0.6%)	0	0	0	0
脾臓病変	0	1 (0.6%)	0	0	0	0
眼障害	1 (0.6%)	0	0	1 (1.2%)	1 (0.5%)	0
視神経症	1 (0.6%)	0	0	0	1 (0.5%)	0
眼瞼浮腫	0	0	0	1 (1.2%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_discon_1.sas
Program Run: 04JUN21:14:57:01

表 8-177 投与中止に至った有害事象（好中球減少状態の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Neutropenic Yes		Neutropenic No		Neutropenic Yes	Neutropenic No
System Organ Class Preferred Term	ISA (N = 163)	VRC (N = 175)	ISA (N = 94)	VRC (N = 84)	ISA (N = 201)	ISA (N = 160)
全身障害および投与局所様態	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
悪寒	1 (0.6%)	1 (0.6%)	0	0	1 (0.5%)	0
傷害、中毒および処置合併症	1 (0.6%)	0	0	0	1 (0.5%)	0
過量投与	1 (0.6%)	0	0	0	1 (0.5%)	0
筋骨格系および結合組織障害	1 (0.6%)	0	0	0	1 (0.5%)	0
筋炎	1 (0.6%)	0	0	0	1 (0.5%)	0
血管障害	1 (0.6%)	0	0	0	1 (0.5%)	0
低血圧	1 (0.6%)	0	0	0	1 (0.5%)	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	4 (2.3%)	0	3 (3.6%)	2 (1.0%)	1 (0.6%)
急性骨髄性白血病	0	3 (1.7%)	0	1 (1.2%)	0	0
再発急性骨髄性白血病	0	1 (0.6%)	0	0	1 (0.5%)	0
慢性リンパ性白血病	0	0	0	1 (1.2%)	0	0
肺の悪性新生物	0	0	0	1 (1.2%)	0	0
白血病再発	0	0	0	0	0	1 (0.6%)
悪性新生物進行	0	0	0	0	1 (0.5%)	0
免疫系障害	0	0	0	1 (1.2%)	0	0
急性肝移植片対宿主病	0	0	0	1 (1.2%)	0	0
代謝および栄養障害	0	1 (0.6%)	0	0	0	0
代謝性アシドーシス	0	1 (0.6%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_neut_discon_1.sas
Program Run: 04JUN21:14:57:01

表 8-178 SOC別の有害事象（腎機能障害の有無別） －AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
Overall	6 (100.0%)	8 (100.0%)	49 (90.7%)	20 (90.9%)	8 (100.0%)	59 (90.8%)
感染症および寄生虫症	4 (66.7%)	3 (37.5%)	18 (33.3%)	7 (31.8%)	4 (50.0%)	21 (32.3%)
胃腸障害	1 (16.7%)	3 (37.5%)	16 (29.6%)	9 (40.9%)	1 (12.5%)	20 (30.8%)
臨床検査	1 (16.7%)	3 (37.5%)	15 (27.8%)	4 (18.2%)	3 (37.5%)	18 (27.7%)
肝胆道系障害	2 (33.3%)	5 (62.5%)	9 (16.7%)	5 (22.7%)	3 (37.5%)	9 (13.8%)
神経系障害	0	2 (25.0%)	10 (18.5%)	4 (18.2%)	0	15 (23.1%)
皮膚および皮下組織障害	1 (16.7%)	1 (12.5%)	8 (14.8%)	3 (13.6%)	1 (12.5%)	10 (15.4%)
眼障害	1 (16.7%)	6 (75.0%)	7 (13.0%)	7 (31.8%)	1 (12.5%)	9 (13.8%)
代謝および栄養障害	2 (33.3%)	1 (12.5%)	6 (11.1%)	1 (4.5%)	2 (25.0%)	9 (13.8%)
一般・全身障害および投与部位の状態	1 (16.7%)	0	7 (13.0%)	1 (4.5%)	1 (12.5%)	8 (12.3%)
呼吸器、胸郭および縦隔障害	0	0	7 (13.0%)	3 (13.6%)	0	9 (13.8%)
腎および尿路障害	2 (33.3%)	0	3 (5.6%)	2 (9.1%)	2 (25.0%)	5 (7.7%)
血管障害	0	0	5 (9.3%)	1 (4.5%)	0	6 (9.2%)
精神障害	1 (16.7%)	1 (12.5%)	2 (3.7%)	6 (27.3%)	1 (12.5%)	3 (4.6%)
筋骨格系および結合組織障害	0	3 (37.5%)	3 (5.6%)	1 (4.5%)	0	4 (6.2%)
傷害、中毒および処置合併症	0	0	3 (5.6%)	2 (9.1%)	0	4 (6.2%)
心臓障害	0	0	3 (5.6%)	1 (4.5%)	0	6 (9.2%)
耳および迷路障害	1 (16.7%)	1 (12.5%)	1 (1.9%)	0	1 (12.5%)	1 (1.5%)
免疫系障害	0	0	1 (1.9%)	1 (4.5%)	0	1 (1.5%)
内分泌障害	0	0	1 (1.9%)	0	0	2 (3.1%)
先天性、家族性および遺伝性障害	0	0	0	3 (13.6%)	0	1 (1.5%)
血液およびリンパ系障害	0	0	0	1 (4.5%)	0	2 (3.1%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_soc_2.sas
Program Run: 16JUN21:13:33:06

表 8-179 注目すべき有害事象（腎機能障害の有無別） －AK1820-301試験のCohort AおよびCohort A/B併合

	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
肝機能異常・肝炎	3 (50.0%)	6 (75.0%)	19 (35.2%)	8 (36.4%)	4 (50.0%)	20 (30.8%)
アナフィラキシー	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0
トルサード ド ポアント	0	0	1 (1.9%)	0	0	2 (3.1%)
急性膵炎	0	0	0	0	0	0
精神神経症状	0	1 (12.5%)	3 (5.6%)	6 (27.3%)	0	5 (7.7%)
視覚障害	1 (16.7%)	6 (75.0%)	6 (11.1%)	9 (40.9%)	1 (12.5%)	7 (10.8%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0
静脈内投与例	(N = 1)	(N = 0)	(N = 7)	(N = 2)	(N = 1)	(N = 8)
注入部位／注射部位反応	1 (100.0%)	0	2 (28.6%)	0	1 (100.0%)	2 (25.0%)
IRR	0	0	0	1 (50.0%)	0	1 (12.5%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_eoi_2.sas
Program Run: 16JUN21:13:33:14

表 8-180 死亡に至った有害事象（腎機能障害の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
Overall	0	0	4 (7.4%)	0	0	6 (9.2%)
呼吸器、胸郭および縦隔障害	0	0	2 (3.7%)	0	0	3 (4.6%)
特発性肺炎症候群	0	0	1 (1.9%)	0	0	1 (1.5%)
肺臓炎	0	0	1 (1.9%)	0	0	1 (1.5%)
誤嚥性肺炎	0	0	0	0	0	1 (1.5%)
感染症および寄生虫症	0	0	2 (3.7%)	0	0	2 (3.1%)
肺炎球菌感染	0	0	1 (1.9%)	0	0	1 (1.5%)
副鼻腔炎	0	0	1 (1.9%)	0	0	1 (1.5%)
神経系障害	0	0	1 (1.9%)	0	0	1 (1.5%)
大脳基底核梗塞	0	0	1 (1.9%)	0	0	1 (1.5%)
心臓障害	0	0	0	0	0	1 (1.5%)
急性心筋梗塞	0	0	0	0	0	1 (1.5%)
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (1.5%)
死亡	0	0	0	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_2.sas
Program Run: 16JUN21:13:33:24

表 8-181 重篤な有害事象（腎機能障害の有無別） －AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
Overall	0	1 (12.5%)	13 (24.1%)	2 (9.1%)	0	17 (26.2%)
感染症および寄生虫症	0	0	6 (11.1%)	2 (9.1%)	0	8 (12.3%)
肺炎	0	0	2 (3.7%)	1 (4.5%)	0	2 (3.1%)
感染性胸水	0	0	2 (3.7%)	0	0	2 (3.1%)
気管支炎	0	0	1 (1.9%)	0	0	1 (1.5%)
肺炎球菌感染	0	0	1 (1.9%)	0	0	1 (1.5%)
副鼻腔炎	0	0	1 (1.9%)	0	0	1 (1.5%)
アスペルギルス感染	0	0	0	1 (4.5%)	0	0
菌血症	0	0	0	0	0	1 (1.5%)
蜂巣炎	0	0	0	0	0	1 (1.5%)
呼吸器、胸郭および縦隔障害	0	0	4 (7.4%)	0	0	5 (7.7%)
喀血	0	0	1 (1.9%)	0	0	1 (1.5%)
特発性肺炎症候群	0	0	1 (1.9%)	0	0	1 (1.5%)
肺臓炎	0	0	1 (1.9%)	0	0	1 (1.5%)
気胸	0	0	1 (1.9%)	0	0	1 (1.5%)
誤嚥性肺炎	0	0	0	0	0	1 (1.5%)
肝胆道系障害	0	1 (12.5%)	1 (1.9%)	0	0	1 (1.5%)
胆嚢炎	0	0	1 (1.9%)	0	0	1 (1.5%)
薬物性肝障害	0	1 (12.5%)	0	0	0	0
筋骨格系および結合組織障害	0	1 (12.5%)	1 (1.9%)	0	0	1 (1.5%)
筋力低下	0	0	1 (1.9%)	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_ser_2.sas
Program Run: 16JUN21:13:33:31

表 8-181 重篤な有害事象（腎機能障害の有無別） －AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
横紋筋融解症	0	1 (12.5%)	0	0	0	0
内分泌障害	0	0	1 (1.9%)	0	0	1 (1.5%)
抗利尿ホルモン不適合分泌	0	0	1 (1.9%)	0	0	1 (1.5%)
代謝および栄養障害	0	0	1 (1.9%)	0	0	1 (1.5%)
低ナトリウム血症	0	0	1 (1.9%)	0	0	1 (1.5%)
神経系障害	0	0	1 (1.9%)	0	0	1 (1.5%)
大脳基底核梗塞	0	0	1 (1.9%)	0	0	1 (1.5%)
腎および尿路障害	0	0	1 (1.9%)	0	0	1 (1.5%)
腎機能障害	0	0	1 (1.9%)	0	0	1 (1.5%)
心臓障害	0	0	0	0	0	2 (3.1%)
急性心筋梗塞	0	0	0	0	0	1 (1.5%)
急性心不全	0	0	0	0	0	1 (1.5%)
血液およびリンパ系障害	0	0	0	0	0	1 (1.5%)
好中球減少症	0	0	0	0	0	1 (1.5%)
一般・全身障害および投与部位の状態	0	0	0	0	0	1 (1.5%)
死亡	0	0	0	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_ser_2.sas
Program Run: 16JUN21:13:33:31

表 8-182 投与中止に至った有害事象（腎機能障害の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
Overall	1 (16.7%)	3 (37.5%)	9 (16.7%)	1 (4.5%)	2 (25.0%)	9 (13.8%)
肝胆道系障害	0	2 (25.0%)	2 (3.7%)	0	0	2 (3.1%)
肝機能異常	0	1 (12.5%)	2 (3.7%)	0	0	2 (3.1%)
薬物性肝障害	0	1 (12.5%)	0	0	0	0
感染症および寄生虫症	0	0	2 (3.7%)	0	0	2 (3.1%)
感染性胸水	0	0	1 (1.9%)	0	0	1 (1.5%)
肺炎球菌感染	0	0	1 (1.9%)	0	0	1 (1.5%)
代謝および栄養障害	1 (16.7%)	0	1 (1.9%)	0	1 (12.5%)	1 (1.5%)
高カリウム血症	1 (16.7%)	0	0	0	1 (12.5%)	0
低ナトリウム血症	0	0	1 (1.9%)	0	0	1 (1.5%)
神経系障害	0	1 (12.5%)	1 (1.9%)	0	0	1 (1.5%)
感覚鈍麻	0	0	1 (1.9%)	0	0	1 (1.5%)
多発ニューロパチー	0	1 (12.5%)	0	0	0	0
臨床検査	0	0	1 (1.9%)	0	1 (12.5%)	1 (1.5%)
肝機能検査値上昇	0	0	1 (1.9%)	0	0	1 (1.5%)
心電図異常	0	0	0	0	1 (12.5%)	0
耳および迷路障害	0	0	1 (1.9%)	0	0	1 (1.5%)
耳管開放	0	0	1 (1.9%)	0	0	1 (1.5%)
胃腸障害	0	0	1 (1.9%)	0	0	1 (1.5%)
悪心	0	0	1 (1.9%)	0	0	1 (1.5%)
一般・全身障害および投与部位の状態	0	0	1 (1.9%)	0	0	1 (1.5%)
注射部位蕁麻疹	0	0	1 (1.9%)	0	0	1 (1.5%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_2.sas
Program Run: 16JUN21:13:33:36

表 8-182 投与中止に至った有害事象（腎機能障害の有無別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A				Cohort A/B併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 6)	VRC (N = 8)	ISA (N = 54)	VRC (N = 22)	ISA (N = 8)	ISA (N = 65)
腎および尿路障害	1 (16.7%)	0	0	0	1 (12.5%)	0
腎機能障害	1 (16.7%)	0	0	0	1 (12.5%)	0
呼吸器、胸郭および縦隔障害	0	0	1 (1.9%)	0	0	1 (1.5%)
呼吸困難	0	0	1 (1.9%)	0	0	1 (1.5%)
口腔咽頭不快感	0	0	1 (1.9%)	0	0	1 (1.5%)
皮膚および皮下組織障害	0	0	1 (1.9%)	0	0	1 (1.5%)
冷汗	0	0	1 (1.9%)	0	0	1 (1.5%)
眼障害	0	0	0	1 (4.5%)	0	0
視力障害	0	0	0	1 (4.5%)	0	0
筋骨格系および結合組織障害	0	1 (12.5%)	0	0	0	0
横紋筋融解症	0	1 (12.5%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_2.sas
Program Run: 16JUN21:13:33:36

表 8-183 SOC別の有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
Overall	20 (100.0%)	32 (97.0%)	220 (95.7%)	215 (98.6%)	79 (100.0%)	299 (94.6%)
胃腸障害	15 (75.0%)	23 (69.7%)	154 (67.0%)	154 (70.6%)	60 (75.9%)	192 (60.8%)
感染症および寄生虫症	13 (65.0%)	21 (63.6%)	136 (59.1%)	132 (60.6%)	53 (67.1%)	187 (59.2%)
全身障害および投与局所様態	12 (60.0%)	17 (51.5%)	133 (57.8%)	124 (56.9%)	42 (53.2%)	170 (53.8%)
呼吸器、胸郭および縦隔障害	8 (40.0%)	22 (66.7%)	132 (57.4%)	121 (55.5%)	34 (43.0%)	169 (53.5%)
代謝および栄養障害	7 (35.0%)	18 (54.5%)	99 (43.0%)	99 (45.4%)	38 (48.1%)	130 (41.1%)
神経系障害	8 (40.0%)	12 (36.4%)	85 (37.0%)	77 (35.3%)	33 (41.8%)	110 (34.8%)
皮膚および皮下組織障害	5 (25.0%)	11 (33.3%)	79 (34.3%)	95 (43.6%)	21 (26.6%)	102 (32.3%)
臨床検査	6 (30.0%)	15 (45.5%)	77 (33.5%)	79 (36.2%)	19 (24.1%)	98 (31.0%)
血液およびリンパ系障害	4 (20.0%)	14 (42.4%)	71 (30.9%)	64 (29.4%)	21 (26.6%)	83 (26.3%)
精神障害	6 (30.0%)	7 (21.2%)	63 (27.4%)	76 (34.9%)	23 (29.1%)	81 (25.6%)
筋骨格系および結合組織障害	4 (20.0%)	5 (15.2%)	63 (27.4%)	71 (32.6%)	23 (29.1%)	84 (26.6%)
血管障害	2 (10.0%)	11 (33.3%)	64 (27.8%)	64 (29.4%)	20 (25.3%)	80 (25.3%)
腎および尿路障害	6 (30.0%)	11 (33.3%)	49 (21.3%)	46 (21.1%)	21 (26.6%)	60 (19.0%)
心臓障害	4 (20.0%)	6 (18.2%)	38 (16.5%)	50 (22.9%)	19 (24.1%)	48 (15.2%)
眼障害	4 (20.0%)	14 (42.4%)	32 (13.9%)	52 (23.9%)	9 (11.4%)	46 (14.6%)
傷害、中毒および処置合併症	5 (25.0%)	4 (12.1%)	25 (10.9%)	33 (15.1%)	17 (21.5%)	35 (11.1%)
肝胆道系障害	3 (15.0%)	5 (15.2%)	20 (8.7%)	34 (15.6%)	12 (15.2%)	27 (8.5%)
免疫系障害	1 (5.0%)	2 (6.1%)	19 (8.3%)	22 (10.1%)	6 (7.6%)	23 (7.3%)
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）	2 (10.0%)	4 (12.1%)	17 (7.4%)	26 (11.9%)	5 (6.3%)	24 (7.6%)
耳および迷路障害	1 (5.0%)	0	12 (5.2%)	13 (6.0%)	5 (6.3%)	15 (4.7%)
生殖系および乳房障害	0	0	8 (3.5%)	12 (5.5%)	4 (5.1%)	13 (4.1%)
内分泌障害	1 (5.0%)	0	4 (1.7%)	3 (1.4%)	4 (5.1%)	6 (1.9%)
先天性、家族性および遺伝性障害	0	1 (3.0%)	3 (1.3%)	1 (0.5%)	0	3 (0.9%)
社会環境	0	1 (3.0%)	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_soc_1.sas
Program Run: 04JUN21:15:20:14

表 8-184 注目すべき有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
肝機能異常・肝炎	5 (25.0%)	12 (36.4%)	47 (20.4%)	67 (30.7%)	15 (19.0%)	66 (20.9%)
アナフィラキシー	0	0	2 (0.9%)	3 (1.4%)	0	2 (0.6%)
重度皮膚障害	0	0	3 (1.3%)	2 (0.9%)	0	3 (0.9%)
心電図QT短縮	0	0	1 (0.4%)	0	0	1 (0.3%)
トルサード ド ポアント	0	2 (6.1%)	15 (6.5%)	16 (7.3%)	2 (2.5%)	16 (5.1%)
急性膵炎	0	0	0	0	0	1 (0.3%)
精神神経症状	6 (30.0%)	7 (21.2%)	66 (28.7%)	69 (31.7%)	24 (30.4%)	85 (26.9%)
視覚障害	4 (20.0%)	12 (36.4%)	16 (7.0%)	32 (14.7%)	6 (7.6%)	22 (7.0%)
皮膚または子宮の悪性腫瘍	0	0	1 (0.4%)	0	0	1 (0.3%)
静脈内投与例	(N = 20)	(N = 33)	(N = 230)	(N = 218)	(N = 67)	(N = 283)
注入部位／注射部位反応	1 (5.0%)	0	9 (3.9%)	3 (1.4%)	5 (7.5%)	10 (3.5%)
IRR	3 (15.0%)	11 (33.3%)	66 (28.7%)	64 (29.4%)	17 (25.4%)	84 (29.7%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-185 死亡に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
Overall	4 (20.0%)	13 (39.4%)	57 (24.8%)	58 (26.6%)	25 (31.6%)	80 (25.3%)
感染症および寄生虫症	2 (10.0%)	4 (12.1%)	25 (10.9%)	14 (6.4%)	13 (16.5%)	35 (11.1%)
敗血症性ショック	1 (5.0%)	0	7 (3.0%)	4 (1.8%)	5 (6.3%)	7 (2.2%)
敗血症	0	2 (6.1%)	7 (3.0%)	3 (1.4%)	1 (1.3%)	7 (2.2%)
真菌感染	0	2 (6.1%)	3 (1.3%)	0	0	3 (0.9%)
アスペルギルス症	0	0	2 (0.9%)	2 (0.9%)	0	3 (0.9%)
肺炎	0	0	1 (0.4%)	2 (0.9%)	0	3 (0.9%)
ムコール症	0	0	1 (0.4%)	0	0	2 (0.6%)
アシネトバクター性菌血症	0	0	1 (0.4%)	0	0	1 (0.3%)
気管支肺アスペルギルス症	0	0	1 (0.4%)	0	0	1 (0.3%)
心内膜炎	0	0	1 (0.4%)	0	0	1 (0.3%)
フサリウム感染	1 (5.0%)	0	0	0	1 (1.3%)	0
感染	0	0	1 (0.4%)	0	0	1 (0.3%)
シュードモナス性敗血症	0	0	0	1 (0.5%)	0	1 (0.3%)
クレブシエラ性敗血症	0	0	0	1 (0.5%)	0	0
シュードモナス性菌血症	0	0	0	1 (0.5%)	0	0
ステノトロフォモナス性敗血症	0	0	0	1 (0.5%)	0	0
真菌性肺炎	0	0	0	0	0	2 (0.6%)
細菌性敗血症	0	0	0	0	1 (1.3%)	0
蓄膿	0	0	0	0	1 (1.3%)	0
真菌性敗血症	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_1.sas
Program Run: 04JUN21:14:57:55

表 8-185 死亡に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
肺感染	0	0	0	0	0	1 (0.3%)
シュードモナス菌性肺感染	0	0	0	0	1 (1.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	1 (1.3%)	0
原発性異型肺炎	0	0	0	0	1 (1.3%)	0
真菌性副鼻腔炎	0	0	0	0	0	1 (0.3%)
ブドウ球菌性敗血症	0	0	0	0	0	1 (0.3%)
呼吸器、胸郭および縦隔障害	0	2 (6.1%)	14 (6.1%)	10 (4.6%)	2 (2.5%)	16 (5.1%)
呼吸不全	0	2 (6.1%)	6 (2.6%)	4 (1.8%)	1 (1.3%)	6 (1.9%)
急性呼吸不全	0	0	3 (1.3%)	1 (0.5%)	0	4 (1.3%)
喀血	0	0	2 (0.9%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
肺出血	0	0	2 (0.9%)	1 (0.5%)	0	2 (0.6%)
呼吸窮迫	0	0	1 (0.4%)	0	0	1 (0.3%)
急性呼吸窮迫症候群	0	0	0	1 (0.5%)	0	0
肺塞栓症	0	0	0	1 (0.5%)	0	0
肺高血圧症	0	0	0	1 (0.5%)	0	0
呼吸困難	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）	2 (10.0%)	3 (9.1%)	8 (3.5%)	18 (8.3%)	4 (5.1%)	13 (4.1%)
急性骨髄性白血病	0	1 (3.0%)	3 (1.3%)	6 (2.8%)	1 (1.3%)	3 (0.9%)
多発性骨髄腫	0	0	2 (0.9%)	0	0	2 (0.6%)
悪性新生物進行	1 (5.0%)	0	0	1 (0.5%)	1 (1.3%)	2 (0.6%)
芽球発症	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_1.sas
Program Run: 04JUN21:14:57:55

表 8-185 死亡に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
骨髄性白血病	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
再発慢性リンパ性白血病	1 (5.0%)	0	0	0	1 (1.3%)	0
骨髄異形成症候群	0	0	1 (0.4%)	0	0	1 (0.3%)
再発急性骨髄性白血病	0	0	0	4 (1.8%)	0	1 (0.3%)
慢性リンパ性白血病	0	0	0	2 (0.9%)	0	1 (0.3%)
再発急性リンパ性白血病	0	0	0	1 (0.5%)	0	1 (0.3%)
Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
バーキット白血病	0	0	0	1 (0.5%)	0	0
リンパ腫	0	0	0	1 (0.5%)	0	0
新生物進行	0	1 (3.0%)	0	0	0	0
白血病再発	0	0	0	0	1 (1.3%)	0
心臓障害	0	0	4 (1.7%)	4 (1.8%)	1 (1.3%)	6 (1.9%)
心停止	0	0	1 (0.4%)	3 (1.4%)	0	1 (0.3%)
心肺停止	0	0	1 (0.4%)	0	1 (1.3%)	2 (0.6%)
うっ血性心筋症	0	0	1 (0.4%)	0	0	1 (0.3%)
心膜炎	0	0	1 (0.4%)	0	0	1 (0.3%)
急性心筋梗塞	0	0	0	1 (0.5%)	0	0
急性心不全	0	0	0	0	0	1 (0.3%)
神経系障害	0	1 (3.0%)	3 (1.3%)	6 (2.8%)	1 (1.3%)	4 (1.3%)
頭蓋内出血	0	0	2 (0.9%)	3 (1.4%)	0	2 (0.6%)
神経毒性	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_1.sas
Program Run: 04JUN21:14:57:55

表 8-185 死亡に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
脳出血	0	0	0	1 (0.5%)	0	0
脳炎	0	0	0	1 (0.5%)	0	0
昏迷	0	0	0	1 (0.5%)	0	0
くも膜下出血	0	1 (3.0%)	0	0	0	0
脳梗塞	0	0	0	0	1 (1.3%)	1 (0.3%)
全身障害および投与局所様態	0	1 (3.0%)	2 (0.9%)	7 (3.2%)	2 (2.5%)	5 (1.6%)
多臓器不全	0	1 (3.0%)	1 (0.4%)	5 (2.3%)	0	2 (0.6%)
死亡	0	0	1 (0.4%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
心突然死	0	0	0	1 (0.5%)	0	0
全身健康状態低下	0	0	0	0	1 (1.3%)	0
血管障害	0	0	2 (0.9%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
出血	0	0	1 (0.4%)	0	0	1 (0.3%)
血液量減少性ショック	0	0	1 (0.4%)	0	0	1 (0.3%)
深部静脈血栓症	0	0	0	1 (0.5%)	0	0
動脈炎	0	0	0	0	1 (1.3%)	0
血液およびリンパ系障害	0	1 (3.0%)	2 (0.9%)	0	0	2 (0.6%)
出血性障害	0	0	1 (0.4%)	0	0	1 (0.3%)
血小板減少症	0	0	1 (0.4%)	0	0	1 (0.3%)
汎血球減少症	0	1 (3.0%)	0	0	0	0
免疫系障害	0	0	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
急性移植片対宿主病	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_1.sas
Program Run: 04JUN21:14:57:55

表 8-185 死亡に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
移植片対宿主病	0	0	0	0	1 (1.3%)	0
腎および尿路障害	0	0	1 (0.4%)	0	0	2 (0.6%)
腎不全	0	0	1 (0.4%)	0	0	1 (0.3%)
急性腎不全	0	0	0	0	0	1 (0.3%)
肝胆道系障害	0	0	1 (0.4%)	0	0	1 (0.3%)
急性肝炎	0	0	1 (0.4%)	0	0	1 (0.3%)
代謝および栄養障害	0	2 (6.1%)	0	0	0	0
低血糖症	0	1 (3.0%)	0	0	0	0
代謝性アシドーシス	0	1 (3.0%)	0	0	0	0
胃腸障害	0	0	0	1 (0.5%)	0	0
直腸出血	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_death_1.sas
Program Run: 04JUN21:14:57:55

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
Overall	9 (45.0%)	21 (63.6%)	121 (52.6%)	123 (56.4%)	52 (65.8%)	167 (52.8%)
感染症および寄生虫症	4 (20.0%)	12 (36.4%)	44 (19.1%)	48 (22.0%)	29 (36.7%)	74 (23.4%)
敗血症性ショック	1 (5.0%)	2 (6.1%)	13 (5.7%)	8 (3.7%)	7 (8.9%)	13 (4.1%)
敗血症	0	3 (9.1%)	7 (3.0%)	5 (2.3%)	2 (2.5%)	8 (2.5%)
肺炎	0	2 (6.1%)	4 (1.7%)	7 (3.2%)	1 (1.3%)	10 (3.2%)
アスペルギルス症	0	0	3 (1.3%)	3 (1.4%)	1 (1.3%)	5 (1.6%)
真菌感染	0	2 (6.1%)	3 (1.3%)	1 (0.5%)	0	4 (1.3%)
サイトメガロウイルス感染	1 (5.0%)	0	1 (0.4%)	2 (0.9%)	2 (2.5%)	2 (0.6%)
気管支肺アスペルギルス症	0	0	2 (0.9%)	1 (0.5%)	0	2 (0.6%)
シュードモナス性敗血症	0	0	1 (0.4%)	1 (0.5%)	0	3 (0.9%)
大腸菌性敗血症	1 (5.0%)	0	0	1 (0.5%)	2 (2.5%)	0
尿路感染	0	1 (3.0%)	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
蜂巣炎	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
クレブシエラ性菌血症	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
クレブシエラ性敗血症	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
ムコール症	0	0	1 (0.4%)	0	0	3 (0.9%)
クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
腸球菌性菌血症	0	0	1 (0.4%)	0	0	2 (0.6%)
ブドウ球菌感染	1 (5.0%)	0	0	0	1 (1.3%)	1 (0.3%)
アシネトバクター性菌血症	0	0	1 (0.4%)	0	0	1 (0.3%)
肺炎球菌性気管支炎	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
気管支肺炎	0	0	1 (0.4%)	0	0	1 (0.3%)
脳アスペルギルス症	0	0	1 (0.4%)	0	0	1 (0.3%)
サイトメガロウイルス血症	0	0	1 (0.4%)	0	0	1 (0.3%)
ヘルペス脳炎	0	0	1 (0.4%)	0	0	1 (0.3%)
心内膜炎	0	0	1 (0.4%)	0	0	1 (0.3%)
フサリウム感染	1 (5.0%)	0	0	0	1 (1.3%)	0
感染	0	0	1 (0.4%)	0	0	1 (0.3%)
筋膿瘍	0	0	1 (0.4%)	0	0	1 (0.3%)
モラクセラ菌性肺炎	0	0	1 (0.4%)	0	0	1 (0.3%)
気道感染	0	0	1 (0.4%)	0	0	1 (0.3%)
敗血症症候群	0	0	1 (0.4%)	0	0	1 (0.3%)
皮膚感染	0	0	1 (0.4%)	0	0	1 (0.3%)
細菌性敗血症	0	1 (3.0%)	0	3 (1.4%)	1 (1.3%)	0
ブドウ球菌性菌血症	0	0	0	3 (1.4%)	1 (1.3%)	0
菌血症	0	0	0	2 (0.9%)	3 (3.8%)	0
ブドウ球菌性敗血症	0	0	0	2 (0.9%)	0	1 (0.3%)
クロストリジウム性菌血症	0	0	0	2 (0.9%)	0	0
髄膜炎	0	0	0	2 (0.9%)	0	0
細菌性肺炎	0	1 (3.0%)	0	0	1 (1.3%)	2 (0.6%)
帯状疱疹	0	0	0	1 (0.5%)	0	2 (0.6%)
蓄膿	0	0	0	1 (0.5%)	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
カンピロバクター胃腸炎	0	0	0	1 (0.5%)	0	0
カテーテル関連感染	0	0	0	1 (0.5%)	0	0
感染性下痢	0	0	0	1 (0.5%)	0	0
ヘリコバクター胃潰瘍	0	1 (3.0%)	0	0	0	0
単純ヘルペス	0	0	0	1 (0.5%)	0	0
肺膿瘍	0	0	0	1 (0.5%)	0	0
壊死性筋膜炎	0	0	0	1 (0.5%)	0	0
肺炎球菌性肺炎	0	0	0	1 (0.5%)	0	0
ブドウ球菌性肺炎	0	0	0	1 (0.5%)	0	0
シュードモナス性菌血症	0	0	0	1 (0.5%)	0	0
シュードモナス感染	0	0	0	1 (0.5%)	0	0
膿胸	0	1 (3.0%)	0	0	0	0
ステノトロフォモナス性敗血症	0	0	0	1 (0.5%)	0	0
全身性カンジダ	0	0	0	1 (0.5%)	0	0
トキソプラズマ症	0	0	0	1 (0.5%)	0	0
結核	0	0	0	1 (0.5%)	0	0
細菌性尿路感染	0	1 (3.0%)	0	0	0	0
真菌性肺炎	0	0	0	0	0	2 (0.6%)
接合真菌症	0	0	0	0	0	2 (0.6%)
腹部膿瘍	0	0	0	0	0	1 (0.3%)
虫垂炎	0	0	0	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
ＢＫウイルス感染	0	0	0	0	1 (1.3%)	0
脳膿瘍	0	0	0	0	1 (1.3%)	0
気管支拡張症	0	0	0	0	0	1 (0.3%)
細気管支炎	0	0	0	0	1 (1.3%)	0
カテーテル留置部位感染	0	0	0	0	0	1 (0.3%)
サイトメガロウイルス性小腸炎	0	0	0	0	0	1 (0.3%)
大腸菌性菌血症	0	0	0	0	0	1 (0.3%)
真菌性敗血症	0	0	0	0	1 (1.3%)	0
ノロウイルス性胃腸炎	0	0	0	0	1 (1.3%)	0
ウイルス性胃腸炎	0	0	0	0	0	1 (0.3%)
インフルエンザ	0	0	0	0	0	1 (0.3%)
肺感染	0	0	0	0	0	1 (0.3%)
シュードモナス菌性肺感染	0	0	0	0	1 (1.3%)	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	1 (1.3%)	0
ブラストミセス菌性肺炎	0	0	0	0	1 (1.3%)	0
インフルエンザ性肺炎	0	0	0	0	1 (1.3%)	0
原発性異型肺炎	0	0	0	0	1 (1.3%)	0
シュードモナス性気管支炎	0	0	0	0	1 (1.3%)	0
副鼻腔炎	0	0	0	0	1 (1.3%)	0
真菌性副鼻腔炎	0	0	0	0	0	1 (0.3%)
レンサ球菌性菌血症	0	0	0	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
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表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
皮下組織膿瘍	0	0	0	0	0	1 (0.3%)
尿路性敗血症	0	0	0	0	1 (1.3%)	0
ウイルス性下痢	0	0	0	0	1 (1.3%)	0
呼吸器、胸郭および縦隔障害	1 (5.0%)	6 (18.2%)	40 (17.4%)	37 (17.0%)	10 (12.7%)	51 (16.1%)
呼吸不全	0	3 (9.1%)	14 (6.1%)	9 (4.1%)	4 (5.1%)	15 (4.7%)
急性呼吸不全	0	1 (3.0%)	5 (2.2%)	4 (1.8%)	0	8 (2.5%)
呼吸困難	1 (5.0%)	0	4 (1.7%)	1 (0.5%)	1 (1.3%)	5 (1.6%)
呼吸窮迫	0	0	4 (1.7%)	3 (1.4%)	0	4 (1.3%)
喀血	0	0	2 (0.9%)	2 (0.9%)	1 (1.3%)	3 (0.9%)
低酸素症	1 (5.0%)	0	1 (0.4%)	1 (0.5%)	2 (2.5%)	1 (0.3%)
肺出血	0	0	2 (0.9%)	1 (0.5%)	0	2 (0.6%)
胸水	0	0	1 (0.4%)	1 (0.5%)	0	2 (0.6%)
肺水腫	0	0	1 (0.4%)	1 (0.5%)	0	2 (0.6%)
肺障害	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)
呼吸抑制	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
嚥下性肺炎	0	0	1 (0.4%)	0	1 (1.3%)	2 (0.6%)
頻呼吸	0	0	1 (0.4%)	0	0	2 (0.6%)
気管支胸膜瘻	0	0	1 (0.4%)	0	0	1 (0.3%)
気管支痙攣	0	0	1 (0.4%)	0	0	1 (0.3%)
水気胸	0	0	1 (0.4%)	0	0	1 (0.3%)
胸膜痛	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
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表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
呼吸性アシドーシス	0	0	1 (0.4%)	0	0	1 (0.3%)
鼻出血	0	1 (3.0%)	0	3 (1.4%)	0	0
肺塞栓症	0	0	0	3 (1.4%)	0	1 (0.3%)
肺浸潤	0	0	0	3 (1.4%)	0	0
急性呼吸窮迫症候群	0	0	0	2 (0.9%)	1 (1.3%)	0
急性肺損傷	0	0	0	1 (0.5%)	0	0
慢性閉塞性肺疾患	0	0	0	1 (0.5%)	0	0
咳嗽	0	0	0	1 (0.5%)	0	0
血胸	0	0	0	1 (0.5%)	0	0
気胸	0	0	0	1 (0.5%)	0	0
湿性咳嗽	0	0	0	1 (0.5%)	0	0
肺高血圧症	0	0	0	1 (0.5%)	0	0
呼吸停止	0	0	0	1 (0.5%)	0	0
高炭酸ガス血症	0	0	0	0	0	1 (0.3%)
肺胞出血	0	0	0	0	1 (1.3%)	0
肺梗塞	0	0	0	0	1 (1.3%)	0
副鼻腔障害	0	0	0	0	0	1 (0.3%)
喘鳴	0	0	0	0	0	1 (0.3%)
血液およびリンパ系障害	4 (20.0%)	4 (12.1%)	22 (9.6%)	11 (5.0%)	6 (7.6%)	25 (7.9%)
発熱性好中球減少症	2 (10.0%)	1 (3.0%)	10 (4.3%)	4 (1.8%)	3 (3.8%)	11 (3.5%)
好中球減少症	2 (10.0%)	0	2 (0.9%)	3 (1.4%)	2 (2.5%)	2 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
汎血球減少症	0	1 (3.0%)	3 (1.3%)	2 (0.9%)	0	4 (1.3%)
血小板減少症	0	1 (3.0%)	3 (1.3%)	2 (0.9%)	0	3 (0.9%)
無顆粒球症	0	0	2 (0.9%)	0	0	2 (0.6%)
貧血	0	0	1 (0.4%)	1 (0.5%)	1 (1.3%)	2 (0.6%)
出血性障害	0	0	1 (0.4%)	0	0	1 (0.3%)
白血球増加症	0	0	1 (0.4%)	0	0	1 (0.3%)
脾臓梗塞	0	0	1 (0.4%)	0	0	1 (0.3%)
出血性貧血	0	1 (3.0%)	0	0	0	0
微小血管症性溶血性貧血	0	0	0	1 (0.5%)	0	0
血小板減少性紫斑病	0	0	0	1 (0.5%)	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）	2 (10.0%)	4 (12.1%)	16 (7.0%)	24 (11.0%)	4 (5.1%)	22 (7.0%)
急性骨髄性白血病	0	1 (3.0%)	3 (1.3%)	7 (3.2%)	2 (2.5%)	3 (0.9%)
リンパ腫	0	0	2 (0.9%)	1 (0.5%)	0	2 (0.6%)
多発性骨髄腫	0	0	2 (0.9%)	0	0	2 (0.6%)
悪性新生物進行	1 (5.0%)	0	0	1 (0.5%)	1 (1.3%)	2 (0.6%)
再発急性リンパ性白血病	0	0	1 (0.4%)	1 (0.5%)	0	2 (0.6%)
芽球発症	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)
骨髄性白血病	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
新生物進行	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)
再発慢性リンパ性白血病	1 (5.0%)	0	0	0	1 (1.3%)	0
子宮内膜癌	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
髄膜転移	0	0	1 (0.4%)	0	0	1 (0.3%)
骨髄異形成症候群	0	0	1 (0.4%)	0	0	1 (0.3%)
非ホジキンリンパ腫	0	0	1 (0.4%)	0	0	1 (0.3%)
原発性体腔性リンパ腫	0	0	1 (0.4%)	0	0	1 (0.3%)
再発急性骨髄性白血病	0	0	0	5 (2.3%)	0	2 (0.6%)
慢性リンパ性白血病	0	0	0	2 (0.9%)	0	1 (0.3%)
急性白血病	0	0	0	1 (0.5%)	0	0
急性リンパ性白血病	0	1 (3.0%)	0	0	0	0
Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
再発Ｂ細胞性リンパ腫	0	0	0	1 (0.5%)	0	0
バーキット白血病	0	0	0	1 (0.5%)	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	0	0	1 (0.5%)	0	0
白血病	0	0	0	1 (0.5%)	0	0
骨転移	0	0	0	1 (0.5%)	0	0
転移部痛	0	0	0	1 (0.5%)	0	0
白血病再発	0	0	0	0	1 (1.3%)	0
白血病浸潤	0	0	0	0	1 (1.3%)	0
神経系障害	0	1 (3.0%)	17 (7.4%)	15 (6.9%)	4 (5.1%)	22 (7.0%)
痙攣	0	0	3 (1.3%)	1 (0.5%)	0	5 (1.6%)
頭蓋内出血	0	0	2 (0.9%)	3 (1.4%)	0	2 (0.6%)
てんかん	0	0	2 (0.9%)	1 (0.5%)	0	2 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
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表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
多発ニューロパチー	0	0	2 (0.9%)	0	0	2 (0.6%)
中枢神経系病変	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
脳症	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
虚血性脳卒中	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
対麻痺	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
頭痛	0	0	1 (0.4%)	0	0	2 (0.6%)
脳幹卒中	0	0	1 (0.4%)	0	0	1 (0.3%)
脳虚血	0	0	1 (0.4%)	0	0	1 (0.3%)
熱性痙攣	0	0	1 (0.4%)	0	0	1 (0.3%)
神経毒性	0	0	1 (0.4%)	0	0	1 (0.3%)
失語症	0	0	0	1 (0.5%)	1 (1.3%)	0
脳出血	0	0	0	1 (0.5%)	0	0
浮動性めまい	0	0	0	1 (0.5%)	0	0
脳炎	0	0	0	1 (0.5%)	0	0
大発作痙攣	0	0	0	1 (0.5%)	0	0
片麻痺	0	0	0	1 (0.5%)	0	0
昏迷	0	0	0	1 (0.5%)	0	0
くも膜下出血	0	1 (3.0%)	0	0	0	0
振戦	0	0	0	1 (0.5%)	0	0
第 7 脳神経麻痺	0	0	0	1 (0.5%)	0	0
脳梗塞	0	0	0	0	2 (2.5%)	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

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Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
脳血管発作	0	0	0	0	1 (1.3%)	0
卒中の出血性変化	0	0	0	0	1 (1.3%)	0
不全片麻痺	0	0	0	0	1 (1.3%)	0
一過性脳虚血発作	0	0	0	0	0	1 (0.3%)
全身障害および投与局所様態	0	2 (6.1%)	11 (4.8%)	17 (7.8%)	4 (5.1%)	16 (5.1%)
発熱	0	1 (3.0%)	8 (3.5%)	9 (4.1%)	1 (1.3%)	9 (2.8%)
多臓器不全	0	1 (3.0%)	1 (0.4%)	6 (2.8%)	0	2 (0.6%)
死亡	0	0	1 (0.4%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
悪寒	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
全身健康状態低下	0	0	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
無力症	0	0	1 (0.4%)	0	0	1 (0.3%)
胸痛	0	0	1 (0.4%)	0	0	1 (0.3%)
心突然死	0	0	0	1 (0.5%)	0	0
非心臓性胸痛	0	0	0	0	1 (1.3%)	1 (0.3%)
末梢性浮腫	0	0	0	0	1 (1.3%)	0
心臓障害	0	0	10 (4.3%)	11 (5.0%)	6 (7.6%)	12 (3.8%)
心肺停止	0	0	2 (0.9%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
心停止	0	0	1 (0.4%)	5 (2.3%)	0	1 (0.3%)
心房細動	0	0	1 (0.4%)	1 (0.5%)	2 (2.5%)	1 (0.3%)
不整脈	0	0	1 (0.4%)	0	0	1 (0.3%)
心原性ショック	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

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Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
うっ血性心筋症	0	0	1 (0.4%)	0	0	1 (0.3%)
心膜炎	0	0	1 (0.4%)	0	0	1 (0.3%)
洞性徐脈	0	0	1 (0.4%)	0	0	1 (0.3%)
上室性頻脈	0	0	1 (0.4%)	0	0	1 (0.3%)
心室性頻脈	0	0	0	2 (0.9%)	0	0
急性心筋梗塞	0	0	0	1 (0.5%)	1 (1.3%)	0
狭心症	0	0	0	1 (0.5%)	0	0
完全房室ブロック	0	0	0	0	1 (1.3%)	0
急性心不全	0	0	0	0	0	1 (0.3%)
電気収縮解離	0	0	0	0	1 (1.3%)	0
腎および尿路障害	2 (10.0%)	4 (12.1%)	8 (3.5%)	6 (2.8%)	9 (11.4%)	10 (3.2%)
急性腎不全	1 (5.0%)	3 (9.1%)	5 (2.2%)	5 (2.3%)	7 (8.9%)	7 (2.2%)
腎不全	1 (5.0%)	1 (3.0%)	2 (0.9%)	1 (0.5%)	2 (2.5%)	2 (0.6%)
血尿	0	0	1 (0.4%)	0	0	1 (0.3%)
胃腸障害	0	3 (9.1%)	8 (3.5%)	9 (4.1%)	8 (10.1%)	18 (5.7%)
下痢	0	0	2 (0.9%)	1 (0.5%)	1 (1.3%)	3 (0.9%)
小腸閉塞	0	0	2 (0.9%)	0	0	2 (0.6%)
悪心	0	0	1 (0.4%)	1 (0.5%)	0	3 (0.9%)
腸出血	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)
腹膜炎	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
大腸炎	0	0	1 (0.4%)	0	0	2 (0.6%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

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Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
便秘	0	0	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
胃穿孔	0	0	1 (0.4%)	0	0	1 (0.3%)
食道潰瘍	0	0	1 (0.4%)	0	0	1 (0.3%)
胃腸出血	0	0	0	3 (1.4%)	3 (3.8%)	0
食中毒	0	1 (3.0%)	0	0	0	0
胃腸の炎症	0	1 (3.0%)	0	0	0	0
麻痺性イレウス	0	0	0	1 (0.5%)	0	0
肛門周囲痛	0	0	0	1 (0.5%)	0	0
直腸出血	0	0	0	1 (0.5%)	0	0
腹痛	0	0	0	0	2 (2.5%)	3 (0.9%)
嘔吐	0	0	0	0	0	4 (1.3%)
嚥下障害	0	0	0	0	1 (1.3%)	1 (0.3%)
潰瘍性大腸炎	0	0	0	0	0	1 (0.3%)
限局性腹腔内液貯留	0	0	0	0	0	1 (0.3%)
食道炎	0	0	0	0	0	1 (0.3%)
膵炎	0	0	0	0	0	1 (0.3%)
慢性膵炎	0	0	0	0	0	1 (0.3%)
再発性膵炎	0	0	0	0	0	1 (0.3%)
免疫系障害	1 (5.0%)	0	3 (1.3%)	6 (2.8%)	4 (5.1%)	5 (1.6%)
急性腸管移植片対宿主病	1 (5.0%)	0	0	2 (0.9%)	1 (1.3%)	0
急性移植片対宿主病	0	0	1 (0.4%)	1 (0.5%)	2 (2.5%)	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
アナフィラキシーショック	0	0	1 (0.4%)	0	0	1 (0.3%)
過敏症	0	0	1 (0.4%)	0	0	1 (0.3%)
アナフィラキシー反応	0	0	0	2 (0.9%)	0	0
急性肝移植片対宿主病	0	0	0	1 (0.5%)	0	0
移植片対宿主病	0	0	0	0	1 (1.3%)	1 (0.3%)
肺移植拒絶反応	0	0	0	0	0	1 (0.3%)
血管障害	0	1 (3.0%)	4 (1.7%)	5 (2.3%)	4 (5.1%)	5 (1.6%)
低血圧	0	1 (3.0%)	1 (0.4%)	1 (0.5%)	2 (2.5%)	1 (0.3%)
出血	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
血液量減少性ショック	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
血管炎	0	0	1 (0.4%)	0	0	1 (0.3%)
深部静脈血栓症	0	0	0	1 (0.5%)	1 (1.3%)	1 (0.3%)
ショック	0	0	0	1 (0.5%)	0	0
動脈炎	0	0	0	0	1 (1.3%)	0
肝胆道系障害	0	3 (9.1%)	3 (1.3%)	3 (1.4%)	3 (3.8%)	5 (1.6%)
胆嚢炎	0	0	1 (0.4%)	0	1 (1.3%)	1 (0.3%)
肝炎	0	0	1 (0.4%)	0	0	1 (0.3%)
急性肝炎	0	0	1 (0.4%)	0	0	1 (0.3%)
肝不全	0	0	0	2 (0.9%)	0	0
肝機能異常	0	1 (3.0%)	0	1 (0.5%)	0	0
高ビリルビン血症	0	1 (3.0%)	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
急性胆嚢炎	0	1 (3.0%)	0	0	0	0
急性肝不全	0	0	0	0	0	1 (0.3%)
細胆管炎	0	0	0	0	1 (1.3%)	0
胆石症	0	0	0	0	1 (1.3%)	0
肝障害	0	0	0	0	0	1 (0.3%)
臨床検査	0	1 (3.0%)	3 (1.3%)	5 (2.3%)	0	3 (0.9%)
肝機能検査異常	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
血中ナトリウム減少	0	0	1 (0.4%)	0	0	1 (0.3%)
ヘモグロビン減少	0	0	1 (0.4%)	0	0	1 (0.3%)
アラニン・アミノトランスフェラーゼ増加	0	0	0	1 (0.5%)	0	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	1 (0.5%)	0	0
血中アルカリホスファターゼ増加	0	0	0	1 (0.5%)	0	0
血中ビリルビン増加	0	1 (3.0%)	0	0	0	0
心電図ＱＴ延長	0	0	0	1 (0.5%)	0	0
肝酵素上昇	0	0	0	1 (0.5%)	0	0
筋骨格系および結合組織障害	0	0	3 (1.3%)	0	2 (2.5%)	5 (1.6%)
筋骨格系胸痛	0	0	1 (0.4%)	0	2 (2.5%)	1 (0.3%)
筋肉内出血	0	0	1 (0.4%)	0	0	1 (0.3%)
筋炎	0	0	1 (0.4%)	0	0	1 (0.3%)
関節炎	0	0	0	0	0	1 (0.3%)
四肢痛	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
全身性エリテマトーデス	0	0	0	0	0	1 (0.3%)
代謝および栄養障害	0	3 (9.1%)	2 (0.9%)	4 (1.8%)	3 (3.8%)	6 (1.9%)
コントロール不良の糖尿病	0	0	1 (0.4%)	0	0	1 (0.3%)
成長障害	0	0	1 (0.4%)	0	0	1 (0.3%)
脱水	0	2 (6.1%)	0	0	2 (2.5%)	1 (0.3%)
代謝性アシドーシス	0	1 (3.0%)	0	1 (0.5%)	0	0
低血糖症	0	1 (3.0%)	0	0	0	1 (0.3%)
高ナトリウム血症	0	0	0	1 (0.5%)	0	0
低カリウム血症	0	0	0	1 (0.5%)	0	0
過小食	0	0	0	1 (0.5%)	0	0
高カリウム血症	0	0	0	0	1 (1.3%)	0
低ナトリウム血症	0	0	0	0	0	1 (0.3%)
栄養障害	0	0	0	0	0	1 (0.3%)
傷害、中毒および処置合併症	0	0	2 (0.9%)	3 (1.4%)	0	2 (0.6%)
薬物毒性	0	0	2 (0.9%)	0	0	2 (0.6%)
家庭内事故	0	0	0	1 (0.5%)	0	0
大腿骨頚部骨折	0	0	0	1 (0.5%)	0	0
橈骨骨折	0	0	0	1 (0.5%)	0	0
皮膚および皮下組織障害	0	1 (3.0%)	2 (0.9%)	1 (0.5%)	0	2 (0.6%)
褥瘡性潰瘍	0	0	1 (0.4%)	0	0	1 (0.3%)
皮膚炎	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-186 重篤な有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
発疹	0	1 (3.0%)	0	1 (0.5%)	0	0
眼障害	1 (5.0%)	1 (3.0%)	1 (0.4%)	0	2 (2.5%)	2 (0.6%)
片側失明	1 (5.0%)	0	0	0	1 (1.3%)	0
視神経症	0	0	1 (0.4%)	0	0	1 (0.3%)
眼瞼浮腫	0	1 (3.0%)	0	0	0	0
網膜動脈閉塞	0	0	0	0	0	1 (0.3%)
網膜出血	0	0	0	0	1 (1.3%)	0
硝子体出血	0	0	0	0	1 (1.3%)	0
精神障害	0	1 (3.0%)	1 (0.4%)	5 (2.3%)	2 (2.5%)	1 (0.3%)
うつ病	0	0	1 (0.4%)	0	0	1 (0.3%)
幻視	0	0	0	2 (0.9%)	0	0
精神状態変化	0	0	0	2 (0.9%)	0	0
錯乱状態	0	0	0	1 (0.5%)	1 (1.3%)	0
幻覚	0	0	0	1 (0.5%)	1 (1.3%)	0
抑うつ気分	0	1 (3.0%)	0	0	0	0
自殺企図	0	0	0	1 (0.5%)	0	0
異常行動	0	0	0	0	1 (1.3%)	0
攻撃性	0	0	0	0	1 (1.3%)	0
激越	0	0	0	0	1 (1.3%)	0
生殖系および乳房障害	0	0	0	0	1 (1.3%)	0
良性前立腺肥大症	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_renal_ser_1.sas
Program Run: 04JUN21:14:58:00

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
Overall	2 (10.0%)	11 (33.3%)	35 (15.2%)	46 (21.1%)	13 (16.5%)	43 (13.6%)
感染症および寄生虫症	0	4 (12.1%)	11 (4.8%)	11 (5.0%)	3 (3.8%)	15 (4.7%)
真菌感染	0	1 (3.0%)	2 (0.9%)	0	0	3 (0.9%)
敗血症性ショック	0	0	2 (0.9%)	0	2 (2.5%)	2 (0.6%)
敗血症	0	1 (3.0%)	1 (0.4%)	2 (0.9%)	0	1 (0.3%)
アスペルギルス症	0	0	1 (0.4%)	1 (0.5%)	0	3 (0.9%)
肺炎	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
気管支肺炎	0	0	1 (0.4%)	0	0	1 (0.3%)
気管支肺アスペルギルス症	0	0	1 (0.4%)	0	0	1 (0.3%)
心内膜炎	0	0	1 (0.4%)	0	0	1 (0.3%)
感染	0	0	1 (0.4%)	0	0	1 (0.3%)
細菌性敗血症	0	1 (3.0%)	0	2 (0.9%)	0	0
肺感染	0	0	0	2 (0.9%)	0	0
髄膜炎	0	0	0	1 (0.5%)	0	0
ムコール症	0	0	0	1 (0.5%)	0	0
シュードモナス性敗血症	0	0	0	1 (0.5%)	0	0
ブドウ球菌感染	0	0	0	1 (0.5%)	0	0
全身性カンジダ	0	1 (3.0%)	0	0	0	0
脳膿瘍	0	0	0	0	1 (1.3%)	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
大腸菌性菌血症	0	0	0	0	0	1 (0.3%)
呼吸器、胸郭および縦隔障害	0	2 (6.1%)	6 (2.6%)	3 (1.4%)	0	6 (1.9%)
呼吸不全	0	2 (6.1%)	2 (0.9%)	2 (0.9%)	0	2 (0.6%)
呼吸困難	0	0	2 (0.9%)	0	0	2 (0.6%)
呼吸窮迫	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
急性呼吸不全	0	0	1 (0.4%)	0	0	1 (0.3%)
神経系障害	0	1 (3.0%)	5 (2.2%)	3 (1.4%)	2 (2.5%)	5 (1.6%)
痙攣	0	0	2 (0.9%)	0	0	2 (0.6%)
てんかん	0	0	2 (0.9%)	0	0	2 (0.6%)
脳症	0	0	1 (0.4%)	0	0	1 (0.3%)
大発作痙攣	0	0	0	1 (0.5%)	0	0
昏迷	0	0	0	1 (0.5%)	0	0
くも膜下出血	0	1 (3.0%)	0	0	0	0
振戦	0	0	0	1 (0.5%)	0	0
脳血管発作	0	0	0	0	1 (1.3%)	0
卒中の出血性変化	0	0	0	0	1 (1.3%)	0
臨床検査	0	0	4 (1.7%)	6 (2.8%)	2 (2.5%)	4 (1.3%)
血中ビリルビン増加	0	0	2 (0.9%)	0	0	2 (0.6%)
血中ナトリウム減少	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
トランスアミナーゼ上昇	0	0	1 (0.4%)	0	0	1 (0.3%)
肝機能検査異常	0	0	0	2 (0.9%)	0	0
アラニン・アミノトランスフェラーゼ増加	0	0	0	1 (0.5%)	1 (1.3%)	0
血中アルカリホスファターゼ増加	0	0	0	1 (0.5%)	1 (1.3%)	0
肝酵素上昇	0	0	0	1 (0.5%)	1 (1.3%)	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	1 (0.5%)	0	0
心電図ＱＴ延長	0	0	0	1 (0.5%)	0	0
血中乳酸脱水素酵素増加	0	0	0	0	1 (1.3%)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	1 (1.3%)	0
心臓障害	0	0	4 (1.7%)	2 (0.9%)	0	4 (1.3%)
心停止	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
心肺停止	0	0	1 (0.4%)	0	0	1 (0.3%)
うっ血性心筋症	0	0	1 (0.4%)	0	0	1 (0.3%)
上室性頻脈	0	0	1 (0.4%)	0	0	1 (0.3%)
心室性頻脈	0	0	0	1 (0.5%)	0	0
腎および尿路障害	1 (5.0%)	1 (3.0%)	2 (0.9%)	2 (0.9%)	3 (3.8%)	2 (0.6%)
腎不全	1 (5.0%)	0	1 (0.4%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
急性腎不全	0	1 (3.0%)	1 (0.4%)	1 (0.5%)	2 (2.5%)	1 (0.3%)
精神障害	1 (5.0%)	1 (3.0%)	1 (0.4%)	5 (2.3%)	2 (2.5%)	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
錯乱状態	1 (5.0%)	0	1 (0.4%)	2 (0.9%)	2 (2.5%)	1 (0.3%)
幻視	0	0	0	3 (1.4%)	0	0
幻覚	0	0	0	1 (0.5%)	1 (1.3%)	0
抑うつ気分	0	1 (3.0%)	0	0	0	0
不快気分	0	0	0	1 (0.5%)	0	0
皮膚および皮下組織障害	0	1 (3.0%)	2 (0.9%)	4 (1.8%)	0	2 (0.6%)
皮膚炎	0	0	1 (0.4%)	0	0	1 (0.3%)
アレルギー性皮膚炎	0	0	1 (0.4%)	0	0	1 (0.3%)
発疹	0	1 (3.0%)	0	3 (1.4%)	0	0
薬疹	0	0	0	1 (0.5%)	0	0
胃腸障害	0	1 (3.0%)	2 (0.9%)	2 (0.9%)	1 (1.3%)	3 (0.9%)
嘔吐	0	1 (3.0%)	1 (0.4%)	1 (0.5%)	1 (1.3%)	1 (0.3%)
嚥下障害	0	0	1 (0.4%)	0	0	1 (0.3%)
小腸閉塞	0	0	1 (0.4%)	0	0	1 (0.3%)
悪心	0	0	0	2 (0.9%)	0	1 (0.3%)
肝胆道系障害	0	0	1 (0.4%)	6 (2.8%)	0	2 (0.6%)
急性肝炎	0	0	1 (0.4%)	0	0	1 (0.3%)
肝不全	0	0	0	2 (0.9%)	0	0
高ビリルビン血症	0	0	0	2 (0.9%)	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
肝機能異常	0	0	0	1 (0.5%)	0	0
肝病変	0	0	0	1 (0.5%)	0	0
肝炎	0	0	0	1 (0.5%)	0	0
高トランスアミナーゼ血症	0	0	0	1 (0.5%)	0	0
急性肝不全	0	0	0	0	0	1 (0.3%)
血液およびリンパ系障害	0	0	1 (0.4%)	3 (1.4%)	0	1 (0.3%)
汎血球減少症	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
微小血管症性溶血性貧血	0	0	0	1 (0.5%)	0	0
脾臓病変	0	0	0	1 (0.5%)	0	0
眼障害	0	1 (3.0%)	1 (0.4%)	0	0	1 (0.3%)
視神経症	0	0	1 (0.4%)	0	0	1 (0.3%)
眼瞼浮腫	0	1 (3.0%)	0	0	0	0
全身障害および投与局所様態	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
悪寒	0	0	1 (0.4%)	1 (0.5%)	0	1 (0.3%)
傷害、中毒および処置合併症	0	0	1 (0.4%)	0	0	1 (0.3%)
過量投与	0	0	1 (0.4%)	0	0	1 (0.3%)
筋骨格系および結合組織障害	0	0	1 (0.4%)	0	0	1 (0.3%)
筋炎	0	0	1 (0.4%)	0	0	1 (0.3%)
血管障害	0	0	1 (0.4%)	0	0	1 (0.3%)

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-187 投与中止に至った有害事象（腎機能障害の有無別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験				海外第III相試験併合	
	Renally Impaired		Non Renally Impaired		Renally Impaired	Non Renally Impaired
System Organ Class Preferred Term	ISA (N = 20)	VRC (N = 33)	ISA (N = 230)	VRC (N = 218)	ISA (N = 79)	ISA (N = 316)
低血圧	0	0	1 (0.4%)	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）	0	1 (3.0%)	0	5 (2.3%)	1 (1.3%)	2 (0.6%)
急性骨髄性白血病	0	1 (3.0%)	0	3 (1.4%)	0	0
再発急性骨髄性白血病	0	0	0	1 (0.5%)	0	1 (0.3%)
慢性リンパ性白血病	0	0	0	1 (0.5%)	0	0
白血病再発	0	0	0	0	1 (1.3%)	0
悪性新生物進行	0	0	0	0	0	1 (0.3%)
免疫系障害	0	0	0	1 (0.5%)	0	0
急性肝移植片対宿主病	0	0	0	1 (0.5%)	0	0
代謝および栄養障害	0	0	0	1 (0.5%)	0	0
代謝性アシドーシス	0	0	0	1 (0.5%)	0	0

ISA: isavuconazole; VRC: voriconazole.
Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_renal_discon_1.sas
Program Run: 04JUN21:14:58:05

表 8-188 eGFR (mL/min/1.73 m^2) の程度別の分布 - 海外第III相試験併合

海外第III相試験併合			
Renally Impaired (N = 79)		Non Renally Impaired (N = 316)	
Isavuconazole < 30	Isavuconazole 30 <= to < 60	Isavuconazole 60 <= to < 90	Isavuconazole 90 <=
20 (25.3%)	59 (74.7%)	111 (35.1%)	205 (64.9%)

Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_egfr_distri_1.sas
Program Run: 04JUN21:14:58:10

表 8-189 SOC別の重篤な有害事象（投与経路別かつ腎機能障害有無別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合					
	IV Dosing Only		ORAL Dosing Only		IV and ORAL Dosing	
	Isavuconazole		Isavuconazole		Isavuconazole	
System Organ Class	Renally Impaired (N = 13)	Non Renally Impaired (N = 68)	Renally Impaired (N = 12)	Non Renally Impaired (N = 33)	Renally Impaired (N = 54)	Non Renally Impaired (N = 215)
Overall	9 (69.2%)	50 (73.5%)	8 (66.7%)	11 (33.3%)	35 (64.8%)	106 (49.3%)
感染症および寄生虫症	5 (38.5%)	30 (44.1%)	4 (33.3%)	6 (18.2%)	20 (37.0%)	38 (17.7%)
呼吸器、胸郭および縦隔障害	3 (23.1%)	19 (27.9%)	1 (8.3%)	3 (9.1%)	6 (11.1%)	29 (13.5%)
血液およびリンパ系障害	0	1 (1.5%)	0	0	6 (11.1%)	24 (11.2%)
胃腸障害	0	0	2 (16.7%)	2 (6.1%)	6 (11.1%)	16 (7.4%)
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	2 (2.9%)	0	2 (6.1%)	4 (7.4%)	18 (8.4%)
神経系障害	0	7 (10.3%)	1 (8.3%)	1 (3.0%)	3 (5.6%)	14 (6.5%)
全身障害および投与局所様態	0	4 (5.9%)	2 (16.7%)	1 (3.0%)	2 (3.7%)	11 (5.1%)
腎および尿路障害	1 (7.7%)	5 (7.4%)	1 (8.3%)	0	7 (13.0%)	5 (2.3%)
心臓障害	3 (23.1%)	5 (7.4%)	0	0	3 (5.6%)	7 (3.3%)
免疫系障害	1 (7.7%)	1 (1.5%)	0	1 (3.0%)	3 (5.6%)	3 (1.4%)
代謝および栄養障害	0	0	1 (8.3%)	2 (6.1%)	2 (3.7%)	4 (1.9%)
血管障害	0	2 (2.9%)	1 (8.3%)	1 (3.0%)	3 (5.6%)	2 (0.9%)
肝胆道系障害	0	2 (2.9%)	2 (16.7%)	0	1 (1.9%)	3 (1.4%)
筋骨格系および結合組織障害	0	0	1 (8.3%)	1 (3.0%)	1 (1.9%)	4 (1.9%)
眼障害	0	0	0	1 (3.0%)	2 (3.7%)	1 (0.5%)
臨床検査	0	0	0	0	0	3 (1.4%)
精神障害	0	0	1 (8.3%)	0	1 (1.9%)	1 (0.5%)
傷害、中毒および処置合併症	0	0	0	0	0	2 (0.9%)
皮膚および皮下組織障害	0	0	0	0	0	2 (0.9%)
生殖系および乳房障害	0	0	0	0	1 (1.9%)	0

Renally Impaired: baseline eGFR < 60 mL/min/1.73m^2
Non Renally Impaired: baseline eGFR >= 60 mL/min/1.73m^2

Program Name: t_ae_soc_ser_route_renal_1.sas
Program Run: 04JUN21:14:58:15

表 8-190 SOC別の有害事象（深在性真菌症の疾患別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
Overall	47 (90.4%)	3 (100.0%)	3 (100.0%)	9 (90.0%)	5 (100.0%)
感染症および寄生虫症	18 (34.6%)	2 (66.7%)	0	3 (30.0%)	2 (40.0%)
胃腸障害	14 (26.9%)	2 (66.7%)	1 (33.3%)	3 (30.0%)	1 (20.0%)
臨床検査	15 (28.8%)	1 (33.3%)	1 (33.3%)	4 (40.0%)	0
神経系障害	8 (15.4%)	1 (33.3%)	1 (33.3%)	4 (40.0%)	1 (20.0%)
肝胆道系障害	10 (19.2%)	1 (33.3%)	0	1 (10.0%)	0
代謝および栄養障害	7 (13.5%)	1 (33.3%)	1 (33.3%)	2 (20.0%)	0
皮膚および皮下組織障害	9 (17.3%)	0	0	2 (20.0%)	0
眼障害	7 (13.5%)	1 (33.3%)	1 (33.3%)	1 (10.0%)	0
一般・全身障害および投与部位の状態	8 (15.4%)	0	1 (33.3%)	0	0
呼吸器、胸郭および縦隔障害	5 (9.6%)	1 (33.3%)	1 (33.3%)	1 (10.0%)	1 (20.0%)
腎および尿路障害	5 (9.6%)	0	0	2 (20.0%)	0
心臓障害	2 (3.8%)	0	1 (33.3%)	2 (20.0%)	1 (20.0%)
血管障害	4 (7.7%)	1 (33.3%)	0	1 (10.0%)	0
傷害、中毒および処置合併症	2 (3.8%)	0	0	1 (10.0%)	1 (20.0%)
筋骨格系および結合組織障害	3 (5.8%)	0	0	1 (10.0%)	0
精神障害	2 (3.8%)	1 (33.3%)	0	1 (10.0%)	0
血液およびリンパ系障害	0	0	0	2 (20.0%)	0
耳および迷路障害	2 (3.8%)	0	0	0	0
内分泌障害	1 (1.9%)	0	0	1 (10.0%)	0
先天性、家族性および遺伝性障害	0	0	1 (33.3%)	0	0
免疫系障害	0	1 (33.3%)	0	0	0

Program Name: t_ae_myco_soc_2.sas
Program Run: 16JUN21:13:33:41

表 8-191 注目すべき有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

	Cohort A/B併合				
	Isavuconazole				
	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
肝機能異常・肝炎	20 (38.5%)	2 (66.7%)	0	2 (20.0%)	0
アナフィラキシー	0	0	0	0	0
重度皮膚障害	0	0	0	0	0
心電図QT短縮	0	0	0	0	0
トルサード ド ポアント	1 (1.9%)	0	0	1 (10.0%)	0
急性膵炎	0	0	0	0	0
精神神経症状	2 (3.8%)	1 (33.3%)	1 (33.3%)	1 (10.0%)	0
視覚障害	7 (13.5%)	0	1 (33.3%)	0	0
皮膚または子宮の悪性腫瘍	0	0	0	0	0
静脈内投与例	(N = 5)	(N = 2)	(N = 1)	(N = 0)	(N = 1)
注入部位／注射部位反応	3 (60.0%)	0	0	0	0
IRR	0	0	1 (100.0%)	0	0

IRR: Infusion related reaction

Program Name: t_ae_myco_eoi_2.sas
Program Run: 16JUN21:13:33:46

表 8-192 死亡に至った有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class Preferred Term	慢性肺 アスペルギルス症 (N = 52)	侵襲性 アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプト コックス症 (N = 10)	その他 (N = 5)
Overall	1 (1.9%)	2 (66.7%)	2 (66.7%)	0	1 (20.0%)
呼吸器、胸郭および縦隔障害	1 (1.9%)	1 (33.3%)	1 (33.3%)	0	0
特発性肺炎症候群	0	1 (33.3%)	0	0	0
誤嚥性肺炎	0	0	1 (33.3%)	0	0
肺臓炎	1 (1.9%)	0	0	0	0
感染症および寄生虫症	0	1 (33.3%)	0	0	1 (20.0%)
肺炎球菌感染	0	0	0	0	1 (20.0%)
副鼻腔炎	0	1 (33.3%)	0	0	0
心臓障害	0	0	1 (33.3%)	0	0
急性心筋梗塞	0	0	1 (33.3%)	0	0
一般・全身障害および投与部位の状態	0	0	1 (33.3%)	0	0
死亡	0	0	1 (33.3%)	0	0
神経系障害	0	1 (33.3%)	0	0	0
大脳基底核梗塞	0	1 (33.3%)	0	0	0

Program Name: t_ae_myco_death_2.sas
Program Run: 16JUN21:13:33:51

表 8-193 重篤な有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class Preferred Term	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
Overall	9 (17.3%)	2 (66.7%)	2 (66.7%)	2 (20.0%)	2 (40.0%)
感染症および寄生虫症	3 (5.8%)	1 (33.3%)	0	2 (20.0%)	2 (40.0%)
感染性胸水	2 (3.8%)	0	0	0	0
肺炎	1 (1.9%)	0	0	0	1 (20.0%)
菌血症	0	0	0	1 (10.0%)	0
気管支炎	1 (1.9%)	0	0	0	0
蜂巣炎	0	0	0	1 (10.0%)	0
肺炎球菌感染	0	0	0	0	1 (20.0%)
副鼻腔炎	0	1 (33.3%)	0	0	0
呼吸器、胸郭および縦隔障害	3 (5.8%)	1 (33.3%)	1 (33.3%)	0	0
喀血	1 (1.9%)	0	0	0	0
特発性肺炎症候群	0	1 (33.3%)	0	0	0
誤嚥性肺炎	0	0	1 (33.3%)	0	0
肺臓炎	1 (1.9%)	0	0	0	0
気胸	1 (1.9%)	0	0	0	0
心臓障害	0	0	1 (33.3%)	1 (10.0%)	0
急性心筋梗塞	0	0	1 (33.3%)	0	0
急性心不全	0	0	0	1 (10.0%)	0
血液およびリンパ系障害	0	0	0	1 (10.0%)	0
好中球減少症	0	0	0	1 (10.0%)	0
内分泌障害	1 (1.9%)	0	0	0	0
抗利尿ホルモン不適合分泌	1 (1.9%)	0	0	0	0

Program Name: t_ae_myco_ser_2.sas
Program Run: 16JUN21:13:33:55

表 8-193 重篤な有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class Preferred Term	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
一般・全身障害および投与部位の状態	0	0	1 (33.3%)	0	0
死亡	0	0	1 (33.3%)	0	0
肝胆道系障害	1 (1.9%)	0	0	0	0
胆嚢炎	1 (1.9%)	0	0	0	0
代謝および栄養障害	1 (1.9%)	0	0	0	0
低ナトリウム血症	1 (1.9%)	0	0	0	0
筋骨格系および結合組織障害	1 (1.9%)	0	0	0	0
筋力低下	1 (1.9%)	0	0	0	0
神経系障害	0	1 (33.3%)	0	0	0
大脳基底核梗塞	0	1 (33.3%)	0	0	0
腎および尿路障害	1 (1.9%)	0	0	0	0
腎機能障害	1 (1.9%)	0	0	0	0

Program Name: t_ae_myco_ser_2.sas
Program Run: 16JUN21:13:33:55

表 8-194 投与中止に至った有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class Preferred Term	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
Overall	8 (15.4%)	1 (33.3%)	0	1 (10.0%)	1 (20.0%)
肝胆道系障害	2 (3.8%)	0	0	0	0
肝機能異常	2 (3.8%)	0	0	0	0
感染症および寄生虫症	1 (1.9%)	0	0	0	1 (20.0%)
感染性胸水	1 (1.9%)	0	0	0	0
肺炎球菌感染	0	0	0	0	1 (20.0%)
臨床検査	0	1 (33.3%)	0	1 (10.0%)	0
心電図異常	0	0	0	1 (10.0%)	0
肝機能検査値上昇	0	1 (33.3%)	0	0	0
代謝および栄養障害	2 (3.8%)	0	0	0	0
高カリウム血症	1 (1.9%)	0	0	0	0
低ナトリウム血症	1 (1.9%)	0	0	0	0
耳および迷路障害	1 (1.9%)	0	0	0	0
耳管開放	1 (1.9%)	0	0	0	0
胃腸障害	1 (1.9%)	0	0	0	0
悪心	1 (1.9%)	0	0	0	0
一般・全身障害および投与部位の状態	1 (1.9%)	0	0	0	0
注射部位蕁麻疹	1 (1.9%)	0	0	0	0

Program Name: t_ae_myco_discon_2.sas
Program Run: 16JUN21:13:34:00

表 8-194 投与中止に至った有害事象（深在性真菌症の種類別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合				
	Isavuconazole				
System Organ Class Preferred Term	慢性肺アスペルギルス症 (N = 52)	侵襲性アスペルギルス症 (N = 3)	ムーコル症 (N = 3)	クリプトコックス症 (N = 10)	その他 (N = 5)
神経系障害	1 (1.9%)	0	0	0	0
感覚鈍麻	1 (1.9%)	0	0	0	0
腎および尿路障害	1 (1.9%)	0	0	0	0
腎機能障害	1 (1.9%)	0	0	0	0
呼吸器、胸郭および縦隔障害	1 (1.9%)	0	0	0	0
呼吸困難	1 (1.9%)	0	0	0	0
口腔咽頭不快感	1 (1.9%)	0	0	0	0
皮膚および皮下組織障害	1 (1.9%)	0	0	0	0
冷汗	1 (1.9%)	0	0	0	0

Program Name: t_ae_myco_discon_2.sas
Program Run: 16JUN21:13:34:00

表 8-195 SOC別の有害事象（深在性真菌症の疾患別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class	侵襲性アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプトコックス症 (N = 9)	その他 (N = 210)
Overall	142 (96.6%)	35 (94.6%)	8 (88.9%)	201 (95.7%)
胃腸障害	100 (68.0%)	22 (59.5%)	5 (55.6%)	130 (61.9%)
感染症および寄生虫症	98 (66.7%)	25 (67.6%)	6 (66.7%)	114 (54.3%)
全身障害および投与局所様態	86 (58.5%)	21 (56.8%)	3 (33.3%)	106 (50.5%)
呼吸器、胸郭および縦隔障害	82 (55.8%)	16 (43.2%)	0	108 (51.4%)
代謝および栄養障害	75 (51.0%)	19 (51.4%)	4 (44.4%)	72 (34.3%)
神経系障害	57 (38.8%)	12 (32.4%)	4 (44.4%)	72 (34.3%)
皮膚および皮下組織障害	49 (33.3%)	10 (27.0%)	3 (33.3%)	63 (30.0%)
臨床検査	43 (29.3%)	13 (35.1%)	1 (11.1%)	62 (29.5%)
筋骨格系および結合組織障害	33 (22.4%)	10 (27.0%)	4 (44.4%)	62 (29.5%)
血液およびリンパ系障害	48 (32.7%)	6 (16.2%)	2 (22.2%)	50 (23.8%)
精神障害	45 (30.6%)	12 (32.4%)	2 (22.2%)	46 (21.9%)
血管障害	35 (23.8%)	7 (18.9%)	2 (22.2%)	57 (27.1%)
腎および尿路障害	29 (19.7%)	9 (24.3%)	3 (33.3%)	40 (19.0%)
心臓障害	23 (15.6%)	9 (24.3%)	2 (22.2%)	34 (16.2%)
眼障害	22 (15.0%)	9 (24.3%)	0	27 (12.9%)
傷害、中毒および処置合併症	22 (15.0%)	7 (18.9%)	1 (11.1%)	25 (11.9%)
肝胆道系障害	16 (10.9%)	4 (10.8%)	0	19 (9.0%)
免疫系障害	9 (6.1%)	4 (10.8%)	0	16 (7.6%)
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）	15 (10.2%)	5 (13.5%)	0	9 (4.3%)
耳および迷路障害	8 (5.4%)	4 (10.8%)	1 (11.1%)	8 (3.8%)
生殖系および乳房障害	5 (3.4%)	3 (8.1%)	0	9 (4.3%)
内分泌障害	2 (1.4%)	4 (10.8%)	0	4 (1.9%)
先天性、家族性および遺伝性障害	0	0	0	3 (1.4%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_soc_1.sas
Program Run: 04JUN21:14:59:05

表 8-196 注目すべき有害事象（深在性真菌症の種類別） - 海外第III相試験併合

	海外第III相試験併合			
	Isavuconazole			
	侵襲性アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプトコックス症 (N = 9)	その他 (N = 210)
肝機能異常・肝炎	40 (27.2%)	11 (29.7%)	0	31 (14.8%)
アナフィラキシー	0	0	0	2 (1.0%)
重度皮膚障害	1 (0.7%)	0	0	2 (1.0%)
心電図QT短縮	0	0	0	1 (0.5%)
トルサード ド ポアント	12 (8.2%)	2 (5.4%)	0	4 (1.9%)
急性膵炎	0	0	0	1 (0.5%)
精神神経症状	45 (30.6%)	11 (29.7%)	3 (33.3%)	51 (24.3%)
視覚障害	13 (8.8%)	5 (13.5%)	0	13 (6.2%)
皮膚または子宮の悪性腫瘍	1 (0.7%)	0	0	0
静脈内投与例	(N = 141)	(N = 30)	(N = 8)	(N = 178)
注入部位／注射部位反応	6 (4.3%)	0	1 (12.5%)	9 (5.1%)
IRR	36 (25.5%)	13 (43.3%)	2 (25.0%)	51 (28.7%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
IRR: Infusion related reaction

Program Name: t_ae_myco_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-197 死亡に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
Overall	42 (28.6%)	19 (51.4%)	1 (11.1%)	44 (21.0%)
感染症および寄生虫症	19 (12.9%)	10 (27.0%)	1 (11.1%)	19 (9.0%)
敗血症性ショック	5 (3.4%)	2 (5.4%)	1 (11.1%)	4 (1.9%)
敗血症	3 (2.0%)	0	0	5 (2.4%)
アスペルギルス症	4 (2.7%)	0	0	0
真菌感染	1 (0.7%)	0	0	2 (1.0%)
肺炎	0	2 (5.4%)	0	1 (0.5%)
ムコール症	1 (0.7%)	1 (2.7%)	0	0
真菌性肺炎	0	2 (5.4%)	0	0
アシネトバクター性菌血症	0	0	0	1 (0.5%)
細菌性敗血症	0	1 (2.7%)	0	0
気管支肺アスペルギルス症	0	0	0	1 (0.5%)
蓄膿	1 (0.7%)	0	0	0
心内膜炎	1 (0.7%)	0	0	0
真菌性敗血症	0	0	0	1 (0.5%)
フサリウム感染	0	0	0	1 (0.5%)
感染	1 (0.7%)	0	0	0
肺感染	0	0	0	1 (0.5%)
シュードモナス菌性肺感染	0	1 (2.7%)	0	0
ブラストミセス菌性肺炎	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_death_1.sas
Program Run: 04JUN21:14:59:15

表 8-197 死亡に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
原発性異型肺炎	1 (0.7%)	0	0	0
シュードモナス性敗血症	1 (0.7%)	0	0	0
真菌性副鼻腔炎	0	1 (2.7%)	0	0
ブドウ球菌性敗血症	0	0	0	1 (0.5%)
呼吸器、胸郭および縦隔障害	4 (2.7%)	1 (2.7%)	0	13 (6.2%)
呼吸不全	1 (0.7%)	1 (2.7%)	0	5 (2.4%)
急性呼吸不全	1 (0.7%)	0	0	3 (1.4%)
喀血	1 (0.7%)	0	0	2 (1.0%)
肺出血	1 (0.7%)	0	0	1 (0.5%)
呼吸困難	0	0	0	1 (0.5%)
呼吸窮迫	0	0	0	1 (0.5%)
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）	8 (5.4%)	3 (8.1%)	0	6 (2.9%)
急性骨髄性白血病	2 (1.4%)	1 (2.7%)	0	1 (0.5%)
悪性新生物進行	1 (0.7%)	2 (5.4%)	0	0
多発性骨髄腫	1 (0.7%)	0	0	1 (0.5%)
再発急性リンパ性白血病	0	0	0	1 (0.5%)
再発急性骨髄性白血病	0	0	0	1 (0.5%)
芽球発症	0	0	0	1 (0.5%)
慢性リンパ性白血病	1 (0.7%)	0	0	0
再発慢性リンパ性白血病	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_death_1.sas
Program Run: 04JUN21:14:59:15

表 8-197 死亡に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
白血病再発	1 (0.7%)	0	0	0
骨髄異形成症候群	0	0	0	1 (0.5%)
骨髄性白血病	1 (0.7%)	0	0	0
心臓障害	3 (2.0%)	2 (5.4%)	0	2 (1.0%)
心肺停止	1 (0.7%)	2 (5.4%)	0	0
心停止	0	0	0	1 (0.5%)
急性心不全	0	0	0	1 (0.5%)
うっ血性心筋症	1 (0.7%)	0	0	0
心膜炎	1 (0.7%)	0	0	0
全身障害および投与局所様態	3 (2.0%)	1 (2.7%)	0	3 (1.4%)
死亡	1 (0.7%)	0	0	3 (1.4%)
多臓器不全	1 (0.7%)	1 (2.7%)	0	0
全身健康状態低下	1 (0.7%)	0	0	0
神経系障害	3 (2.0%)	1 (2.7%)	0	1 (0.5%)
脳梗塞	1 (0.7%)	1 (2.7%)	0	0
頭蓋内出血	1 (0.7%)	0	0	1 (0.5%)
神経毒性	1 (0.7%)	0	0	0
血管障害	1 (0.7%)	0	0	2 (1.0%)
動脈炎	0	0	0	1 (0.5%)
出血	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_death_1.sas
Program Run: 04JUN21:14:59:15

表 8-197 死亡に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプトコックス症 (N = 9)	その他 (N = 210)
血液量減少性ショック	1 (0.7%)	0	0	0
血液およびリンパ系障害	0	0	0	2 (1.0%)
出血性障害	0	0	0	1 (0.5%)
血小板減少症	0	0	0	1 (0.5%)
免疫系障害	2 (1.4%)	0	0	0
急性移植片対宿主病	1 (0.7%)	0	0	0
移植片対宿主病	1 (0.7%)	0	0	0
腎および尿路障害	0	1 (2.7%)	0	1 (0.5%)
腎不全	0	0	0	1 (0.5%)
急性腎不全	0	1 (2.7%)	0	0
肝胆道系障害	1 (0.7%)	0	0	0
急性肝炎	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_death_1.sas
Program Run: 04JUN21:14:59:15

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
Overall	90 (61.2%)	28 (75.7%)	4 (44.4%)	101 (48.1%)
感染症および寄生虫症	37 (25.2%)	19 (51.4%)	1 (11.1%)	49 (23.3%)
敗血症性ショック	7 (4.8%)	3 (8.1%)	1 (11.1%)	9 (4.3%)
肺炎	3 (2.0%)	3 (8.1%)	0	6 (2.9%)
敗血症	4 (2.7%)	0	0	6 (2.9%)
アスペルギルス症	6 (4.1%)	0	0	1 (0.5%)
サイトメガロウイルス感染	3 (2.0%)	1 (2.7%)	0	0
真菌感染	1 (0.7%)	0	0	3 (1.4%)
菌血症	2 (1.4%)	1 (2.7%)	0	0
ムコール症	1 (0.7%)	1 (2.7%)	0	1 (0.5%)
細菌性肺炎	0	2 (5.4%)	0	1 (0.5%)
シュードモナス性敗血症	1 (0.7%)	0	0	2 (1.0%)
気管支肺アスペルギルス症	1 (0.7%)	0	0	1 (0.5%)
クロストリジウム・ディフィシレ大腸炎	2 (1.4%)	0	0	0
腸球菌性菌血症	0	1 (2.7%)	0	1 (0.5%)
大腸菌性敗血症	1 (0.7%)	1 (2.7%)	0	0
帯状疱疹	0	0	0	2 (1.0%)
真菌性肺炎	0	2 (5.4%)	0	0
ブドウ球菌感染	0	1 (2.7%)	0	1 (0.5%)
尿路感染	1 (0.7%)	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。

9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
接合真菌症	0	1 (2.7%)	0	1 (0.5%)
腹部膿瘍	0	1 (2.7%)	0	0
アシネトバクター性菌血症	0	0	0	1 (0.5%)
虫垂炎	1 (0.7%)	0	0	0
ＢＫウイルス感染	0	0	0	1 (0.5%)
細菌性敗血症	0	1 (2.7%)	0	0
脳膿瘍	0	0	0	1 (0.5%)
気管支拡張症	0	0	0	1 (0.5%)
細気管支炎	0	0	0	1 (0.5%)
肺炎球菌性気管支炎	1 (0.7%)	0	0	0
気管支肺炎	1 (0.7%)	0	0	0
カテーテル留置部位感染	0	0	0	1 (0.5%)
蜂巣炎	1 (0.7%)	0	0	0
脳アスペルギルス症	1 (0.7%)	0	0	0
サイトメガロウイルス性小腸炎	0	1 (2.7%)	0	0
サイトメガロウイルス血症	0	0	0	1 (0.5%)
蓄膿	1 (0.7%)	0	0	0
ヘルペス脳炎	0	0	0	1 (0.5%)
心内膜炎	1 (0.7%)	0	0	0
大腸菌性菌血症	0	1 (2.7%)	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。

9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
真菌性敗血症	0	0	0	1 (0.5%)
フサリウム感染	0	0	0	1 (0.5%)
ノロウイルス性胃腸炎	0	1 (2.7%)	0	0
ウイルス性胃腸炎	0	1 (2.7%)	0	0
感染	1 (0.7%)	0	0	0
インフルエンザ	0	1 (2.7%)	0	0
注入部位感染	0	0	0	1 (0.5%)
クレブシエラ性菌血症	0	0	0	1 (0.5%)
クレブシエラ性敗血症	0	0	0	1 (0.5%)
肺感染	0	0	0	1 (0.5%)
シュードモナス菌性肺感染	0	1 (2.7%)	0	0
筋膿瘍	0	0	0	1 (0.5%)
ニューモシスティスジロヴェシ肺炎	0	0	0	1 (0.5%)
ブラストミセス菌性肺炎	0	0	0	1 (0.5%)
インフルエンザ性肺炎	0	0	0	1 (0.5%)
モラクセラ菌性肺炎	0	0	0	1 (0.5%)
原発性異型肺炎	1 (0.7%)	0	0	0
シュードモナス性気管支炎	1 (0.7%)	0	0	0
気道感染	0	0	0	1 (0.5%)
敗血症症候群	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
副鼻腔炎	0	0	0	1 (0.5%)
真菌性副鼻腔炎	0	1 (2.7%)	0	0
皮膚感染	1 (0.7%)	0	0	0
ブドウ球菌性菌血症	0	0	0	1 (0.5%)
ブドウ球菌性敗血症	0	0	0	1 (0.5%)
レンサ球菌性菌血症	0	0	0	1 (0.5%)
皮下組織膿瘍	0	0	0	1 (0.5%)
尿路性敗血症	1 (0.7%)	0	0	0
ウイルス性下痢	1 (0.7%)	0	0	0
呼吸器、胸郭および縦隔障害	26 (17.7%)	6 (16.2%)	0	29 (13.8%)
呼吸不全	4 (2.7%)	2 (5.4%)	0	13 (6.2%)
急性呼吸不全	1 (0.7%)	1 (2.7%)	0	6 (2.9%)
呼吸困難	3 (2.0%)	0	0	3 (1.4%)
喀血	2 (1.4%)	0	0	2 (1.0%)
呼吸窮迫	2 (1.4%)	0	0	2 (1.0%)
低酸素症	3 (2.0%)	0	0	0
嚥下性肺炎	1 (0.7%)	2 (5.4%)	0	0
胸水	0	1 (2.7%)	0	1 (0.5%)
肺出血	1 (0.7%)	0	0	1 (0.5%)
肺水腫	1 (0.7%)	1 (2.7%)	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
頻呼吸	1 (0.7%)	0	0	1 (0.5%)
急性呼吸窮迫症候群	1 (0.7%)	0	0	0
気管支胸膜瘻	1 (0.7%)	0	0	0
気管支痙攣	1 (0.7%)	0	0	0
水気胸	1 (0.7%)	0	0	0
高炭酸ガス血症	0	0	0	1 (0.5%)
肺障害	1 (0.7%)	0	0	0
胸膜痛	1 (0.7%)	0	0	0
肺胞出血	0	0	0	1 (0.5%)
肺塞栓症	0	0	0	1 (0.5%)
肺梗塞	1 (0.7%)	0	0	0
呼吸性アシドーシス	1 (0.7%)	0	0	0
呼吸抑制	1 (0.7%)	0	0	0
副鼻腔障害	1 (0.7%)	0	0	0
喘鳴	0	0	0	1 (0.5%)
血液およびリンパ系障害	18 (12.2%)	0	0	15 (7.1%)
発熱性好中球減少症	8 (5.4%)	0	0	8 (3.8%)
汎血球減少症	3 (2.0%)	0	0	2 (1.0%)
好中球減少症	2 (1.4%)	0	0	2 (1.0%)
貧血	1 (0.7%)	0	0	2 (1.0%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
血小板減少症	1 (0.7%)	0	0	2 (1.0%)
無顆粒球症	2 (1.4%)	0	0	0
出血性障害	0	0	0	1 (0.5%)
白血球増加症	1 (0.7%)	0	0	0
脾臓梗塞	1 (0.7%)	0	0	0
胃腸障害	7 (4.8%)	8 (21.6%)	0	12 (5.7%)
腹痛	0	2 (5.4%)	0	4 (1.9%)
下痢	1 (0.7%)	2 (5.4%)	0	1 (0.5%)
嘔吐	0	1 (2.7%)	0	3 (1.4%)
胃腸出血	1 (0.7%)	1 (2.7%)	0	1 (0.5%)
悪心	0	1 (2.7%)	0	2 (1.0%)
大腸炎	1 (0.7%)	0	0	1 (0.5%)
便秘	1 (0.7%)	0	0	1 (0.5%)
嚥下障害	0	1 (2.7%)	0	1 (0.5%)
小腸閉塞	2 (1.4%)	0	0	0
潰瘍性大腸炎	0	1 (2.7%)	0	0
胃穿孔	1 (0.7%)	0	0	0
腸出血	1 (0.7%)	0	0	0
限局性腹腔内液貯留	0	1 (2.7%)	0	0
食道潰瘍	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
食道炎	0	1 (2.7%)	0	0
膵炎	0	0	0	1 (0.5%)
慢性膵炎	0	0	0	1 (0.5%)
再発性膵炎	0	0	0	1 (0.5%)
腹膜炎	1 (0.7%)	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）	14 (9.5%)	4 (10.8%)	0	8 (3.8%)
急性骨髄性白血病	3 (2.0%)	1 (2.7%)	0	1 (0.5%)
悪性新生物進行	1 (0.7%)	2 (5.4%)	0	0
再発急性リンパ性白血病	1 (0.7%)	0	0	1 (0.5%)
再発急性骨髄性白血病	0	1 (2.7%)	0	1 (0.5%)
リンパ腫	2 (1.4%)	0	0	0
多発性骨髄腫	1 (0.7%)	0	0	1 (0.5%)
芽球発症	0	0	0	1 (0.5%)
慢性リンパ性白血病	1 (0.7%)	0	0	0
再発慢性リンパ性白血病	1 (0.7%)	0	0	0
子宮内膜癌	1 (0.7%)	0	0	0
白血病再発	1 (0.7%)	0	0	0
白血病浸潤	0	1 (2.7%)	0	0
髄膜転移	0	0	0	1 (0.5%)
骨髄異形成症候群	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
骨髄性白血病	1 (0.7%)	0	0	0
新生物進行	0	0	0	1 (0.5%)
非ホジキンリンパ腫	1 (0.7%)	0	0	0
原発性体腔性リンパ腫	1 (0.7%)	0	0	0
神経系障害	12 (8.2%)	4 (10.8%)	2 (22.2%)	8 (3.8%)
痙攣	0	1 (2.7%)	1 (11.1%)	3 (1.4%)
脳梗塞	1 (0.7%)	1 (2.7%)	1 (11.1%)	0
てんかん	1 (0.7%)	0	0	1 (0.5%)
頭蓋内出血	1 (0.7%)	0	0	1 (0.5%)
頭痛	1 (0.7%)	1 (2.7%)	0	0
多発ニューロパチー	2 (1.4%)	0	0	0
失語症	1 (0.7%)	0	0	0
脳幹卒中	1 (0.7%)	0	0	0
中枢神経系病変	0	0	0	1 (0.5%)
脳虚血	1 (0.7%)	0	0	0
脳血管発作	0	0	0	1 (0.5%)
脳症	0	0	0	1 (0.5%)
熱性痙攣	1 (0.7%)	0	0	0
卒中の出血性変化	1 (0.7%)	0	0	0
不全片麻痺	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
虚血性脳卒中	1 (0.7%)	0	0	0
神経毒性	1 (0.7%)	0	0	0
対麻痺	1 (0.7%)	0	0	0
一過性脳虚血発作	0	1 (2.7%)	0	0
全身障害および投与局所様態	10 (6.8%)	3 (8.1%)	0	7 (3.3%)
発熱	6 (4.1%)	2 (5.4%)	0	2 (1.0%)
死亡	1 (0.7%)	0	0	3 (1.4%)
全身健康状態低下	2 (1.4%)	0	0	0
多臓器不全	1 (0.7%)	1 (2.7%)	0	0
非心臓性胸痛	1 (0.7%)	0	0	1 (0.5%)
無力症	0	0	0	1 (0.5%)
胸痛	1 (0.7%)	0	0	0
悪寒	1 (0.7%)	0	0	0
末梢性浮腫	0	0	0	1 (0.5%)
心臓障害	8 (5.4%)	4 (10.8%)	0	7 (3.3%)
心肺停止	2 (1.4%)	2 (5.4%)	0	0
心房細動	2 (1.4%)	0	0	1 (0.5%)
急性心筋梗塞	0	0	0	2 (1.0%)
不整脈	0	0	0	1 (0.5%)
完全房室ブロック	0	1 (2.7%)	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
心停止	0	0	0	1 (0.5%)
急性心不全	0	0	0	1 (0.5%)
心原性ショック	0	0	0	1 (0.5%)
うっ血性心筋症	1 (0.7%)	0	0	0
電気収縮解離	0	1 (2.7%)	0	0
心膜炎	1 (0.7%)	0	0	0
洞性徐脈	1 (0.7%)	0	0	0
上室性頻脈	1 (0.7%)	0	0	0
腎および尿路障害	6 (4.1%)	2 (5.4%)	0	11 (5.2%)
急性腎不全	4 (2.7%)	2 (5.4%)	0	8 (3.8%)
腎不全	1 (0.7%)	0	0	3 (1.4%)
血尿	1 (0.7%)	0	0	0
免疫系障害	3 (2.0%)	2 (5.4%)	0	4 (1.9%)
急性移植片対宿主病	1 (0.7%)	1 (2.7%)	0	1 (0.5%)
移植片対宿主病	1 (0.7%)	1 (2.7%)	0	0
急性腸管移植片対宿主病	1 (0.7%)	0	0	0
アナフィラキシーショック	0	0	0	1 (0.5%)
過敏症	0	0	0	1 (0.5%)
肺移植拒絶反応	0	0	0	1 (0.5%)
代謝および栄養障害	3 (2.0%)	3 (8.1%)	0	3 (1.4%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。

9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
脱水	1 (0.7%)	1 (2.7%)	0	1 (0.5%)
コントロール不良の糖尿病	0	0	0	1 (0.5%)
成長障害	1 (0.7%)	0	0	0
高カリウム血症	1 (0.7%)	0	0	0
低血糖症	0	1 (2.7%)	0	0
低ナトリウム血症	0	0	0	1 (0.5%)
栄養障害	0	1 (2.7%)	0	0
血管障害	4 (2.7%)	0	0	5 (2.4%)
低血圧	1 (0.7%)	0	0	2 (1.0%)
深部静脈血栓症	1 (0.7%)	0	0	1 (0.5%)
動脈炎	0	0	0	1 (0.5%)
出血	0	0	0	1 (0.5%)
血液量減少性ショック	1 (0.7%)	0	0	0
血管炎	1 (0.7%)	0	0	0
肝胆道系障害	3 (2.0%)	1 (2.7%)	0	4 (1.9%)
胆嚢炎	0	0	0	2 (1.0%)
急性肝不全	0	1 (2.7%)	0	0
細胆管炎	1 (0.7%)	0	0	0
胆石症	0	0	0	1 (0.5%)
肝炎	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。

9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
急性肝炎	1 (0.7%)	0	0	0
肝障害	0	0	0	1 (0.5%)
筋骨格系および結合組織障害	3 (2.0%)	0	1 (11.1%)	3 (1.4%)
筋骨格系胸痛	1 (0.7%)	0	0	2 (1.0%)
関節炎	0	0	0	1 (0.5%)
筋肉内出血	1 (0.7%)	0	0	0
筋炎	1 (0.7%)	0	0	0
四肢痛	1 (0.7%)	0	0	0
全身性エリテマトーデス	0	0	1 (11.1%)	0
眼障害	2 (1.4%)	1 (2.7%)	0	1 (0.5%)
片側失明	1 (0.7%)	0	0	0
視神経症	1 (0.7%)	0	0	0
網膜動脈閉塞	0	1 (2.7%)	0	0
網膜出血	0	0	0	1 (0.5%)
硝子体出血	0	0	0	1 (0.5%)
傷害、中毒および処置合併症	1 (0.7%)	0	0	2 (1.0%)
薬物毒性	1 (0.7%)	0	0	1 (0.5%)
転倒・転落	0	0	0	1 (0.5%)
臨床検査	1 (0.7%)	0	0	2 (1.0%)
血中ナトリウム減少	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-198 重篤な有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
ヘモグロビン減少	1 (0.7%)	0	0	0
肝機能検査異常	0	0	0	1 (0.5%)
精神障害	1 (0.7%)	0	0	2 (1.0%)
異常行動	1 (0.7%)	0	0	0
攻撃性	1 (0.7%)	0	0	0
激越	1 (0.7%)	0	0	0
錯乱状態	0	0	0	1 (0.5%)
うつ病	0	0	0	1 (0.5%)
幻覚	0	0	0	1 (0.5%)
皮膚および皮下組織障害	2 (1.4%)	0	0	1 (0.5%)
褥瘡性潰瘍	1 (0.7%)	0	0	0
皮膚炎	1 (0.7%)	0	0	0
脂肪織炎	0	0	0	1 (0.5%)
生殖系および乳房障害	1 (0.7%)	0	0	0
良性前立腺肥大症	1 (0.7%)	0	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_myco_ser_1.sas
Program Run: 04JUN21:14:59:20

表 8-199 投与中止に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
Overall	27 (18.4%)	7 (18.9%)	0	22 (10.5%)
感染症および寄生虫症	8 (5.4%)	2 (5.4%)	0	8 (3.8%)
敗血症性ショック	1 (0.7%)	1 (2.7%)	0	2 (1.0%)
アスペルギルス症	1 (0.7%)	0	0	2 (1.0%)
真菌感染	1 (0.7%)	0	0	2 (1.0%)
脳膿瘍	0	0	0	1 (0.5%)
気管支肺炎	1 (0.7%)	0	0	0
気管支肺アスペルギルス症	0	0	0	1 (0.5%)
心内膜炎	1 (0.7%)	0	0	0
大腸菌性菌血症	0	1 (2.7%)	0	0
感染	1 (0.7%)	0	0	0
肺炎	1 (0.7%)	0	0	0
敗血症	1 (0.7%)	0	0	0
神経系障害	3 (2.0%)	0	0	4 (1.9%)
痙攣	1 (0.7%)	0	0	1 (0.5%)
てんかん	1 (0.7%)	0	0	1 (0.5%)
脳血管発作	0	0	0	1 (0.5%)
脳症	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_discon_1.sas
Program Run: 04JUN21:14:59:25

表 8-199 投与中止に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
卒中の出血性変化	1 (0.7%)	0	0	0
臨床検査	3 (2.0%)	1 (2.7%)	0	2 (1.0%)
血中ビリルビン増加	2 (1.4%)	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (2.7%)	0	0
血中アルカリホスファターゼ増加	0	1 (2.7%)	0	0
血中乳酸脱水素酵素増加	0	1 (2.7%)	0	0
血中ナトリウム減少	0	0	0	1 (0.5%)
γ－グルタミルトランスフェラーゼ増加	0	1 (2.7%)	0	0
肝酵素上昇	1 (0.7%)	0	0	0
トランスアミナーゼ上昇	0	0	0	1 (0.5%)
呼吸器、胸郭および縦隔障害	1 (0.7%)	0	0	5 (2.4%)
呼吸困難	1 (0.7%)	0	0	1 (0.5%)
呼吸不全	0	0	0	2 (1.0%)
急性呼吸不全	0	0	0	1 (0.5%)
呼吸窮迫	0	0	0	1 (0.5%)
腎および尿路障害	2 (1.4%)	0	0	3 (1.4%)
急性腎不全	1 (0.7%)	0	0	2 (1.0%)
腎不全	1 (0.7%)	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_discon_1.sas
Program Run: 04JUN21:14:59:25

表 8-199 投与中止に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプトコックス症 (N = 9)	その他 (N = 210)
心臓障害	3 (2.0%)	0	0	1 (0.5%)
心停止	0	0	0	1 (0.5%)
心肺停止	1 (0.7%)	0	0	0
うっ血性心筋症	1 (0.7%)	0	0	0
上室性頻脈	1 (0.7%)	0	0	0
胃腸障害	1 (0.7%)	1 (2.7%)	0	2 (1.0%)
嘔吐	1 (0.7%)	0	0	1 (0.5%)
嚥下障害	0	0	0	1 (0.5%)
悪心	0	1 (2.7%)	0	0
小腸閉塞	1 (0.7%)	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）	1 (0.7%)	2 (5.4%)	0	0
再発急性骨髄性白血病	0	1 (2.7%)	0	0
白血病再発	1 (0.7%)	0	0	0
悪性新生物進行	0	1 (2.7%)	0	0
精神障害	1 (0.7%)	0	0	2 (1.0%)
錯乱状態	1 (0.7%)	0	0	2 (1.0%)
幻覚	0	0	0	1 (0.5%)
肝胆道系障害	1 (0.7%)	1 (2.7%)	0	0

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_discon_1.sas
Program Run: 04JUN21:14:59:25

表 8-199 投与中止に至った有害事象（深在性真菌症の種類別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合			
	Isavuconazole			
System Organ Class Preferred Term	侵襲性 アスペルギルス症 (N = 147)	ムーコル症 (N = 37)	クリプト コックス症 (N = 9)	その他 (N = 210)
急性肝不全	0	1 (2.7%)	0	0
急性肝炎	1 (0.7%)	0	0	0
皮膚および皮下組織障害	1 (0.7%)	0	0	1 (0.5%)
皮膚炎	1 (0.7%)	0	0	0
アレルギー性皮膚炎	0	0	0	1 (0.5%)
血液およびリンパ系障害	1 (0.7%)	0	0	0
汎血球減少症	1 (0.7%)	0	0	0
眼障害	1 (0.7%)	0	0	0
視神経症	1 (0.7%)	0	0	0
全身障害および投与局所様態	1 (0.7%)	0	0	0
悪寒	1 (0.7%)	0	0	0
傷害、中毒および処置合併症	1 (0.7%)	0	0	0
過量投与	1 (0.7%)	0	0	0
筋骨格系および結合組織障害	1 (0.7%)	0	0	0
筋炎	1 (0.7%)	0	0	0
血管障害	0	0	0	1 (0.5%)
低血圧	0	0	0	1 (0.5%)

海外第III相試験併合に含まれる2試験のうち、9766-CL-0104試験ではmyITT集団（mITTのうち、DRC判定により、細胞診、病理組織診、培養検査、ガラクトマンナン抗原等に基づき侵襲性アスペルギルス症の「確定例」または「臨床診断例」とされた全被験者）を侵襲性アスペルギルス症に、myITT集団以外をその他に分類した。
9766-CL-0103試験では複数菌種を混在しない、侵襲性アスペルギルス症のみ、ムーコル症のみ、クリプトコックス症のみをそれぞれ侵襲性アスペルギルス症、ムーコル症、クリプトコックス症に分類し、それら以外をその他に分類した。

Program Name: t_ae_myco_discon_1.sas
Program Run: 04JUN21:14:59:25

表 8-200 SOC別の有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
Overall	9 (100.0%)	6 (100.0%)	23 (95.8%)	9 (100.0%)	23 (85.2%)	13 (86.7%)	12 (100.0%)	27 (96.4%)	28 (84.8%)
感染症および寄生虫症	4 (44.4%)	2 (33.3%)	10 (41.7%)	2 (22.2%)	8 (29.6%)	6 (40.0%)	4 (33.3%)	12 (42.9%)	9 (27.3%)
胃腸障害	2 (22.2%)	2 (33.3%)	8 (33.3%)	5 (55.6%)	7 (25.9%)	5 (33.3%)	3 (25.0%)	10 (35.7%)	8 (24.2%)
臨床検査	0	0	9 (37.5%)	4 (44.4%)	7 (25.9%)	3 (20.0%)	2 (16.7%)	10 (35.7%)	9 (27.3%)
肝胆道系障害	1 (11.1%)	2 (33.3%)	6 (25.0%)	4 (44.4%)	4 (14.8%)	4 (26.7%)	1 (8.3%)	6 (21.4%)	5 (15.2%)
神経系障害	3 (33.3%)	1 (16.7%)	3 (12.5%)	3 (33.3%)	4 (14.8%)	2 (13.3%)	4 (33.3%)	4 (14.3%)	7 (21.2%)
皮膚および皮下組織障害	1 (11.1%)	0	2 (8.3%)	3 (33.3%)	6 (22.2%)	1 (6.7%)	1 (8.3%)	3 (10.7%)	7 (21.2%)
眼障害	2 (22.2%)	4 (66.7%)	2 (8.3%)	3 (33.3%)	4 (14.8%)	6 (40.0%)	2 (16.7%)	2 (7.1%)	6 (18.2%)
代謝および栄養障害	3 (33.3%)	1 (16.7%)	2 (8.3%)	1 (11.1%)	3 (11.1%)	0	4 (33.3%)	3 (10.7%)	4 (12.1%)
一般・全身障害および投与部位の状態	1 (11.1%)	1 (16.7%)	2 (8.3%)	0	5 (18.5%)	0	2 (16.7%)	2 (7.1%)	5 (15.2%)
呼吸器、胸郭および縦隔障害	3 (33.3%)	1 (16.7%)	3 (12.5%)	1 (11.1%)	1 (3.7%)	1 (6.7%)	4 (33.3%)	3 (10.7%)	2 (6.1%)
腎および尿路障害	1 (11.1%)	0	1 (4.2%)	1 (11.1%)	3 (11.1%)	1 (6.7%)	1 (8.3%)	1 (3.6%)	5 (15.2%)
血管障害	1 (11.1%)	0	2 (8.3%)	0	2 (7.4%)	1 (6.7%)	1 (8.3%)	2 (7.1%)	3 (9.1%)
精神障害	1 (11.1%)	3 (50.0%)	2 (8.3%)	1 (11.1%)	0	3 (20.0%)	1 (8.3%)	2 (7.1%)	1 (3.0%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_soc_2.sas
Program Run: 18JUN21:09:44:31

表 8-200 SOC別の有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
筋骨格系および結合組織障害	0	2 (33.3%)	3 (12.5%)	2 (22.2%)	0	0	0	3 (10.7%)	1 (3.0%)
傷害、中毒および処置合併症	1 (11.1%)	0	1 (4.2%)	2 (22.2%)	1 (3.7%)	0	1 (8.3%)	2 (7.1%)	1 (3.0%)
心臓障害	1 (11.1%)	1 (16.7%)	2 (8.3%)	0	0	0	2 (16.7%)	3 (10.7%)	1 (3.0%)
耳および迷路障害	1 (11.1%)	0	0	1 (11.1%)	1 (3.7%)	0	1 (8.3%)	0	1 (3.0%)
免疫系障害	1 (11.1%)	1 (16.7%)	0	0	0	0	1 (8.3%)	0	0
内分泌障害	0	0	1 (4.2%)	0	0	0	0	2 (7.1%)	0
先天性、家族性および遺伝性障害	0	1 (16.7%)	0	1 (11.1%)	0	1 (6.7%)	0	0	1 (3.0%)
血液およびリンパ系障害	0	0	0	0	0	1 (6.7%)	0	1 (3.6%)	1 (3.0%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_soc_2.sas
Program Run: 18JUN21:09:44:31

表 8-201 注目すべき有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

Duration (days) Subgroup	Cohort A						Cohort A/B併合		
	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
肝機能異常・肝炎	1 (11.1%)	2 (33.3%)	13 (54.2%)	6 (66.7%)	8 (29.6%)	6 (40.0%)	1 (8.3%)	14 (50.0%)	9 (27.3%)
アナフィラキシー	0	0	0	0	0	0	0	0	0
重度皮膚障害	0	0	0	0	0	0	0	0	0
心電図QT短縮	0	0	0	0	0	0	0	0	0
トルサード ド ポアント	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	1 (3.0%)
急性膵炎	0	0	0	0	0	0	0	0	0
精神神経症状	1 (11.1%)	3 (50.0%)	2 (8.3%)	1 (11.1%)	0	3 (20.0%)	2 (16.7%)	2 (7.1%)	1 (3.0%)
視覚障害	1 (11.1%)	5 (83.3%)	2 (8.3%)	4 (44.4%)	4 (14.8%)	6 (40.0%)	1 (8.3%)	2 (7.1%)	5 (15.2%)
皮膚または子宮の悪性腫瘍	0	0	0	0	0	0	0	0	0
静脈内投与例	(N = 5)	(N = 1)	(N = 0)	(N = 0)	(N = 3)	(N = 1)	(N = 6)	(N = 0)	(N = 3)
注入部位／注射部位反応	1 (20.0%)	0	0	0	2 (66.7%)	0	1 (16.7%)	0	2 (66.7%)
IRR	0	1 (100.0%)	0	0	0	0	1 (16.7%)	0	0

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_duration_eoi_2.sas
Program Run: 18JUN21:09:44:35

表 8-202 死亡に至った有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
Overall	4 (44.4%)	0	0	0	0	0	6 (50.0%)	0	0
呼吸器、胸郭および縦隔障害	2 (22.2%)	0	0	0	0	0	3 (25.0%)	0	0
特発性肺炎症候群	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
肺臓炎	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
誤嚥性肺炎	0	0	0	0	0	0	1 (8.3%)	0	0
感染症および寄生虫症	2 (22.2%)	0	0	0	0	0	2 (16.7%)	0	0
肺炎球菌感染	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
副鼻腔炎	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
神経系障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
大脳基底核梗塞	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
心臓障害	0	0	0	0	0	0	1 (8.3%)	0	0
急性心筋梗塞	0	0	0	0	0	0	1 (8.3%)	0	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (8.3%)	0	0
死亡	0	0	0	0	0	0	1 (8.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_2.sas
Program Run: 18JUN21:09:44:39

表 8-203 重篤な有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
Overall	4 (44.4%)	1 (16.7%)	5 (20.8%)	0	4 (14.8%)	2 (13.3%)	6 (50.0%)	6 (21.4%)	5 (15.2%)
感染症および寄生虫症	2 (22.2%)	0	2 (8.3%)	0	2 (7.4%)	2 (13.3%)	2 (16.7%)	3 (10.7%)	3 (9.1%)
肺炎	0	0	0	0	2 (7.4%)	1 (6.7%)	0	0	2 (6.1%)
感染性胸水	0	0	2 (8.3%)	0	0	0	0	2 (7.1%)	0
気管支炎	0	0	0	0	1 (3.7%)	0	0	0	1 (3.0%)
肺炎球菌感染	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
副鼻腔炎	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
アスペルギルス感染	0	0	0	0	0	1 (6.7%)	0	0	0
菌血症	0	0	0	0	0	0	0	0	1 (3.0%)
蜂巣炎	0	0	0	0	0	0	0	1 (3.6%)	0
呼吸器、胸郭および縦隔障害	2 (22.2%)	0	2 (8.3%)	0	0	0	3 (25.0%)	2 (7.1%)	0
喀血	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_ser_2.sas
Program Run: 18JUN21:09:44:44

表 8-203 重篤な有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
特発性肺炎症候群	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
肺臓炎	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
気胸	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
誤嚥性肺炎	0	0	0	0	0	0	1 (8.3%)	0	0
肝胆道系障害	0	1 (16.7%)	0	0	1 (3.7%)	0	0	0	1 (3.0%)
胆嚢炎	0	0	0	0	1 (3.7%)	0	0	0	1 (3.0%)
薬物性肝障害	0	1 (16.7%)	0	0	0	0	0	0	0
筋骨格系および結合組織障害	0	1 (16.7%)	1 (4.2%)	0	0	0	0	1 (3.6%)	0
筋力低下	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
横紋筋融解症	0	1 (16.7%)	0	0	0	0	0	0	0
内分泌障害	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
抗利尿ホルモン不適合分泌	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_ser_2.sas
Program Run: 18JUN21:09:44:44

表 8-203 重篤な有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
代謝および栄養障害	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
低ナトリウム血症	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
神経系障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
大脳基底核梗塞	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
腎および尿路障害	0	0	0	0	1 (3.7%)	0	0	0	1 (3.0%)
腎機能障害	0	0	0	0	1 (3.7%)	0	0	0	1 (3.0%)
心臓障害	0	0	0	0	0	0	1 (8.3%)	1 (3.6%)	0
急性心筋梗塞	0	0	0	0	0	0	1 (8.3%)	0	0
急性心不全	0	0	0	0	0	0	0	1 (3.6%)	0
血液およびリンパ系障害	0	0	0	0	0	0	0	0	1 (3.0%)
好中球減少症	0	0	0	0	0	0	0	0	1 (3.0%)
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (8.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_ser_2.sas
Program Run: 18JUN21:09:44:44

表 8-203 重篤な有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
死亡	0	0	0	0	0	0	1 (8.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_ser_2.sas
Program Run: 18JUN21:09:44:44

表 8-204 投与中止に至った有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
Overall	5 (55.6%)	4 (66.7%)	5 (20.8%)	0	0	0	6 (50.0%)	5 (17.9%)	0
肝胆道系障害	0	2 (33.3%)	2 (8.3%)	0	0	0	0	2 (7.1%)	0
肝機能異常	0	1 (16.7%)	2 (8.3%)	0	0	0	0	2 (7.1%)	0
薬物性肝障害	0	1 (16.7%)	0	0	0	0	0	0	0
感染症および寄生虫症	1 (11.1%)	0	1 (4.2%)	0	0	0	1 (8.3%)	1 (3.6%)	0
感染性胸水	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
肺炎球菌感染	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
代謝および栄養障害	1 (11.1%)	0	1 (4.2%)	0	0	0	1 (8.3%)	1 (3.6%)	0
高カリウム血症	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
低ナトリウム血症	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
神経系障害	1 (11.1%)	1 (16.7%)	0	0	0	0	1 (8.3%)	0	0
感覚鈍麻	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_2.sas
Program Run: 18JUN21:09:44:51

表 8-204 投与中止に至った有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
多発ニューロパチー	0	1 (16.7%)	0	0	0	0	0	0	0
臨床検査	0	0	1 (4.2%)	0	0	0	1 (8.3%)	1 (3.6%)	0
肝機能検査値上昇	0	0	1 (4.2%)	0	0	0	0	1 (3.6%)	0
心電図異常	0	0	0	0	0	0	1 (8.3%)	0	0
耳および迷路障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
耳管開放	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
胃腸障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
悪心	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
一般・全身障害および投与部位の状態	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
注射部位蕁麻疹	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
腎および尿路障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
腎機能障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_2.sas
Program Run: 18JUN21:09:44:51

表 8-204 投与中止に至った有害事象（投与期間別） - AK1820-301試験のCohort AおよびCohort A/B併合

MedDRA v23.1	Cohort A						Cohort A/B併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 9)	VRC (N = 6)	ISA (N = 24)	VRC (N = 9)	ISA (N = 27)	VRC (N = 15)	ISA (N = 12)	ISA (N = 28)	ISA (N = 33)
呼吸器、胸郭および縦隔障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
呼吸困難	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
口腔咽頭不快感	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
皮膚および皮下組織障害	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
冷汗	1 (11.1%)	0	0	0	0	0	1 (8.3%)	0	0
眼障害	0	1 (16.7%)	0	0	0	0	0	0	0
視力障害	0	1 (16.7%)	0	0	0	0	0	0	0
筋骨格系および結合組織障害	0	1 (16.7%)	0	0	0	0	0	0	0
横紋筋融解症	0	1 (16.7%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_2.sas
Program Run: 18JUN21:09:44:51

表 8-205 SOC別の有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
Overall	119 (96.7%)	122 (97.6%)	105 (95.5%)	113 (99.1%)	23 (95.8%)	20 (100.0%)	162 (96.4%)	125 (96.2%)	99 (94.3%)
胃腸障害	71 (57.7%)	78 (62.4%)	87 (79.1%)	88 (77.2%)	16 (66.7%)	14 (70.0%)	92 (54.8%)	104 (80.0%)	61 (58.1%)
感染症および寄生虫症	72 (58.5%)	65 (52.0%)	64 (58.2%)	82 (71.9%)	16 (66.7%)	11 (55.0%)	101 (60.1%)	77 (59.2%)	65 (61.9%)
全身障害および投与局所様態	71 (57.7%)	67 (53.6%)	67 (60.9%)	67 (58.8%)	10 (41.7%)	10 (50.0%)	88 (52.4%)	82 (63.1%)	46 (43.8%)
呼吸器、胸郭および縦隔障害	73 (59.3%)	68 (54.4%)	59 (53.6%)	70 (61.4%)	11 (45.8%)	9 (45.0%)	92 (54.8%)	69 (53.1%)	45 (42.9%)
代謝および栄養障害	55 (44.7%)	53 (42.4%)	48 (43.6%)	59 (51.8%)	5 (20.8%)	9 (45.0%)	75 (44.6%)	62 (47.7%)	33 (31.4%)
神経系障害	38 (30.9%)	37 (29.6%)	48 (43.6%)	47 (41.2%)	9 (37.5%)	5 (25.0%)	51 (30.4%)	56 (43.1%)	38 (36.2%)
皮膚および皮下組織障害	37 (30.1%)	34 (27.2%)	44 (40.0%)	69 (60.5%)	5 (20.8%)	7 (35.0%)	44 (26.2%)	51 (39.2%)	30 (28.6%)
臨床検査	41 (33.3%)	50 (40.0%)	38 (34.5%)	40 (35.1%)	6 (25.0%)	6 (30.0%)	55 (32.7%)	40 (30.8%)	24 (22.9%)
血液およびリンパ系障害	21 (17.1%)	20 (16.0%)	45 (40.9%)	57 (50.0%)	11 (45.8%)	5 (25.0%)	27 (16.1%)	50 (38.5%)	29 (27.6%)
精神障害	36 (29.3%)	48 (38.4%)	29 (26.4%)	35 (30.7%)	5 (20.8%)	3 (15.0%)	50 (29.8%)	34 (26.2%)	21 (20.0%)
筋骨格系および結合組織障害	29 (23.6%)	26 (20.8%)	32 (29.1%)	46 (40.4%)	8 (33.3%)	5 (25.0%)	35 (20.8%)	40 (30.8%)	34 (32.4%)
血管障害	40 (32.5%)	31 (24.8%)	23 (20.9%)	41 (36.0%)	4 (16.7%)	5 (25.0%)	50 (29.8%)	29 (22.3%)	22 (21.0%)
腎および尿路障害	30 (24.4%)	28 (22.4%)	23 (20.9%)	27 (23.7%)	2 (8.3%)	3 (15.0%)	39 (23.2%)	29 (22.3%)	13 (12.4%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_soc_1.sas
Program Run: 04JUN21:15:00:05

表 8-205 SOC別の有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
心臓障害	22 (17.9%)	32 (25.6%)	16 (14.5%)	23 (20.2%)	5 (20.8%)	2 (10.0%)	35 (20.8%)	20 (15.4%)	13 (12.4%)
眼障害	19 (15.4%)	19 (15.2%)	18 (16.4%)	42 (36.8%)	2 (8.3%)	8 (40.0%)	27 (16.1%)	19 (14.6%)	12 (11.4%)
傷害、中毒および処置合併症	8 (6.5%)	16 (12.8%)	17 (15.5%)	21 (18.4%)	8 (33.3%)	2 (10.0%)	10 (6.0%)	24 (18.5%)	21 (20.0%)
肝胆道系障害	12 (9.8%)	17 (13.6%)	8 (7.3%)	21 (18.4%)	3 (12.5%)	4 (20.0%)	15 (8.9%)	11 (8.5%)	13 (12.4%)
免疫系障害	8 (6.5%)	10 (8.0%)	12 (10.9%)	15 (13.2%)	0	0	10 (6.0%)	12 (9.2%)	7 (6.7%)
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）	9 (7.3%)	17 (13.6%)	9 (8.2%)	13 (11.4%)	1 (4.2%)	1 (5.0%)	12 (7.1%)	9 (6.9%)	8 (7.6%)
耳および迷路障害	4 (3.3%)	8 (6.4%)	9 (8.2%)	5 (4.4%)	1 (4.2%)	0	4 (2.4%)	11 (8.5%)	6 (5.7%)
生殖系および乳房障害	2 (1.6%)	3 (2.4%)	6 (5.5%)	8 (7.0%)	0	2 (10.0%)	4 (2.4%)	6 (4.6%)	7 (6.7%)
内分泌障害	3 (2.4%)	3 (2.4%)	2 (1.8%)	0	0	0	3 (1.8%)	3 (2.3%)	4 (3.8%)
先天性、家族性および遺伝性障害	2 (1.6%)	0	1 (0.9%)	1 (0.9%)	0	1 (5.0%)	2 (1.2%)	1 (0.8%)	0
社会環境	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_soc_1.sas
Program Run: 04JUN21:15:00:05

表 8-206 注目すべき有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

Duration (days) Subgroup	9766-CL-0104試験						海外第III相試験併合		
	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肝機能異常・肝炎	22 (17.9%)	37 (29.6%)	26 (23.6%)	39 (34.2%)	5 (20.8%)	6 (30.0%)	32 (19.0%)	28 (21.5%)	22 (21.0%)
アナフィラキシー	1 (0.8%)	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	0
重度皮膚障害	1 (0.8%)	0	1 (0.9%)	2 (1.8%)	1 (4.2%)	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
心電図QT短縮	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
トルサード ド ポアント	6 (4.9%)	11 (8.8%)	8 (7.3%)	7 (6.1%)	1 (4.2%)	1 (5.0%)	9 (5.4%)	8 (6.2%)	1 (1.0%)
急性膵炎	0	0	0	0	0	0	0	0	1 (1.0%)
精神神経症状	35 (28.5%)	42 (33.6%)	33 (30.0%)	34 (29.8%)	5 (20.8%)	3 (15.0%)	48 (28.6%)	38 (29.2%)	24 (22.9%)
視覚障害	14 (11.4%)	15 (12.0%)	8 (7.3%)	27 (23.7%)	1 (4.2%)	5 (25.0%)	19 (11.3%)	8 (6.2%)	4 (3.8%)
皮膚または子宮の悪性腫瘍	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
静脈内投与例	(N = 123)	(N = 125)	(N = 110)	(N = 114)	(N = 24)	(N = 20)	(N = 159)	(N = 126)	(N = 72)
注入部位／注射部位反応	6 (4.9%)	1 (0.8%)	4 (3.6%)	3 (2.6%)	1 (4.2%)	0	7 (4.4%)	5 (4.0%)	4 (5.6%)
IRR	40 (32.5%)	46 (36.8%)	29 (26.4%)	27 (23.7%)	1 (4.2%)	3 (15.0%)	57 (35.8%)	33 (26.2%)	12 (16.7%)

ISA: isavuconazole; VRC: voriconazole; IRR: Infusion related reaction.

Program Name: t_ae_duration_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
Overall	49 (39.8%)	53 (42.4%)	11 (10.0%)	17 (14.9%)	2 (8.3%)	2 (10.0%)	76 (45.2%)	17 (13.1%)	13 (12.4%)
感染症および寄生虫症	26 (21.1%)	13 (10.4%)	1 (0.9%)	4 (3.5%)	1 (4.2%)	1 (5.0%)	39 (23.2%)	4 (3.1%)	6 (5.7%)
敗血症性ショック	7 (5.7%)	1 (0.8%)	0	3 (2.6%)	1 (4.2%)	0	11 (6.5%)	0	1 (1.0%)
敗血症	7 (5.7%)	4 (3.2%)	0	0	0	1 (5.0%)	7 (4.2%)	0	1 (1.0%)
アスペルギルス症	3 (2.4%)	2 (1.6%)	0	0	0	0	3 (1.8%)	0	1 (1.0%)
真菌感染	3 (2.4%)	2 (1.6%)	0	0	0	0	3 (1.8%)	0	0
肺炎	1 (0.8%)	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.6%)	0	2 (1.9%)
ムコール症	1 (0.8%)	0	0	0	0	0	2 (1.2%)	0	0
アシネトバクター性菌血症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
気管支肺アスペルギルス症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心内膜炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
フサリウム感染	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
感染	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
シュードモナス性敗血症	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	0
クレブシエラ性敗血症	0	1 (0.8%)	0	0	0	0	0	0	0
シュードモナス性菌血症	0	1 (0.8%)	0	0	0	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.8%)	0	0	0	0	0	0	0
真菌性肺炎	0	0	0	0	0	0	2 (1.2%)	0	0
細菌性敗血症	0	0	0	0	0	0	0	1 (0.8%)	0
蓄膿	0	0	0	0	0	0	0	1 (0.8%)	0
真菌性敗血症	0	0	0	0	0	0	1 (0.6%)	0	0
肺感染	0	0	0	0	0	0	0	0	1 (1.0%)
シュードモナス菌性肺感染	0	0	0	0	0	0	1 (0.6%)	0	0
ブラストミセス菌性肺炎	0	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
原発性異型肺炎	0	0	0	0	0	0	1 (0.6%)	0	0
真菌性副鼻腔炎	0	0	0	0	0	0	1 (0.6%)	0	0
ブドウ球菌性敗血症	0	0	0	0	0	0	1 (0.6%)	0	0
呼吸器、胸郭および縦隔障害	13 (10.6%)	10 (8.0%)	1 (0.9%)	2 (1.8%)	0	0	17 (10.1%)	1 (0.8%)	0
呼吸不全	6 (4.9%)	6 (4.8%)	0	0	0	0	7 (4.2%)	0	0
急性呼吸不全	3 (2.4%)	0	0	1 (0.9%)	0	0	4 (2.4%)	0	0
喀血	2 (1.6%)	1 (0.8%)	0	0	0	0	3 (1.8%)	0	0
肺出血	1 (0.8%)	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
呼吸窮迫	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
急性呼吸窮迫症候群	0	1 (0.8%)	0	0	0	0	0	0	0
肺塞栓症	0	1 (0.8%)	0	0	0	0	0	0	0
肺高血圧症	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
呼吸困難	0	0	0	0	0	0	1 (0.6%)	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）	5 (4.1%)	14 (11.2%)	5 (4.5%)	7 (6.1%)	0	0	6 (3.6%)	5 (3.8%)	6 (5.7%)
急性骨髄性白血病	2 (1.6%)	6 (4.8%)	1 (0.9%)	1 (0.9%)	0	0	2 (1.2%)	1 (0.8%)	1 (1.0%)
多発性骨髄腫	0	0	2 (1.8%)	0	0	0	0	2 (1.5%)	0
悪性新生物進行	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
芽球発症	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
骨髄性白血病	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	0
再発慢性リンパ性白血病	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
骨髄異形成症候群	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
再発急性骨髄性白血病	0	2 (1.6%)	0	2 (1.8%)	0	0	0	0	1 (1.0%)
慢性リンパ性白血病	0	2 (1.6%)	0	0	0	0	0	0	1 (1.0%)
再発急性リンパ性白血病	0	1 (0.8%)	0	0	0	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
B細胞性リンパ腫	0	0	0	1 (0.9%)	0	0	0	0	0
バーキット白血病	0	1 (0.8%)	0	0	0	0	0	0	0
リンパ腫	0	0	0	1 (0.9%)	0	0	0	0	0
新生物進行	0	1 (0.8%)	0	0	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (1.0%)
心臓障害	2 (1.6%)	5 (4.0%)	1 (0.9%)	0	1 (4.2%)	0	4 (2.4%)	2 (1.5%)	1 (1.0%)
心停止	1 (0.8%)	3 (2.4%)	0	0	0	0	1 (0.6%)	0	0
心肺停止	0	1 (0.8%)	1 (0.9%)	0	0	0	2 (1.2%)	1 (0.8%)	0
うっ血性心筋症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心膜炎	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
急性心筋梗塞	0	1 (0.8%)	0	0	0	0	0	0	0
急性心不全	0	0	0	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
神経系障害	0	5 (4.0%)	3 (2.7%)	1 (0.9%)	0	1 (5.0%)	1 (0.6%)	3 (2.3%)	1 (1.0%)
頭蓋内出血	0	3 (2.4%)	2 (1.8%)	0	0	0	0	2 (1.5%)	0
神経毒性	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
脳出血	0	0	0	0	0	1 (5.0%)	0	0	0
脳炎	0	0	0	1 (0.9%)	0	0	0	0	0
昏迷	0	1 (0.8%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.8%)	0	0	0	0	0	0	0
脳梗塞	0	0	0	0	0	0	1 (0.6%)	0	1 (1.0%)
全身障害および投与局所様態	2 (1.6%)	6 (4.8%)	0	2 (1.8%)	0	0	6 (3.6%)	1 (0.8%)	0
多臓器不全	1 (0.8%)	5 (4.0%)	0	1 (0.9%)	0	0	2 (1.2%)	0	0
死亡	1 (0.8%)	1 (0.8%)	0	0	0	0	4 (2.4%)	0	0
心突然死	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
全身健康状態低下	0	0	0	0	0	0	0	1 (0.8%)	0
血管障害	2 (1.6%)	1 (0.8%)	0	0	0	0	2 (1.2%)	1 (0.8%)	0
出血	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
血液量減少性ショック	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
深部静脈血栓症	0	1 (0.8%)	0	0	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	1 (0.8%)	0
血液およびリンパ系障害	1 (0.8%)	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	0
出血性障害	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
血小板減少症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
汎血球減少症	0	0	0	1 (0.9%)	0	0	0	0	0
免疫系障害	0	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
急性移植片対宿主病	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-207 死亡に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
移植片対宿主病	0	0	0	0	0	0	1 (0.6%)	0	0
腎および尿路障害	1 (0.8%)	0	0	0	0	0	2 (1.2%)	0	0
腎不全	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
急性腎不全	0	0	0	0	0	0	1 (0.6%)	0	0
肝胆道系障害	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
急性肝炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
代謝および栄養障害	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
低血糖症	0	0	0	1 (0.9%)	0	0	0	0	0
代謝性アシドーシス	0	1 (0.8%)	0	0	0	0	0	0	0
胃腸障害	0	1 (0.8%)	0	0	0	0	0	0	0
直腸出血	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_death_1.sas
Program Run: 04JUN21:15:00:16

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
Overall	69 (56.1%)	80 (64.0%)	53 (48.2%)	61 (53.5%)	12 (50.0%)	8 (40.0%)	104 (61.9%)	67 (51.5%)	52 (49.5%)
感染症および寄生虫症	34 (27.6%)	32 (25.6%)	14 (12.7%)	26 (22.8%)	3 (12.5%)	3 (15.0%)	53 (31.5%)	23 (17.7%)	30 (28.6%)
敗血症性ショック	10 (8.1%)	5 (4.0%)	3 (2.7%)	5 (4.4%)	1 (4.2%)	0	16 (9.5%)	3 (2.3%)	1 (1.0%)
敗血症	7 (5.7%)	6 (4.8%)	0	1 (0.9%)	0	1 (5.0%)	8 (4.8%)	0	2 (1.9%)
肺炎	2 (1.6%)	5 (4.0%)	2 (1.8%)	5 (4.4%)	1 (4.2%)	0	2 (1.2%)	3 (2.3%)	7 (6.7%)
アスペルギルス症	3 (2.4%)	3 (2.4%)	1 (0.9%)	0	0	0	3 (1.8%)	2 (1.5%)	2 (1.9%)
真菌感染	3 (2.4%)	3 (2.4%)	0	0	0	0	3 (1.8%)	0	1 (1.0%)
サイトメガロウイルス感染	0	2 (1.6%)	2 (1.8%)	0	0	0	0	3 (2.3%)	1 (1.0%)
気管支肺アスペルギルス症	1 (0.8%)	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
シュードモナス性敗血症	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
大腸菌性敗血症	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	1 (1.0%)
尿路感染	0	0	1 (0.9%)	0	0	1 (5.0%)	0	2 (1.5%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
蜂巣炎	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	0
クレブシエラ性菌血症	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	0
クレブシエラ性敗血症	0	1 (0.8%)	1 (0.9%)	0	0	0	0	1 (0.8%)	0
ムコール症	1 (0.8%)	0	0	0	0	0	2 (1.2%)	0	1 (1.0%)
クロストリジウム・ディフィシレ大腸炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	1 (0.8%)	0
腸球菌性菌血症	0	0	0	0	1 (4.2%)	0	1 (0.6%)	0	1 (1.0%)
ブドウ球菌感染	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	1 (1.0%)
アシネトバクター性菌血症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
肺炎球菌性気管支炎	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
気管支肺炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
脳アスペルギルス症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
サイトメガロウイルス血症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
ヘルペス脳炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心内膜炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
フサリウム感染	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
感染	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
注入部位感染	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
筋膿瘍	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
モラクセラ菌性肺炎	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
気道感染	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
敗血症症候群	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
皮膚感染	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
細菌性敗血症	0	1 (0.8%)	0	3 (2.6%)	0	0	0	1 (0.8%)	0
ブドウ球菌性菌血症	0	0	0	2 (1.8%)	0	1 (5.0%)	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
菌血症	0	1 (0.8%)	0	1 (0.9%)	0	0	1 (0.6%)	0	2 (1.9%)
ブドウ球菌性敗血症	0	0	0	2 (1.8%)	0	0	1 (0.6%)	0	0
クロストリジウム性菌血症	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
髄膜炎	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
細菌性肺炎	0	1 (0.8%)	0	0	0	0	2 (1.2%)	0	1 (1.0%)
帯状疱疹	0	0	0	1 (0.9%)	0	0	0	0	2 (1.9%)
蓄膿	0	0	0	1 (0.9%)	0	0	0	1 (0.8%)	0
カンピロバクター胃腸炎	0	0	0	1 (0.9%)	0	0	0	0	0
カテーテル関連感染	0	0	0	1 (0.9%)	0	0	0	0	0
感染性下痢	0	0	0	1 (0.9%)	0	0	0	0	0
ヘリコバクター胃潰瘍	0	0	0	1 (0.9%)	0	0	0	0	0
単純ヘルペス	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肺膿瘍	0	0	0	1 (0.9%)	0	0	0	0	0
壊死性筋膜炎	0	1 (0.8%)	0	0	0	0	0	0	0
肺炎球菌性肺炎	0	0	0	1 (0.9%)	0	0	0	0	0
ブドウ球菌性肺炎	0	0	0	1 (0.9%)	0	0	0	0	0
シュードモナス性菌血症	0	1 (0.8%)	0	0	0	0	0	0	0
シュードモナス感染	0	1 (0.8%)	0	0	0	0	0	0	0
膿胸	0	1 (0.8%)	0	0	0	0	0	0	0
ステノトロフォモナス性敗血症	0	1 (0.8%)	0	0	0	0	0	0	0
全身性カンジダ	0	0	0	1 (0.9%)	0	0	0	0	0
トキソプラズマ症	0	0	0	1 (0.9%)	0	0	0	0	0
結核	0	0	0	1 (0.9%)	0	0	0	0	0
細菌性尿路感染	0	0	0	0	0	1 (5.0%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
真菌性肺炎	0	0	0	0	0	0	2 (1.2%)	0	0
接合真菌症	0	0	0	0	0	0	1 (0.6%)	1 (0.8%)	0
腹部膿瘍	0	0	0	0	0	0	0	0	1 (1.0%)
虫垂炎	0	0	0	0	0	0	0	0	1 (1.0%)
ＢＫウイルス感染	0	0	0	0	0	0	0	0	1 (1.0%)
脳膿瘍	0	0	0	0	0	0	1 (0.6%)	0	0
気管支拡張症	0	0	0	0	0	0	1 (0.6%)	0	0
細気管支炎	0	0	0	0	0	0	0	0	1 (1.0%)
カテーテル留置部位感染	0	0	0	0	0	0	1 (0.6%)	0	0
サイトメガロウイルス性小腸炎	0	0	0	0	0	0	0	0	1 (1.0%)
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (1.0%)
真菌性敗血症	0	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
ノロウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (1.0%)
ウイルス性胃腸炎	0	0	0	0	0	0	0	0	1 (1.0%)
インフルエンザ	0	0	0	0	0	0	0	0	1 (1.0%)
肺感染	0	0	0	0	0	0	0	0	1 (1.0%)
シュードモナス菌性肺感染	0	0	0	0	0	0	1 (0.6%)	0	0
ニューモシスティスジロヴェシ肺炎	0	0	0	0	0	0	1 (0.6%)	0	0
ブラストミセス菌性肺炎	0	0	0	0	0	0	1 (0.6%)	0	0
インフルエンザ性肺炎	0	0	0	0	0	0	0	0	1 (1.0%)
原発性異型肺炎	0	0	0	0	0	0	1 (0.6%)	0	0
シュードモナス性気管支炎	0	0	0	0	0	0	0	1 (0.8%)	0
副鼻腔炎	0	0	0	0	0	0	0	1 (0.8%)	0
真菌性副鼻腔炎	0	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
レンサ球菌性菌血症	0	0	0	0	0	0	0	0	1 (1.0%)
皮下組織膿瘍	0	0	0	0	0	0	0	0	1 (1.0%)
尿路性敗血症	0	0	0	0	0	0	0	1 (0.8%)	0
ウイルス性下痢	0	0	0	0	0	0	0	0	1 (1.0%)
呼吸器、胸郭および縦隔障害	25 (20.3%)	23 (18.4%)	15 (13.6%)	19 (16.7%)	1 (4.2%)	1 (5.0%)	34 (20.2%)	17 (13.1%)	10 (9.5%)
呼吸不全	10 (8.1%)	10 (8.0%)	4 (3.6%)	2 (1.8%)	0	0	12 (7.1%)	4 (3.1%)	3 (2.9%)
急性呼吸不全	5 (4.1%)	3 (2.4%)	0	2 (1.8%)	0	0	7 (4.2%)	1 (0.8%)	0
呼吸困難	2 (1.6%)	0	3 (2.7%)	1 (0.9%)	0	0	3 (1.8%)	3 (2.3%)	0
呼吸窮迫	3 (2.4%)	2 (1.6%)	1 (0.9%)	1 (0.9%)	0	0	3 (1.8%)	1 (0.8%)	0
喀血	2 (1.6%)	1 (0.8%)	0	1 (0.9%)	0	0	3 (1.8%)	0	1 (1.0%)
低酸素症	0	1 (0.8%)	2 (1.8%)	0	0	0	0	2 (1.5%)	1 (1.0%)
肺出血	1 (0.8%)	1 (0.8%)	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
胸水	0	0	0	1 (0.9%)	1 (4.2%)	0	1 (0.6%)	0	1 (1.0%)
肺水腫	1 (0.8%)	0	0	1 (0.9%)	0	0	2 (1.2%)	0	0
肺障害	1 (0.8%)	0	0	1 (0.9%)	0	0	1 (0.6%)	0	0
呼吸抑制	1 (0.8%)	0	0	1 (0.9%)	0	0	1 (0.6%)	0	0
嚥下性肺炎	0	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
頻呼吸	0	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
気管支胸膜瘻	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
気管支痙攣	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
水気胸	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
胸膜痛	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
呼吸性アシドーシス	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
鼻出血	0	2 (1.6%)	0	2 (1.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肺塞栓症	0	1 (0.8%)	0	2 (1.8%)	0	0	0	0	1 (1.0%)
肺浸潤	0	1 (0.8%)	0	1 (0.9%)	0	1 (5.0%)	0	0	0
急性呼吸窮迫症候群	0	2 (1.6%)	0	0	0	0	0	0	1 (1.0%)
急性肺損傷	0	0	0	1 (0.9%)	0	0	0	0	0
慢性閉塞性肺疾患	0	0	0	1 (0.9%)	0	0	0	0	0
咳嗽	0	0	0	1 (0.9%)	0	0	0	0	0
血胸	0	0	0	1 (0.9%)	0	0	0	0	0
気胸	0	0	0	1 (0.9%)	0	0	0	0	0
湿性咳嗽	0	0	0	1 (0.9%)	0	0	0	0	0
肺高血圧症	0	0	0	1 (0.9%)	0	0	0	0	0
呼吸停止	0	0	0	1 (0.9%)	0	0	0	0	0
高炭酸ガス血症	0	0	0	0	0	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肺胞出血	0	0	0	0	0	0	0	0	1 (1.0%)
肺梗塞	0	0	0	0	0	0	0	1 (0.8%)	0
副鼻腔障害	0	0	0	0	0	0	0	0	1 (1.0%)
喘鳴	0	0	0	0	0	0	1 (0.6%)	0	0
血液およびリンパ系障害	3 (2.4%)	4 (3.2%)	19 (17.3%)	11 (9.6%)	6 (25.0%)	2 (10.0%)	3 (1.8%)	21 (16.2%)	9 (8.6%)
発熱性好中球減少症	0	3 (2.4%)	13 (11.8%)	1 (0.9%)	1 (4.2%)	1 (5.0%)	0	14 (10.8%)	2 (1.9%)
汎血球減少症	1 (0.8%)	0	3 (2.7%)	2 (1.8%)	0	1 (5.0%)	1 (0.6%)	3 (2.3%)	1 (1.0%)
好中球減少症	0	0	1 (0.9%)	3 (2.6%)	3 (12.5%)	0	0	1 (0.8%)	3 (2.9%)
血小板減少症	0	0	2 (1.8%)	4 (3.5%)	1 (4.2%)	0	0	2 (1.5%)	1 (1.0%)
無顆粒球症	0	0	1 (0.9%)	0	1 (4.2%)	0	0	1 (0.8%)	1 (1.0%)
貧血	0	1 (0.8%)	1 (0.9%)	1 (0.9%)	0	0	0	2 (1.5%)	1 (1.0%)
出血性障害	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
白血球増加症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
脾臓梗塞	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
出血性貧血	0	0	0	1 (0.9%)	0	0	0	0	0
微小血管症性溶血性貧血	0	0	0	1 (0.9%)	0	0	0	0	0
血小板減少性紫斑病	0	0	0	1 (0.9%)	0	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）	9 (7.3%)	16 (12.8%)	8 (7.3%)	12 (10.5%)	1 (4.2%)	1 (5.0%)	11 (6.5%)	8 (6.2%)	7 (6.7%)
急性骨髄性白血病	2 (1.6%)	6 (4.8%)	1 (0.9%)	2 (1.8%)	0	0	2 (1.2%)	1 (0.8%)	2 (1.9%)
リンパ腫	1 (0.8%)	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	0
多発性骨髄腫	0	0	2 (1.8%)	0	0	0	0	2 (1.5%)	0
悪性新生物進行	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
再発急性リンパ性白血病	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	1 (1.0%)
芽球発症	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
骨髄性白血病	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	0
新生物進行	0	1 (0.8%)	0	0	1 (4.2%)	0	0	0	1 (1.0%)
再発慢性リンパ性白血病	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
子宮内膜癌	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
髄膜転移	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
骨髄異形成症候群	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
非ホジキンリンパ腫	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
原発性体腔性リンパ腫	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
再発急性骨髄性白血病	0	2 (1.6%)	0	3 (2.6%)	0	0	1 (0.6%)	0	1 (1.0%)
慢性リンパ性白血病	0	2 (1.6%)	0	0	0	0	0	0	1 (1.0%)
急性白血病	0	0	0	1 (0.9%)	0	0	0	0	0
急性リンパ性白血病	0	0	0	0	0	1 (5.0%)	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
B細胞性リンパ腫	0	0	0	1 (0.9%)	0	0	0	0	0
再発B細胞性リンパ腫	0	0	0	1 (0.9%)	0	0	0	0	0
バーキット白血病	0	1 (0.8%)	0	0	0	0	0	0	0
エプスタイン・バーウイルス関連リンパ増殖性障害	0	1 (0.8%)	0	0	0	0	0	0	0
白血病	0	0	0	1 (0.9%)	0	0	0	0	0
肺の悪性新生物	0	0	0	1 (0.9%)	0	0	0	0	0
骨転移	0	1 (0.8%)	0	0	0	0	0	0	0
転移部痛	0	0	0	1 (0.9%)	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (1.0%)
白血病浸潤	0	0	0	0	0	0	0	0	1 (1.0%)
神経系障害	9 (7.3%)	10 (8.0%)	8 (7.3%)	5 (4.4%)	0	1 (5.0%)	12 (7.1%)	9 (6.9%)	5 (4.8%)
痙攣	2 (1.6%)	1 (0.8%)	1 (0.9%)	0	0	0	3 (1.8%)	1 (0.8%)	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
頭蓋内出血	0	3 (2.4%)	2 (1.8%)	0	0	0	0	2 (1.5%)	0
てんかん	2 (1.6%)	1 (0.8%)	0	0	0	0	2 (1.2%)	0	0
多発ニューロパチー	1 (0.8%)	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
中枢神経系病変	0	0	1 (0.9%)	1 (0.9%)	0	0	0	1 (0.8%)	0
脳症	1 (0.8%)	0	0	1 (0.9%)	0	0	1 (0.6%)	0	0
虚血性脳卒中	1 (0.8%)	0	0	1 (0.9%)	0	0	1 (0.6%)	0	0
対麻痺	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
頭痛	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	1 (1.0%)
脳幹卒中	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
脳虚血	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
熱性痙攣	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
神経毒性	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
失語症	0	0	0	0	0	1 (5.0%)	0	0	1 (1.0%)
脳出血	0	0	0	0	0	1 (5.0%)	0	0	0
浮動性めまい	0	1 (0.8%)	0	0	0	0	0	0	0
脳炎	0	0	0	1 (0.9%)	0	0	0	0	0
大発作痙攣	0	0	0	1 (0.9%)	0	0	0	0	0
片麻痺	0	0	0	0	0	1 (5.0%)	0	0	0
昏迷	0	1 (0.8%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.8%)	0	0	0	0	0	0	0
振戦	0	1 (0.8%)	0	0	0	0	0	0	0
第７脳神経麻痺	0	0	0	0	0	1 (5.0%)	0	0	0
脳梗塞	0	0	0	0	0	0	1 (0.6%)	0	2 (1.9%)
脳血管発作	0	0	0	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
卒中の出血性変化	0	0	0	0	0	0	1 (0.6%)	0	0
不全片麻痺	0	0	0	0	0	0	0	1 (0.8%)	0
一過性脳虚血発作	0	0	0	0	0	0	0	0	1 (1.0%)
全身障害および投与局所様態	4 (3.3%)	9 (7.2%)	5 (4.5%)	8 (7.0%)	2 (8.3%)	2 (10.0%)	10 (6.0%)	6 (4.6%)	4 (3.8%)
発熱	2 (1.6%)	2 (1.6%)	5 (4.5%)	6 (5.3%)	1 (4.2%)	2 (10.0%)	2 (1.2%)	5 (3.8%)	3 (2.9%)
多臓器不全	1 (0.8%)	6 (4.8%)	0	1 (0.9%)	0	0	2 (1.2%)	0	0
死亡	1 (0.8%)	1 (0.8%)	0	0	0	0	4 (2.4%)	0	0
悪寒	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
全身健康状態低下	0	0	1 (0.9%)	0	0	0	0	2 (1.5%)	0
無力症	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
胸痛	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
心突然死	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
非心臓性胸痛	0	0	0	0	0	0	2 (1.2%)	0	0
末梢性浮腫	0	0	0	0	0	0	1 (0.6%)	0	0
心臓障害	5 (4.1%)	8 (6.4%)	3 (2.7%)	4 (3.5%)	3 (12.5%)	0	10 (6.0%)	5 (3.8%)	4 (3.8%)
心肺停止	1 (0.8%)	2 (1.6%)	1 (0.9%)	0	0	0	3 (1.8%)	1 (0.8%)	0
心停止	1 (0.8%)	4 (3.2%)	0	1 (0.9%)	0	0	1 (0.6%)	0	0
心房細動	0	0	1 (0.9%)	1 (0.9%)	0	0	0	2 (1.5%)	1 (1.0%)
急性心筋梗塞	0	1 (0.8%)	0	0	1 (4.2%)	0	1 (0.6%)	0	1 (1.0%)
不整脈	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心原性ショック	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
うっ血性心筋症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心膜炎	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
洞性徐脈	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
上室性頻脈	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心室性頻脈	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
狭心症	0	0	0	1 (0.9%)	0	0	0	0	0
完全房室ブロック	0	0	0	0	0	0	1 (0.6%)	0	0
急性心不全	0	0	0	0	0	0	0	1 (0.8%)	0
電気収縮解離	0	0	0	0	0	0	1 (0.6%)	0	0
腎および尿路障害	8 (6.5%)	5 (4.0%)	2 (1.8%)	5 (4.4%)	0	0	12 (7.1%)	5 (3.8%)	2 (1.9%)
急性腎不全	5 (4.1%)	4 (3.2%)	1 (0.9%)	4 (3.5%)	0	0	9 (5.4%)	4 (3.1%)	1 (1.0%)
腎不全	3 (2.4%)	1 (0.8%)	0	1 (0.9%)	0	0	3 (1.8%)	0	1 (1.0%)
血尿	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
胃腸障害	2 (1.6%)	4 (3.2%)	4 (3.6%)	6 (5.3%)	3 (12.5%)	2 (10.0%)	6 (3.6%)	6 (4.6%)	15 (14.3%)
下痢	0	0	1 (0.9%)	1 (0.9%)	1 (4.2%)	0	0	1 (0.8%)	3 (2.9%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
小腸閉塞	1 (0.8%)	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
悪心	0	0	0	1 (0.9%)	1 (4.2%)	0	0	0	3 (2.9%)
腸出血	0	1 (0.8%)	1 (0.9%)	0	0	0	0	1 (0.8%)	0
腹膜炎	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
腹痛	0	0	0	0	1 (4.2%)	0	0	0	6 (5.7%)
大腸炎	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	1 (1.0%)
便秘	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	1 (1.0%)
胃穿孔	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
食道潰瘍	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
胃腸出血	0	0	0	2 (1.8%)	0	1 (5.0%)	2 (1.2%)	1 (0.8%)	0
食中毒	0	0	0	0	0	1 (5.0%)	0	0	0
胃腸の炎症	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
麻痺性イレウス	0	0	0	1 (0.9%)	0	0	0	0	0
肛門周囲痛	0	0	0	1 (0.9%)	0	0	0	0	0
直腸出血	0	1 (0.8%)	0	0	0	0	0	0	0
嘔吐	0	0	0	0	0	0	1 (0.6%)	0	3 (2.9%)
嚥下障害	0	0	0	0	0	0	0	1 (0.8%)	1 (1.0%)
潰瘍性大腸炎	0	0	0	0	0	0	0	0	1 (1.0%)
限局性腹腔内液貯留	0	0	0	0	0	0	1 (0.6%)	0	0
食道炎	0	0	0	0	0	0	0	0	1 (1.0%)
膵炎	0	0	0	0	0	0	0	0	1 (1.0%)
慢性膵炎	0	0	0	0	0	0	0	0	1 (1.0%)
再発性膵炎	0	0	0	0	0	0	0	0	1 (1.0%)
免疫系障害	0	2 (1.6%)	4 (3.6%)	4 (3.5%)	0	0	2 (1.2%)	4 (3.1%)	3 (2.9%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
急性腸管移植片対宿主病	0	0	1 (0.9%)	2 (1.8%)	0	0	0	1 (0.8%)	0
急性移植片対宿主病	0	0	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
アナフィラキシーショック	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
過敏症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
アナフィラキシー反応	0	2 (1.6%)	0	0	0	0	0	0	0
急性肝移植片対宿主病	0	0	0	1 (0.9%)	0	0	0	0	0
移植片対宿主病	0	0	0	0	0	0	1 (0.6%)	0	1 (1.0%)
肺移植拒絶反応	0	0	0	0	0	0	0	0	1 (1.0%)
血管障害	3 (2.4%)	2 (1.6%)	0	4 (3.5%)	1 (4.2%)	0	3 (1.8%)	2 (1.5%)	4 (3.8%)
低血圧	1 (0.8%)	0	0	2 (1.8%)	0	0	1 (0.6%)	0	2 (1.9%)
出血	1 (0.8%)	0	0	1 (0.9%)	0	0	1 (0.6%)	0	0
血液量減少性ショック	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
血管炎	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
深部静脈血栓症	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	1 (1.0%)
ショック	0	0	0	1 (0.9%)	0	0	0	0	0
動脈炎	0	0	0	0	0	0	0	1 (0.8%)	0
肝胆道系障害	2 (1.6%)	4 (3.2%)	1 (0.9%)	2 (1.8%)	0	0	3 (1.8%)	2 (1.5%)	3 (2.9%)
胆嚢炎	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	1 (1.0%)
肝炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
急性肝炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
肝不全	0	2 (1.6%)	0	0	0	0	0	0	0
肝機能異常	0	2 (1.6%)	0	0	0	0	0	0	0
高ビリルビン血症	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
急性胆嚢炎	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
急性肝不全	0	0	0	0	0	0	1 (0.6%)	0	0
細胆管炎	0	0	0	0	0	0	0	1 (0.8%)	0
胆石症	0	0	0	0	0	0	0	0	1 (1.0%)
肝障害	0	0	0	0	0	0	0	0	1 (1.0%)
臨床検査	1 (0.8%)	6 (4.8%)	1 (0.9%)	0	1 (4.2%)	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
肝機能検査異常	0	1 (0.8%)	1 (0.9%)	0	0	0	0	1 (0.8%)	0
血中ナトリウム減少	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
ヘモグロビン減少	0	0	0	0	1 (4.2%)	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	1 (0.8%)	0	0	0	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.8%)	0	0	0	0	0	0	0
血中アルカリホスファターゼ増加	0	1 (0.8%)	0	0	0	0	0	0	0
血中ビリルビン増加	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
心電図ＱＴ延長	0	1 (0.8%)	0	0	0	0	0	0	0
肝酵素上昇	0	1 (0.8%)	0	0	0	0	0	0	0
傷害、中毒および処置合併症	0	2 (1.6%)	1 (0.9%)	1 (0.9%)	2 (8.3%)	0	0	1 (0.8%)	2 (1.9%)
薬物毒性	0	0	1 (0.9%)	0	1 (4.2%)	0	0	1 (0.8%)	1 (1.0%)
転倒・転落	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
家庭内事故	0	1 (0.8%)	0	0	0	0	0	0	0
大腿骨頚部骨折	0	1 (0.8%)	0	0	0	0	0	0	0
橈骨骨折	0	0	0	1 (0.9%)	0	0	0	0	0
皮膚および皮下組織障害	1 (0.8%)	2 (1.6%)	1 (0.9%)	0	1 (4.2%)	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
褥瘡性潰瘍	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
皮膚炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
脂肪織炎	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
発疹	0	2 (1.6%)	0	0	0	0	0	0	0
筋骨格系および結合組織障害	1 (0.8%)	0	2 (1.8%)	0	0	0	2 (1.2%)	2 (1.5%)	3 (2.9%)
筋骨格系胸痛	0	0	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	1 (1.0%)
筋肉内出血	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
筋炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
関節炎	0	0	0	0	0	0	0	0	1 (1.0%)
四肢痛	0	0	0	0	0	0	1 (0.6%)	0	0
全身性エリテマトーデス	0	0	0	0	0	0	0	0	1 (1.0%)
代謝および栄養障害	1 (0.8%)	3 (2.4%)	1 (0.9%)	3 (2.6%)	0	1 (5.0%)	3 (1.8%)	1 (0.8%)	5 (4.8%)
コントロール不良の糖尿病	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
成長障害	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
脱水	0	0	0	2 (1.8%)	0	0	1 (0.6%)	0	2 (1.9%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
代謝性アシドーシス	0	1 (0.8%)	0	1 (0.9%)	0	0	0	0	0
低血糖症	0	0	0	1 (0.9%)	0	0	0	0	1 (1.0%)
高ナトリウム血症	0	1 (0.8%)	0	0	0	0	0	0	0
低カリウム血症	0	1 (0.8%)	0	0	0	0	0	0	0
過小食	0	0	0	0	0	1 (5.0%)	0	0	0
高カリウム血症	0	0	0	0	0	0	1 (0.6%)	0	0
低ナトリウム血症	0	0	0	0	0	0	0	0	1 (1.0%)
栄養障害	0	0	0	0	0	0	0	0	1 (1.0%)
眼障害	0	1 (0.8%)	1 (0.9%)	0	1 (4.2%)	0	1 (0.6%)	1 (0.8%)	2 (1.9%)
片側失明	0	0	0	0	1 (4.2%)	0	0	0	1 (1.0%)
視神経症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
眼瞼浮腫	0	1 (0.8%)	0	0	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
網膜動脈閉塞	0	0	0	0	0	0	1 (0.6%)	0	0
網膜出血	0	0	0	0	0	0	0	0	1 (1.0%)
硝子体出血	0	0	0	0	0	0	0	0	1 (1.0%)
精神障害	0	5 (4.0%)	1 (0.9%)	1 (0.9%)	0	0	1 (0.6%)	2 (1.5%)	0
うつ病	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
幻視	0	2 (1.6%)	0	0	0	0	0	0	0
精神状態変化	0	2 (1.6%)	0	0	0	0	0	0	0
錯乱状態	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	0
幻覚	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	0
抑うつ気分	0	0	0	1 (0.9%)	0	0	0	0	0
自殺企図	0	1 (0.8%)	0	0	0	0	0	0	0
異常行動	0	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-208 重篤な有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
攻撃性	0	0	0	0	0	0	1 (0.6%)	0	0
激越	0	0	0	0	0	0	1 (0.6%)	0	0
生殖系および乳房障害	0	0	0	0	0	0	0	0	1 (1.0%)
良性前立腺肥大症	0	0	0	0	0	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.
A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_duration_ser_1.sas
Program Run: 04JUN21:15:00:21

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
Overall	32 (26.0%)	51 (40.8%)	5 (4.5%)	8 (7.0%)	0	0	42 (25.0%)	8 (6.2%)	6 (5.7%)
感染症および寄生虫症	11 (8.9%)	12 (9.6%)	0	3 (2.6%)	0	0	14 (8.3%)	0	4 (3.8%)
真菌感染	2 (1.6%)	1 (0.8%)	0	0	0	0	2 (1.2%)	0	1 (1.0%)
敗血症性ショック	2 (1.6%)	0	0	0	0	0	4 (2.4%)	0	0
敗血症	1 (0.8%)	3 (2.4%)	0	0	0	0	1 (0.6%)	0	0
アスペルギルス症	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	2 (1.9%)
肺炎	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
気管支肺炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
気管支肺アスペルギルス症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心内膜炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
感染	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
細菌性敗血症	0	1 (0.8%)	0	2 (1.8%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肺感染	0	2 (1.6%)	0	0	0	0	0	0	0
髄膜炎	0	1 (0.8%)	0	0	0	0	0	0	0
ムコール症	0	0	0	1 (0.9%)	0	0	0	0	0
シュードモナス性敗血症	0	1 (0.8%)	0	0	0	0	0	0	0
ブドウ球菌感染	0	1 (0.8%)	0	0	0	0	0	0	0
全身性カンジダ	0	1 (0.8%)	0	0	0	0	0	0	0
脳膿瘍	0	0	0	0	0	0	1 (0.6%)	0	0
大腸菌性菌血症	0	0	0	0	0	0	0	0	1 (1.0%)
呼吸器、胸郭および縦隔障害	5 (4.1%)	5 (4.0%)	1 (0.9%)	0	0	0	5 (3.0%)	1 (0.8%)	0
呼吸不全	1 (0.8%)	4 (3.2%)	1 (0.9%)	0	0	0	1 (0.6%)	1 (0.8%)	0
呼吸困難	2 (1.6%)	0	0	0	0	0	2 (1.2%)	0	0
呼吸窮迫	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
急性呼吸不全	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
神経系障害	5 (4.1%)	3 (2.4%)	0	1 (0.9%)	0	0	6 (3.6%)	1 (0.8%)	0
痙攣	2 (1.6%)	0	0	0	0	0	2 (1.2%)	0	0
てんかん	2 (1.6%)	0	0	0	0	0	2 (1.2%)	0	0
脳症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
大発作痙攣	0	0	0	1 (0.9%)	0	0	0	0	0
昏迷	0	1 (0.8%)	0	0	0	0	0	0	0
くも膜下出血	0	1 (0.8%)	0	0	0	0	0	0	0
振戦	0	1 (0.8%)	0	0	0	0	0	0	0
脳血管発作	0	0	0	0	0	0	0	1 (0.8%)	0
卒中の出血性変化	0	0	0	0	0	0	1 (0.6%)	0	0
臨床検査	4 (3.3%)	6 (4.8%)	0	0	0	0	5 (3.0%)	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
血中ビリルビン増加	2 (1.6%)	0	0	0	0	0	2 (1.2%)	0	0
血中ナトリウム減少	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
トランスアミナーゼ上昇	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
肝機能検査異常	0	2 (1.6%)	0	0	0	0	0	0	0
アラニン・アミノトランスフェラーゼ増加	0	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
血中アルカリホスファターゼ増加	0	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
肝酵素上昇	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.8%)	0	0	0	0	0	0	0
心電図ＱＴ延長	0	1 (0.8%)	0	0	0	0	0	0	0
血中乳酸脱水素酵素増加	0	0	0	0	0	0	1 (0.6%)	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	1 (0.6%)	0	0
心臓障害	3 (2.4%)	3 (2.4%)	1 (0.9%)	0	0	0	3 (1.8%)	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
心停止	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
心肺停止	0	1 (0.8%)	1 (0.9%)	0	0	0	0	1 (0.8%)	0
うっ血性心筋症	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
上室性頻脈	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
心室性頻脈	0	1 (0.8%)	0	0	0	0	0	0	0
腎および尿路障害	3 (2.4%)	1 (0.8%)	0	2 (1.8%)	0	0	4 (2.4%)	1 (0.8%)	0
腎不全	2 (1.6%)	0	0	1 (0.9%)	0	0	2 (1.2%)	0	0
急性腎不全	1 (0.8%)	1 (0.8%)	0	1 (0.9%)	0	0	2 (1.2%)	1 (0.8%)	0
精神障害	2 (1.6%)	5 (4.0%)	0	1 (0.9%)	0	0	2 (1.2%)	1 (0.8%)	0
錯乱状態	2 (1.6%)	2 (1.6%)	0	0	0	0	2 (1.2%)	1 (0.8%)	0
幻視	0	3 (2.4%)	0	0	0	0	0	0	0
幻覚	0	1 (0.8%)	0	0	0	0	0	1 (0.8%)	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
抑うつ気分	0	0	0	1 (0.9%)	0	0	0	0	0
不快気分	0	1 (0.8%)	0	0	0	0	0	0	0
皮膚および皮下組織障害	2 (1.6%)	5 (4.0%)	0	0	0	0	2 (1.2%)	0	0
皮膚炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
アレルギー性皮膚炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
発疹	0	4 (3.2%)	0	0	0	0	0	0	0
薬疹	0	1 (0.8%)	0	0	0	0	0	0	0
胃腸障害	1 (0.8%)	3 (2.4%)	1 (0.9%)	0	0	0	2 (1.2%)	1 (0.8%)	1 (1.0%)
嘔吐	1 (0.8%)	2 (1.6%)	0	0	0	0	2 (1.2%)	0	0
嚥下障害	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
小腸閉塞	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
悪心	0	2 (1.6%)	0	0	0	0	0	0	1 (1.0%)

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days) Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	> 42 to <= 84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
肝胆道系障害	1 (0.8%)	6 (4.8%)	0	0	0	0	2 (1.2%)	0	0
急性肝炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
肝不全	0	2 (1.6%)	0	0	0	0	0	0	0
高ビリルビン血症	0	2 (1.6%)	0	0	0	0	0	0	0
肝機能異常	0	1 (0.8%)	0	0	0	0	0	0	0
肝病変	0	1 (0.8%)	0	0	0	0	0	0	0
肝炎	0	1 (0.8%)	0	0	0	0	0	0	0
高トランスアミナーゼ血症	0	1 (0.8%)	0	0	0	0	0	0	0
急性肝不全	0	0	0	0	0	0	1 (0.6%)	0	0
血液およびリンパ系障害	1 (0.8%)	2 (1.6%)	0	1 (0.9%)	0	0	1 (0.6%)	0	0
汎血球減少症	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
微小血管症性溶血性貧血	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
脾臓病変	0	1 (0.8%)	0	0	0	0	0	0	0
眼障害	0	1 (0.8%)	1 (0.9%)	0	0	0	0	1 (0.8%)	0
視神経症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
眼瞼浮腫	0	1 (0.8%)	0	0	0	0	0	0	0
全身障害および投与局所様態	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
悪寒	1 (0.8%)	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
傷害、中毒および処置合併症	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
過量投与	0	0	1 (0.9%)	0	0	0	0	1 (0.8%)	0
筋骨格系および結合組織障害	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
筋炎	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
血管障害	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0
低血圧	1 (0.8%)	0	0	0	0	0	1 (0.6%)	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-209 投与中止に至った有害事象（投与期間別） - 9766-CL-0104試験および海外第III相試験併合

MedDRA v12.1	9766-CL-0104試験						海外第III相試験併合		
Duration (days)								> 42 to <=	
Subgroup	<= 42		> 42 to <= 84		> 84		<= 42	84	> 84
System Organ Class Preferred Term	ISA (N = 123)	VRC (N = 125)	ISA (N = 110)	VRC (N = 114)	ISA (N = 24)	VRC (N = 20)	ISA (N = 168)	ISA (N = 130)	ISA (N = 105)
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	5 (4.0%)	0	2 (1.8%)	0	0	2 (1.2%)	0	1 (1.0%)
急性骨髄性白血病	0	3 (2.4%)	0	1 (0.9%)	0	0	0	0	0
再発急性骨髄性白血病	0	1 (0.8%)	0	0	0	0	1 (0.6%)	0	0
慢性リンパ性白血病	0	1 (0.8%)	0	0	0	0	0	0	0
肺の悪性新生物	0	0	0	1 (0.9%)	0	0	0	0	0
白血病再発	0	0	0	0	0	0	0	0	1 (1.0%)
悪性新生物進行	0	0	0	0	0	0	1 (0.6%)	0	0
免疫系障害	0	1 (0.8%)	0	0	0	0	0	0	0
急性肝移植片対宿主病	0	1 (0.8%)	0	0	0	0	0	0	0
代謝および栄養障害	0	0	0	1 (0.9%)	0	0	0	0	0
代謝性アシドーシス	0	0	0	1 (0.9%)	0	0	0	0	0

ISA: isavuconazole; VRC: voriconazole.

Program Name: t_ae_duration_discon_1.sas
Program Run: 04JUN21:15:00:27

表 8-210 SOC別の有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から経口投与へ切り替え (N = 4)
Overall	5 (100.0%)	58 (90.6%)	4 (100.0%)
感染症および寄生虫症	2 (40.0%)	22 (34.4%)	1 (25.0%)
胃腸障害	2 (40.0%)	18 (28.1%)	1 (25.0%)
臨床検査	1 (20.0%)	20 (31.3%)	0
神経系障害	2 (40.0%)	13 (20.3%)	0
肝胆道系障害	1 (20.0%)	9 (14.1%)	2 (50.0%)
代謝および栄養障害	1 (20.0%)	10 (15.6%)	0
皮膚および皮下組織障害	0	10 (15.6%)	1 (25.0%)
眼障害	2 (40.0%)	8 (12.5%)	0
一般・全身障害および投与部位の状態	1 (20.0%)	6 (9.4%)	2 (50.0%)
呼吸器、胸郭および縦隔障害	2 (40.0%)	6 (9.4%)	1 (25.0%)
腎および尿路障害	0	7 (10.9%)	0
心臓障害	2 (40.0%)	4 (6.3%)	0
血管障害	1 (20.0%)	5 (7.8%)	0
傷害、中毒および処置合併症	0	3 (4.7%)	1 (25.0%)
筋骨格系および結合組織障害	0	4 (6.3%)	0
精神障害	1 (20.0%)	3 (4.7%)	0
血液およびリンパ系障害	0	2 (3.1%)	0
耳および迷路障害	0	1 (1.6%)	1 (25.0%)
内分泌障害	0	2 (3.1%)	0
先天性、家族性および遺伝性障害	0	1 (1.6%)	0
免疫系障害	1 (20.0%)	0	0

Program Name: t_ae_route_soc_2.sas
Program Run: 16JUN21:13:34:40

表 8-211 注目すべき有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

	Cohort A/B併合		
	Isavuconazole		
	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から経口投与へ切り替え (N = 4)
肝機能異常・肝炎	1 (20.0%)	21 (32.8%)	2 (50.0%)
アナフィラキシー	0	0	0
重度皮膚障害	0	0	0
心電図QT短縮	0	0	0
トルサード ド ポアント	0	2 (3.1%)	0
急性膵炎	0	0	0
精神神経症状	2 (40.0%)	3 (4.7%)	0
視覚障害	1 (20.0%)	7 (10.9%)	0
皮膚または子宮の悪性腫瘍	0	0	0
静脈内投与例	(N = 5)	(N = 0)	(N = 4)
注入部位／注射部位反応	1 (20.0%)	0	2 (50.0%)
IRR	1 (20.0%)	0	0

IRR: Infusion related reaction

Program Name: t_ae_route_eoi_2.sas
Program Run: 16JUN21:13:34:48

表 8-212 死亡に至った有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から 経口投与へ切り替え (N = 4)
Overall	3 (60.0%)	2 (3.1%)	1 (25.0%)
呼吸器、胸郭および縦隔障害	2 (40.0%)	0	1 (25.0%)
特発性肺炎症候群	1 (20.0%)	0	0
誤嚥性肺炎	1 (20.0%)	0	0
肺臓炎	0	0	1 (25.0%)
感染症および寄生虫症	1 (20.0%)	1 (1.6%)	0
肺炎球菌感染	0	1 (1.6%)	0
副鼻腔炎	1 (20.0%)	0	0
心臓障害	1 (20.0%)	0	0
急性心筋梗塞	1 (20.0%)	0	0
一般・全身障害および投与部位の状態	0	1 (1.6%)	0
死亡	0	1 (1.6%)	0
神経系障害	1 (20.0%)	0	0
大脳基底核梗塞	1 (20.0%)	0	0

Program Name: t_ae_route_death_2.sas
Program Run: 16JUN21:13:34:53

表 8-213 重篤な有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から 経口投与へ切り替え (N = 4)
Overall	3 (60.0%)	13 (20.3%)	1 (25.0%)
感染症および寄生虫症	1 (20.0%)	7 (10.9%)	0
感染性胸水	0	2 (3.1%)	0
肺炎	0	2 (3.1%)	0
菌血症	0	1 (1.6%)	0
気管支炎	0	1 (1.6%)	0
蜂巣炎	0	1 (1.6%)	0
肺炎球菌感染	0	1 (1.6%)	0
副鼻腔炎	1 (20.0%)	0	0
呼吸器、胸郭および縦隔障害	2 (40.0%)	2 (3.1%)	1 (25.0%)
喀血	0	1 (1.6%)	0
特発性肺炎症候群	1 (20.0%)	0	0
誤嚥性肺炎	1 (20.0%)	0	0
肺臓炎	0	0	1 (25.0%)
気胸	0	1 (1.6%)	0
心臓障害	1 (20.0%)	1 (1.6%)	0
急性心筋梗塞	1 (20.0%)	0	0
急性心不全	0	1 (1.6%)	0
血液およびリンパ系障害	0	1 (1.6%)	0
好中球減少症	0	1 (1.6%)	0

Program Name: t_ae_route_ser_2.sas
Program Run: 16JUN21:13:34:58

表 8-213 重篤な有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から 経口投与へ切り替え (N = 4)
内分泌障害	0	1 (1.6%)	0
抗利尿ホルモン不適合分泌	0	1 (1.6%)	0
一般・全身障害および投与部位の状態	0	1 (1.6%)	0
死亡	0	1 (1.6%)	0
肝胆道系障害	0	1 (1.6%)	0
胆嚢炎	0	1 (1.6%)	0
代謝および栄養障害	0	1 (1.6%)	0
低ナトリウム血症	0	1 (1.6%)	0
筋骨格系および結合組織障害	0	1 (1.6%)	0
筋力低下	0	1 (1.6%)	0
神経系障害	1 (20.0%)	0	0
大脳基底核梗塞	1 (20.0%)	0	0
腎および尿路障害	0	1 (1.6%)	0
腎機能障害	0	1 (1.6%)	0

Program Name: t_ae_route_ser_2.sas
Program Run: 16JUN21:13:34:58

表 8-214 投与中止に至った有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から 経口投与へ切り替え (N = 4)
Overall	1 (20.0%)	10 (15.6%)	0
肝胆道系障害	0	2 (3.1%)	0
肝機能異常	0	2 (3.1%)	0
感染症および寄生虫症	0	2 (3.1%)	0
感染性胸水	0	1 (1.6%)	0
肺炎球菌感染	0	1 (1.6%)	0
臨床検査	0	2 (3.1%)	0
心電図異常	0	1 (1.6%)	0
肝機能検査値上昇	0	1 (1.6%)	0
代謝および栄養障害	0	2 (3.1%)	0
高カリウム血症	0	1 (1.6%)	0
低ナトリウム血症	0	1 (1.6%)	0
耳および迷路障害	0	1 (1.6%)	0
耳管開放	0	1 (1.6%)	0
胃腸障害	0	1 (1.6%)	0
悪心	0	1 (1.6%)	0
一般・全身障害および投与部位の状態	1 (20.0%)	0	0
注射部位蕁麻疹	1 (20.0%)	0	0
神経系障害	0	1 (1.6%)	0
感覚鈍麻	0	1 (1.6%)	0
腎および尿路障害	0	1 (1.6%)	0
腎機能障害	0	1 (1.6%)	0

Program Name: t_ae_route_discon_2.sas
Program Run: 16JUN21:13:35:05

表 8-214 投与中止に至った有害事象（投与経路別） - AK1820-301試験のCohort A/B併合

MedDRA v23.1	Cohort A/B併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 5)	経口投与のみ (N = 64)	静脈内投与から 経口投与へ切り替え (N = 4)
呼吸器、胸郭および縦隔障害	0	1 (1.6%)	0
呼吸困難	0	1 (1.6%)	0
口腔咽頭不快感	0	1 (1.6%)	0
皮膚および皮下組織障害	0	1 (1.6%)	0
冷汗	0	1 (1.6%)	0

Program Name: t_ae_route_discon_2.sas
Program Run: 16JUN21:13:35:05

表 8-215 SOC別の有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
Overall	80 (96.4%)	40 (87.0%)	266 (97.1%)
胃腸障害	40 (48.2%)	17 (37.0%)	200 (73.0%)
感染症および寄生虫症	58 (69.9%)	20 (43.5%)	165 (60.2%)
全身障害および投与局所様態	42 (50.6%)	13 (28.3%)	161 (58.8%)
呼吸器、胸郭および縦隔障害	48 (57.8%)	15 (32.6%)	143 (52.2%)
代謝および栄養障害	37 (44.6%)	11 (23.9%)	122 (44.5%)
神経系障害	29 (34.9%)	12 (26.1%)	104 (38.0%)
皮膚および皮下組織障害	18 (21.7%)	7 (15.2%)	100 (36.5%)
臨床検査	28 (33.7%)	10 (21.7%)	81 (29.6%)
筋骨格系および結合組織障害	16 (19.3%)	10 (21.7%)	83 (30.3%)
血液およびリンパ系障害	6 (7.2%)	5 (10.9%)	95 (34.7%)
精神障害	26 (31.3%)	7 (15.2%)	72 (26.3%)
血管障害	27 (32.5%)	4 (8.7%)	70 (25.5%)
腎および尿路障害	20 (24.1%)	1 (2.2%)	60 (21.9%)
心臓障害	25 (30.1%)	1 (2.2%)	42 (15.3%)
眼障害	17 (20.5%)	3 (6.5%)	38 (13.9%)
傷害、中毒および処置合併症	7 (8.4%)	3 (6.5%)	45 (16.4%)
肝胆道系障害	10 (12.0%)	3 (6.5%)	26 (9.5%)
免疫系障害	7 (8.4%)	1 (2.2%)	21 (7.7%)
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 (3.6%)	3 (6.5%)	23 (8.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_soc_1.sas
Program Run: 04JUN21:15:01:05

表 8-215 SOC別の有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
耳および迷路障害	1 (1.2%)	0	20 (7.3%)
生殖系および乳房障害	4 (4.8%)	2 (4.3%)	11 (4.0%)
内分泌障害	1 (1.2%)	1 (2.2%)	8 (2.9%)
先天性、家族性および遺伝性障害	1 (1.2%)	0	2 (0.7%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_soc_1.sas
Program Run: 04JUN21:15:01:05

表 8-216 注目すべき有害事象（投与経路別） - 海外第III相試験併合

	海外第III相試験併合		
	Isavuconazole		
	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
肝機能異常・肝炎	20 (24.1%)	8 (17.4%)	54 (19.7%)
アナフィラキシー	0	0	2 (0.7%)
重度皮膚障害	0	0	3 (1.1%)
心電図QT短縮	1 (1.2%)	0	0
トルサード ド ポアント	7 (8.4%)	0	11 (4.0%)
急性膵炎	0	0	1 (0.4%)
精神神経症状	27 (32.5%)	7 (15.2%)	76 (27.7%)
視覚障害	12 (14.5%)	0	19 (6.9%)
皮膚または子宮の悪性腫瘍	1 (1.2%)	0	0
静脈内投与例	(N = 83)	(N = 0)	(N = 274)
注入部位／注射部位反応	2 (2.4%)	0	14 (5.1%)
IRR	43 (51.8%)	0	59 (21.5%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

IRR: Infusion related reaction

Program Name: t_ae_route_eoi_1.sas
Program Run: 09JUN21:14:07:13

表 8-217 死亡に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
Overall	48 (57.8%)	6 (13.0%)	52 (19.0%)
感染症および寄生虫症	30 (36.1%)	3 (6.5%)	16 (5.8%)
敗血症性ショック	9 (10.8%)	0	3 (1.1%)
敗血症	6 (7.2%)	0	2 (0.7%)
アスペルギルス症	3 (3.6%)	1 (2.2%)	0
真菌感染	2 (2.4%)	0	1 (0.4%)
肺炎	1 (1.2%)	0	2 (0.7%)
ムコール症	2 (2.4%)	0	0
真菌性肺炎	1 (1.2%)	0	1 (0.4%)
アシネトバクター性菌血症	0	0	1 (0.4%)
細菌性敗血症	0	0	1 (0.4%)
気管支肺アスペルギルス症	1 (1.2%)	0	0
蓄膿	0	0	1 (0.4%)
心内膜炎	1 (1.2%)	0	0
真菌性敗血症	1 (1.2%)	0	0
フサリウム感染	1 (1.2%)	0	0
感染	1 (1.2%)	0	0
肺感染	0	0	1 (0.4%)
シュードモナス菌性肺感染	0	0	1 (0.4%)
ブラストミセス菌性肺炎	0	0	1 (0.4%)
原発性異型肺炎	0	1 (2.2%)	0
シュードモナス性敗血症	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_death_1.sas
Program Run: 04JUN21:15:01:16

表 8-217 死亡に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
真菌性副鼻腔炎	0	1 (2.2%)	0
ブドウ球菌性敗血症	1 (1.2%)	0	0
呼吸器、胸郭および縦隔障害	8 (9.6%)	1 (2.2%)	9 (3.3%)
呼吸不全	4 (4.8%)	0	3 (1.1%)
急性呼吸不全	2 (2.4%)	0	2 (0.7%)
喀血	1 (1.2%)	1 (2.2%)	1 (0.4%)
肺出血	0	0	2 (0.7%)
呼吸困難	1 (1.2%)	0	0
呼吸窮迫	0	0	1 (0.4%)
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 (1.2%)	2 (4.3%)	14 (5.1%)
急性骨髄性白血病	0	0	4 (1.5%)
悪性新生物進行	0	1 (2.2%)	2 (0.7%)
多発性骨髄腫	0	0	2 (0.7%)
再発急性リンパ性白血病	0	0	1 (0.4%)
再発急性骨髄性白血病	0	0	1 (0.4%)
芽球発症	1 (1.2%)	0	0
慢性リンパ性白血病	0	1 (2.2%)	0
再発慢性リンパ性白血病	0	0	1 (0.4%)
白血病再発	0	0	1 (0.4%)
骨髄異形成症候群	0	0	1 (0.4%)
骨髄性白血病	0	0	1 (0.4%)
心臓障害	3 (3.6%)	0	4 (1.5%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_death_1.sas
Program Run: 04JUN21:15:01:16

表 8-217 死亡に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
心肺停止	2 (2.4%)	0	1 (0.4%)
心停止	1 (1.2%)	0	0
急性心不全	0	0	1 (0.4%)
うっ血性心筋症	0	0	1 (0.4%)
心膜炎	0	0	1 (0.4%)
全身障害および投与局所様態	3 (3.6%)	1 (2.2%)	3 (1.1%)
死亡	2 (2.4%)	1 (2.2%)	1 (0.4%)
多臓器不全	1 (1.2%)	0	1 (0.4%)
全身健康状態低下	0	0	1 (0.4%)
神経系障害	1 (1.2%)	0	4 (1.5%)
脳梗塞	1 (1.2%)	0	1 (0.4%)
頭蓋内出血	0	0	2 (0.7%)
神経毒性	0	0	1 (0.4%)
血管障害	1 (1.2%)	0	2 (0.7%)
動脈炎	0	0	1 (0.4%)
出血	0	0	1 (0.4%)
血液量減少性ショック	1 (1.2%)	0	0
血液およびリンパ系障害	0	0	2 (0.7%)
出血性障害	0	0	1 (0.4%)
血小板減少症	0	0	1 (0.4%)
免疫系障害	2 (2.4%)	0	0
急性移植片対宿主病	1 (1.2%)	0	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_death_1.sas
Program Run: 04JUN21:15:01:16

表 8-217 死亡に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
移植片対宿主病	1 (1.2%)	0	0
腎および尿路障害	0	0	2 (0.7%)
腎不全	0	0	1 (0.4%)
急性腎不全	0	0	1 (0.4%)
肝胆道系障害	1 (1.2%)	0	0
急性肝炎	1 (1.2%)	0	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_death_1.sas
Program Run: 04JUN21:15:01:16

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1 System Organ Class Preferred Term	海外第III相試験併合 Isavuconazole 静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
Overall	60 (72.3%)	19 (41.3%)	144 (52.6%)
感染症および寄生虫症	36 (43.4%)	10 (21.7%)	60 (21.9%)
敗血症性ショック	11 (13.3%)	0	9 (3.3%)
肺炎	1 (1.2%)	2 (4.3%)	9 (3.3%)
敗血症	7 (8.4%)	0	3 (1.1%)
アスペルギルス症	3 (3.6%)	1 (2.2%)	3 (1.1%)
サイトメガロウイルス感染	0	1 (2.2%)	3 (1.1%)
真菌感染	2 (2.4%)	0	2 (0.7%)
菌血症	0	0	3 (1.1%)
ムコール症	2 (2.4%)	1 (2.2%)	0
細菌性肺炎	1 (1.2%)	1 (2.2%)	1 (0.4%)
シュードモナス性敗血症	0	0	3 (1.1%)
気管支肺アスペルギルス症	1 (1.2%)	0	1 (0.4%)
クロストリジウム・ディフィシレ大腸炎	0	0	2 (0.7%)
腸球菌性菌血症	0	0	2 (0.7%)
大腸菌性敗血症	0	0	2 (0.7%)
帯状疱疹	0	0	2 (0.7%)
真菌性肺炎	1 (1.2%)	0	1 (0.4%)
ブドウ球菌感染	0	0	2 (0.7%)
尿路感染	0	0	2 (0.7%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
接合真菌症	1 (1.2%)	0	1 (0.4%)
腹部膿瘍	0	0	1 (0.4%)
アシネトバクター性菌血症	0	0	1 (0.4%)
虫垂炎	0	0	1 (0.4%)
ＢＫウイルス感染	0	0	1 (0.4%)
細菌性敗血症	0	0	1 (0.4%)
脳膿瘍	0	1 (2.2%)	0
気管支拡張症	0	1 (2.2%)	0
細気管支炎	0	0	1 (0.4%)
肺炎球菌性気管支炎	0	0	1 (0.4%)
気管支肺炎	1 (1.2%)	0	0
カテーテル留置部位感染	1 (1.2%)	0	0
蜂巣炎	0	0	1 (0.4%)
脳アスペルギルス症	1 (1.2%)	0	0
サイトメガロウイルス性小腸炎	0	0	1 (0.4%)
サイトメガロウイルス血症	0	0	1 (0.4%)
蓄膿	0	0	1 (0.4%)
ヘルペス脳炎	0	0	1 (0.4%)
心内膜炎	1 (1.2%)	0	0
大腸菌性菌血症	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
真菌性敗血症	1 (1.2%)	0	0
フサリウム感染	1 (1.2%)	0	0
ノロウイルス性胃腸炎	0	0	1 (0.4%)
ウイルス性胃腸炎	0	0	1 (0.4%)
感染	1 (1.2%)	0	0
インフルエンザ	0	0	1 (0.4%)
注入部位感染	0	0	1 (0.4%)
クレブシエラ性菌血症	0	0	1 (0.4%)
クレブシエラ性敗血症	0	0	1 (0.4%)
肺感染	0	0	1 (0.4%)
シュードモナス菌性肺感染	0	0	1 (0.4%)
筋膿瘍	1 (1.2%)	0	0
ニューモシスティスジロヴェシ肺炎	0	0	1 (0.4%)
ブラストミセス菌性肺炎	0	0	1 (0.4%)
インフルエンザ性肺炎	0	1 (2.2%)	0
モラクセラ菌性肺炎	0	0	1 (0.4%)
原発性異型肺炎	0	1 (2.2%)	0
シュードモナス性気管支炎	0	1 (2.2%)	0
気道感染	0	0	1 (0.4%)
敗血症症候群	1 (1.2%)	0	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
副鼻腔炎	0	0	1 (0.4%)
真菌性副鼻腔炎	0	1 (2.2%)	0
皮膚感染	0	0	1 (0.4%)
ブドウ球菌性菌血症	0	0	1 (0.4%)
ブドウ球菌性敗血症	1 (1.2%)	0	0
レンサ球菌性菌血症	0	0	1 (0.4%)
皮下組織膿瘍	0	0	1 (0.4%)
尿路性敗血症	0	0	1 (0.4%)
ウイルス性下痢	0	0	1 (0.4%)
呼吸器、胸郭および縦隔障害	22 (26.5%)	4 (8.7%)	35 (12.8%)
呼吸不全	8 (9.6%)	0	11 (4.0%)
急性呼吸不全	5 (6.0%)	0	3 (1.1%)
呼吸困難	3 (3.6%)	0	3 (1.1%)
喀血	1 (1.2%)	1 (2.2%)	2 (0.7%)
呼吸窮迫	2 (2.4%)	0	2 (0.7%)
低酸素症	0	0	3 (1.1%)
嚥下性肺炎	2 (2.4%)	0	1 (0.4%)
胸水	0	0	2 (0.7%)
肺出血	0	0	2 (0.7%)
肺水腫	2 (2.4%)	0	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
頻呼吸	0	1 (2.2%)	1 (0.4%)
急性呼吸窮迫症候群	0	0	1 (0.4%)
気管支胸膜瘻	0	0	1 (0.4%)
気管支痙攣	0	0	1 (0.4%)
水気胸	0	0	1 (0.4%)
高炭酸ガス血症	0	0	1 (0.4%)
肺障害	0	0	1 (0.4%)
胸膜痛	0	0	1 (0.4%)
肺胞出血	0	0	1 (0.4%)
肺塞栓症	0	1 (2.2%)	0
肺梗塞	0	0	1 (0.4%)
呼吸性アシドーシス	0	0	1 (0.4%)
呼吸抑制	1 (1.2%)	0	0
副鼻腔障害	0	1 (2.2%)	0
喘鳴	0	1 (2.2%)	0
血液およびリンパ系障害	1 (1.2%)	0	32 (11.7%)
発熱性好中球減少症	0	0	16 (5.8%)
汎血球減少症	0	0	5 (1.8%)
好中球減少症	0	0	4 (1.5%)
貧血	0	0	3 (1.1%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
血小板減少症	0	0	3 (1.1%)
無顆粒球症	0	0	2 (0.7%)
出血性障害	0	0	1 (0.4%)
白血球増加症	0	0	1 (0.4%)
脾臓梗塞	1 (1.2%)	0	0
胃腸障害	0	4 (8.7%)	23 (8.4%)
腹痛	0	2 (4.3%)	4 (1.5%)
下痢	0	0	4 (1.5%)
嘔吐	0	2 (4.3%)	2 (0.7%)
胃腸出血	0	0	3 (1.1%)
悪心	0	1 (2.2%)	2 (0.7%)
大腸炎	0	0	2 (0.7%)
便秘	0	0	2 (0.7%)
嚥下障害	0	1 (2.2%)	1 (0.4%)
小腸閉塞	0	0	2 (0.7%)
潰瘍性大腸炎	0	0	1 (0.4%)
胃穿孔	0	0	1 (0.4%)
腸出血	0	0	1 (0.4%)
限局性腹腔内液貯留	0	0	1 (0.4%)
食道潰瘍	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
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表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1 System Organ Class Preferred Term	海外第III相試験併合 Isavuconazole 静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
食道炎	0	0	1 (0.4%)
膵炎	0	0	1 (0.4%)
慢性膵炎	0	0	1 (0.4%)
再発性膵炎	0	0	1 (0.4%)
腹膜炎	0	0	1 (0.4%)
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 (2.4%)	2 (4.3%)	22 (8.0%)
急性骨髄性白血病	0	0	5 (1.8%)
悪性新生物進行	0	1 (2.2%)	2 (0.7%)
再発急性リンパ性白血病	0	0	2 (0.7%)
再発急性骨髄性白血病	0	0	2 (0.7%)
リンパ腫	0	0	2 (0.7%)
多発性骨髄腫	0	0	2 (0.7%)
芽球発症	1 (1.2%)	0	0
慢性リンパ性白血病	0	1 (2.2%)	0
再発慢性リンパ性白血病	0	0	1 (0.4%)
子宮内膜癌	1 (1.2%)	0	0
白血病再発	0	0	1 (0.4%)
白血病浸潤	0	0	1 (0.4%)
髄膜転移	0	0	1 (0.4%)
骨髄異形成症候群	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
骨髄性白血病	0	0	1 (0.4%)
新生物進行	0	0	1 (0.4%)
非ホジキンリンパ腫	0	0	1 (0.4%)
原発性体腔性リンパ腫	0	0	1 (0.4%)
神経系障害	7 (8.4%)	2 (4.3%)	17 (6.2%)
痙攣	2 (2.4%)	1 (2.2%)	2 (0.7%)
脳梗塞	1 (1.2%)	0	2 (0.7%)
てんかん	0	0	2 (0.7%)
頭蓋内出血	0	0	2 (0.7%)
頭痛	0	0	2 (0.7%)
多発ニューロパチー	0	0	2 (0.7%)
失語症	0	0	1 (0.4%)
脳幹卒中	1 (1.2%)	0	0
中枢神経系病変	0	0	1 (0.4%)
脳虚血	1 (1.2%)	0	0
脳血管発作	0	1 (2.2%)	0
脳症	1 (1.2%)	0	0
熱性痙攣	0	0	1 (0.4%)
卒中の出血性変化	0	0	1 (0.4%)
不全片麻痺	0	1 (2.2%)	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
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表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
虚血性脳卒中	1 (1.2%)	0	0
神経毒性	0	0	1 (0.4%)
対麻痺	1 (1.2%)	0	0
一過性脳虚血発作	0	0	1 (0.4%)
全身障害および投与局所様態	4 (4.8%)	3 (6.5%)	13 (4.7%)
発熱	0	0	10 (3.6%)
死亡	2 (2.4%)	1 (2.2%)	1 (0.4%)
全身健康状態低下	0	0	2 (0.7%)
多臓器不全	1 (1.2%)	0	1 (0.4%)
非心臓性胸痛	0	2 (4.3%)	0
無力症	0	0	1 (0.4%)
胸痛	0	0	1 (0.4%)
悪寒	1 (1.2%)	0	0
末梢性浮腫	0	1 (2.2%)	0
心臓障害	8 (9.6%)	0	11 (4.0%)
心肺停止	3 (3.6%)	0	1 (0.4%)
心房細動	0	0	3 (1.1%)
急性心筋梗塞	1 (1.2%)	0	1 (0.4%)
不整脈	1 (1.2%)	0	0
完全房室ブロック	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
心停止	1 (1.2%)	0	0
急性心不全	0	0	1 (0.4%)
心原性ショック	0	0	1 (0.4%)
うっ血性心筋症	0	0	1 (0.4%)
電気収縮解離	1 (1.2%)	0	0
心膜炎	0	0	1 (0.4%)
洞性徐脈	0	0	1 (0.4%)
上室性頻脈	1 (1.2%)	0	0
腎および尿路障害	6 (7.2%)	1 (2.2%)	12 (4.4%)
急性腎不全	5 (6.0%)	1 (2.2%)	8 (2.9%)
腎不全	1 (1.2%)	0	3 (1.1%)
血尿	0	0	1 (0.4%)
免疫系障害	2 (2.4%)	1 (2.2%)	6 (2.2%)
急性移植片対宿主病	1 (1.2%)	0	2 (0.7%)
移植片対宿主病	1 (1.2%)	0	1 (0.4%)
急性腸管移植片対宿主病	0	0	1 (0.4%)
アナフィラキシーショック	0	0	1 (0.4%)
過敏症	0	0	1 (0.4%)
肺移植拒絶反応	0	1 (2.2%)	0
代謝および栄養障害	0	3 (6.5%)	6 (2.2%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
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表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
脱水	0	2 (4.3%)	1 (0.4%)
コントロール不良の糖尿病	0	0	1 (0.4%)
成長障害	0	0	1 (0.4%)
高カリウム血症	0	0	1 (0.4%)
低血糖症	0	0	1 (0.4%)
低ナトリウム血症	0	1 (2.2%)	0
栄養障害	0	0	1 (0.4%)
血管障害	2 (2.4%)	2 (4.3%)	5 (1.8%)
低血圧	1 (1.2%)	1 (2.2%)	1 (0.4%)
深部静脈血栓症	0	1 (2.2%)	1 (0.4%)
動脈炎	0	0	1 (0.4%)
出血	0	0	1 (0.4%)
血液量減少性ショック	1 (1.2%)	0	0
血管炎	0	0	1 (0.4%)
肝胆道系障害	2 (2.4%)	2 (4.3%)	4 (1.5%)
胆嚢炎	0	0	2 (0.7%)
急性肝不全	1 (1.2%)	0	0
細胆管炎	0	1 (2.2%)	0
胆石症	0	1 (2.2%)	0
肝炎	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

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表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
急性肝炎	1 (1.2%)	0	0
肝障害	0	0	1 (0.4%)
筋骨格系および結合組織障害	0	2 (4.3%)	5 (1.8%)
筋骨格系胸痛	0	1 (2.2%)	2 (0.7%)
関節炎	0	1 (2.2%)	0
筋肉内出血	0	0	1 (0.4%)
筋炎	0	0	1 (0.4%)
四肢痛	0	0	1 (0.4%)
全身性エリテマトーデス	0	0	1 (0.4%)
眼障害	0	1 (2.2%)	3 (1.1%)
片側失明	0	0	1 (0.4%)
視神経症	0	0	1 (0.4%)
網膜動脈閉塞	0	1 (2.2%)	0
網膜出血	0	0	1 (0.4%)
硝子体出血	0	0	1 (0.4%)
傷害、中毒および処置合併症	0	0	3 (1.1%)
薬物毒性	0	0	2 (0.7%)
転倒・転落	0	0	1 (0.4%)
臨床検査	0	0	3 (1.1%)
血中ナトリウム減少	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-218 重篤な有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
ヘモグロビン減少	0	0	1 (0.4%)
肝機能検査異常	0	0	1 (0.4%)
精神障害	0	1 (2.2%)	2 (0.7%)
異常行動	0	0	1 (0.4%)
攻撃性	0	0	1 (0.4%)
激越	0	0	1 (0.4%)
錯乱状態	0	1 (2.2%)	0
うつ病	0	0	1 (0.4%)
幻覚	0	1 (2.2%)	0
皮膚および皮下組織障害	0	0	3 (1.1%)
褥瘡性潰瘍	0	0	1 (0.4%)
皮膚炎	0	0	1 (0.4%)
脂肪織炎	0	0	1 (0.4%)
生殖系および乳房障害	0	0	1 (0.4%)
良性前立腺肥大症	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

A TEAE with a missing seriousness was considered a serious TEAE.

Program Name: t_ae_route_ser_1.sas
Program Run: 04JUN21:15:01:21

表 8-219 投与中止に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
Overall	24 (28.9%)	6 (13.0%)	26 (9.5%)
感染症および寄生虫症	11 (13.3%)	2 (4.3%)	5 (1.8%)
敗血症性ショック	4 (4.8%)	0	0
アスペルギルス症	1 (1.2%)	1 (2.2%)	1 (0.4%)
真菌感染	1 (1.2%)	0	2 (0.7%)
脳膿瘍	0	1 (2.2%)	0
気管支肺炎	1 (1.2%)	0	0
気管支肺アスペルギルス症	1 (1.2%)	0	0
心内膜炎	1 (1.2%)	0	0
大腸菌性菌血症	0	0	1 (0.4%)
感染	1 (1.2%)	0	0
肺炎	0	0	1 (0.4%)
敗血症	1 (1.2%)	0	0
神経系障害	3 (3.6%)	1 (2.2%)	3 (1.1%)
痙攣	2 (2.4%)	0	0
てんかん	0	0	2 (0.7%)
脳血管発作	0	1 (2.2%)	0
脳症	1 (1.2%)	0	0
卒中の出血性変化	0	0	1 (0.4%)
臨床検査	2 (2.4%)	1 (2.2%)	3 (1.1%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_discon_1.sas
Program Run: 04JUN21:15:01:26

表 8-219 投与中止に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
血中ビリルビン増加	1 (1.2%)	0	1 (0.4%)
アラニン・アミノトランスフェラーゼ増加	0	1 (2.2%)	0
血中アルカリホスファターゼ増加	0	1 (2.2%)	0
血中乳酸脱水素酵素増加	0	1 (2.2%)	0
血中ナトリウム減少	0	0	1 (0.4%)
γ－グルタミルトランスフェラーゼ増加	0	1 (2.2%)	0
肝酵素上昇	0	0	1 (0.4%)
トランスアミナーゼ上昇	1 (1.2%)	0	0
呼吸器、胸郭および縦隔障害	3 (3.6%)	0	3 (1.1%)
呼吸困難	2 (2.4%)	0	0
呼吸不全	1 (1.2%)	0	1 (0.4%)
急性呼吸不全	0	0	1 (0.4%)
呼吸窮迫	0	0	1 (0.4%)
腎および尿路障害	3 (3.6%)	1 (2.2%)	1 (0.4%)
急性腎不全	2 (2.4%)	1 (2.2%)	0
腎不全	1 (1.2%)	0	1 (0.4%)
心臓障害	2 (2.4%)	0	2 (0.7%)
心停止	1 (1.2%)	0	0
心肺停止	0	0	1 (0.4%)
うっ血性心筋症	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_discon_1.sas
Program Run: 04JUN21:15:01:26

表 8-219 投与中止に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
上室性頻脈	1 (1.2%)	0	0
胃腸障害	0	0	4 (1.5%)
嘔吐	0	0	2 (0.7%)
嚥下障害	0	0	1 (0.4%)
悪心	0	0	1 (0.4%)
小腸閉塞	0	0	1 (0.4%)
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	1 (2.2%)	2 (0.7%)
再発急性骨髄性白血病	0	0	1 (0.4%)
白血病再発	0	0	1 (0.4%)
悪性新生物進行	0	1 (2.2%)	0
精神障害	1 (1.2%)	1 (2.2%)	1 (0.4%)
錯乱状態	1 (1.2%)	1 (2.2%)	1 (0.4%)
幻覚	0	1 (2.2%)	0
肝胆道系障害	2 (2.4%)	0	0
急性肝不全	1 (1.2%)	0	0
急性肝炎	1 (1.2%)	0	0
皮膚および皮下組織障害	1 (1.2%)	0	1 (0.4%)
皮膚炎	0	0	1 (0.4%)
アレルギー性皮膚炎	1 (1.2%)	0	0
血液およびリンパ系障害	0	0	1 (0.4%)

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_discon_1.sas
Program Run: 04JUN21:15:01:26

表 8-219 投与中止に至った有害事象（投与経路別） - 海外第III相試験併合

MedDRA v12.1	海外第III相試験併合		
	Isavuconazole		
System Organ Class Preferred Term	静脈内投与のみ (N = 83)	経口投与のみ (N = 46)	投与経路の切り替えあり (N = 274)
汎血球減少症	0	0	1 (0.4%)
眼障害	0	0	1 (0.4%)
視神経症	0	0	1 (0.4%)
全身障害および投与局所様態	1 (1.2%)	0	0
悪寒	1 (1.2%)	0	0
傷害、中毒および処置合併症	0	0	1 (0.4%)
過量投与	0	0	1 (0.4%)
筋骨格系および結合組織障害	0	0	1 (0.4%)
筋炎	0	0	1 (0.4%)
血管障害	1 (1.2%)	0	0
低血圧	1 (1.2%)	0	0

投与経路の切り替えあり：試験期間中に静脈内投与から経口投与、または経口投与から静脈内投与への切り替えを1度でも行った場合

Program Name: t_ae_route_discon_1.sas
Program Run: 04JUN21:15:01:26