

Asciminib/Scemblix[®]

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AMNOG Analyses

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Acute pancreatitis (including isolated pancreatic enzyme elevations)	Pancreatitis (including laboratory terms) (CMQ) (broad)	90008368
	Amylase increased (PT)	10002016
	Lipase increased (PT)	10024574
	Lipase urine increased (PT)	10024578
	Pancreatic enzyme abnormality (PT)	10033619
	Lipase abnormal (PT)	10054821
	Pancreatic enzymes abnormal (PT)	10061899
	Pancreatic enzymes increased (PT)	10061900
	Hyperamylasaemia (PT)	10062770
	Blood trypsin increased (PT)	10064751
	Hyperlipasaemia (PT)	10067725
	Amylase abnormal (PT)	10072327
	Amylase creatinine clearance ratio abnormal (PT)	10073699
	Acute pancreatitis (SMQ) (narrow)	20000022
	Pancreatic haemorrhage (PT)	10033625
	Pancreatic pseudocyst (PT)	10033635
	Pancreatic pseudocyst drainage (PT)	10033636
	Pancreatitis (PT)	10033645
	Pancreatitis acute (PT)	10033647
	Pancreatitis haemorrhagic (PT)	10033650
	Pancreatitis necrotising (PT)	10033654
	Pancreatitis relapsing (PT)	10033657
	Pancreatic abscess (PT)	10048984
	Oedematous pancreatitis (PT)	10052400
	Pancreatorenal syndrome (PT)	10056277
	Pancreatic phlegmon (PT)	10056975
	Cullen's sign (PT)	10059029
	Ischaemic pancreatitis (PT)	10066127
	Grey Turner's sign (PT)	10075426
	Haemorrhagic necrotic pancreatitis (PT)	10076058
	Pancreatic pseudoaneurysm (PT)	10081762

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Acute pancreatitis (including isolated pancreatic enzyme elevations)	Pancreatic cyst drainage (PT)	10082531
	Immune-mediated pancreatitis (PT)	10083072
	Pancreatic pseudocyst rupture (PT)	10083811
	Pancreatic pseudocyst haemorrhage (PT)	10083813
	Subacute pancreatitis (PT)	10084554
	Walled-off pancreatic necrosis (PT)	10085347
	Idiopathic pancreatitis (PT)	10088882
Arterial-occlusive events (AOEs)	Ischaemic heart disease (SMQ) (narrow)	20000043
	Myocardial infarction (SMQ) (narrow)	20000047
	Acute myocardial infarction (PT)	10000891
	Angina unstable (PT)	10002388
	Blood creatine phosphokinase MB abnormal (PT)	10005472
	Blood creatine phosphokinase MB increased (PT)	10005474
	Coronary artery embolism (PT)	10011084
	Coronary artery occlusion (PT)	10011086
	Coronary artery thrombosis (PT)	10011091
	Myocardial infarction (PT)	10028596
	Myocardial necrosis (PT)	10028602
	Papillary muscle infarction (PT)	10033697
	Silent myocardial infarction (PT)	10049768
	Acute coronary syndrome (PT)	10051592
	Myocardial reperfusion injury (PT)	10051624
	Coronary artery reocclusion (PT)	10053261
	Postinfarction angina (PT)	10058144
	Troponin increased (PT)	10058267
	Troponin I increased (PT)	10058268
	Troponin T increased (PT)	10058269
	Coronary bypass thrombosis (PT)	10059025
	Post procedural myocardial infarction (PT)	10066592
	Kounis syndrome (PT)	10069167

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Myocardial stunning (PT)	10072186
	Coronary vascular graft occlusion (PT)	10075162
	Periprocedural myocardial infarction (PT)	10079319
	Acute cardiac event (PT)	10081099
	Heart-type fatty acid-binding protein increased (PT)	10088828
	Other ischaemic heart disease (SMQ) (narrow)	20000168
	Angina pectoris (PT)	10002383
	Arteriosclerosis coronary artery (PT)	10003211
	Arteriospasm coronary (PT)	10003225
	Coronary artery bypass (PT)	10011077
	Coronary artery disease (PT)	10011078
	Coronary artery stenosis (PT)	10011089
	Coronary artery surgery (PT)	10011090
	Coronary endarterectomy (PT)	10011101
	Coronary ostial stenosis (PT)	10011105
	Myocardial ischaemia (PT)	10028600
	Prinzmetal angina (PT)	10036759
	Coronary artery dissection (PT)	10048631
	Ischaemic cardiomyopathy (PT)	10048858
	Coronary revascularisation (PT)	10049887
	Coronary angioplasty (PT)	10050329
	Coronary arterial stent insertion (PT)	10052086
	Coronary artery insufficiency (PT)	10052895
	Haemorrhage coronary artery (PT)	10055803
	Coronary artery restenosis (PT)	10056489
	Subendocardial ischaemia (PT)	10058145
	ECG signs of myocardial ischaemia (PT)	10058317
	Subclavian coronary steal syndrome (PT)	10064994
	Percutaneous coronary intervention (PT)	10065608
	Stress cardiomyopathy (PT)	10066286
	External counterpulsation (PT)	10067876

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Arterial-occlusive events (AOEs)	Coronary no-reflow phenomenon (PT)	10068534
	Microvascular coronary artery disease (PT)	10072685
	Anginal equivalent (PT)	10076419
	Coronary brachytherapy (PT)	10076627
	Coronary vascular graft stenosis (PT)	10077334
	Coronary bypass stenosis (PT)	10077824
	Ischaemic mitral regurgitation (PT)	10077864
	Myocardial hypoxia (PT)	10078980
	Coronary artery compression (PT)	10079589
	Wellens' syndrome (PT)	10080787
	Diabetic coronary microangiopathy (PT)	10080788
	Myocardial hypoperfusion (PT)	10082580
	Cardiac perfusion defect (PT)	10083602
	Coronary steal syndrome (PT)	10084081
	Chronic coronary syndrome (PT)	10085242
	Ischaemic central nervous system vascular conditions (SMQ)	20000063
	Amaurosis fugax (PT)	10001903
	Basilar artery stenosis (PT)	10004163
	Brain hypoxia (PT)	10006127
	Brain stem infarction (PT)	10006147
	Brain stem ischaemia (PT)	10006148
	Carotid arterial embolus (PT)	10007684
	Carotid artery stenosis (PT)	10007687
	Carotid artery thrombosis (PT)	10007688
	Carotid endarterectomy (PT)	10007692
	Cerebellar artery thrombosis (PT)	10008023
	Cerebellar infarction (PT)	10008034
	Cerebral artery embolism (PT)	10008088
	Cerebral artery occlusion (PT)	10008089
	Cerebral artery thrombosis (PT)	10008092
	Cerebral infarction (PT)	10008118

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Arterial-occlusive events (AOEs)	Cerebral infarction foetal (PT)	10008119
	Cerebral ischaemia (PT)	10008120
	Cerebral thrombosis (PT)	10008132
	Cerebral venous thrombosis (PT)	10008138
	Cerebrovascular accident (PT)	10008190
	Cerebrovascular disorder (PT)	10008196
	Embolic stroke (PT)	10014498
	Lateral medullary syndrome (PT)	10024033
	Moyamoya disease (PT)	10028047
	Precerebral artery occlusion (PT)	10036511
	Subclavian steal syndrome (PT)	10042335
	Thrombotic stroke (PT)	10043647
	Transient ischaemic attack (PT)	10044390
	Vertebral artery stenosis (PT)	10047330
	Vertebrobasilar insufficiency (PT)	10047334
	Basilar artery occlusion (PT)	10048963
	Carotid artery occlusion (PT)	10048964
	Vertebral artery occlusion (PT)	10048965
	Spinal artery embolism (PT)	10049440
	Spinal cord ischaemia (PT)	10050209
	Reversible ischaemic neurological deficit (PT)	10050496
	Lacunar infarction (PT)	10051078
	Carotid artery bypass (PT)	10053003
	Cerebellar artery occlusion (PT)	10053633
	Migrainous infarction (PT)	10056237
	Vertebral artery thrombosis (PT)	10057777
	Spinal cord infarction (PT)	10058571
	Cerebrovascular insufficiency (PT)	10058842
	Cerebral vasoconstriction (PT)	10059109
	Stroke in evolution (PT)	10059613
	Embolic cerebral infarction (PT)	10060839
	Ischaemic cerebral infarction (PT)	10060840

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Ischaemic stroke (PT)	10061256
	Carotid artery disease (PT)	10061744
	Cerebrovascular stenosis (PT)	10061751
	Brain stem thrombosis (PT)	10062573
	Basilar artery thrombosis (PT)	10063093
	Cerebral artery stenosis (PT)	10063648
	Vascular encephalopathy (PT)	10063661
	Carotid artery insufficiency (PT)	10064949
	Thalamic infarction (PT)	10064961
	CADASIL (PT)	10065555
	Cerebral arteriosclerosis (PT)	10065559
	Carotid artery stent insertion (PT)	10066102
	Post procedural stroke (PT)	10066591
	Carotid arteriosclerosis (PT)	10067116
	Cerebellar embolism (PT)	10067167
	Thrombotic cerebral infarction (PT)	10067347
	Millard-Gubler syndrome (PT)	10067462
	Capsular warning syndrome (PT)	10067744
	Cerebellar ischaemia (PT)	10068621
	Brain stem stroke (PT)	10068644
	Basal ganglia infarction (PT)	10069020
	Brachiocephalic artery occlusion (PT)	10069694
	Carotid artery stent removal (PT)	10069952
	Hypoxic-ischaemic encephalopathy (PT)	10070511
	Cerebral septic infarct (PT)	10070671
	Inner ear infarction (PT)	10070754
	Cerebral gas embolism (PT)	10070813
	Cerebral small vessel ischaemic disease (PT)	10070878
	Basal ganglia stroke (PT)	10071043
	Carotid angioplasty (PT)	10071260
	Spinal artery thrombosis (PT)	10071316
	Cerebral revascularisation (PT)	10071508

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Carotid artery restenosis (PT)	10072558
	Carotid revascularisation (PT)	10072559
	Reversible cerebral vasoconstriction syndrome (PT)	10073240
	Perinatal stroke (PT)	10073945
	Brain stem embolism (PT)	10074422
	Precerebral artery thrombosis (PT)	10074717
	Cerebral artery restenosis (PT)	10075423
	Brachiocephalic arteriosclerosis (PT)	10075449
	Brachiocephalic artery stenosis (PT)	10075450
	Cerebral vascular occlusion (PT)	10076895
	Lacunar stroke (PT)	10076994
	Precerebral arteriosclerosis (PT)	10077033
	Vascular stent occlusion (PT)	10077143
	Vascular stent stenosis (PT)	10077144
	Post cardiac arrest syndrome (PT)	10078202
	Cerebral microembolism (PT)	10078311
	Delayed ischaemic neurological deficit (PT)	10078388
	Cerebellar stroke (PT)	10079062
	Brain stent insertion (PT)	10080887
	CARASIL syndrome (PT)	10081315
	Cerebral artery stent insertion (PT)	10081893
	Spinal stroke (PT)	10082031
	Vertebrobasilar stroke (PT)	10082484
	Foville syndrome (PT)	10082594
	Internal capsule infarction (PT)	10083408
	Cerebral microinfarction (PT)	10083668
	Embolic cerebellar infarction (PT)	10084072
	Vertebral artery arteriosclerosis (PT)	10084347
	Cerebellar atherosclerosis (PT)	10084736
	Precerebral artery embolism (PT)	10085250
	Claude's syndrome (PT)	10085447

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Weber's syndrome (PT)	10085448
	Benedikt's syndrome (PT)	10085451
	Pseudo-occlusion of internal carotid artery (PT)	10085779
	Cerebral angioplasty (PT)	10087440
	Thalamic stroke (PT)	10087626
	Embolic and thrombotic events, arterial (SMQ)	20000082
	Amaurosis (PT)	10001902
	Angioplasty (PT)	10002475
	Aortic embolus (PT)	10002897
	Aortic thrombosis (PT)	10002910
	Arterectomy with graft replacement (PT)	10003140
	Arterial thrombosis (PT)	10003178
	Arteriogram carotid abnormal (PT)	10003195
	Blindness transient (PT)	10005184
	Embolism arterial (PT)	10014513
	Endarterectomy (PT)	10014648
	Hepatic artery embolism (PT)	10019635
	Hepatic artery thrombosis (PT)	10019636
	Iliac artery embolism (PT)	10021338
	Leriche syndrome (PT)	10024242
	Mesenteric arterial occlusion (PT)	10027394
	Mesenteric artery embolism (PT)	10027395
	Mesenteric artery stenosis (PT)	10027396
	Mesenteric artery thrombosis (PT)	10027397
	Pulmonary artery thrombosis (PT)	10037340
	Renal artery thrombosis (PT)	10038380
	Retinal artery embolism (PT)	10038826
	Retinal artery occlusion (PT)	10038827
	Retinal artery thrombosis (PT)	10038831
	Subclavian artery embolism (PT)	10042332
	Subclavian artery thrombosis (PT)	10042334
	Thrombotic microangiopathy (PT)	10043645

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Thrombotic thrombocytopenic purpura (PT)	10043648
	Visual acuity reduced transiently (PT)	10047532
	Renal artery occlusion (PT)	10048988
	Hepatic artery occlusion (PT)	10051991
	Arterial therapeutic procedure (PT)	10052949
	Intra-aortic balloon placement (PT)	10052989
	Intraoperative cerebral artery occlusion (PT)	10056382
	Arterial bypass operation (PT)	10056418
	Renal artery angioplasty (PT)	10057493
	Peripheral artery angioplasty (PT)	10057518
	Peripheral artery occlusion (PT)	10057525
	Aortic bypass (PT)	10057617
	Aortogram abnormal (PT)	10057794
	Embolia cutis medicamentosa (PT)	10058729
	Peripheral embolism (PT)	10061340
	Aortic surgery (PT)	10061651
	Arterial graft (PT)	10061655
	Arterial stent insertion (PT)	10061657
	Arteriogram abnormal (PT)	10061659
	Truncus coeliacus thrombosis (PT)	10062363
	Peripheral arterial occlusive disease (PT)	10062585
	Arterial occlusive disease (PT)	10062599
	Atherectomy (PT)	10063025
	Hypothenar hammer syndrome (PT)	10063518
	Renal embolism (PT)	10063544
	Pulmonary artery therapeutic procedure (PT)	10063731
	Iliac artery occlusion (PT)	10064601
	Thromboembolectomy (PT)	10064958
	Cerebral hypoperfusion (PT)	10065384
	Mesenteric arteriosclerosis (PT)	10065560
	Penile artery occlusion (PT)	10068035
	Femoral artery embolism (PT)	10068365

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Splenic embolism (PT)	10068677
	Peripheral arterial reocclusion (PT)	10069379
	Subclavian artery occlusion (PT)	10069695
	Coeliac artery occlusion (PT)	10069696
	Arterectomy (PT)	10071026
	Mesenteric artery stent insertion (PT)	10071261
	Popliteal artery entrapment syndrome (PT)	10071642
	Peripheral endarterectomy (PT)	10072560
	Peripheral artery bypass (PT)	10072561
	Peripheral artery stent insertion (PT)	10072562
	Peripheral artery thrombosis (PT)	10072564
	Pulmonary endarterectomy (PT)	10072893
	Acute aortic syndrome (PT)	10074337
	Splenic artery thrombosis (PT)	10074600
	Atherosclerotic plaque rupture (PT)	10076604
	Pulmonary artery occlusion (PT)	10078201
	Vascular pseudoaneurysm thrombosis (PT)	10078269
	Arteriotomy (PT)	10078636
	Profundaplasty (PT)	10078867
	Atrial appendage closure (PT)	10079735
	Pulmonary tumour thrombotic microangiopathy (PT)	10079988
	Atrial appendage resection (PT)	10080843
	Ophthalmic artery thrombosis (PT)	10081144
	Arterial angioplasty (PT)	10081731
	Peripheral artery surgery (PT)	10082470
	Arterial revascularisation (PT)	10084482
	Left atrial appendage closure implant (PT)	10085044
	Renal-limited thrombotic microangiopathy (PT)	10085346
	Ophthalmic artery occlusion (PT)	10086395
	Segmental arterial mediolysis (PT)	10086467
	Aneurysm thrombosis (PT)	10086560
	Metabolic stroke (PT)	10086596

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Arterial-occlusive events (AOEs)	Arterial recanalisation procedure (PT)	10087576
	Aortic aneurysm thrombosis (PT)	10087600
	Angiostomy (PT)	10087774
	Renal artery revascularisation (PT)	10087816
	Pulmonary angioplasty (PT)	10087828
	Pulmonary artery stent insertion (PT)	10088551
	Incomplete atrial appendage closure (PT)	10088942
Cardiac failure (clinical events)	Cardiac failure (SMQ) (narrow)	20000004
	Acute pulmonary oedema (PT)	10001029
	Cardiac asthma (PT)	10007522
	Cardiac failure (PT)	10007554
	Cardiac failure acute (PT)	10007556
	Cardiac failure chronic (PT)	10007558
	Cardiac failure congestive (PT)	10007559
	Cardiac failure high output (PT)	10007560
	Cardiogenic shock (PT)	10007625
	Cor pulmonale (PT)	10010968
	Cor pulmonale acute (PT)	10010969
	Cor pulmonale chronic (PT)	10010970
	Left ventricular failure (PT)	10024119
	Low cardiac output syndrome (PT)	10024899
	Pulmonary oedema (PT)	10037423
	Right ventricular failure (PT)	10039163
	Neonatal cardiac failure (PT)	10049780
	Pulmonary oedema neonatal (PT)	10050459
	Ejection fraction decreased (PT)	10050528
	Cardiopulmonary failure (PT)	10051093
	Hepatojugular reflux (PT)	10051448
	Ventricular failure (PT)	10060953
	Acute left ventricular failure (PT)	10063081
	Acute right ventricular failure (PT)	10063082

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Cardiac failure (clinical events)	Chronic left ventricular failure (PT)	10063083
	Chronic right ventricular failure (PT)	10063084
	Cardiorenal syndrome (PT)	10068230
	Obstructive shock (PT)	10073708
	Right ventricular ejection fraction decreased (PT)	10075337
	Radiation associated cardiac failure (PT)	10076203
	Cardiohepatic syndrome (PT)	10082480
	Congestive hepatopathy (PT)	10084058
Edema and fluid retention	Haemodynamic oedema, effusions and fluid overload (SMQ)	20000145
	Acute pulmonary oedema (PT)	10001029
	Application site oedema (PT)	10003050
	Ascites (PT)	10003445
	Capillary leak syndrome (PT)	10007196
	Cerebral oedema management (PT)	10008128
	Fluid retention (PT)	10016807
	Gallbladder oedema (PT)	10017637
	Generalised oedema (PT)	10018092
	Gravitational oedema (PT)	10018713
	Heat oedema (PT)	10019340
	Hypervolaemia (PT)	10020919
	Injection site oedema (PT)	10022085
	Joint effusion (PT)	10023215
	Joint swelling (PT)	10023232
	Lymphoedema (PT)	10025282
	Non-cardiogenic pulmonary oedema (PT)	10029538
	Oedema (PT)	10030095
	Oedema mucosal (PT)	10030111
	Oedema peripheral (PT)	10030124
	Pericardial effusion (PT)	10034474

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Edema and fluid retention	Pleural effusion (PT)	10035598
	Pulmonary oedema (PT)	10037423
	Retroperitoneal oedema (PT)	10038983
	Swelling (PT)	10042674
	Testicular swelling (PT)	10043354
	Hydrothorax (PT)	10048612
	Peripheral swelling (PT)	10048959
	Localised oedema (PT)	10048961
	Brain oedema (PT)	10048962
	Injection site joint swelling (PT)	10049260
	Oedema due to renal disease (PT)	10049630
	Oedema due to hepatic disease (PT)	10049631
	Oedema due to cardiac disease (PT)	10049632
	Peripheral oedema neonatal (PT)	10049779
	Pulmonary oedema neonatal (PT)	10050459
	Bone marrow oedema (PT)	10051763
	Skin swelling (PT)	10053262
	Application site swelling (PT)	10053424
	Injection site swelling (PT)	10053425
	Infusion site swelling (PT)	10053505
	Bone swelling (PT)	10053631
	Infusion site oedema (PT)	10053998
	Subdural effusion (PT)	10054797
	Catheter site oedema (PT)	10055909
	Scleroedema (PT)	10055953
	Bronchial oedema (PT)	10056695
	Gastrointestinal oedema (PT)	10058061
	Skin oedema (PT)	10058679
	Perinephric collection (PT)	10059209
	Haemodilution (PT)	10059484
	Hydraemia (PT)	10060374
	Oedema neonatal (PT)	10061317

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Edema and fluid retention	Spinal cord oedema (PT)	10063036
	Effusion (PT)	10063045
	Gestational oedema (PT)	10063412
	Retroperitoneal effusion (PT)	10063637
	Implant site oedema (PT)	10063776
	Cervix oedema (PT)	10063817
	Implant site swelling (PT)	10063867
	Lipoedema (PT)	10063955
	Bone marrow oedema syndrome (PT)	10064269
	Oesophageal oedema (PT)	10064342
	Muscle swelling (PT)	10064470
	Reexpansion pulmonary oedema (PT)	10064715
	Myocardial oedema (PT)	10064966
	Extensive swelling of vaccinated limb (PT)	10065106
	Pelvic fluid collection (PT)	10065388
	Incision site oedema (PT)	10065614
	Visceral oedema (PT)	10065768
	Cerebral mass effect (PT)	10067086
	Vasogenic cerebral oedema (PT)	10067275
	Cytotoxic oedema (PT)	10067276
	Elephantiasis nostras verrucosa (PT)	10071025
	Muscle oedema (PT)	10071759
	Amyloid related imaging abnormality-oedema/ effusion (PT)	10072260
	Amyloid related imaging abnormalities (PT)	10072599
	Amyloid related imaging abnormality- microhaemorrhages and hemosiderin deposits (PT)	10072601
	Oedematous kidney (PT)	10073381
	Instillation site oedema (PT)	10073619
	Puncture site oedema (PT)	10074069
	Incision site swelling (PT)	10074758
	Hypoosmolar state (PT)	10074867

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Edema and fluid retention	Prevertebral soft tissue swelling of cervical space (PT)	10074880
	Administration site oedema (PT)	10075104
	Administration site swelling (PT)	10075107
	Mouth swelling (PT)	10075203
	Administration site joint effusion (PT)	10075944
	Application site joint effusion (PT)	10076010
	Application site joint swelling (PT)	10076016
	Infusion site joint effusion (PT)	10076072
	Infusion site joint swelling (PT)	10076078
	Medical device site joint effusion (PT)	10076117
	Medical device site joint swelling (PT)	10076123
	Vaccination site joint effusion (PT)	10076172
	Vaccination site joint swelling (PT)	10076178
	Oropharyngeal oedema (PT)	10078783
	Perinephric oedema (PT)	10078818
	Compression garment application (PT)	10079209
	Oedema blister (PT)	10080039
	Negative pressure pulmonary oedema (PT)	10080589
	Hydrovarium (PT)	10081546
	Durotomy procedure (PT)	10081615
	Circumoral swelling (PT)	10081703
	Modified Rodnan skin score abnormal (PT)	10081776
	Non-pitting oedema (PT)	10083903
	Second impact syndrome (PT)	10084563
	Flood syndrome (PT)	10084797
	Lymphovenous bypass (PT)	10084980
	Inadequate peritoneal dialysis (PT)	10085005
	Tendon sheath effusion (PT)	10086724
	Omental oedema (PT)	10087030
	Pressotherapy (PT)	10087655
	Placental oedema (PT)	10088054

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Edema and fluid retention	Dilutional anaemia (PT)	10088450
GI toxicity	Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ) (narrow)	20000140
	Abdominal discomfort (PT)	10000059
	Abdominal distension (PT)	10000060
	Abdominal pain (PT)	10000081
	Abdominal pain lower (PT)	10000084
	Abdominal pain upper (PT)	10000087
	Abdominal tenderness (PT)	10000097
	Abnormal faeces (PT)	10000133
	Change of bowel habit (PT)	10008399
	Constipation (PT)	10010774
	Defaecation urgency (PT)	10012110
	Diarrhoea (PT)	10012735
	Eructation (PT)	10015137
	Faeces hard (PT)	10016101
	Flatulence (PT)	10016766
	Frequent bowel movements (PT)	10017367
	Gastrointestinal pain (PT)	10017999
	Nausea (PT)	10028813
	Oesophageal pain (PT)	10030180
	Vomiting (PT)	10047700
	Faecal volume increased (PT)	10049939
	Faecal volume decreased (PT)	10050248
	Aerophagia (PT)	10052813
	Epigastric discomfort (PT)	10053155
	Oesophageal discomfort (PT)	10053634
	Gastrointestinal toxicity (PT)	10059024
	Infrequent bowel movements (PT)	10059158
	Abdominal symptom (PT)	10060926
	Non-cardiac chest pain (PT)	10062501

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Safety topic	MedDRA term selection of adverse events	MedDRA code
GI toxicity	Bowel movement irregularity (PT)	10063541
	Gastrointestinal sounds abnormal (PT)	10067715
	Anorectal discomfort (PT)	10068286
	Faeces soft (PT)	10074859
	Discoloured vomit (PT)	10079120
	Defaecation disorder (PT)	10079938
	Overflow diarrhoea (PT)	10082507
Hemorrhage	Haemorrhages (SMQ) (narrow)	20000038
	Haemorrhage terms (excl laboratory terms) (SMQ) (narrow)	20000039
	Adrenal haemorrhage (PT)	10001361
	Anastomotic ulcer haemorrhage (PT)	10002244
	Aortic aneurysm rupture (PT)	10002886
	Arterial rupture (PT)	10003173
	Auricular haematoma (PT)	10003797
	Bleeding varicose vein (PT)	10005144
	Blood blister (PT)	10005372
	Blood urine (PT)	10005863
	Brain stem haemorrhage (PT)	10006145
	Breast haemorrhage (PT)	10006254
	Broad ligament haematoma (PT)	10006375
	Cephalhaematoma (PT)	10008014
	Cerebellar haemorrhage (PT)	10008030
	Cerebral aneurysm ruptured syphilitic (PT)	10008076
	Cerebral arteriovenous malformation haemorrhagic (PT)	10008086
	Cerebral haemorrhage (PT)	10008111
	Cerebral haemorrhage neonatal (PT)	10008112
	Choroidal haemorrhage (PT)	10008786
	Colonic haematoma (PT)	10009996
	Conjunctival haemorrhage (PT)	10010719

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Hemorrhage	Cystitis haemorrhagic (PT)	10011793
	Diarrhoea haemorrhagic (PT)	10012741
	Disseminated intravascular coagulation (PT)	10013442
	Diverticulitis intestinal haemorrhagic (PT)	10013541
	Diverticulum intestinal haemorrhagic (PT)	10013560
	Duodenal ulcer haemorrhage (PT)	10013839
	Duodenitis haemorrhagic (PT)	10013865
	Ear haemorrhage (PT)	10014009
	Ecchymosis (PT)	10014080
	Encephalitis haemorrhagic (PT)	10014589
	Enterocolitis haemorrhagic (PT)	10014896
	Epistaxis (PT)	10015090
	Exsanguination (PT)	10015719
	Extradural haematoma (PT)	10015769
	Extravasation blood (PT)	10015867
	Eye haemorrhage (PT)	10015926
	Foetal-maternal haemorrhage (PT)	10016871
	Gastric haemorrhage (PT)	10017788
	Gastric ulcer haemorrhage (PT)	10017826
	Gastric ulcer haemorrhage, obstructive (PT)	10017829
	Gastritis alcoholic haemorrhagic (PT)	10017857
	Gastritis haemorrhagic (PT)	10017866
	Gastrointestinal haemorrhage (PT)	10017955
	Gingival bleeding (PT)	10018276
	Haemarthrosis (PT)	10018829
	Haematemesia (PT)	10018830
	Haematocoele (PT)	10018833
	Haematochezia (PT)	10018836
	Haematoma (PT)	10018852
	Haemospermia (PT)	10018866
	Haematuria (PT)	10018867
	Blood urine present (PT)	10018870

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Haematuria traumatic (PT)	10018871
	Haemoperitoneum (PT)	10018935
	Haemoptysis (PT)	10018964
	Haemorrhage in pregnancy (PT)	10018981
	Haemorrhage intracranial (PT)	10018985
	Haemorrhage subcutaneous (PT)	10018999
	Haemorrhage subepidermal (PT)	10019001
	Haemorrhagic cerebral infarction (PT)	10019005
	Haemorrhagic disease of newborn (PT)	10019008
	Haemorrhagic disorder (PT)	10019009
	Haemorrhagic infarction (PT)	10019013
	Haemorrhagic stroke (PT)	10019016
	Haemothorax (PT)	10019027
	Henoch-Schonlein purpura (PT)	10019617
	Hepatic haematoma (PT)	10019676
	Hepatic haemorrhage (PT)	10019677
	Hereditary haemorrhagic telangiectasia (PT)	10019883
	Hyphaema (PT)	10020923
	Increased tendency to bruise (PT)	10021688
	Injection site bruising (PT)	10022052
	Injection site haematoma (PT)	10022066
	Injection site haemorrhage (PT)	10022067
	Intermenstrual bleeding (PT)	10022559
	Intracranial tumour haemorrhage (PT)	10022775
	Intraventricular haemorrhage (PT)	10022840
	Intraventricular haemorrhage neonatal (PT)	10022841
	Kidney contusion (PT)	10023413
	Mallory-Weiss syndrome (PT)	10026712
	Melaena (PT)	10027141
	Menometrorrhagia (PT)	10027295
	Mouth haemorrhage (PT)	10028024
	Muscle haemorrhage (PT)	10028309

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Myocardial rupture (PT)	10028604
	Nephritis haemorrhagic (PT)	10029132
	Nipple exudate bloody (PT)	10029418
	Oesophageal haemorrhage (PT)	10030172
	Oesophageal ulcer haemorrhage (PT)	10030202
	Oesophageal varices haemorrhage (PT)	10030210
	Oesophagitis haemorrhagic (PT)	10030219
	Optic disc haemorrhage (PT)	10030919
	Optic nerve sheath haemorrhage (PT)	10030941
	Orbital haemorrhage (PT)	10031045
	Ovarian haematoma (PT)	10033263
	Pancreatic haemorrhage (PT)	10033625
	Pancreatitis haemorrhagic (PT)	10033650
	Pelvic haematoma obstetric (PT)	10034248
	Penile haemorrhage (PT)	10034305
	Peptic ulcer haemorrhage (PT)	10034344
	Pericardial haemorrhage (PT)	10034476
	Perineal haematoma (PT)	10034520
	Periorbital haematoma (PT)	10034544
	Petechiae (PT)	10034754
	Pharyngeal haemorrhage (PT)	10034827
	Placenta praevia haemorrhage (PT)	10035121
	Post abortion haemorrhage (PT)	10036246
	Postpartum haemorrhage (PT)	10036417
	Premature separation of placenta (PT)	10036608
	Proctitis haemorrhagic (PT)	10036778
	Prostatic haemorrhage (PT)	10036960
	Pulmonary alveolar haemorrhage (PT)	10037313
	Pulmonary contusion (PT)	10037370
	Pulmonary haemorrhage (PT)	10037394
	Purpura (PT)	10037549
	Purpura fulminans (PT)	10037556

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Purpura neonatal (PT)	10037557
	Purpura senile (PT)	10037560
	Rectal haemorrhage (PT)	10038063
	Rectal ulcer haemorrhage (PT)	10038081
	Renal haematoma (PT)	10038459
	Renal haemorrhage (PT)	10038460
	Respiratory tract haemorrhage (PT)	10038727
	Respiratory tract haemorrhage neonatal (PT)	10038728
	Retinal haemorrhage (PT)	10038867
	Retroperitoneal haemorrhage (PT)	10038980
	Ruptured cerebral aneurysm (PT)	10039330
	Scrotal haematoma (PT)	10039749
	Splenic haematoma (PT)	10041646
	Splenic haemorrhage (PT)	10041647
	Splinter haemorrhages (PT)	10041663
	Stomatitis haemorrhagic (PT)	10042132
	Subarachnoid haemorrhage (PT)	10042316
	Subarachnoid haemorrhage neonatal (PT)	10042317
	Subcutaneous haematoma (PT)	10042345
	Subdural haematoma (PT)	10042361
	Subdural haematoma evacuation (PT)	10042363
	Subdural haemorrhage (PT)	10042364
	Subdural haemorrhage neonatal (PT)	10042365
	Third stage postpartum haemorrhage (PT)	10043449
	Thrombocytopenic purpura (PT)	10043561
	Thrombotic thrombocytopenic purpura (PT)	10043648
	Tongue haematoma (PT)	10043959
	Traumatic haematoma (PT)	10044522
	Umbilical haemorrhage (PT)	10045455
	Upper gastrointestinal haemorrhage (PT)	10046274
	Urinary bladder haemorrhage (PT)	10046528
	Uterine haemorrhage (PT)	10046788

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Vaginal haematoma (PT)	10046909
	Vaginal haemorrhage (PT)	10046910
	Varicose vein ruptured (PT)	10046999
	Vascular purpura (PT)	10047097
	Ventricle rupture (PT)	10047279
	Vitreous haemorrhage (PT)	10047655
	Vulval haematoma (PT)	10047756
	Vulval haematoma evacuation (PT)	10047757
	Withdrawal bleed (PT)	10047998
	Aneurysm ruptured (PT)	10048380
	Atrial rupture (PT)	10048761
	Myocardial haemorrhage (PT)	10048849
	Nail bed bleeding (PT)	10048891
	Spinal cord haemorrhage (PT)	10048992
	Spinal epidural haemorrhage (PT)	10049236
	Lip haemorrhage (PT)	10049297
	Anal haemorrhage (PT)	10049555
	Urethral haemorrhage (PT)	10049710
	Tumour haemorrhage (PT)	10049750
	Pituitary haemorrhage (PT)	10049760
	Shock haemorrhagic (PT)	10049771
	Melaena neonatal (PT)	10049777
	Tongue haemorrhage (PT)	10049870
	Mediastinal haematoma (PT)	10049941
	Cervix haematoma uterine (PT)	10050020
	Cervix haemorrhage uterine (PT)	10050022
	Urogenital haemorrhage (PT)	10050058
	Application site bruise (PT)	10050114
	Cerebral haemorrhage foetal (PT)	10050157
	Spinal epidural haematoma (PT)	10050162
	Spinal subdural haematoma (PT)	10050164
	Application site purpura (PT)	10050182

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Skin ulcer haemorrhage (PT)	10050377
	Chronic gastrointestinal bleeding (PT)	10050399
	Haematosalpinx (PT)	10050468
	Scleral haemorrhage (PT)	10050508
	Contusion (PT)	10050584
	Lower gastrointestinal haemorrhage (PT)	10050953
	Post procedural haemorrhage (PT)	10051077
	Catheter site haemorrhage (PT)	10051099
	Incision site haemorrhage (PT)	10051100
	Puncture site haemorrhage (PT)	10051101
	Parotid gland haemorrhage (PT)	10051166
	Soft tissue haemorrhage (PT)	10051297
	Carotid aneurysm rupture (PT)	10051328
	Wound haemorrhage (PT)	10051373
	Retinopathy haemorrhagic (PT)	10051447
	Corneal bleeding (PT)	10051558
	Haematoma infection (PT)	10051564
	Testicular haemorrhage (PT)	10051877
	Osteorrhagia (PT)	10051937
	Urinary occult blood positive (PT)	10052287
	Brain contusion (PT)	10052346
	Large intestinal haemorrhage (PT)	10052534
	Small intestinal haemorrhage (PT)	10052535
	Meningorrhagia (PT)	10052593
	Induced abortion haemorrhage (PT)	10052844
	Eyelid bleeding (PT)	10053196
	Traumatic haemorrhage (PT)	10053476
	Vascular rupture (PT)	10053649
	Gastroduodenal haemorrhage (PT)	10053768
	Cerebral haematoma (PT)	10053942
	Vascular pseudoaneurysm ruptured (PT)	10053949
	Implant site haemorrhage (PT)	10053995

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Vessel puncture site haemorrhage (PT)	10054092
	Haemorrhagic tumour necrosis (PT)	10054096
	Haemorrhoidal haemorrhage (PT)	10054787
	Retroplacental haematoma (PT)	10054798
	Hepatic haemangioma rupture (PT)	10054885
	Pelvic haematoma (PT)	10054974
	Pulmonary haematoma (PT)	10054991
	Arteriovenous fistula site haemorrhage (PT)	10055123
	Arteriovenous graft site haemorrhage (PT)	10055126
	Arteriovenous fistula site haematoma (PT)	10055150
	Arteriovenous graft site haematoma (PT)	10055152
	Catheter site haematoma (PT)	10055662
	Haemorrhagic transformation stroke (PT)	10055677
	Haemorrhage (PT)	10055798
	Haemorrhage coronary artery (PT)	10055803
	Haemorrhage urinary tract (PT)	10055847
	Postmenopausal haemorrhage (PT)	10055870
	Haematoma muscle (PT)	10055890
	Mediastinal haemorrhage (PT)	10056343
	Anastomotic haemorrhage (PT)	10056346
	Pituitary apoplexy (PT)	10056447
	Intra-abdominal haematoma (PT)	10056457
	Gastrointestinal ulcer haemorrhage (PT)	10056743
	Palpable purpura (PT)	10056872
	Ciliary body haemorrhage (PT)	10057417
	Iris haemorrhage (PT)	10057418
	Tonsillar haemorrhage (PT)	10057450
	Ocular retrobulbar haemorrhage (PT)	10057571
	Gastric varices haemorrhage (PT)	10057572
	Bloody discharge (PT)	10057687
	Purpura non-thrombocytopenic (PT)	10057739
	Peritoneal haematoma (PT)	10058095

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Retroperitoneal haematoma (PT)	10058360
	Thalamus haemorrhage (PT)	10058939
	Putamen haemorrhage (PT)	10058940
	Haemobilia (PT)	10058947
	Acute haemorrhagic leukoencephalitis (PT)	10058994
	Cullen's sign (PT)	10059029
	Parathyroid haemorrhage (PT)	10059051
	Papillary muscle haemorrhage (PT)	10059164
	Intestinal haemorrhage (PT)	10059175
	Haemorrhagic cyst (PT)	10059189
	Adrenal haematoma (PT)	10059194
	Infusion site bruising (PT)	10059203
	Incision site haematoma (PT)	10059241
	Intracranial haematoma (PT)	10059491
	Haemorrhagic urticaria (PT)	10059499
	Haemorrhagic ascites (PT)	10059766
	Renal cyst haemorrhage (PT)	10059846
	Skin neoplasm bleeding (PT)	10060712
	Mesenteric haemorrhage (PT)	10060717
	Haematoma evacuation (PT)	10060733
	Haemorrhagic ovarian cyst (PT)	10060781
	Aortic rupture (PT)	10060874
	Arterial haemorrhage (PT)	10060964
	Cerebellar haematoma (PT)	10061038
	Genital haemorrhage (PT)	10061178
	Haemorrhage foetal (PT)	10061191
	Intra-abdominal haemorrhage (PT)	10061249
	Large intestinal ulcer haemorrhage (PT)	10061262
	Mucosal haemorrhage (PT)	10061298
	Scrotal haemorrhage (PT)	10061361
	Traumatic intracranial haemorrhage (PT)	10061387
	Scrotal haematocoele (PT)	10061517

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Small intestinal ulcer haemorrhage (PT)	10061550
	Ulcer haemorrhage (PT)	10061577
	Haemorrhage neonatal (PT)	10061993
	Intracerebral haematoma evacuation (PT)	10062025
	Tracheal haemorrhage (PT)	10062543
	Bladder tamponade (PT)	10062656
	Haemorrhagic diathesis (PT)	10062713
	Thoracic haemorrhage (PT)	10062744
	Naevus haemorrhage (PT)	10062955
	Haematotympanum (PT)	10063013
	Post procedural haematoma (PT)	10063188
	Graft haemorrhage (PT)	10063577
	Catheter site bruise (PT)	10063587
	Pelvic haemorrhage (PT)	10063678
	Implant site haematoma (PT)	10063780
	Vulval haemorrhage (PT)	10063816
	Implant site bruising (PT)	10063850
	Uterine haematoma (PT)	10063875
	Vessel puncture site bruise (PT)	10063881
	Anal ulcer haemorrhage (PT)	10063896
	Polymenorrhagia (PT)	10064050
	Angina bullosa haemorrhagica (PT)	10064223
	Thyroid haemorrhage (PT)	10064224
	Skin haemorrhage (PT)	10064265
	Umbilical cord haemorrhage (PT)	10064534
	Haemorrhagic arteriovenous malformation (PT)	10064595
	Breast haematoma (PT)	10064753
	Tooth socket haemorrhage (PT)	10064946
	Eyelid haematoma (PT)	10064976
	Coital bleeding (PT)	10065019
	Haemophilic arthropathy (PT)	10065057
	Spontaneous haematoma (PT)	10065304

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Venous haemorrhage (PT)	10065441
	Infusion site haematoma (PT)	10065463
	Infusion site haemorrhage (PT)	10065464
	Bronchial haemorrhage (PT)	10065739
	Laryngeal haemorrhage (PT)	10065740
	Ovarian haemorrhage (PT)	10065741
	Spermatic cord haemorrhage (PT)	10065742
	Ureteric haemorrhage (PT)	10065743
	Vessel puncture site haematoma (PT)	10065902
	Post procedural haematuria (PT)	10066225
	Bone contusion (PT)	10066251
	Lip haematoma (PT)	10066304
	Basal ganglia haemorrhage (PT)	10067057
	Liver contusion (PT)	10067266
	Cerebral microhaemorrhage (PT)	10067277
	Astringent therapy (PT)	10067372
	Abdominal wall haematoma (PT)	10067383
	Haemostasis (PT)	10067439
	Bloody peritoneal effluent (PT)	10067442
	Intrapartum haemorrhage (PT)	10067703
	Haemorrhagic erosive gastritis (PT)	10067786
	Abdominal wall haemorrhage (PT)	10067788
	Haemorrhagic hepatic cyst (PT)	10067796
	Aortic intramural haematoma (PT)	10067975
	Aortic dissection rupture (PT)	10068119
	Pharyngeal haematoma (PT)	10068121
	Application site haematoma (PT)	10068317
	Choroidal haematoma (PT)	10068642
	Splenic varices haemorrhage (PT)	10068662
	Umbilical haematoma (PT)	10068712
	Anorectal varices haemorrhage (PT)	10068925
	Abnormal withdrawal bleeding (PT)	10069195

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Vaccination site haematoma (PT)	10069472
	Vaccination site haemorrhage (PT)	10069475
	Vaccination site bruising (PT)	10069484
	Subgaleal haematoma (PT)	10069510
	Paranasal sinus haematoma (PT)	10069702
	Intestinal haematoma (PT)	10069829
	Lacrimonal haemorrhage (PT)	10069930
	Penile haematoma (PT)	10070656
	Muscle contusion (PT)	10070757
	Laryngeal haematoma (PT)	10070885
	Subchorionic haemorrhage (PT)	10071010
	Brain stem microhaemorrhage (PT)	10071205
	Cerebellar microhaemorrhage (PT)	10071206
	Procedural haemorrhage (PT)	10071229
	Haemorrhagic vasculitis (PT)	10071252
	Wound haematoma (PT)	10071504
	Mesenteric haematoma (PT)	10071557
	Post-traumatic punctate intraepidermal haemorrhage (PT)	10071639
	Periorbital haemorrhage (PT)	10071697
	Intraocular haematoma (PT)	10071934
	Subretinal haematoma (PT)	10071935
	Vitreous haematoma (PT)	10071936
	Central nervous system haemorrhage (PT)	10072043
	Tooth pulp haemorrhage (PT)	10072228
	Haemorrhagic thyroid cyst (PT)	10072256
	Post transfusion purpura (PT)	10072265
	Radiation associated haemorrhage (PT)	10072281
	Subchorionic haematoma (PT)	10072596
	Peripartum haemorrhage (PT)	10072693
	Application site haemorrhage (PT)	10072694
	Chronic pigmented purpura (PT)	10072726

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Iliac artery rupture (PT)	10072789
	Brain stem haematoma (PT)	10073230
	Penile contusion (PT)	10073352
	Post procedural contusion (PT)	10073353
	Eye contusion (PT)	10073354
	Genital contusion (PT)	10073355
	Cardiac contusion (PT)	10073356
	Spleen contusion (PT)	10073533
	Spinal subdural haemorrhage (PT)	10073563
	Spinal subarachnoid haemorrhage (PT)	10073564
	Bone marrow haemorrhage (PT)	10073581
	Instillation site haematoma (PT)	10073609
	Instillation site haemorrhage (PT)	10073610
	Instillation site bruise (PT)	10073630
	Epidural haemorrhage (PT)	10073681
	Haemophilic pseudotumour (PT)	10073770
	Neonatal gastrointestinal haemorrhage (PT)	10074159
	Lymph node haemorrhage (PT)	10074270
	Gastrointestinal polyp haemorrhage (PT)	10074437
	Traumatic haemothorax (PT)	10074487
	Stoma site haemorrhage (PT)	10074508
	Spontaneous haemorrhage (PT)	10074557
	Deep dissecting haematoma (PT)	10074718
	Hyperfibrinolysis (PT)	10074737
	Oral mucosa haematoma (PT)	10074779
	Arterial intramural haematoma (PT)	10074971
	Eyelid contusion (PT)	10075018
	Nasal septum haematoma (PT)	10075027
	Administration site bruise (PT)	10075094
	Administration site haematoma (PT)	10075100
	Administration site haemorrhage (PT)	10075101
	Internal haemorrhage (PT)	10075192

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Aponeurosis contusion (PT)	10075330
	Cerebral aneurysm perforation (PT)	10075394
	Grey Turner's sign (PT)	10075426
	Medical device site bruise (PT)	10075570
	Medical device site haematoma (PT)	10075577
	Medical device site haemorrhage (PT)	10075578
	Acute haemorrhagic ulcerative colitis (PT)	10075634
	Carotid artery perforation (PT)	10075728
	Aortic perforation (PT)	10075729
	Lower limb artery perforation (PT)	10075730
	Iliac artery perforation (PT)	10075731
	Arterial perforation (PT)	10075732
	Venous perforation (PT)	10075733
	Cerebral artery perforation (PT)	10075734
	Vertebral artery perforation (PT)	10075735
	Basilar artery perforation (PT)	10075736
	Renal artery perforation (PT)	10075737
	Splenic artery perforation (PT)	10075738
	Femoral artery perforation (PT)	10075739
	Subclavian artery perforation (PT)	10075740
	Superior vena cava perforation (PT)	10075741
	Inferior vena cava perforation (PT)	10075742
	Subclavian vein perforation (PT)	10075743
	Iliac vein perforation (PT)	10075744
	Femoral vein perforation (PT)	10075745
	Mucocutaneous haemorrhage (PT)	10076048
	Spinal cord haematoma (PT)	10076051
	Haemorrhagic necrotic pancreatitis (PT)	10076058
	Oral blood blister (PT)	10076590
	Chest wall haematoma (PT)	10076597
	Subarachnoid haematoma (PT)	10076701
	Periventricular haemorrhage neonatal (PT)	10076706

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Basal ganglia haematoma (PT)	10077031
	Vein rupture (PT)	10077110
	Periosteal haematoma (PT)	10077341
	Haemorrhagic breast cyst (PT)	10077443
	Oesophageal intramural haematoma (PT)	10077486
	Vascular access site haemorrhage (PT)	10077643
	Vascular access site haematoma (PT)	10077647
	Vascular access site rupture (PT)	10077652
	Joint microhaemorrhage (PT)	10077666
	Vascular graft haemorrhage (PT)	10077721
	Vascular access site bruising (PT)	10077767
	Bursal haematoma (PT)	10077818
	Intestinal varices haemorrhage (PT)	10078058
	Oral contusion (PT)	10078170
	Extra-axial haemorrhage (PT)	10078254
	Traumatic intracranial haematoma (PT)	10079013
	Retinal aneurysm rupture (PT)	10079121
	Bronchial varices haemorrhage (PT)	10079163
	Achenbach syndrome (PT)	10079562
	Anal fissure haemorrhage (PT)	10079765
	Eye haematoma (PT)	10079891
	Haemorrhagic adrenal infarction (PT)	10079902
	Peripheral artery aneurysm rupture (PT)	10079908
	Paranasal sinus haemorrhage (PT)	10080108
	Gastrointestinal vascular malformation haemorrhagic (PT)	10080561
	Subgaleal haemorrhage (PT)	10080900
	Fothergill sign positive (PT)	10081749
	Puncture site haematoma (PT)	10081957
	Puncture site bruise (PT)	10082035
	Cerebral cyst haemorrhage (PT)	10082099
	Pulmonary haemorrhage neonatal (PT)	10082194

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hemorrhage	Blood loss anaemia (PT)	10082297
	Subendocardial haemorrhage (PT)	10082459
	Extradural haematoma evacuation (PT)	10082797
	Pharyngeal contusion (PT)	10083176
	Anticoagulant-related nephropathy (PT)	10083346
	Urinary bladder haematoma (PT)	10083358
	Subcapsular hepatic haematoma (PT)	10083383
	Subcapsular splenic haematoma (PT)	10083384
	Subcapsular renal haematoma (PT)	10083385
	Oral purpura (PT)	10083533
	Orbital haematoma (PT)	10083565
	Bullous haemorrhagic dermatosis (PT)	10083809
	Pancreatic pseudocyst haemorrhage (PT)	10083813
	Immune thrombocytopenia (PT)	10083842
	Haemangioma rupture (PT)	10084040
	Vascular anastomotic haemorrhage (PT)	10084092
	Intratumoural haematoma (PT)	10084177
	Antiplatelet reversal therapy (PT)	10084904
	Urinary occult blood (PT)	10084960
	Omental haemorrhage (PT)	10085045
	Haemorrhagic occlusive retinal vasculitis (PT)	10085070
	Haemorrhagic gastroenteritis (PT)	10085136
	Scleral haematoma (PT)	10085163
	Jugular vein haemorrhage (PT)	10085298
	Gastrointestinal anastomotic haemorrhage (PT)	10085369
	Heavy menstrual bleeding (PT)	10085423
	Abnormal uterine bleeding (PT)	10085424
	Gallbladder haematoma (PT)	10085893
	Haemorrhagic cerebellar infarction (PT)	10085944
	Peripheral exudative haemorrhagic chorioretinopathy (PT)	10086195
	Hypergammaglobulinaemic purpura of Waldenstrom	10086403

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Safety topic	MedDRA term selection of adverse events	MedDRA code
	(PT)	
	Intracranial haemorrhage neonatal (PT)	10086946
	Hepatic artery haemorrhage (PT)	10087132
	Scalp haematoma (PT)	10087456
	Abnormal menstrual clots (PT)	10087591
	Carotid blowout syndrome (PT)	10088005
	Unexpected vaginal bleeding on hormonal IUD (PT)	10088030
	Menstrual clots (PT)	10088498
	Vocal cord haemorrhage (PT)	10088766
	Haemorrhage laboratory terms (SMQ) (narrow)	20000040
	Plasmin increased (PT)	10035489
	Occult blood positive (PT)	10061880
	Gastric occult blood positive (PT)	10067855
	Prekallikrein increased (PT)	10072493
	Thrombomodulin increased (PT)	10087292
Hepatitis B virus reactivation	Hepatitis B virus reactivation (CMQ)	90006969
	Chronic hepatitis B (PT)	10008910
	Hepatitis B (PT)	10019731
	Hepatitis B antibody abnormal (PT)	10019733
	Hepatitis B antibody positive (PT)	10019736
	Hepatitis B surface antigen positive (PT)	10019742
	Hepatitis chronic active (PT)	10019755
	Hepatitis chronic persistent (PT)	10019759
	Hepatitis viral (PT)	10019799
	Viral hepatitis carrier (PT)	10047458
	Hepatitis B core antigen positive (PT)	10052328
	Hepatitis B e antigen positive (PT)	10052329
	Hepatitis B reactivation (PT)	10058827
	HBV-DNA polymerase increased (PT)	10058937
	Acute hepatitis B (PT)	10059193
	Hepatitis B DNA assay positive (PT)	10060047

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatitis B virus reactivation	Hepatitis B antigen positive (PT)	10063411
	Asymptomatic viral hepatitis (PT)	10063838
	Hepatitis B DNA increased (PT)	10068379
	Hepatitis B virus test positive (PT)	10070217
	Withdrawal hepatitis (PT)	10071220
	Hepatitis B core antibody positive (PT)	10071344
	Hepatitis B surface antibody positive (PT)	10071346
	Hepatitis B e antibody positive (PT)	10071348
Hepatotoxicity (clinical events)	Hepatitis viral test positive (PT)	10072748
	Hepatitis, non-infectious (SMQ) (broad)	20000010
	Autoimmune hepatitis (PT)	10003827
	Chronic hepatitis (PT)	10008909
	Granulomatous liver disease (PT)	10018704
	Hepatitis (PT)	10019717
	Hepatitis acute (PT)	10019727
	Hepatitis cholestatic (PT)	10019754
	Hepatitis chronic active (PT)	10019755
	Hepatitis chronic persistent (PT)	10019759
	Hepatitis fulminant (PT)	10019772
	Hepatitis toxic (PT)	10019795
	Ischaemic hepatitis (PT)	10023025
	Hepatic cytolysis (PT)	10049199
	Radiation hepatitis (PT)	10051015
	Non-alcoholic steatohepatitis (PT)	10053219
	Graft versus host disease in liver (PT)	10064676
	Acute graft versus host disease in liver (PT)	10066263
	Lupus hepatitis (PT)	10067737
	Liver sarcoidosis (PT)	10068664
	Allergic hepatitis (PT)	10071198
	Chronic graft versus host disease in liver (PT)	10072160
	Portal tract inflammation (PT)	10075331

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (clinical events)	Steatohepatitis (PT)	10076331
	Immune-mediated hepatitis (PT)	10078962
	Alloimmune hepatitis (PT)	10080576
	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) (broad)	20000013
	Acute hepatic failure (PT)	10000804
	Ascites (PT)	10003445
	Asterixis (PT)	10003547
	Biliary cirrhosis (PT)	10004659
	Biliary fibrosis (PT)	10004664
	Coma hepatic (PT)	10010075
	Complications of transplanted liver (PT)	10010186
	Hepatic atrophy (PT)	10019637
	Hepatic cirrhosis (PT)	10019641
	Hepatic encephalopathy (PT)	10019660
	Hepatic failure (PT)	10019663
	Hepatic fibrosis (PT)	10019668
	Hepatic necrosis (PT)	10019692
	Hepatic steatosis (PT)	10019708
	Hepatocellular injury (PT)	10019837
	Hepatorenal failure (PT)	10019845
	Hepatorenal syndrome (PT)	10019846
	Hepatotoxicity (PT)	10019851
	Liver disorder (PT)	10024670
	Liver transplant (PT)	10024714
	Liver transplant rejection (PT)	10024715
	Lupoid hepatic cirrhosis (PT)	10025129
	Non-alcoholic fatty liver (PT)	10029530
	Oesophageal varices haemorrhage (PT)	10030210
	Portal hypertension (PT)	10036200
	Portal shunt (PT)	10036204
	Reye's syndrome (PT)	10039012

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (clinical events)	Spider naevus (PT)	10041519
	Splenorenal shunt (PT)	10041661
	Oedema due to hepatic disease (PT)	10049631
	Portal hypertensive gastropathy (PT)	10050897
	Duodenal varices (PT)	10051010
	Gastric varices (PT)	10051012
	Nodular regenerative hyperplasia (PT)	10051081
	Liver and pancreas transplant rejection (PT)	10051603
	Hepatopulmonary syndrome (PT)	10052274
	Renal and liver transplant (PT)	10052279
	Peritoneovenous shunt (PT)	10052716
	Hepatocellular foamy cell syndrome (PT)	10053244
	Varices oesophageal (PT)	10056091
	Subacute hepatic failure (PT)	10056956
	Gastric varices haemorrhage (PT)	10057572
	Chronic hepatic failure (PT)	10057573
	Spontaneous bacterial peritonitis (PT)	10061135
	Hepatectomy (PT)	10061997
	Hepatic lesion (PT)	10061998
	Hepatobiliary disease (PT)	10062000
	Liver operation (PT)	10062040
	Cryptogenic cirrhosis (PT)	10063075
	Hepatic infiltration eosinophilic (PT)	10064668
	Hepatic calcification (PT)	10065274
	Gastrooesophageal variceal haemorrhage prophylaxis (PT)	10066597
	Hepatic encephalopathy prophylaxis (PT)	10066599
	Mixed liver injury (PT)	10066758
	Liver injury (PT)	10067125
	Portopulmonary hypertension (PT)	10067281
	Retrograde portal vein flow (PT)	10067338
	Hepatic hydrothorax (PT)	10067365

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (clinical events)	Splenic varices (PT)	10067823
	Cholestatic liver injury (PT)	10067969
	Bacterascites (PT)	10068547
	Splenic varices haemorrhage (PT)	10068662
	Portal hypertensive enteropathy (PT)	10068923
	Anorectal varices (PT)	10068924
	Anorectal varices haemorrhage (PT)	10068925
	Small-for-size liver syndrome (PT)	10069380
	Acute yellow liver atrophy (PT)	10070815
	Reynold's syndrome (PT)	10070953
	Diabetic hepatopathy (PT)	10071265
	Intestinal varices (PT)	10071502
	Drug-induced liver injury (PT)	10072268
	Varicose veins of abdominal wall (PT)	10072284
	Gallbladder varices (PT)	10072319
	Intrahepatic portal hepatic venous fistula (PT)	10072629
	Portal vein dilatation (PT)	10073209
	Peripancreatic varices (PT)	10073215
	Portal vein cavernous transformation (PT)	10073979
	Portal fibrosis (PT)	10074726
	Stomal varices (PT)	10075186
	Gastric variceal injection (PT)	10076237
	Gastric variceal ligation (PT)	10076238
	Spontaneous intrahepatic portosystemic venous shunt (PT)	10076239
	Liver dialysis (PT)	10076640
	Hepatic steato-fibrosis (PT)	10077215
	Non-cirrhotic portal hypertension (PT)	10077259
	Splenorenal shunt procedure (PT)	10077281
	Acute on chronic liver failure (PT)	10077305
	Portal shunt procedure (PT)	10077479
	Intestinal varices haemorrhage (PT)	10078058

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (clinical events)	White nipple sign (PT)	10078438
	Portal hypertensive colopathy (PT)	10079446
	Primary biliary cholangitis (PT)	10080429
	Regenerative siderotic hepatic nodule (PT)	10080679
	Acquired hepatocerebral degeneration (PT)	10080860
	Increased liver stiffness (PT)	10082444
	Multivisceral transplantation (PT)	10082450
	Cardiohepatic syndrome (PT)	10082480
	Sugiura procedure (PT)	10083010
	Liver transplant failure (PT)	10083175
	Immune-mediated cholangitis (PT)	10083406
	Immune-mediated hepatic disorder (PT)	10083521
	Splenic artery embolisation (PT)	10083795
	Hepatic perfusion disorder (PT)	10083840
	Flood syndrome (PT)	10084797
	Omental oedema (PT)	10087030
	Portal hypertensive biliopathy (PT)	10087656
	Suspected drug-induced liver injury (PT)	10088572
Hepatotoxicity (including laboratory terms)	Liver related investigations, signs and symptoms (SMQ) (broad)	20000008
	5'nucleotidase increased (PT)	10000028
	Alanine aminotransferase abnormal (PT)	10001547
	Alanine aminotransferase increased (PT)	10001551
	Ammonia abnormal (PT)	10001942
	Ammonia increased (PT)	10001946
	Ascites (PT)	10003445
	Aspartate aminotransferase abnormal (PT)	10003477
	Aspartate aminotransferase increased (PT)	10003481
	Bilirubin conjugated increased (PT)	10004685
	Biopsy liver abnormal (PT)	10004792
	Blood bilirubin increased (PT)	10005364

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Blood bilirubin unconjugated increased (PT)	10005370
	Blood cholinesterase abnormal (PT)	10005429
	Blood cholinesterase decreased (PT)	10005430
	Bromosulphthalein test abnormal (PT)	10006408
	Gamma-glutamyltransferase abnormal (PT)	10017688
	Gamma-glutamyltransferase increased (PT)	10017693
	Hepaplastin abnormal (PT)	10019621
	Hepaplastin decreased (PT)	10019622
	Hepatic function abnormal (PT)	10019670
	Hepatic pain (PT)	10019705
	Hepatomegaly (PT)	10019842
	Hepatosplenomegaly (PT)	10019847
	Hyperammonaemia (PT)	10020575
	Hyperbilirubinaemia (PT)	10020578
	Hypoalbuminaemia (PT)	10020942
	Kayser-Fleischer ring (PT)	10023321
	Leucine aminopeptidase increased (PT)	10024275
	Liver function test abnormal (PT)	10024690
	Liver tenderness (PT)	10024712
	Ultrasound liver abnormal (PT)	10045428
	Retinol binding protein decreased (PT)	10048473
	Glutamate dehydrogenase increased (PT)	10049483
	Oedema due to hepatic disease (PT)	10049631
	Urine bilirubin increased (PT)	10050792
	Guanase increased (PT)	10051333
	Bile output decreased (PT)	10051343
	Bile output abnormal (PT)	10051344
	Hypercholia (PT)	10051924
	Liver induration (PT)	10052550
	Foetor hepaticus (PT)	10052554
	Perihepatic discomfort (PT)	10054125

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Transaminases increased (PT)	10054889
	X-ray hepatobiliary abnormal (PT)	10056536
	Hepatic mass (PT)	10057110
	Blood bilirubin abnormal (PT)	10058477
	Blood alkaline phosphatase increased (PT)	10059570
	Blood alkaline phosphatase abnormal (PT)	10059571
	Galactose elimination capacity test abnormal (PT)	10059710
	Galactose elimination capacity test decreased (PT)	10059712
	Haemorrhagic ascites (PT)	10059766
	Liver-kidney microsomal antibody positive (PT)	10060107
	Hepatic enzyme decreased (PT)	10060794
	Hepatic enzyme increased (PT)	10060795
	Liver scan abnormal (PT)	10061947
	Hepatic enzyme abnormal (PT)	10062685
	Transaminases abnormal (PT)	10062688
	Mitochondrial aspartate aminotransferase increased (PT)	10064712
	Portal vein pressure increased (PT)	10064936
	Pneumobilia (PT)	10066004
	Hepatobiliary scan abnormal (PT)	10066195
	Hepatic sequestration (PT)	10066244
	Molar ratio of total branched-chain amino acid to tyrosine (PT)	10066869
	Portal vein flow decreased (PT)	10067337
	Retrograde portal vein flow (PT)	10067338
	Hepatic hydrothorax (PT)	10067365
	Bilirubin conjugated abnormal (PT)	10067718
	Hypertransaminasaemia (PT)	10068237
	Child-Pugh-Turcotte score increased (PT)	10068287

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Hepatic vascular resistance increased (PT)	10068358
	Cytokeratin 18 increased (PT)	10068471
	Bacterascites (PT)	10068547
	Periportal oedema (PT)	10068821
	Hepatic artery flow decreased (PT)	10068997
	Peritoneal fluid protein increased (PT)	10068998
	Peritoneal fluid protein decreased (PT)	10068999
	Peritoneal fluid protein abnormal (PT)	10069000
	Urobilinogen urine increased (PT)	10070479
	Urobilinogen urine decreased (PT)	10070480
	Deficiency of bile secretion (PT)	10071634
	Hepatic fibrosis marker abnormal (PT)	10074084
	Biliary ascites (PT)	10074150
	Liver iron concentration abnormal (PT)	10074352
	Liver iron concentration increased (PT)	10074354
	Hepatic fibrosis marker increased (PT)	10074413
	Liver palpable (PT)	10075895
	Hepatic hypertrophy (PT)	10076254
	Child-Pugh-Turcotte score abnormal (PT)	10077020
	Model for end stage liver disease score abnormal (PT)	10077291
	Model for end stage liver disease score increased (PT)	10077292
	Bilirubin urine present (PT)	10077356
	Liver function test decreased (PT)	10077677
	Liver function test increased (PT)	10077692
	Computerised tomogram liver abnormal (PT)	10078360
	White nipple sign (PT)	10078438
	Hepatic lymphocytic infiltration (PT)	10079686
	Glycocholic acid increased (PT)	10080824
	Magnetic resonance proton density fat fraction	10082443

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Safety topic	MedDRA term selection of adverse events	MedDRA code
terms)	measurement (PT)	
	Osteopontin increased (PT)	10082708
	AST/ALT ratio abnormal (PT)	10082832
	Hepatic venous pressure gradient increased (PT)	10083171
	Hepatic venous pressure gradient abnormal (PT)	10083172
	Congestive hepatopathy (PT)	10084058
	Liver opacity (PT)	10084071
	AST to platelet ratio index increased (PT)	10084175
	Hepatic hypoperfusion (PT)	10084751
	Magnetic resonance imaging hepatobiliary abnormal (PT)	10085121
	Acquired factor V deficiency (PT)	10086006
	Hepatitis B immunity confirmed (PT)	10086043
	Hepatitis A immunity confirmed (PT)	10086044
	Hepatitis E immunity confirmed (PT)	10086045
	Anti-liver cytosol antibody type 1 positive (PT)	10086970
	Bile acids increased (PT)	10088182
	Transient hepatic attenuation differences (PT)	10088641
	Cholestasis and jaundice of hepatic origin (SMQ) (broad)	20000009
	Cholestasis (PT)	10008635
	Hepatitis cholestatic (PT)	10019754
	Icterus index increased (PT)	10021209
	Jaundice (PT)	10023126
	Jaundice cholestatic (PT)	10023129
	Jaundice hepatocellular (PT)	10023136
	Yellow skin (PT)	10048245
	Cholaemia (PT)	10048611
	Ocular icterus (PT)	10058117
	Bilirubin excretion disorder (PT)	10061009
	Cholestatic pruritus (PT)	10064190
	Mixed liver injury (PT)	10066758

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Cholestatic liver injury (PT)	10067969
	Drug-induced liver injury (PT)	10072268
	Parenteral nutrition associated liver disease (PT)	10074151
	Suspected drug-induced liver injury (PT)	10088572
	Hepatitis, non-infectious (SMQ) (broad)	20000010
	Autoimmune hepatitis (PT)	10003827
	Chronic hepatitis (PT)	10008909
	Granulomatous liver disease (PT)	10018704
	Hepatitis (PT)	10019717
	Hepatitis acute (PT)	10019727
	Hepatitis chronic active (PT)	10019755
	Hepatitis chronic persistent (PT)	10019759
	Hepatitis fulminant (PT)	10019772
	Hepatitis toxic (PT)	10019795
	Ischaemic hepatitis (PT)	10023025
	Hepatic cytolysis (PT)	10049199
	Radiation hepatitis (PT)	10051015
	Non-alcoholic steatohepatitis (PT)	10053219
	Graft versus host disease in liver (PT)	10064676
	Acute graft versus host disease in liver (PT)	10066263
	Lupus hepatitis (PT)	10067737
	Liver sarcoidosis (PT)	10068664
	Allergic hepatitis (PT)	10071198
	Chronic graft versus host disease in liver (PT)	10072160
	Portal tract inflammation (PT)	10075331
	Steatohepatitis (PT)	10076331
	Immune-mediated hepatitis (PT)	10078962
	Alloimmune hepatitis (PT)	10080576
	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) (broad)	20000013

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Acute hepatic failure (PT)	10000804
	Asterixis (PT)	10003547
	Biliary cirrhosis (PT)	10004659
	Biliary fibrosis (PT)	10004664
	Coma hepatic (PT)	10010075
	Complications of transplanted liver (PT)	10010186
	Hepatic atrophy (PT)	10019637
	Hepatic cirrhosis (PT)	10019641
	Hepatic encephalopathy (PT)	10019660
	Hepatic failure (PT)	10019663
	Hepatic fibrosis (PT)	10019668
	Hepatic necrosis (PT)	10019692
	Hepatic steatosis (PT)	10019708
	Hepatocellular injury (PT)	10019837
	Hepatorenal failure (PT)	10019845
	Hepatorenal syndrome (PT)	10019846
	Hepatotoxicity (PT)	10019851
	Liver disorder (PT)	10024670
	Liver transplant (PT)	10024714
	Liver transplant rejection (PT)	10024715
	Lupoid hepatic cirrhosis (PT)	10025129
	Non-alcoholic fatty liver (PT)	10029530
	Oesophageal varices haemorrhage (PT)	10030210
	Portal hypertension (PT)	10036200
	Portal shunt (PT)	10036204
	Reye's syndrome (PT)	10039012
	Spider naevus (PT)	10041519
	Splenorenal shunt (PT)	10041661
	Portal hypertensive gastropathy (PT)	10050897
	Duodenal varices (PT)	10051010
	Gastric varices (PT)	10051012

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Nodular regenerative hyperplasia (PT)	10051081
	Liver and pancreas transplant rejection (PT)	10051603
	Hepatopulmonary syndrome (PT)	10052274
	Renal and liver transplant (PT)	10052279
	Peritoneovenous shunt (PT)	10052716
	Hepatocellular foamy cell syndrome (PT)	10053244
	Varices oesophageal (PT)	10056091
	Subacute hepatic failure (PT)	10056956
	Gastric varices haemorrhage (PT)	10057572
	Chronic hepatic failure (PT)	10057573
	Spontaneous bacterial peritonitis (PT)	10061135
	Hepatectomy (PT)	10061997
	Hepatic lesion (PT)	10061998
	Hepatobiliary disease (PT)	10062000
	Liver operation (PT)	10062040
	Cryptogenic cirrhosis (PT)	10063075
	Hepatic infiltration eosinophilic (PT)	10064668
	Hepatic calcification (PT)	10065274
	Gastrooesophageal variceal haemorrhage prophylaxis (PT)	10066597
	Hepatic encephalopathy prophylaxis (PT)	10066599
	Liver injury (PT)	10067125
	Portopulmonary hypertension (PT)	10067281
	Splenic varices (PT)	10067823
	Splenic varices haemorrhage (PT)	10068662
	Portal hypertensive enteropathy (PT)	10068923
	Anorectal varices (PT)	10068924
	Anorectal varices haemorrhage (PT)	10068925
	Small-for-size liver syndrome (PT)	10069380
	Acute yellow liver atrophy (PT)	10070815
	Reynold's syndrome (PT)	10070953

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Diabetic hepatopathy (PT)	10071265
	Intestinal varices (PT)	10071502
	Varicose veins of abdominal wall (PT)	10072284
	Gallbladder varices (PT)	10072319
	Intrahepatic portal hepatic venous fistula (PT)	10072629
	Portal vein dilatation (PT)	10073209
	Peripancreatic varices (PT)	10073215
	Portal vein cavernous transformation (PT)	10073979
	Portal fibrosis (PT)	10074726
	Stomal varices (PT)	10075186
	Gastric variceal injection (PT)	10076237
	Gastric variceal ligation (PT)	10076238
	Spontaneous intrahepatic portosystemic venous shunt (PT)	10076239
	Liver dialysis (PT)	10076640
	Hepatic steato-fibrosis (PT)	10077215
	Non-cirrhotic portal hypertension (PT)	10077259
	Splenorenal shunt procedure (PT)	10077281
	Acute on chronic liver failure (PT)	10077305
	Portal shunt procedure (PT)	10077479
	Intestinal varices haemorrhage (PT)	10078058
	Portal hypertensive colopathy (PT)	10079446
	Primary biliary cholangitis (PT)	10080429
	Regenerative siderotic hepatic nodule (PT)	10080679
	Acquired hepatocerebral degeneration (PT)	10080860
	Increased liver stiffness (PT)	10082444
	Multivisceral transplantation (PT)	10082450
	Cardiohepatic syndrome (PT)	10082480
	Sugiura procedure (PT)	10083010
	Liver transplant failure (PT)	10083175
	Immune-mediated cholangitis (PT)	10083406

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hepatotoxicity (including laboratory terms)	Immune-mediated hepatic disorder (PT)	10083521
	Splenic artery embolisation (PT)	10083795
	Hepatic perfusion disorder (PT)	10083840
	Flood syndrome (PT)	10084797
	Omental oedema (PT)	10087030
	Portal hypertensive biliopathy (PT)	10087656
Hypersensitivity	Hypersensitivity (SMQ) (narrow)	20000214
	Anaphylactic reaction (PT)	10002198
	Anaphylactic shock (PT)	10002199
	Anaphylactoid reaction (PT)	10002216
	Anaphylaxis treatment (PT)	10002222
	Angioedema (PT)	10002424
	Application site dermatitis (PT)	10003036
	Application site rash (PT)	10003054
	Atopy (PT)	10003645
	Blepharitis allergic (PT)	10005149
	Blood immunoglobulin E abnormal (PT)	10005589
	Blood immunoglobulin E increased (PT)	10005591
	Bromoderma (PT)	10006404
	Bronchospasm (PT)	10006482
	Circulatory collapse (PT)	10009192
	Conjunctival oedema (PT)	10010726
	Conjunctivitis allergic (PT)	10010744
	Contrast media reaction (PT)	10010836
	Corneal oedema (PT)	10011033
	Cross sensitivity reaction (PT)	10011411
	Cutaneous vasculitis (PT)	10011686
	Dermatitis (PT)	10012431
	Dermatitis acneiform (PT)	10012432
	Dermatitis allergic (PT)	10012434

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Dermatitis atopic (PT)	10012438
	Dermatitis bullous (PT)	10012441
	Dermatitis contact (PT)	10012442
	Dermatitis exfoliative (PT)	10012455
	Dermatitis exfoliative generalised (PT)	10012456
	Dermatitis herpetiformis (PT)	10012468
	Dermatitis infected (PT)	10012470
	Drug eruption (PT)	10013687
	Drug hypersensitivity (PT)	10013700
	Eczema (PT)	10014184
	Eczema infantile (PT)	10014198
	Eczema nummular (PT)	10014201
	Encephalopathy allergic (PT)	10014627
	Epidermolysis bullosa (PT)	10014989
	Epiglottic oedema (PT)	10015029
	Erythema multiforme (PT)	10015218
	Erythema nodosum (PT)	10015226
	Eye allergy (PT)	10015907
	Eye swelling (PT)	10015967
	Eyelid oedema (PT)	10015993
	Face oedema (PT)	10016029
	Fixed eruption (PT)	10016741
	Giant papillary conjunctivitis (PT)	10018258
	Gingival swelling (PT)	10018291
	Henoch-Schonlein purpura (PT)	10019617
	Hypersensitivity (PT)	10020751
	Hypersensitivity vasculitis (PT)	10020764
	Idiopathic urticaria (PT)	10021247
	Injection site dermatitis (PT)	10022056
	Injection site hypersensitivity (PT)	10022071
	Injection site rash (PT)	10022094
	Injection site urticaria (PT)	10022107

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Laryngeal oedema (PT)	10023845
	Laryngospasm (PT)	10023891
	Laryngotracheal oedema (PT)	10023893
	Lip oedema (PT)	10024558
	Lip swelling (PT)	10024570
	Multiple allergies (PT)	10028164
	Nephritis allergic (PT)	10029120
	Nikolsky's sign (PT)	10029415
	Oculomucocutaneous syndrome (PT)	10030081
	Oedema mouth (PT)	10030110
	Oropharyngeal spasm (PT)	10031111
	Oropharyngeal swelling (PT)	10031118
	Perioral dermatitis (PT)	10034541
	Periorbital oedema (PT)	10034545
	Pharyngeal oedema (PT)	10034829
	Radioallergosorbent test positive (PT)	10037789
	Rash (PT)	10037844
	Rash erythematous (PT)	10037855
	Rash follicular (PT)	10037857
	Rash macular (PT)	10037867
	Rash maculo-papular (PT)	10037868
	Rash morbilliform (PT)	10037870
	Rash neonatal (PT)	10037871
	Rash papulosquamous (PT)	10037879
	Rash pruritic (PT)	10037884
	Rash pustular (PT)	10037888
	Rash scarlatiniform (PT)	10037890
	Rash vesicular (PT)	10037898
	Reaction to azo-dyes (PT)	10037973
	Reaction to colouring (PT)	10037974
	Reaction to food additive (PT)	10037977
	Rhinitis allergic (PT)	10039085

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Scrotal oedema (PT)	10039755
	Serum sickness (PT)	10040400
	Serum sickness-like reaction (PT)	10040402
	Shock (PT)	10040560
	Shock symptom (PT)	10040581
	Skin necrosis (PT)	10040893
	Skin reaction (PT)	10040914
	Skin test positive (PT)	10040934
	Solar urticaria (PT)	10041307
	Solvent sensitivity (PT)	10041316
	Stevens-Johnson syndrome (PT)	10042033
	Swelling face (PT)	10042682
	Swelling of eyelid (PT)	10042690
	Swollen tongue (PT)	10042727
	Tongue oedema (PT)	10043967
	Toxic epidermal necrolysis (PT)	10044223
	Tracheal oedema (PT)	10044296
	Type I hypersensitivity (PT)	10045240
	Urticaria (PT)	10046735
	Urticaria cholinergic (PT)	10046740
	Urticaria contact (PT)	10046742
	Urticaria papular (PT)	10046750
	Urticaria physical (PT)	10046751
	Urticaria pigmentosa (PT)	10046752
	Urticaria vesiculosa (PT)	10046755
	Vaginal ulceration (PT)	10046943
	Vasculitic rash (PT)	10047111
	Vulval ulceration (PT)	10047768
	Acute generalised exanthematous pustulosis (PT)	10048799
	Urticarial vasculitis (PT)	10048820
	Allergic sinusitis (PT)	10049153
	Gingival oedema (PT)	10049305

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Rash maculovesicular (PT)	10050004
	Application site eczema (PT)	10050099
	Application site urticaria (PT)	10050104
	Vulvovaginal ulceration (PT)	10050181
	Allergic pharyngitis (PT)	10050639
	Anti-neutrophil cytoplasmic antibody positive vasculitis (PT)	10050894
	Scleritis allergic (PT)	10051126
	Allergic cystitis (PT)	10051394
	Infusion related reaction (PT)	10051792
	Iodine allergy (PT)	10052098
	Eye oedema (PT)	10052139
	Circumoral oedema (PT)	10052250
	Catheter site rash (PT)	10052271
	Catheter site urticaria (PT)	10052272
	Urticaria chronic (PT)	10052568
	Allergic bronchitis (PT)	10052613
	Epidermolysis (PT)	10053177
	Type IV hypersensitivity reaction (PT)	10053613
	Type III immune complex mediated reaction (PT)	10053614
	Allergic cough (PT)	10053779
	Type II hypersensitivity (PT)	10054000
	Allergy to vaccine (PT)	10055048
	Eczema weeping (PT)	10055182
	Allergy test positive (PT)	10056352
	Encephalitis allergic (PT)	10056387
	Periorbital swelling (PT)	10056647
	Mucocutaneous rash (PT)	10056671
	Palpable purpura (PT)	10056872
	Palatal oedema (PT)	10056998
	Allergic keratitis (PT)	10057380
	Scleral oedema (PT)	10057431

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Toxic skin eruption (PT)	10057970
	Rash rubelliform (PT)	10057984
	Dermatitis psoriasiform (PT)	10058675
	Eczema vesicular (PT)	10058681
	Hand dermatitis (PT)	10058898
	Stoma site rash (PT)	10059071
	Epidermal necrosis (PT)	10059284
	Allergic colitis (PT)	10059447
	Haemorrhagic urticaria (PT)	10059499
	Infusion site rash (PT)	10059830
	Allergic oedema (PT)	10060934
	Arthritis allergic (PT)	10061430
	Allergic otitis media (PT)	10061557
	Heparin-induced thrombocytopenia (PT)	10062506
	Dennie-Morgan fold (PT)	10062918
	Anaphylactoid shock (PT)	10063119
	Pruritus allergic (PT)	10063438
	Allergic respiratory symptom (PT)	10063527
	Allergic respiratory disease (PT)	10063532
	Application site hypersensitivity (PT)	10063683
	Implant site rash (PT)	10063786
	Implant site urticaria (PT)	10063787
	Implant site dermatitis (PT)	10063855
	Implant site hypersensitivity (PT)	10063858
	Antiallergic therapy (PT)	10064059
	Exfoliative rash (PT)	10064579
	Reaction to preservatives (PT)	10064788
	Laryngitis allergic (PT)	10064866
	Infusion site dermatitis (PT)	10065458
	Infusion site hypersensitivity (PT)	10065471
	Infusion site urticaria (PT)	10065490
	Antiendomysial antibody positive (PT)	10065514

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Eczema vaccinatum (PT)	10066042
	Allergic transfusion reaction (PT)	10066173
	Injection site eczema (PT)	10066221
	Vulval eczema (PT)	10066273
	Injection site recall reaction (PT)	10066797
	Gleich's syndrome (PT)	10066837
	Contrast media allergy (PT)	10066973
	Anaphylactic transfusion reaction (PT)	10067113
	Immediate post-injection reaction (PT)	10067142
	Oculorespiratory syndrome (PT)	10067317
	Contact stomatitis (PT)	10067510
	Oropharyngeal blistering (PT)	10067950
	Interstitial granulomatous dermatitis (PT)	10067972
	Injection site vasculitis (PT)	10067995
	Oral allergy syndrome (PT)	10068355
	Palisaded neutrophilic granulomatous dermatitis (PT)	10068809
	Vaccination site hypersensitivity (PT)	10068880
	Kounis syndrome (PT)	10069167
	Henoch-Schonlein purpura nephritis (PT)	10069440
	Vaccination site dermatitis (PT)	10069477
	Vaccination site rash (PT)	10069482
	Vaccination site exfoliation (PT)	10069489
	Vaccination site urticaria (PT)	10069622
	Vaccination site vesicles (PT)	10069623
	Administration related reaction (PT)	10069773
	Limbal swelling (PT)	10070492
	Distributive shock (PT)	10070559
	Immune tolerance induction (PT)	10070581
	Injection related reaction (PT)	10071152
	Administration site rash (PT)	10071156
	Allergic hepatitis (PT)	10071198

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Chronic hyperplastic eosinophilic sinusitis (PT)	10071380
	Chronic eosinophilic rhinosinusitis (PT)	10071399
	Vulvovaginal rash (PT)	10071588
	Device allergy (PT)	10072867
	Incision site dermatitis (PT)	10073168
	Incision site rash (PT)	10073411
	Drug reaction with eosinophilia and systemic symptoms (PT)	10073508
	Instillation site hypersensitivity (PT)	10073612
	Instillation site rash (PT)	10073622
	Instillation site urticaria (PT)	10073627
	Catheter site dermatitis (PT)	10073992
	Catheter site eczema (PT)	10073995
	Catheter site hypersensitivity (PT)	10073998
	Catheter site vasculitis (PT)	10074014
	Allergy to immunoglobulin therapy (PT)	10074079
	Pathergy reaction (PT)	10074332
	Drug provocation test (PT)	10074350
	Palatal swelling (PT)	10074403
	Stoma site hypersensitivity (PT)	10074509
	Infusion site eczema (PT)	10074850
	Infusion site vasculitis (PT)	10074851
	Allergic otitis externa (PT)	10075072
	Administration site dermatitis (PT)	10075096
	Administration site eczema (PT)	10075099
	Administration site hypersensitivity (PT)	10075102
	Administration site urticaria (PT)	10075109
	Allergic eosinophilia (PT)	10075185
	Mouth swelling (PT)	10075203
	Mast cell activation syndrome (PT)	10075217
	Allergic gastroenteritis (PT)	10075308
	Allergy alert test positive (PT)	10075479

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Medical device site dermatitis (PT)	10075572
	Medical device site eczema (PT)	10075575
	Medical device site hypersensitivity (PT)	10075579
	Medical device site rash (PT)	10075585
	Medical device site urticaria (PT)	10075588
	Nodular rash (PT)	10075807
	Administration site recall reaction (PT)	10075964
	Administration site vasculitis (PT)	10075969
	Application site recall reaction (PT)	10076024
	Application site vasculitis (PT)	10076027
	Infusion site recall reaction (PT)	10076085
	Medical device site recall reaction (PT)	10076140
	Vaccination site eczema (PT)	10076161
	Vaccination site recall reaction (PT)	10076188
	Vaccination site vasculitis (PT)	10076191
	Intestinal angioedema (PT)	10076229
	Documented hypersensitivity to administered product (PT)	10076470
	Mast cell degranulation present (PT)	10076606
	Dialysis membrane reaction (PT)	10076665
	Vessel puncture site rash (PT)	10077117
	Allergy to surgical sutures (PT)	10077279
	Vessel puncture site vesicles (PT)	10077813
	Eosinophilic granulomatosis with polyangiitis (PT)	10078117
	Symmetrical drug-related intertriginous and flexural exanthema (PT)	10078325
	Anal eczema (PT)	10078682
	Oropharyngeal oedema (PT)	10078783
	Allergic reaction to excipient (PT)	10078853
	Allergic stomatitis (PT)	10079554
	Reaction to excipient (PT)	10079925

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	Vulvovaginitis allergic (PT)	10080783
	Procedural shock (PT)	10080894
	Vernal keratoconjunctivitis (PT)	10081000
	Hypersensitivity myocarditis (PT)	10081004
	Acquired C1 inhibitor deficiency (PT)	10081035
	Atopic cough (PT)	10081492
	Circumoral swelling (PT)	10081703
	Hypersensitivity pneumonitis (PT)	10081988
	Pharyngeal swelling (PT)	10082270
	Urticarial dermatitis (PT)	10082290
	Reaction to flavouring (PT)	10082681
	Infusion related hypersensitivity reaction (PT)	10082742
	SJS-TEN overlap (PT)	10083164
	Scrotal dermatitis (PT)	10083260
	Bullous haemorrhagic dermatosis (PT)	10083809
	Immune thrombocytopenia (PT)	10083842
	Nutritional supplement allergy (PT)	10084049
	Generalised bullous fixed drug eruption (PT)	10084905
	Vascular access site dermatitis (PT)	10085938
	Vascular access site eczema (PT)	10085939
	Allergic lymphangitis (PT)	10086007
	Polymers allergy (PT)	10086347
	Reaction to sweetener (PT)	10086454
	Dermal filler reaction (PT)	10086476
	Vancomycin infusion reaction (PT)	10086737
	Periorbital dermatitis (PT)	10087203
	Bone cement allergy (PT)	10087325
	Penile dermatitis (PT)	10087419
	NSAID exacerbated respiratory disease (PT)	10087423
	Tattoo associated skin reaction (PT)	10087549
	Puncture site rash (PT)	10087940
	Systemic contact dermatitis (PT)	10087943

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Hypersensitivity	AGEP-DRESS overlap (PT)	10089003
Ischemic heart and CNS conditions	Ischaemic heart disease (SMQ) (broad)	20000043
	Myocardial infarction (SMQ) (broad)	20000047
	Acute myocardial infarction (PT)	10000891
	Angina unstable (PT)	10002388
	Blood creatine phosphokinase abnormal (PT)	10005468
	Blood creatine phosphokinase increased (PT)	10005470
	Blood creatine phosphokinase MB abnormal (PT)	10005472
	Blood creatine phosphokinase MB increased (PT)	10005474
	Coronary artery embolism (PT)	10011084
	Coronary artery occlusion (PT)	10011086
	Coronary artery thrombosis (PT)	10011091
	Electrocardiogram ST segment abnormal (PT)	10014390
	Electrocardiogram ST segment elevation (PT)	10014392
	Myocardial infarction (PT)	10028596
	Myocardial necrosis (PT)	10028602
	Papillary muscle infarction (PT)	10033697
	Vascular graft occlusion (PT)	10049060
	Electrocardiogram ST-T segment elevation (PT)	10049225
	Silent myocardial infarction (PT)	10049768
	Electrocardiogram Q wave abnormal (PT)	10051177
	Acute coronary syndrome (PT)	10051592
	Myocardial reperfusion injury (PT)	10051624
	Coronary artery reocclusion (PT)	10053261
	Postinfarction angina (PT)	10058144
	Troponin increased (PT)	10058267
	Troponin I increased (PT)	10058268
	Troponin T increased (PT)	10058269
	Coronary bypass thrombosis (PT)	10059025
	Infarction (PT)	10061216
	Scan myocardial perfusion abnormal (PT)	10061501

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Ischemic heart and CNS conditions	Electrocardiogram U wave inversion (PT)	10062314
	Vascular stent thrombosis (PT)	10063934
	Post procedural myocardial infarction (PT)	10066592
	Kounis syndrome (PT)	10069167
	Myocardial stunning (PT)	10072186
	ECG electrically inactive area (PT)	10072252
	Coronary vascular graft occlusion (PT)	10075162
	Myocardial necrosis marker increased (PT)	10075211
	ECG signs of myocardial infarction (PT)	10075299
	Cardiac ventricular scarring (PT)	10076898
	Vascular stent occlusion (PT)	10077143
	Periprocedural myocardial infarction (PT)	10079319
	Acute cardiac event (PT)	10081099
	Heart-type fatty acid-binding protein increased (PT)	10088828
	Other ischaemic heart disease (SMQ) (broad)	20000168
	Angina pectoris (PT)	10002383
	Arteriogram coronary abnormal (PT)	10003201
	Arteriosclerosis coronary artery (PT)	10003211
	Arteriospasm coronary (PT)	10003225
	Coronary artery bypass (PT)	10011077
	Coronary artery disease (PT)	10011078
	Coronary artery stenosis (PT)	10011089
	Coronary artery surgery (PT)	10011090
	Coronary endarterectomy (PT)	10011101
	Coronary ostial stenosis (PT)	10011105
	Electrocardiogram ST segment depression (PT)	10014391
	Electrocardiogram T wave inversion (PT)	10014395
	Exercise electrocardiogram abnormal (PT)	10015645
	Exercise test abnormal (PT)	10015653
	Myocardial ischaemia (PT)	10028600
	Prinzmetal angina (PT)	10036759

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Ischemic heart and CNS conditions	Coronary artery dissection (PT)	10048631
	Ischaemic cardiomyopathy (PT)	10048858
	Electrocardiogram ST-T segment depression (PT)	10049224
	Coronary revascularisation (PT)	10049887
	Coronary angioplasty (PT)	10050329
	Electrocardiogram T wave abnormal (PT)	10050380
	Coronary arterial stent insertion (PT)	10052086
	Electrocardiogram ST-T segment abnormal (PT)	10052333
	Coronary artery insufficiency (PT)	10052895
	Cardiac stress test abnormal (PT)	10055014
	Haemorrhage coronary artery (PT)	10055803
	Coronary artery restenosis (PT)	10056489
	Subendocardial ischaemia (PT)	10058145
	ECG signs of myocardial ischaemia (PT)	10058317
	Cardiovascular event prophylaxis (PT)	10064939
	Subclavian coronary steal syndrome (PT)	10064994
	Percutaneous coronary intervention (PT)	10065608
	Stress cardiomyopathy (PT)	10066286
	External counterpulsation (PT)	10067876
	Coronary no-reflow phenomenon (PT)	10068534
	Stress echocardiogram abnormal (PT)	10070746
	Microvascular coronary artery disease (PT)	10072685
	Cardiopulmonary exercise test abnormal (PT)	10074359
	Anginal equivalent (PT)	10076419
	Coronary brachytherapy (PT)	10076627
	Vascular stent stenosis (PT)	10077144
	Post angioplasty restenosis (PT)	10077146
	Coronary vascular graft stenosis (PT)	10077334
	Coronary bypass stenosis (PT)	10077824
	Ischaemic mitral regurgitation (PT)	10077864
	Myocardial hypoxia (PT)	10078980
	Wall motion score index abnormal (PT)	10079016

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Ischemic heart and CNS conditions	Coronary artery compression (PT)	10079589
	Wellens' syndrome (PT)	10080787
	Diabetic coronary microangiopathy (PT)	10080788
	Electrocardiogram PR segment depression (PT)	10081493
	Restenosis (PT)	10082493
	Elastic vessel recoil complication (PT)	10082504
	Myocardial hypoperfusion (PT)	10082580
	Cardiac perfusion defect (PT)	10083602
	Coronary steal syndrome (PT)	10084081
	Arterial revascularisation (PT)	10084482
	Chronic coronary syndrome (PT)	10085242
	Computerised tomogram heart abnormal (PT)	10088902
	Ischaemic central nervous system vascular conditions (SMQ)	20000063
	Amaurosis fugax (PT)	10001903
	Basilar artery stenosis (PT)	10004163
	Brain hypoxia (PT)	10006127
	Brain stem infarction (PT)	10006147
	Brain stem ischaemia (PT)	10006148
	Carotid arterial embolus (PT)	10007684
	Carotid artery stenosis (PT)	10007687
	Carotid artery thrombosis (PT)	10007688
	Carotid endarterectomy (PT)	10007692
	Cerebellar artery thrombosis (PT)	10008023
	Cerebellar infarction (PT)	10008034
	Cerebral artery embolism (PT)	10008088
	Cerebral artery occlusion (PT)	10008089
	Cerebral artery thrombosis (PT)	10008092
	Cerebral infarction (PT)	10008118
	Cerebral infarction foetal (PT)	10008119
	Cerebral ischaemia (PT)	10008120
	Cerebral thrombosis (PT)	10008132

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Ischemic heart and CNS conditions	Cerebral venous thrombosis (PT)	10008138
	Cerebrovascular accident (PT)	10008190
	Cerebrovascular disorder (PT)	10008196
	Embolic stroke (PT)	10014498
	Lateral medullary syndrome (PT)	10024033
	Moyamoya disease (PT)	10028047
	Precerebral artery occlusion (PT)	10036511
	Subclavian steal syndrome (PT)	10042335
	Thrombotic stroke (PT)	10043647
	Transient ischaemic attack (PT)	10044390
	Vertebral artery stenosis (PT)	10047330
	Vertebrobasilar insufficiency (PT)	10047334
	Basilar artery occlusion (PT)	10048963
	Carotid artery occlusion (PT)	10048964
	Vertebral artery occlusion (PT)	10048965
	Spinal artery embolism (PT)	10049440
	Spinal cord ischaemia (PT)	10050209
	Reversible ischaemic neurological deficit (PT)	10050496
	Lacunar infarction (PT)	10051078
	Carotid artery bypass (PT)	10053003
	Cerebellar artery occlusion (PT)	10053633
	Migrainous infarction (PT)	10056237
	Vertebral artery thrombosis (PT)	10057777
	Spinal cord infarction (PT)	10058571
	Cerebrovascular insufficiency (PT)	10058842
	Cerebral vasoconstriction (PT)	10059109
	Stroke in evolution (PT)	10059613
	Embolic cerebral infarction (PT)	10060839
	Ischaemic cerebral infarction (PT)	10060840
	Ischaemic stroke (PT)	10061256
	Carotid artery disease (PT)	10061744
	Cerebrovascular stenosis (PT)	10061751

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Ischemic heart and CNS conditions	Brain stem thrombosis (PT)	10062573
	Basilar artery thrombosis (PT)	10063093
	Cerebral artery stenosis (PT)	10063648
	Vascular encephalopathy (PT)	10063661
	Carotid artery insufficiency (PT)	10064949
	Thalamic infarction (PT)	10064961
	CADASIL (PT)	10065555
	Cerebral arteriosclerosis (PT)	10065559
	Carotid artery stent insertion (PT)	10066102
	Post procedural stroke (PT)	10066591
	Carotid arteriosclerosis (PT)	10067116
	Cerebellar embolism (PT)	10067167
	Thrombotic cerebral infarction (PT)	10067347
	Millard-Gubler syndrome (PT)	10067462
	Capsular warning syndrome (PT)	10067744
	Cerebellar ischaemia (PT)	10068621
	Brain stem stroke (PT)	10068644
	Basal ganglia infarction (PT)	10069020
	Brachiocephalic artery occlusion (PT)	10069694
	Carotid artery stent removal (PT)	10069952
	Hypoxic-ischaemic encephalopathy (PT)	10070511
	Cerebral septic infarct (PT)	10070671
	Inner ear infarction (PT)	10070754
	Cerebral gas embolism (PT)	10070813
	Cerebral small vessel ischaemic disease (PT)	10070878
	Basal ganglia stroke (PT)	10071043
	Carotid angioplasty (PT)	10071260
	Spinal artery thrombosis (PT)	10071316
	Cerebral revascularisation (PT)	10071508
	Carotid artery restenosis (PT)	10072558
	Carotid revascularisation (PT)	10072559
	Reversible cerebral vasoconstriction syndrome	10073240

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Safety topic	MedDRA term selection of adverse events	MedDRA code
	(PT)	
	Perinatal stroke (PT)	10073945
	Brain stem embolism (PT)	10074422
	Precerebral artery thrombosis (PT)	10074717
	Cerebral artery restenosis (PT)	10075423
	Brachiocephalic arteriosclerosis (PT)	10075449
	Brachiocephalic artery stenosis (PT)	10075450
	Cerebral vascular occlusion (PT)	10076895
	Lacunar stroke (PT)	10076994
	Precerebral arteriosclerosis (PT)	10077033
	Post cardiac arrest syndrome (PT)	10078202
	Cerebral microembolism (PT)	10078311
	Delayed ischaemic neurological deficit (PT)	10078388
	Cerebellar stroke (PT)	10079062
	Brain stent insertion (PT)	10080887
	CARASIL syndrome (PT)	10081315
	Cerebral artery stent insertion (PT)	10081893
	Spinal stroke (PT)	10082031
	Vertebrobasilar stroke (PT)	10082484
	Foville syndrome (PT)	10082594
	Internal capsule infarction (PT)	10083408
	Cerebral microinfarction (PT)	10083668
	Embolitic cerebellar infarction (PT)	10084072
	Vertebral artery arteriosclerosis (PT)	10084347
	Cerebellar atherosclerosis (PT)	10084736
	Precerebral artery embolism (PT)	10085250
	Claude's syndrome (PT)	10085447
	Weber's syndrome (PT)	10085448
	Benedikt's syndrome (PT)	10085451
	Pseudo-occlusion of internal carotid artery (PT)	10085779
	Cerebral angioplasty (PT)	10087440
	Thalamic stroke (PT)	10087626

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Myelosuppression (Erythropenia)	Haematopoietic erythropenia (SMQ) (broad)	20000029
	Anaemia (PT)	10002034
	Anaemia macrocytic (PT)	10002064
	Anaemia neonatal (PT)	10002068
	Aplasia pure red cell (PT)	10002965
	Aplastic anaemia (PT)	10002967
	Erythroid maturation arrest (PT)	10015279
	Erythropenia (PT)	10015287
	Haematocrit decreased (PT)	10018838
	Haemoglobin abnormal (PT)	10018879
	Haemoglobin decreased (PT)	10018884
	Hypoplastic anaemia (PT)	10021074
	Microcytic anaemia (PT)	10027538
	Normochromic anaemia (PT)	10029782
	Normochromic normocytic anaemia (PT)	10029783
	Normocytic anaemia (PT)	10029784
	Red blood cell count abnormal (PT)	10038151
	Red blood cell count decreased (PT)	10038153
	Reticulocyte count abnormal (PT)	10038788
	Reticulocyte count decreased (PT)	10038790
	Reticulocytopenia (PT)	10038795
	Haematocrit abnormal (PT)	10049221
	Erythropoiesis abnormal (PT)	10049467
	Leukoerythroblastic anaemia (PT)	10053199
	Erythroblast count decreased (PT)	10058505
	Erythroblast count abnormal (PT)	10058508
	Reticulocyte percentage decreased (PT)	10059921
	Proerythroblast count abnormal (PT)	10060227
	Proerythroblast count decreased (PT)	10060229
	Foetal anaemia (PT)	10077577
	Erythroid dysplasia (PT)	10086470

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Myelosuppression (Leucopenia)	Haematopoietic leukopenia (SMQ) (narrow)	20000030
	Agranulocytosis (PT)	10001507
	Basophil count decreased (PT)	10004167
	Eosinopenia (PT)	10014940
	Eosinophil count decreased (PT)	10014943
	Febrile neutropenia (PT)	10016288
	Granulocyte count decreased (PT)	10018681
	Granulocytopenia (PT)	10018687
	Leukopenia (PT)	10024384
	Lymphocyte count decreased (PT)	10025256
	Lymphopenia (PT)	10025327
	Monocyte count decreased (PT)	10027878
	Monocytopenia (PT)	10027905
	Neutropenia (PT)	10029354
	Neutrophil count decreased (PT)	10029366
	White blood cell count decreased (PT)	10047942
	Neutropenic sepsis (PT)	10049151
	Granulocytes maturation arrest (PT)	10050443
	Myeloblast count decreased (PT)	10050961
	Metamyelocyte count decreased (PT)	10050984
	Myelocyte count decreased (PT)	10050986
	Promyelocyte count decreased (PT)	10050987
	B-lymphocyte count decreased (PT)	10051313
	T-lymphocyte count decreased (PT)	10051318
	Idiopathic neutropenia (PT)	10051645
	Cyclic neutropenia (PT)	10053176
	Band neutrophil count decreased (PT)	10057950
	Monoblast count decreased (PT)	10058772
	Band neutrophil percentage decreased (PT)	10059130
	Neutropenic infection (PT)	10059482
	CD19 lymphocytes decreased (PT)	10064428
	Radiation leukopenia (PT)	10067354

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Myelosuppression (Leucopenia)	Pure white cell aplasia (PT)	10068043
	Basophilopenia (PT)	10075813
	Granulocyte percentage decreased (PT)	10085996
	Radiation neutropenia (PT)	10087412
Myelosuppression (Neutropenia)	ADR_Neutropenia (CMQ)	90012523
	Neutropenia (PT)	10029354
	Neutrophil count decreased (PT)	10029366
Myelosuppression (Thrombocytopenia)	Haematopoietic thrombocytopenia (SMQ) (narrow)	20000031
	Megakaryocytes decreased (PT)	10027119
	Platelet count decreased (PT)	10035528
	Platelet maturation arrest (PT)	10035537
	Platelet production decreased (PT)	10035540
	Thrombocytopenia (PT)	10043554
	Platelet toxicity (PT)	10059440
	Acquired amegakaryocytic thrombocytopenia (PT)	10076747
	Radiation thrombocytopenia (PT)	10087413
Myelosuppression (cytopenias affecting more than one lineage)	Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) (narrow)	20000028
	Aplastic anaemia (PT)	10002967
	Full blood count decreased (PT)	10017413
	Myelosuppression (PT)	10028584
	Pancytopenia (PT)	10033661
	Panmyelopathy (PT)	10050026
	Febrile bone marrow aplasia (PT)	10053213
	Bicytopenia (PT)	10058956
	Bone marrow failure (PT)	10065553
	Cytopenia (PT)	10066274
	Autoimmune aplastic anaemia (PT)	10071576
	Gelatinous transformation of the bone marrow	10078097

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Safety topic	MedDRA term selection of adverse events	MedDRA code
more than one lineage)	(PT) Immune-mediated cytopenia (PT)	10084828
Pancreatic toxicity (clinical events)	Acute pancreatitis (SMQ) (narrow) Pancreatic haemorrhage (PT) Pancreatic pseudocyst (PT) Pancreatic pseudocyst drainage (PT) Pancreatitis (PT) Pancreatitis acute (PT) Pancreatitis haemorrhagic (PT) Pancreatitis necrotising (PT) Pancreatitis relapsing (PT) Pancreatic abscess (PT) Oedematous pancreatitis (PT) Pancreatorenal syndrome (PT) Pancreatic phlegmon (PT) Cullen's sign (PT) Ischaemic pancreatitis (PT) Grey Turner's sign (PT) Haemorrhagic necrotic pancreatitis (PT) Pancreatic pseudoaneurysm (PT) Pancreatic cyst drainage (PT) Immune-mediated pancreatitis (PT) Pancreatic pseudocyst rupture (PT) Pancreatic pseudocyst haemorrhage (PT) Subacute pancreatitis (PT) Walled-off pancreatic necrosis (PT) Idiopathic pancreatitis (PT)	20000022 10033625 10033635 10033636 10033645 10033647 10033650 10033654 10033657 10048984 10052400 10056277 10056975 10059029 10066127 10075426 10076058 10081762 10082531 10083072 10083811 10083813 10084554 10085347 10088882
Phototoxicity	Photosensitivity reactions (NMQ) Juvenile spring eruption (PT) Photoonycholysis (PT)	90000921 10023269 10034959

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Phototoxicity	Photosensitivity reaction (PT)	10034972
	Polymorphic light eruption (PT)	10036087
	Pseudoporphyria (PT)	10037145
	Solar dermatitis (PT)	10041303
	Solar urticaria (PT)	10041307
	Sunburn (PT)	10042496
	Photodermatosis (PT)	10051246
	Injection site photosensitivity reaction (PT)	10053396
	Application site photosensitivity reaction (PT)	10058730
	Infusion site photosensitivity reaction (PT)	10065486
	Retinal phototoxicity (PT)	10069652
	Chronic actinic dermatitis (PT)	10072578
	Implant site photosensitivity (PT)	10073415
	Hydroa vacciniforme (PT)	10083442
QTc prolongation	Torsade de pointes/QT prolongation (SMQ) (broad)	20000001
	Cardiac arrest (PT)	10007515
	Cardio-respiratory arrest (PT)	10007617
	Electrocardiogram QT prolonged (PT)	10014387
	Long QT syndrome (PT)	10024803
	Loss of consciousness (PT)	10024855
	Sudden death (PT)	10042434
	Syncope (PT)	10042772
	Torsade de pointes (PT)	10044066
	Ventricular arrhythmia (PT)	10047281
	Ventricular fibrillation (PT)	10047290
	Ventricular flutter (PT)	10047294
	Ventricular tachycardia (PT)	10047302
	Sudden cardiac death (PT)	10049418
	Cardiac death (PT)	10049993
	Electrocardiogram repolarisation abnormality (PT)	10052464

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Safety topic	MedDRA term selection of adverse events	MedDRA code
QTc prolongation	Electrocardiogram U-wave abnormality (PT)	10055032
	Electrocardiogram U wave present (PT)	10057913
	Long QT syndrome congenital (PT)	10057926
	Cardiac fibrillation (PT)	10061592
	Electrocardiogram U wave inversion (PT)	10062314
	Electrocardiogram QT interval abnormal (PT)	10063748
	Ventricular tachyarrhythmia (PT)	10065341
	Arrhythmic storm (PT)	10067339
Reproductive toxicity	Pregnancy and neonatal topics (SMQ) (broad)	20000185
	Congenital, familial and genetic disorders (SMQ) (broad)	20000077
	11-beta-hydroxylase deficiency (PT)	10000002
	17,20-desmolase deficiency (PT)	10000013
	17-alpha-hydroxylase deficiency (PT)	10000014
	20,22-desmolase deficiency (PT)	10000020
	21-hydroxylase deficiency (PT)	10000021
	5-alpha-reductase deficiency (PT)	10000029
	Abdominal transposition (PT)	10000098
	Abdominal wall anomaly (PT)	10000101
	Abnormal palmar/plantar creases (PT)	10000162
	ABO haemolytic disease of newborn (PT)	10000205
	Accessory auricle (PT)	10000361
	Accessory carpal bone (PT)	10000362
	Accessory muscle (PT)	10000364
	Accessory salivary gland (PT)	10000368
	Acrocephalosyndactyly (PT)	10000590
	Acrodermatitis enteropathica (PT)	10000596
	Adrenal insufficiency neonatal (PT)	10001368
	Aglossia (PT)	10001501
	Albinism (PT)	10001557
	Alkaptonuria (PT)	10001689

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Alport's syndrome (PT)	10001843
	Amblyopia congenital (PT)	10001908
	Aminoaciduria (PT)	10001939
	Anal atresia (PT)	10002120
	Anencephaly (PT)	10002320
	Aniridia (PT)	10002532
	Anodontia (PT)	10002583
	Anomaly of orbit, congenital (PT)	10002633
	Anophthalmos (PT)	10002640
	Anorchism (PT)	10002641
	Anotia (PT)	10002654
	Antithrombin III deficiency (PT)	10002832
	Aphakia congenital (PT)	10002947
	Aplasia (PT)	10002961
	Aplasia cutis congenita (PT)	10002963
	Arnold-Chiari malformation (PT)	10003101
	Arteriovenous malformation (PT)	10003193
	Ataxia telangiectasia (PT)	10003594
	Atrial septal defect (PT)	10003664
	Benign familial pemphigus (PT)	10004265
	Bicuspid aortic valve (PT)	10004552
	Birth mark (PT)	10004950
	Blindness congenital (PT)	10005176
	Branchial cleft sinus (PT)	10006162
	Branchial cyst (PT)	10006164
	Breast malformation (PT)	10006271
	Carcinogenic effect in offspring (PT)	10007268
	Cardiac malposition (PT)	10007585
	Carpus curvus (PT)	10007700
	Cataract congenital (PT)	10007747
	Central nervous system dermoid tumour (PT)	10007942
	Cerebellar hypoplasia (PT)	10008033

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Cerebral arteriovenous malformation haemorrhagic (PT)	10008086
	Cerebral palsy (PT)	10008129
	Cervical auricle (PT)	10008227
	Chediak-Higashi syndrome (PT)	10008415
	Choanal atresia (PT)	10008587
	Chondroectodermal dysplasia (PT)	10008724
	Chordee (PT)	10008746
	Chorioretinal degeneration congenital (PT)	10008763
	Chronic granulomatous disease (PT)	10008906
	Cleft lip (PT)	10009259
	Cleft lip and palate (PT)	10009260
	Cleft palate (PT)	10009269
	Coarctation of the aorta (PT)	10009807
	Cockayne's syndrome (PT)	10009835
	Collodion baby (PT)	10009926
	Coloboma (PT)	10009934
	Colour blindness (PT)	10010050
	Combined immunodeficiency (PT)	10010099
	Congenital absence of bile ducts (PT)	10010317
	Congenital absence of cranial vault (PT)	10010318
	Congenital absence of vertebra (PT)	10010320
	Congenital anaemia (PT)	10010329
	Congenital anomalies of ear ossicles (PT)	10010341
	Congenital anomaly (PT)	10010356
	Congenital aortic atresia (PT)	10010368
	Congenital aortic stenosis (PT)	10010369
	Congenital aortic valve incompetence (PT)	10010370
	Congenital aortic valve stenosis (PT)	10010371
	Congenital arteriovenous fistula (PT)	10010374
	Congenital bladder diverticulum (PT)	10010381
	Congenital bladder neck obstruction (PT)	10010382

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital brain damage (PT)	10010390
	Congenital bronchiectasis (PT)	10010391
	Congenital bronchomalacia (PT)	10010392
	Congenital central nervous system anomaly (PT)	10010411
	Congenital clavicular agenesis (PT)	10010416
	Congenital claw toe (PT)	10010417
	Congenital cystic kidney disease (PT)	10010428
	Congenital cytomegalovirus infection (PT)	10010430
	Congenital deformity of clavicle (PT)	10010434
	Congenital diaphragmatic eventration (PT)	10010438
	Congenital diaphragmatic hernia (PT)	10010439
	Congenital ectodermal dysplasia (PT)	10010452
	Congenital ectopic bladder (PT)	10010453
	Congenital elevation of scapula (PT)	10010455
	Congenital emphysema (PT)	10010456
	Congenital facial diplegia (PT)	10010466
	Congenital flaccid paralysis (PT)	10010474
	Congenital flat feet (PT)	10010475
	Congenital genital malformation female (PT)	10010481
	Congenital hearing disorder (PT)	10010493
	Congenital hepatitis B infection (PT)	10010496
	Congenital hiatus hernia (PT)	10010501
	Congenital HIV infection (PT)	10010504
	Congenital hydrocephalus (PT)	10010506
	Congenital hypertrichosis (PT)	10010507
	Congenital hypothyroidism (PT)	10010510
	Congenital knee dislocation (PT)	10010520
	Congenital lacrimal gland anomaly (PT)	10010523
	Congenital large intestinal atresia (PT)	10010526
	Congenital laryngeal stridor (PT)	10010527
	Congenital lip fistula (PT)	10010532
	Congenital lymphoedema (PT)	10010535

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital malaria (PT)	10010538
	Congenital megacolon (PT)	10010539
	Congenital megaureter (PT)	10010540
	Congenital melanosis (PT)	10010541
	Congenital methaemoglobinaemia (PT)	10010543
	Congenital mitral valve incompetence (PT)	10010547
	Congenital mitral valve stenosis (PT)	10010548
	Congenital muscle absence (PT)	10010550
	Congenital nail disorder (PT)	10010557
	Congenital neurological degeneration (PT)	10010558
	Congenital night blindness (PT)	10010559
	Congenital nystagmus (PT)	10010562
	Congenital oesophageal stenosis (PT)	10010564
	Congenital oesophageal web (PT)	10010565
	Congenital osteodystrophy (PT)	10010582
	Congenital perforated nasal septum (PT)	10010588
	Congenital pigmentation disorder (PT)	10010593
	Congenital pneumonia (PT)	10010594
	Congenital renal cyst (PT)	10010607
	Congenital rubella infection (PT)	10010619
	Congenital salivary gland anomaly (PT)	10010620
	Congenital small intestinal atresia (PT)	10010626
	Congenital spinal fusion (PT)	10010629
	Congenital spondylolisthesis (PT)	10010633
	Congenital spondylolysis (PT)	10010634
	Congenital syphilis (PT)	10010641
	Congenital syphilitic encephalitis (PT)	10010643
	Congenital syphilitic meningitis (PT)	10010644
	Congenital torticollis (PT)	10010650
	Congenital toxoplasmosis (PT)	10010652
	Congenital tracheomalacia (PT)	10010654
	Congenital tricuspid valve stenosis (PT)	10010656

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital tuberculosis (PT)	10010657
	Congenital umbilical hernia (PT)	10010658
	Congenital urinary tract obstruction (PT)	10010663
	Congenital varicella infection (PT)	10010668
	Congenital vas deferens absence (PT)	10010670
	Congenital vesicoureteric reflux (PT)	10010672
	Conjoined twins (PT)	10010688
	Conjunctivitis gonococcal neonatal (PT)	10010749
	Cor biloculare (PT)	10010967
	Cor triatriatum (PT)	10010972
	Corneal dystrophy (PT)	10011005
	Corneal opacity congenital (PT)	10011037
	Corrected transposition of great vessels (PT)	10011120
	Craniorachischisis (PT)	10011321
	Cri du Chat syndrome (PT)	10011385
	Crigler-Najjar syndrome (PT)	10011386
	Cryptophthalmos (PT)	10011497
	Cryptorchism (PT)	10011498
	Cystic eyeball, congenital (PT)	10011761
	Cystic fibrosis (PT)	10011762
	Cystic fibrosis lung (PT)	10011763
	Cystic fibrosis pancreatic (PT)	10011766
	Cystinosis (PT)	10011777
	Cystinuria (PT)	10011778
	Dacryostenosis congenital (PT)	10011850
	Deaf mutism (PT)	10011875
	Deafness congenital (PT)	10011882
	Delta-beta thalassaemia (PT)	10012236
	Dentofacial anomaly (PT)	10012331
	Dermoid cyst (PT)	10012522
	Developmental glaucoma (PT)	10012565
	Dextrocardia (PT)	10012592

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Diaphragmatic aplasia (PT)	10012711
	Diastematomyelia (PT)	10012750
	Diethylstilboestrol syndrome (PT)	10012780
	DiGeorge's syndrome (PT)	10012979
	Dilatation intrahepatic duct congenital (PT)	10013003
	Diverticulitis Meckel's (PT)	10013542
	Diverticulum of pharynx, congenital (PT)	10013568
	Double heterozygous sickling disorders (PT)	10013609
	Double outlet right ventricle (PT)	10013611
	Double ureter (PT)	10013613
	Duane's syndrome (PT)	10013799
	Dubin-Johnson syndrome (PT)	10013800
	Duchenne muscular dystrophy (PT)	10013801
	Ductus arteriosus stenosis foetal (PT)	10013808
	Duodenal atresia (PT)	10013812
	Dysplastic naevus syndrome (PT)	10013960
	Ear malformation (PT)	10014016
	Ebstein's anomaly (PT)	10014075
	Ectopia cordis (PT)	10014144
	Ectopic ureter (PT)	10014172
	Ehlers-Danlos syndrome (PT)	10014316
	Elliptocytosis hereditary (PT)	10014490
	Encephalocele (PT)	10014617
	Endocardial fibroelastosis (PT)	10014663
	Entropion congenital (PT)	10014923
	Epidermal naevus (PT)	10014985
	Epidermolysis bullosa (PT)	10014989
	Epilepsy congenital (PT)	10015039
	Epispadias (PT)	10015088
	Erythroblastosis foetalis (PT)	10015251
	Essential fructosuria (PT)	10015487
	Exomphalos (PT)	10015677

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Eyelid ptosis congenital (PT)	10015996
	Fabry's disease (PT)	10016016
	Factor I deficiency (PT)	10016075
	Factor II deficiency (PT)	10016076
	Factor IX deficiency (PT)	10016077
	Factor VII deficiency (PT)	10016079
	Factor VIII deficiency (PT)	10016080
	Factor XI deficiency (PT)	10016082
	Factor XIII deficiency (PT)	10016083
	Fallot's tetralogy (PT)	10016193
	Familial amyloidosis (PT)	10016202
	Familial mediterranean fever (PT)	10016207
	Familial periodic paralysis (PT)	10016208
	Familial polycythaemia (PT)	10016209
	Familial tremor (PT)	10016212
	Fanconi syndrome (PT)	10016219
	Fibrous dysplasia of bone (PT)	10016664
	Fissure of tongue, congenital (PT)	10016715
	Foetal alcohol syndrome (PT)	10016845
	Fragile X syndrome (PT)	10017324
	Friedreich's ataxia (PT)	10017374
	Galactosaemia (PT)	10017604
	Gastrointestinal arteriovenous malformation (PT)	10017932
	Gastroschisis (PT)	10018046
	Gaucher's disease (PT)	10018048
	Generalised resistance to thyroid hormone (PT)	10018096
	Genitalia external ambiguous (PT)	10018183
	Gilbert's syndrome (PT)	10018267
	Glanzmann's disease (PT)	10018303
	Glucose-6-phosphate dehydrogenase deficiency (PT)	10018444
	Glycogen storage disease type V (PT)	10018462

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Glycogen storage disease type I (PT)	10018464
	Goitre congenital (PT)	10018499
	Gonadal dysgenesis (PT)	10018504
	Haemangioma congenital (PT)	10018818
	Haemangioma of retina (PT)	10018822
	Haemoglobin C disease (PT)	10018883
	Hamartoma vascular (PT)	10019106
	Harlequin foetus (PT)	10019163
	Hartnup disease (PT)	10019165
	Heart block congenital (PT)	10019263
	Heart disease congenital (PT)	10019273
	Hemihypertrophy (PT)	10019463
	Hemivertebra (PT)	10019477
	Hepatic arteriovenous malformation (PT)	10019633
	Hepato-lenticular degeneration (PT)	10019819
	Hereditary angioedema (PT)	10019860
	Hereditary choroidal dystrophy (PT)	10019864
	Hereditary fructose intolerance (PT)	10019878
	Hereditary haemorrhagic telangiectasia (PT)	10019883
	Hereditary neuropathic amyloidosis (PT)	10019889
	Hereditary optic atrophy (PT)	10019895
	Hereditary retinal dystrophy (PT)	10019899
	Hereditary sideroblastic anaemia (PT)	10019902
	Hereditary spastic paraplegia (PT)	10019903
	Hereditary spherocytosis (PT)	10019904
	Hermaphroditism (PT)	10019906
	Hernia congenital (PT)	10019912
	Congenital herpes simplex infection (PT)	10019949
	Hexokinase deficiency anaemia (PT)	10020022
	High arched palate (PT)	10020046
	Homocystinuria (PT)	10020365
	Hydrocele (PT)	10020488

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Hypermobility syndrome (PT)	10020677
	Hypertrophic cardiomyopathy (PT)	10020871
	Hypochondroplasia (PT)	10020967
	Hypopituitarism foetal (PT)	10021068
	Hypoplastic left heart syndrome (PT)	10021076
	Hypospadias (PT)	10021093
	Ichthyosis (PT)	10021198
	Immunodeficiency congenital (PT)	10021450
	Imperforate hymen (PT)	10021529
	Imperforate oesophagus (PT)	10021530
	Iniencephaly (PT)	10022034
	Interruption of aortic arch (PT)	10022599
	Intestinal transposition (PT)	10022712
	Keratosis follicular (PT)	10023369
	Kidney duplex (PT)	10023416
	Kidney malformation (PT)	10023430
	Klinefelter's syndrome (PT)	10023463
	Klippel-Feil syndrome (PT)	10023464
	Krabbe's disease (PT)	10023492
	Lacrimal punctum agenesis (PT)	10023636
	Laryngeal web (PT)	10023871
	Laryngocele (PT)	10023885
	Lens abnormality, congenital (PT)	10024202
	Leukodystrophy (PT)	10024381
	Lichen spinulosus (PT)	10024436
	Limb reduction defect (PT)	10024503
	Lipidosis (PT)	10024585
	Low set ears (PT)	10024929
	Lown-Ganong-Levine syndrome (PT)	10024984
	Macrocheilia (PT)	10025378
	Macroductyly (PT)	10025386
	Macrogenia (PT)	10025387

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Macroglossia (PT)	10025391
	Macrostomia (PT)	10025395
	Macrotia (PT)	10025396
	Macular dystrophy congenital (PT)	10025412
	Malformation biliary (PT)	10025523
	Malformation venous (PT)	10025532
	Maple syrup disease (PT)	10026817
	Marfan's syndrome (PT)	10026829
	Melkersson-Rosenthal syndrome (PT)	10027166
	Meningocele (PT)	10027266
	Meningomyelocele (PT)	10027287
	Menkes' syndrome (PT)	10027294
	Mesonephric duct cyst (PT)	10027405
	Metatarsus primus varus (PT)	10027489
	Microcephaly (PT)	10027534
	Microcheilia (PT)	10027535
	Microgenia (PT)	10027541
	Microglossia (PT)	10027542
	Micrognathia (PT)	10027543
	Microphthalmos (PT)	10027548
	Microstomia (PT)	10027553
	Microtia (PT)	10027555
	Mitochondrial myopathy (PT)	10027710
	Morning glory syndrome (PT)	10027974
	Mucopolysaccharidosis (PT)	10028093
	Mucopolysaccharidosis IV (PT)	10028095
	Multiple carboxylase deficiency (PT)	10028176
	Multiple cardiac defects (PT)	10028178
	Multiple congenital abnormalities (PT)	10028182
	Multiple epiphyseal dysplasia (PT)	10028197
	Muscular dystrophy (PT)	10028356
	Mutagenic effect (PT)	10028400

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Myotonia congenita (PT)	10028655
	Neonatal leukaemia (PT)	10028958
	Neurofibromatosis (PT)	10029268
	Niemann-Pick disease (PT)	10029403
	Noonan syndrome (PT)	10029748
	Oesophageal atresia (PT)	10030146
	Osteogenesis imperfecta (PT)	10031243
	Osteopetrosis (PT)	10031280
	Osteopoikilosis (PT)	10031281
	Ovarian agenesis (PT)	10033120
	Patent ductus arteriosus (PT)	10034130
	Pectus carinatum (PT)	10034203
	Pectus excavatum (PT)	10034204
	Pelvic kidney (PT)	10034259
	Persistent foetal circulation (PT)	10034708
	Peutz-Jeghers syndrome (PT)	10034764
	Phenylketonuria (PT)	10034872
	Phimosis (PT)	10034878
	Poland's syndrome (PT)	10036007
	Polydactyly (PT)	10036063
	Porencephaly (PT)	10036172
	Porokeratosis (PT)	10036175
	Porphyria (PT)	10036181
	Porphyria acute (PT)	10036182
	Porphyria non-acute (PT)	10036186
	Porphyrinuria (PT)	10036193
	Postauricular fistula (PT)	10036329
	Potter's syndrome (PT)	10036462
	Prader-Willi syndrome (PT)	10036476
	Preauricular cyst (PT)	10036509
	Primary cerebellar degeneration (PT)	10036686
	Progeria (PT)	10036794

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Progressive cerebellar degeneration (PT)	10036801
	Progressive external ophthalmoplegia (PT)	10036802
	Pseudohermaphroditism (PT)	10037122
	Pseudohermaphroditism female (PT)	10037123
	Pseudohermaphroditism male (PT)	10037124
	Pseudohypoparathyroidism (PT)	10037126
	Pseudoxanthoma elasticum (PT)	10037150
	Pulmonary aplasia (PT)	10037322
	Pulmonary arteriovenous fistula (PT)	10037332
	Pulmonary artery atresia (PT)	10037337
	Pulmonary artery stenosis congenital (PT)	10037339
	Pulmonary hypoplasia (PT)	10037407
	Pulmonary malformation (PT)	10037419
	Pulmonary valve stenosis congenital (PT)	10037451
	Pyloric stenosis (PT)	10037621
	Pyruvate kinase deficiency anaemia (PT)	10037682
	Rectal atresia (PT)	10038031
	Refsum's disease (PT)	10038275
	Renal arteriovenous malformation (PT)	10038368
	Renal dysplasia (PT)	10038433
	Renal vessel congenital anomaly (PT)	10038552
	Respiratory tract malformation (PT)	10038733
	Retinal anomaly congenital (PT)	10038821
	Retinal arteriovenous malformation (PT)	10038824
	Retinitis pigmentosa (PT)	10038914
	Retinoschisis congenital (PT)	10038938
	Rhesus haemolytic disease of newborn (PT)	10039037
	Riley-Day syndrome (PT)	10039179
	Rotor's syndrome (PT)	10039234
	Rubinstein-Taybi syndrome (PT)	10039281
	Sebaceous naevus (PT)	10039785
	Sensory neuropathy hereditary (PT)	10040037

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Sickle cell anaemia (PT)	10040641
	Sickle cell disease (PT)	10040644
	Sickle cell trait (PT)	10040650
	Skin hypoplasia (PT)	10040869
	Skin malformation (PT)	10040888
	Special senses congenital anomaly (PT)	10041420
	Spherophakia (PT)	10041513
	Spina bifida (PT)	10041524
	Spina bifida occulta (PT)	10041525
	Spinal muscular atrophy (PT)	10041582
	Spinal vessel congenital anomaly (PT)	10041603
	Strabismus congenital (PT)	10042161
	Sturge-Weber syndrome (PT)	10042265
	Supernumerary nipple (PT)	10042571
	Supernumerary teeth (PT)	10042572
	Syndactyly (PT)	10042778
	Synostosis (PT)	10042856
	Syringomyelia (PT)	10042928
	Talipes (PT)	10043101
	Teratogenicity (PT)	10043275
	Thalassaemia (PT)	10043388
	Thalassaemia alpha (PT)	10043390
	Thalassaemia beta (PT)	10043391
	Thalassaemia minor (PT)	10043393
	Thalassaemia sickle cell (PT)	10043395
	Tooth discolouration congenital (PT)	10044033
	Tooth hypoplasia (PT)	10044041
	Tooth malformation hereditary (PT)	10044047
	Tourette's disorder (PT)	10044126
	Tracheo-oesophageal fistula (PT)	10044310
	Tracheobronchomegaly (PT)	10044316
	Transposition of the great vessels (PT)	10044443

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Trisomy 11 (PT)	10044685
	Trisomy 13 (PT)	10044686
	Trisomy 21 (PT)	10044688
	Trisomy 22 (PT)	10044689
	Truncus arteriosus persistent (PT)	10044703
	Turner's syndrome (PT)	10045181
	Type II hyperlipidaemia (PT)	10045254
	Type IIa hyperlipidaemia (PT)	10045261
	Type IIb hyperlipidaemia (PT)	10045263
	Umbilical artery hypoplasia (PT)	10045445
	Umbilical malformation (PT)	10045469
	Univentricular heart (PT)	10045545
	Urethral valves (PT)	10046479
	Urinary tract malformation (PT)	10046580
	Vaginal atresia (PT)	10046879
	Ventricular hypoplasia (PT)	10047296
	Ventricular septal defect (PT)	10047298
	Virilism foetal (PT)	10047487
	Von Willebrand's disease (PT)	10047715
	Von Hippel-Lindau disease (PT)	10047716
	Wiskott-Aldrich syndrome (PT)	10047992
	Xeroderma pigmentosum (PT)	10048220
	XXXY syndrome (PT)	10048228
	XXYY syndrome (PT)	10048230
	Brain malformation (PT)	10048409
	Dandy-Walker syndrome (PT)	10048411
	Limb hypoplasia congenital (PT)	10048575
	Kyphosis congenital (PT)	10048576
	Plagiocephaly (PT)	10048586
	Wyburn Mason's syndrome (PT)	10048661
	Sjogren-Larsson syndrome (PT)	10048676
	Schimke immunoosseous dysplasia (PT)	10048699

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Homocystinaemia (PT)	10048707
	Infantile septic granulomatosis (PT)	10048708
	Congenital dermal sinus (PT)	10048728
	Phakomatosis (PT)	10048734
	Accessory kidney (PT)	10048781
	Congenital cerebellar agenesis (PT)	10048784
	Congenital choroid plexus cyst (PT)	10048785
	Keratitis-ichthyosis-deafness syndrome (PT)	10048786
	Congenital scrotal hypertrophy (PT)	10048800
	Congenital thymus absence (PT)	10048801
	Kearns-Sayre syndrome (PT)	10048804
	Polycystic liver disease (PT)	10048834
	Congenital kyphoscoliosis (PT)	10048890
	Rib hypoplasia (PT)	10048893
	Steatocystoma multiplex (PT)	10048905
	Pachygyria (PT)	10048910
	Lissencephaly (PT)	10048911
	Congenital cerebral haemangioma (PT)	10048924
	Factor V deficiency (PT)	10048930
	Uhl's anomaly (PT)	10048951
	Congenital hyperextension of spine (PT)	10048953
	Congenital hyperextension of knee (PT)	10048954
	Angelman's syndrome (PT)	10049004
	Congenital limb hyperextension (PT)	10049011
	Camptodactyly congenital (PT)	10049028
	Erythrokeratoderma variabilis (PT)	10049048
	Congenital adrenal gland hypoplasia (PT)	10049057
	Cohen syndrome (PT)	10049066
	Renal hypoplasia (PT)	10049102
	Red blood cell enzymes abnormal (PT)	10049191
	Adactyly (PT)	10049207
	Aorta hypoplasia (PT)	10049209

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Phalangeal hypoplasia (PT)	10049212
	Monopodia (PT)	10049214
	Blepharophimosis congenital (PT)	10049241
	Ankyloglossia congenital (PT)	10049244
	Hypersplenism congenital (PT)	10049282
	Wolff-Parkinson-White syndrome congenital (PT)	10049291
	Scaphocephaly (PT)	10049426
	Werner's syndrome (PT)	10049429
	Congenital facial nerve hypoplasia (PT)	10049449
	Williams syndrome (PT)	10049644
	Congenital tricuspid valve atresia (PT)	10049767
	Accessory breast (PT)	10049786
	Single umbilical artery (PT)	10049807
	Thanatophoric dwarfism (PT)	10049808
	Achromotrichia congenital (PT)	10049864
	Craniosynostosis (PT)	10049889
	Hypophosphatasia (PT)	10049933
	Congenital pyelocaliectasis (PT)	10049938
	Ductus arteriosus premature closure (PT)	10049996
	Pseudotruncus arteriosus (PT)	10050053
	Lipomeningocele (PT)	10050084
	Macrocephaly (PT)	10050183
	Carnitine palmitoyltransferase deficiency (PT)	10050215
	Congenital labia pudendi adhesions (PT)	10050268
	Beckwith-Wiedemann syndrome (PT)	10050344
	Wolf-Hirschhorn syndrome (PT)	10050361
	Holt-Oram syndrome (PT)	10050469
	Langer-Giedion syndrome (PT)	10050638
	Congenital scoliosis (PT)	10050694
	Exophthalmos congenital (PT)	10050696
	Congenital pulmonary hypertension (PT)	10050701
	Retinopathy congenital (PT)	10050706

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital acrochordon (PT)	10050730
	Bartter's syndrome (PT)	10050839
	Naevus spider congenital (PT)	10050896
	Congenital hydronephrosis (PT)	10050975
	Eagle Barrett syndrome (PT)	10051025
	Hyper IgE syndrome (PT)	10051040
	Congenital eye naevus (PT)	10051050
	Angiotensin converting enzyme inhibitor foetopathy (PT)	10051098
	Congenital dysfibrinogenaemia (PT)	10051123
	Congenital hepatomegaly (PT)	10051130
	Congenital hydrocele renalis (PT)	10051147
	Hypermethioniuria (PT)	10051231
	Hypermethioninaemia (PT)	10051245
	Adrenoleukodystrophy (PT)	10051260
	Protein S deficiency (PT)	10051292
	Protein C deficiency (PT)	10051298
	Congenital hypoparathyroidism (PT)	10051315
	Thyroglossal cyst (PT)	10051320
	Mitochondrial DNA deletion (PT)	10051403
	Foetal warfarin syndrome (PT)	10051445
	Klippel-Trenaunay syndrome (PT)	10051452
	Mandibulofacial dysostosis (PT)	10051456
	Congenital multiplex arthrogryposis (PT)	10051643
	Haemophilia carrier (PT)	10051658
	Lipid proteinosis (PT)	10051661
	Pachydermoperiostosis (PT)	10051686
	Oculocerebrorenal syndrome (PT)	10051707
	Ota's naevus (PT)	10051713
	Multiple endocrine neoplasia (PT)	10051747
	Factor XII deficiency (PT)	10051806
	Tangier disease (PT)	10051875

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Benign congenital hypotonia (PT)	10051900
	Cowden's disease (PT)	10051906
	Hereditary non-polyposis colorectal cancer syndrome (PT)	10051922
	Oculoauriculovertebral dysplasia (PT)	10051934
	Scimitar syndrome (PT)	10051951
	Trichorhinophalangeal syndrome (PT)	10051956
	Pterygium colli (PT)	10051972
	Foetal cystic hygroma (PT)	10052011
	Congenital teratoma (PT)	10052012
	Albright's disease (PT)	10052032
	Neural tube defect (PT)	10052046
	Oculopharyngeal dystrophy (PT)	10052181
	Infantile genetic agranulocytosis (PT)	10052210
	Cerebral atrophy congenital (PT)	10052236
	Myocardial bridging (PT)	10052289
	Keratolysis exfoliativa congenital (PT)	10052290
	Kaufman-McKusick syndrome (PT)	10052312
	Liddle's syndrome (PT)	10052313
	Ornithine transcarbamoylase deficiency (PT)	10052450
	Osteoporosis-pseudoglioma syndrome (PT)	10052452
	Congenital poikiloderma (PT)	10052465
	Factor III deficiency (PT)	10052473
	Factor X deficiency (PT)	10052474
	Dihydropyrimidine dehydrogenase deficiency (PT)	10052622
	Mitochondrial DNA duplication (PT)	10052640
	Mitochondrial DNA mutation (PT)	10052641
	Iris coloboma (PT)	10052642
	Retinal coloboma (PT)	10052643
	Congenital pulmonary valve atresia (PT)	10052644
	Thymus hypoplasia (PT)	10052645
	Cancer gene carrier (PT)	10052648

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Amyotrophic lateral sclerosis gene carrier (PT)	10052653
	Duchenne muscular dystrophy gene carrier (PT)	10052655
	Cystic fibrosis carrier (PT)	10052656
	Fragile X carrier (PT)	10052657
	Macrognathia (PT)	10052658
	Accessory liver lobe (PT)	10052752
	Oroticaciduria congenital (PT)	10052773
	Congenital aplastic anaemia (PT)	10053138
	Olfacto genital dysplasia (PT)	10053142
	Hydroxyprolinaemia (PT)	10053148
	Congenital floppy infant (PT)	10053153
	Epidermolysis (PT)	10053177
	Glycogen storage disease type II (PT)	10053185
	Posterior segment of eye anomaly congenital (PT)	10053202
	Haemoglobin E disease (PT)	10053215
	Glycogen storage disease type VI (PT)	10053240
	Glycogen storage disease type VII (PT)	10053241
	Glycogen storage disease type VIII (PT)	10053242
	Glycogen storage disease type IV (PT)	10053249
	Glycogen storage disease type III (PT)	10053250
	Venous angioma of brain (PT)	10053485
	Uvula aplasia (PT)	10053506
	Cleft uvula (PT)	10053507
	Congenital generalised lipodystrophy (PT)	10053547
	Disseminated neonatal herpes simplex (PT)	10053585
	Hereditary stomatocytosis (PT)	10053589
	Newborn persistent pulmonary hypertension (PT)	10053592
	Asplenia (PT)	10053622
	Cholangiectasis congenital (PT)	10053630
	Brachycephaly (PT)	10053682
	Cerebrohepatorenal syndrome (PT)	10053684
	Vaginal hypoplasia (PT)	10053843

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Alagille syndrome (PT)	10053870
	Trisomy 8 (PT)	10053871
	MELAS syndrome (PT)	10053872
	Congenital oculomotor apraxia (PT)	10053877
	Greig's syndrome (PT)	10053878
	Trisomy 18 (PT)	10053884
	Trisomy 17 (PT)	10053925
	Congenital syphilitic osteochondritis (PT)	10054002
	Pilonidal cyst congenital (PT)	10054019
	Lafora's myoclonic epilepsy (PT)	10054030
	Congenital bowing of long bones (PT)	10054064
	Congenital aural fistula (PT)	10054215
	Lymphangiectasia intestinal congenital (PT)	10054722
	External auditory canal atresia (PT)	10054875
	Phalangeal agenesis (PT)	10054879
	Fibula agenesis (PT)	10054882
	Baltic myoclonic epilepsy (PT)	10054895
	Aicardi's syndrome (PT)	10054935
	Congenital cerebral cyst (PT)	10054954
	Tracheal atresia (PT)	10054955
	Hypodontia (PT)	10055001
	Cardiac lymphangioma (PT)	10055010
	Haemoglobin D disease (PT)	10055019
	Haemoglobin D trait (PT)	10055020
	Haemoglobin C trait (PT)	10055021
	Anorectal agenesis (PT)	10056271
	Androgen insensitivity syndrome (PT)	10056292
	Holoprosencephaly (PT)	10056304
	Blood incompatibility haemolytic anaemia of newborn (PT)	10056369
	Cerebrovascular arteriovenous malformation (PT)	10056371
	Congenital ureterocele (PT)	10056434

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Cerebral dysgenesis (PT)	10056467
	Haemophilia A with anti factor VIII (PT)	10056492
	Haemophilia A without inhibitors (PT)	10056493
	Haemophilia B with anti factor IX (PT)	10056494
	Haemophilia B without inhibitors (PT)	10056495
	Congenital epiblepharon (PT)	10056531
	Congenital hepatic fibrosis (PT)	10056533
	X-linked chromosomal disorder (PT)	10056554
	Y-linked chromosomal disorder (PT)	10056555
	Bladder agenesis (PT)	10056655
	Sacral hypoplasia (PT)	10056659
	Laurence-Moon-Bardet-Biedl syndrome (PT)	10056715
	Dermatofibrosis lenticularis disseminata (PT)	10056878
	Mucopolysaccharidosis I (PT)	10056886
	Mucopolysaccharidosis II (PT)	10056889
	Mucopolysaccharidosis III (PT)	10056890
	Mucopolysaccharidosis V (PT)	10056891
	Mucopolysaccharidosis VI (PT)	10056892
	Mucopolysaccharidosis VII (PT)	10056893
	XXY syndrome (PT)	10056894
	Hereditary pancreatitis (PT)	10056976
	Adenomatous polyposis coli (PT)	10056981
	Congenital ectopic pancreas (PT)	10056987
	Congenital cutis laxa (PT)	10057042
	Platybasia (PT)	10057115
	Acquired mitochondrial DNA deletion (PT)	10057251
	Acquired mitochondrial DNA mutation (PT)	10057252
	Choroidal coloboma (PT)	10057402
	Congenital iris anomaly (PT)	10057411
	Microcornea (PT)	10057414
	Bernard-Soulier syndrome (PT)	10057473
	Periodontal congenital anomaly (PT)	10057476

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital calyceal diverticulum (PT)	10057510
	Interferon gamma receptor deficiency (PT)	10057605
	Central core disease (PT)	10057620
	Asphyxiating thoracic dystrophy (PT)	10057621
	Cyclopia (PT)	10057648
	Encephalocutaneous angiomas (PT)	10057653
	Hypotelorism of orbit (PT)	10057855
	Reproductive tract hypoplasia, male (PT)	10057858
	Hypertelorism (PT)	10057862
	Hereditary haemochromatosis (PT)	10057873
	Congenital choroidal anomaly (PT)	10057886
	Neonatal lupus erythematosus (PT)	10057887
	Long QT syndrome congenital (PT)	10057926
	Congenital mitochondrial cytopathy (PT)	10057954
	Anomalous pulmonary venous connection (PT)	10058079
	Arrhythmogenic right ventricular dysplasia (PT)	10058093
	Otocephaly (PT)	10058118
	Congenital aortic dilatation (PT)	10058150
	Branchiogenic syndrome (PT)	10058169
	Hyperreflexia (PT)	10058271
	Factor V Leiden mutation (PT)	10058279
	Carbamoyl phosphate synthetase deficiency (PT)	10058297
	Argininosuccinate synthetase deficiency (PT)	10058298
	Argininosuccinate lyase deficiency (PT)	10058299
	Lysinuric protein intolerance (PT)	10058300
	Hyperprolinaemia (PT)	10058509
	Clinodactyly (PT)	10058668
	Mitochondrial encephalomyopathy (PT)	10058799
	Congenital thrombocyte disorder (PT)	10058896
	Rathke's cleft cyst (PT)	10058969
	Brugada syndrome (PT)	10059027
	Diabetic foetopathy (PT)	10059116

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Becker's muscular dystrophy (PT)	10059117
	Congenital visual acuity reduced (PT)	10059157
	Congenital eye disorder (PT)	10059159
	Pulmonary sequestration (PT)	10059160
	Familial hypertriglyceridaemia (PT)	10059183
	Anterior chamber cleavage syndrome (PT)	10059199
	Fallot's pentalogy (PT)	10059205
	Macrocornea (PT)	10059253
	Testicular dysplasia (PT)	10059271
	Sarcosinaemia (PT)	10059299
	Caudal regression syndrome (PT)	10059387
	Mitochondrial DNA depletion (PT)	10059396
	Congenital genital malformation male (PT)	10059492
	Dubowitz syndrome (PT)	10059589
	Predodenal portal vein (PT)	10059798
	Persistent urogenital sinus (PT)	10059800
	Bruton's agammaglobulinaemia (PT)	10060360
	Congenital nephrotic syndrome (PT)	10060737
	Congenital hypogammaglobulinaemia (PT)	10060747
	Type I hyperlipidaemia (PT)	10060749
	Type III hyperlipidaemia (PT)	10060751
	Type IV hyperlipidaemia (PT)	10060753
	Type V hyperlipidaemia (PT)	10060755
	Laryngomalacia (PT)	10060786
	Hollow visceral myopathy (PT)	10060811
	Benign familial haematuria (PT)	10060876
	Haemoglobinopathy (PT)	10060892
	Hereditary haemolytic anaemia (PT)	10060893
	Foetal malformation (PT)	10060919
	Anomaly of middle ear congenital (PT)	10060957
	Autosomal chromosome anomaly (PT)	10060975
	Carbohydrate metabolism disorder (PT)	10061023

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Eye anterior chamber congenital anomaly (PT)	10061051
	Congenital aortic anomaly (PT)	10061052
	Congenital bladder anomaly (PT)	10061053
	Congenital cardiovascular anomaly (PT)	10061054
	Congenital corneal anomaly (PT)	10061059
	Congenital coronary artery malformation (PT)	10061060
	Congenital diaphragmatic anomaly (PT)	10061061
	Congenital fallopian tube anomaly (PT)	10061062
	Congenital gastric anomaly (PT)	10061063
	Congenital hair disorder (PT)	10061064
	Congenital hepatobiliary anomaly (PT)	10061065
	Congenital intestinal malformation (PT)	10061067
	Congenital knee deformity (PT)	10061068
	Congenital oesophageal anomaly (PT)	10061069
	Congenital oral malformation (PT)	10061070
	Congenital ovarian anomaly (PT)	10061071
	Congenital pancreatic anomaly (PT)	10061072
	Congenital pharyngeal anomaly (PT)	10061073
	Congenital pulmonary artery anomaly (PT)	10061074
	Congenital pulmonary valve disorder (PT)	10061075
	Congenital spinal cord anomaly (PT)	10061076
	Congenital tongue anomaly (PT)	10061077
	Congenital ureteric anomaly (PT)	10061078
	Congenital uterine anomaly (PT)	10061079
	Congenital great vessel anomaly (PT)	10061080
	Congenital vitreous anomaly (PT)	10061085
	Congenital white blood cell disorder (PT)	10061086
	Congenital eyelid malformation (PT)	10061146
	Gallbladder anomaly congenital (PT)	10061163
	Hamartoma (PT)	10061193
	Hereditary cerebral degeneration (PT)	10061204
	Hereditary disorder (PT)	10061205

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Porphyrin metabolism disorder (PT)	10061356
	Dermatoglyphic anomaly (PT)	10061455
	Sex chromosome abnormality (PT)	10061513
	Congenital optic nerve anomaly (PT)	10061528
	Congenital scleral disorder (PT)	10061530
	Congenital pseudarthrosis (PT)	10061573
	Telangiectasia congenital (PT)	10061575
	Gastrointestinal malformation (PT)	10061596
	Adrenogenital syndrome (PT)	10061630
	Asymptomatic gene carrier (PT)	10061662
	Chromosomal deletion (PT)	10061764
	Chromosomal mutation (PT)	10061765
	Gastrointestinal disorder congenital (PT)	10061973
	Glycogen storage disorder (PT)	10061990
	Haemophilia (PT)	10061992
	Hereditary ataxia (PT)	10062002
	Inborn error of bilirubin metabolism (PT)	10062017
	Inborn error of metabolism (PT)	10062018
	Intestinal atresia (PT)	10062022
	Thyroid malformation (PT)	10062125
	Congenital hyperthyroidism (PT)	10062264
	Septum pellucidum agenesis (PT)	10062267
	Silver-Russell syndrome (PT)	10062282
	Congenital arterial malformation (PT)	10062325
	Congenital cerebrovascular anomaly (PT)	10062327
	Congenital cyst (PT)	10062328
	Congenital endocrine anomaly (PT)	10062329
	Congenital epiglottal anomaly (PT)	10062330
	Congenital Eustachian tube anomaly (PT)	10062331
	Congenital foot malformation (PT)	10062332
	Congenital genital malformation (PT)	10062333
	Congenital genitourinary abnormality (PT)	10062334

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital hand malformation (PT)	10062335
	Congenital jaw malformation (PT)	10062336
	Congenital joint malformation (PT)	10062337
	Congenital lacrimal passage anomaly (PT)	10062338
	Anomaly of external ear congenital (PT)	10062339
	Congenital anomaly of inner ear (PT)	10062340
	Congenital anomaly of adrenal gland (PT)	10062341
	Congenital gastrointestinal vessel anomaly (PT)	10062342
	Congenital infection (PT)	10062343
	Congenital neurological disorder (PT)	10062345
	Congenital neuropathy (PT)	10062346
	Congenital nose malformation (PT)	10062347
	Congenital urethral anomaly (PT)	10062349
	Spleen malformation (PT)	10062350
	Congenital myopathy (PT)	10062547
	Lowry-Wood syndrome (PT)	10062600
	Thyroglossal fistula (PT)	10062601
	Accessory navicular syndrome (PT)	10062626
	Pseudocholinesterase deficiency (PT)	10062674
	Arginase deficiency (PT)	10062695
	Congenital carnitine deficiency (PT)	10062698
	Trisomy 15 (PT)	10062757
	Congenital dyskeratosis (PT)	10062759
	Stargardt's disease (PT)	10062766
	Basal cell naevus syndrome (PT)	10062804
	Multiple lentigines syndrome (PT)	10062901
	Gitelman's syndrome (PT)	10062906
	Netherton's syndrome (PT)	10062909
	Haemoglobin E-thalassaemia disease (PT)	10062917
	Spondyloepiphyseal dysplasia (PT)	10062920
	Mitochondrial hepatopathy (PT)	10062938
	Neuropathy, ataxia, retinitis pigmentosa	10062940

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Safety topic	MedDRA term selection of adverse events	MedDRA code
	syndrome (PT)	
	Pearson's syndrome (PT)	10062941
	Optic nerve hypoplasia (PT)	10062942
	Laryngo-onycho-cutaneous syndrome (PT)	10062987
	Kinematic imbalances due to suboccipital strain (PT)	10062992
	Muir-Torre syndrome (PT)	10063042
	Ectopic kidney (PT)	10063044
	Trisomy 12 (PT)	10063092
	Uterine cervix hypoplasia (PT)	10063120
	Uterine hypoplasia (PT)	10063146
	Wagner's disease (PT)	10063383
	Usher's syndrome (PT)	10063396
	Stickler's syndrome (PT)	10063402
	Lumbarisation (PT)	10063410
	Odontogenic cyst (PT)	10063413
	Aase syndrome (PT)	10063429
	Nail-patella syndrome (PT)	10063431
	Tyrosinaemia (PT)	10063443
	Hereditary areflexic dystasia (PT)	10063449
	Congenital vaginal cyst (PT)	10063457
	Congenital androgen deficiency (PT)	10063469
	Schinz-Giedion syndrome (PT)	10063540
	Congenital coagulopathy (PT)	10063563
	Testotoxicosis (PT)	10063654
	Young's syndrome (PT)	10063689
	Oculodentodigital dysplasia (PT)	10063691
	Congenital anomaly in offspring (PT)	10063726
	Bicuspid pulmonary valve (PT)	10063730
	Aorticopulmonary septal defect (PT)	10063732
	Haemoglobin E trait (PT)	10063740
	Atrioventricular septal defect (PT)	10063836

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Arachnodactyly (PT)	10063847
	Dolichocolon (PT)	10063917
	Kabuki make-up syndrome (PT)	10063935
	Phytosterolaemia (PT)	10063985
	Fallot's trilogy (PT)	10064011
	Cardiac septal defect (PT)	10064021
	Intestinal malrotation (PT)	10064024
	Foetal chromosome abnormality (PT)	10064041
	CHARGE syndrome (PT)	10064063
	Congenital heart valve disorder (PT)	10064086
	Facioscapulohumeral muscular dystrophy (PT)	10064087
	Amniotic band syndrome (PT)	10064100
	Foramen magnum stenosis (PT)	10064157
	Parachute mitral valve (PT)	10064192
	Persistent left superior vena cava (PT)	10064193
	Right ventricle outflow tract obstruction (PT)	10064195
	Sotos' syndrome (PT)	10064387
	Vaginal septum (PT)	10064513
	Femoral retroversion (PT)	10064514
	Tibial torsion (PT)	10064515
	Femoral anteversion (PT)	10064516
	Chronic infantile neurological cutaneous and articular syndrome (PT)	10064568
	Muckle-Wells syndrome (PT)	10064569
	Familial cold autoinflammatory syndrome (PT)	10064570
	Gene mutation (PT)	10064571
	Marcus Gunn syndrome (PT)	10064583
	Bronchogenic cyst (PT)	10064585
	Haemorrhagic arteriovenous malformation (PT)	10064595
	Berdon's syndrome (PT)	10064596
	Renal aplasia (PT)	10064655
	Congenital lenticonus (PT)	10064660

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Primary immunodeficiency syndrome (PT)	10064859
	Urethral atresia (PT)	10064895
	Anomalous arrangement of pancreaticobiliary duct (PT)	10064902
	Preternatural anus (PT)	10064917
	Sacralisation (PT)	10064932
	Penoscrotal fusion (PT)	10064951
	Hypoplastic right heart syndrome (PT)	10064962
	Weill-Marchesani syndrome (PT)	10064963
	Factor II mutation (PT)	10065003
	Membranous lipodystrophy (PT)	10065127
	Mayer-Rokitansky-Kuster-Hauser syndrome (PT)	10065148
	Mitochondrial neurogastrointestinal encephalopathy (PT)	10065271
	Prominent epicanthal folds (PT)	10065273
	Ocular albinism (PT)	10065276
	Craniotabes (PT)	10065419
	Coagulation factor mutation (PT)	10065442
	CADASIL (PT)	10065555
	Mount-Reback syndrome (PT)	10065658
	Congenital fibrosarcoma (PT)	10065859
	Left ventricle outflow tract obstruction (PT)	10065930
	VACTERL syndrome (PT)	10066022
	Dysmorphism (PT)	10066054
	Congenital aqueductal stenosis (PT)	10066084
	Urachal abnormality (PT)	10066125
	Distichiasis (PT)	10066128
	Hyper IgM syndrome (PT)	10066130
	Congenital central hypoventilation syndrome (PT)	10066131
	Metaphyseal dysplasia (PT)	10066147
	Vertical talus (PT)	10066242
	Sucrase-isomaltase deficiency (PT)	10066387

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Glucose-galactose malabsorption (PT)	10066388
	Velo-cardio-facial syndrome (PT)	10066430
	Foetal anticonvulsant syndrome (PT)	10066485
	Li-Fraumeni syndrome (PT)	10066795
	Heterochromia iridis (PT)	10066799
	Mitral valve atresia (PT)	10066800
	Aortic valve atresia (PT)	10066801
	Shone complex (PT)	10066802
	Sertoli-cell-only syndrome (PT)	10066833
	Congenital renal disorder (PT)	10066875
	Vertebral artery hypoplasia (PT)	10066907
	Congenital condyloma (PT)	10066944
	Craniofacial dysostosis (PT)	10066946
	Vitello-intestinal duct remnant (PT)	10066969
	Familial hemiplegic migraine (PT)	10067039
	Buried penis syndrome (PT)	10067131
	Faciodigitogenital dysplasia (PT)	10067141
	Septo-optic dysplasia (PT)	10067159
	Congenital abdominal hernia (PT)	10067183
	Naevus flammeus (PT)	10067193
	Congenital naevus (PT)	10067248
	Heterotaxia (PT)	10067265
	Penoscrotal transposition (PT)	10067287
	Costello syndrome (PT)	10067380
	Right aortic arch (PT)	10067407
	Cloacal exstrophy (PT)	10067424
	Cytogenetic abnormality (PT)	10067477
	Dysmyelination (PT)	10067601
	Canavan disease (PT)	10067608
	Metachromatic leukodystrophy (PT)	10067609
	Pelizaeus-Merzbacher disease (PT)	10067610
	Uterine aplasia (PT)	10067704

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Beta ketothiolase deficiency (PT)	10067728
	Mitochondrial enzyme deficiency (PT)	10067729
	Birt-Hogg-Dube syndrome (PT)	10067736
	Congenital skin disorder (PT)	10067769
	Tumour necrosis factor receptor-associated periodic syndrome (PT)	10067774
	Arcuate foramen (PT)	10067850
	Nijmegen breakage syndrome (PT)	10067857
	Benign familial neonatal convulsions (PT)	10067866
	Kidney malrotation (PT)	10067877
	Congenital tricuspid valve incompetence (PT)	10067887
	Shwachman-Diamond syndrome (PT)	10067940
	Hereditary papillary renal carcinoma (PT)	10067943
	Hereditary leiomyomatosis renal cell carcinoma (PT)	10067944
	PHACES syndrome (PT)	10068032
	Renal fusion anomaly (PT)	10068033
	Chimerism (PT)	10068051
	Mosaicism (PT)	10068052
	Accessory spleen (PT)	10068059
	Congenital ureterovesical junction anomaly (PT)	10068133
	Aspartylglucosaminuria (PT)	10068220
	Trimethylaminuria (PT)	10068233
	Cystic fibrosis related diabetes (PT)	10068271
	Cystic fibrosis hepatic disease (PT)	10068289
	Congenital nephrogenic diabetes insipidus (PT)	10068304
	Microencephaly (PT)	10068320
	Congenital inguinal hernia (PT)	10068321
	X-linked lymphoproliferative syndrome (PT)	10068348
	Femur-fibula-ulna complex (PT)	10068448
	Septate hymen (PT)	10068484
	Microvillous inclusion disease (PT)	10068494

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Reproductive toxicity	18q minus syndrome (PT)	10068533
	Congenital oxalosis (PT)	10068593
	Bulbospinal muscular atrophy congenital (PT)	10068597
	Platyspondylia (PT)	10068629
	Dowling-Degos disease (PT)	10068651
	Ductus venosus agenesis (PT)	10068665
	Familial hypocalciuric hypercalcaemia (PT)	10068698
	Fibrodysplasia ossificans progressiva (PT)	10068715
	Alstroem syndrome (PT)	10068783
	Sticky platelet syndrome (PT)	10068788
	Metabolic myopathy (PT)	10068836
	Cobb syndrome (PT)	10068841
	Olmsted syndrome (PT)	10068842
	Gnathoschisis (PT)	10068845
	Cryopyrin associated periodic syndrome (PT)	10068850
	Myotonic dystrophy (PT)	10068871
	Omenn syndrome (PT)	10069097
	Cutaneovisceral angiomatosis with thrombocytopenia (PT)	10069098
	Laryngeal cleft (PT)	10069115
	Tetrahydrobiopterin deficiency (PT)	10069116
	Congenital myopia (PT)	10069153
	Dent's disease (PT)	10069199
	Waardenburg syndrome (PT)	10069203
	Naevus anaemicus (PT)	10069365
	Hereditary neuropathy with liability to pressure palsies (PT)	10069382
	Chiari network (PT)	10069393
	Wildervanck syndrome (PT)	10069402
	Rippling muscle disease (PT)	10069417
	Pancreas divisum (PT)	10069419
	Persistent cloaca (PT)	10069442

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Reproductive toxicity	Acrokeratosis verruciformis (PT)	10069445
	Azygos lobe (PT)	10069490
	Ectopic thyroid (PT)	10069503
	Congenital monorchidism (PT)	10069505
	Autoimmune lymphoproliferative syndrome (PT)	10069521
	Cartilage-hair hypoplasia (PT)	10069596
	Methylenetetrahydrofolate reductase polymorphism (PT)	10069666
	Molybdenum cofactor deficiency (PT)	10069687
	Nasopharyngeal atresia (PT)	10069701
	Primary ciliary dyskinesia (PT)	10069713
	Acquired gene mutation (PT)	10069754
	K-ras gene mutation (PT)	10069755
	Norrie's disease (PT)	10069760
	Congenital cranial nerve paralysis (PT)	10069774
	Os trigonum (PT)	10069805
	Myoclonic epilepsy and ragged-red fibres (PT)	10069825
	Denys-Drash syndrome (PT)	10070179
	Penile torsion (PT)	10070235
	Inherited cardiac conduction disorder (PT)	10070294
	Methylenetetrahydrofolate reductase deficiency (PT)	10070309
	Congenital intrinsic factor deficiency (PT)	10070440
	Sclerotylosis (PT)	10070504
	Fibrous dysplasia of jaw (PT)	10070535
	Disorder of sex development (PT)	10070597
	Meier-Gorlin syndrome (PT)	10070612
	Mesoblastic nephroma (PT)	10070665
	Cortical dysplasia (PT)	10070666
	Leber's congenital amaurosis (PT)	10070667
	Huntington's disease (PT)	10070668
	Persistent pupillary membrane (PT)	10070872

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Familial haemophagocytic lymphohistiocytosis (PT)	10070904
	Congenital hypercoagulation (PT)	10070954
	Spina bifida cystica (PT)	10071011
	Laevocardia (PT)	10071015
	Platelet glycoprotein gene mutation (PT)	10071024
	Plasminogen activator inhibitor polymorphism (PT)	10071045
	Primary insulin like growth factor-1 deficiency (PT)	10071079
	N-acetylglutamate synthase deficiency (PT)	10071092
	Cystathionine beta-synthase deficiency (PT)	10071093
	Branchio-oto-renal syndrome (PT)	10071135
	Foetal methotrexate syndrome (PT)	10071183
	Protuberant ear (PT)	10071232
	Constricted ear deformity (PT)	10071233
	Thalidomide embryopathy (PT)	10071249
	Gorham's disease (PT)	10071283
	Hereditary motor neurone disease (PT)	10071328
	Congenital hemiparesis (PT)	10071359
	Biotinidase deficiency (PT)	10071434
	Acetylcholinesterase deficiency (PT)	10071435
	Dyschondrosteosis (PT)	10071437
	Trisomy 9 (PT)	10071547
	NAT2 polymorphism (PT)	10071600
	CYP2D6 polymorphism (PT)	10071601
	Genetic polymorphism (PT)	10071602
	CYP2C19 polymorphism (PT)	10071603
	Anterior displaced anus (PT)	10071651
	Micropenis (PT)	10071706
	Thrombocytopenia-absent radius syndrome (PT)	10071719
	Cerebral cavernous malformation (PT)	10071747

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Blau syndrome (PT)	10071755
	Annular pancreas (PT)	10071757
	Trisomy 14 (PT)	10071762
	Hermansky-Pudlak syndrome (PT)	10071775
	H-ras gene mutation (PT)	10071971
	N-ras gene mutation (PT)	10071972
	C-kit gene mutation (PT)	10071973
	C-kit gene overexpression (PT)	10071974
	EGFR gene mutation (PT)	10071975
	HERG gene mutation (PT)	10071976
	Anaplastic lymphoma kinase gene mutation (PT)	10071977
	Anaplastic lymphoma kinase gene and nucleophosmin gene fusion overexpression (PT)	10071978
	Androgen receptor gene overexpression (PT)	10071979
	BRCA1 gene mutation (PT)	10071980
	BRCA2 gene mutation (PT)	10071981
	Carbonic anhydrase gene mutation (PT)	10071982
	Oestrogen receptor gene overexpression (PT)	10071983
	Platelet-derived growth factor receptor overexpression (PT)	10071984
	Progesterone receptor gene overexpression (PT)	10071985
	PTEN gene mutation (PT)	10071986
	RET gene mutation (PT)	10071987
	UGT1A1 gene mutation (PT)	10071988
	Vascular endothelial growth factor overexpression (PT)	10071989
	Tyrosine kinase mutation (PT)	10071990
	Transmembrane receptor tyrosine kinase overexpression (PT)	10071991
	EGFR gene overexpression (PT)	10071992
	Frenulum breve (PT)	10072007
	Hyper IgD syndrome (PT)	10072010

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Renal malposition (PT)	10072019
	Congenital melanocytic naevus (PT)	10072036
	Fatal familial insomnia (PT)	10072077
	Congenital haematological disorder (PT)	10072107
	Craniofacial dysmaturity (PT)	10072116
	Hooded prepuce (PT)	10072135
	Auditory neuropathy spectrum disorder (PT)	10072198
	Endothelial protein C receptor polymorphism (PT)	10072205
	Janus kinase 2 mutation (PT)	10072206
	Mevalonic aciduria (PT)	10072219
	Mevalonate kinase deficiency (PT)	10072221
	Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome (PT)	10072222
	Majeed's syndrome (PT)	10072223
	Deficiency of the interleukin-1 receptor antagonist (PT)	10072224
	Familial scaphocephaly syndrome (PT)	10072229
	Inborn error of lipid metabolism (PT)	10072272
	3-hydroxyacetyl-coenzyme A dehydrogenase deficiency (PT)	10072273
	Intracranial lipoma (PT)	10072288
	Hand-foot-genital syndrome (PT)	10072361
	Sirenomelia (PT)	10072457
	Hereditary palmoplantar keratoderma (PT)	10072537
	Platonychia (PT)	10072590
	Adenine phosphoribosyl transferase deficiency (PT)	10072609
	Skeletal dysplasia (PT)	10072610
	Long-chain acyl-coenzyme A dehydrogenase deficiency (PT)	10072653
	Medium-chain acyl-coenzyme A dehydrogenase deficiency (PT)	10072654

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Short-chain acyl-coenzyme A dehydrogenase deficiency (PT)	10072655
	Very long-chain acyl-coenzyme A dehydrogenase deficiency (PT)	10072656
	Amastia (PT)	10072717
	Extrarenal pelvis (PT)	10072727
	Brachydactyly (PT)	10072883
	Mucopolipidosis type I (PT)	10072927
	Mucopolipidosis type II (PT)	10072928
	Mucopolipidosis type III (PT)	10072929
	Mucopolipidosis type IV (PT)	10072930
	Mucopolipidosis (PT)	10072939
	Olfactory nerve agenesis (PT)	10072941
	Cerebellar dysplasia (PT)	10072942
	Congenital skin dimples (PT)	10072978
	Congenital central diabetes insipidus (PT)	10073008
	Bloom syndrome (PT)	10073032
	Multiple endocrine neoplasia Type 2A (PT)	10073148
	Multiple endocrine neoplasia Type 2 (PT)	10073149
	Multiple endocrine neoplasia Type 1 (PT)	10073150
	Multiple endocrine neoplasia Type 2B (PT)	10073151
	Familial medullary thyroid cancer (PT)	10073153
	Infantile cortical hyperostosis (PT)	10073206
	Congenital intestinal obstruction (PT)	10073207
	Haemochromatosis trait (PT)	10073217
	Kenny-Caffey syndrome (PT)	10073228
	Twin reversed arterial perfusion sequence malformation (PT)	10073455
	Microcolon (PT)	10073456
	Congenital retinoblastoma (PT)	10073470
	Hydranencephaly (PT)	10073472
	Lipodermoid tumour (PT)	10073484

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Schizencephaly (PT)	10073487
	Polymicrogyria (PT)	10073489
	Double cortex syndrome (PT)	10073490
	Congenital malignant neoplasm (PT)	10073492
	Congenital benign neoplasm (PT)	10073493
	Triple A syndrome (PT)	10073592
	Congenital trichomegaly (PT)	10073654
	Freeman-Sheldon syndrome (PT)	10073655
	Intestinal neuronal dysplasia (PT)	10073659
	Foetal megacystis (PT)	10073660
	Pulmonary lymphangiectasia (PT)	10073661
	Hypocalvaria (PT)	10073670
	Severe myoclonic epilepsy of infancy (PT)	10073677
	Familial renal glycosuria (PT)	10073689
	Foetal retinoid syndrome (PT)	10073720
	Developmental hip dysplasia (PT)	10073767
	Osteopathia striata (PT)	10073776
	Larsen syndrome (PT)	10073856
	CYP2B6 polymorphism (PT)	10073943
	CANDLE syndrome (PT)	10073960
	Choanal stenosis (PT)	10074053
	Proteus syndrome (PT)	10074067
	Craniofacial deformity (PT)	10074180
	Congenital high airway obstruction syndrome (PT)	10074187
	Ectopic ovary (PT)	10074217
	Transitional vertebrae (PT)	10074306
	Mobile caecum syndrome (PT)	10074307
	Dysgnathia (PT)	10074336
	Paranasal sinus aplasia (PT)	10074401
	Congenital varicocele (PT)	10074459
	Congenital Horner's syndrome (PT)	10074554
	Neuronal ceroid lipofuscinosis (PT)	10074607

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Biliary hamartoma (PT)	10074610
	Methylenetetrahydrofolate reductase gene mutation (PT)	10074753
	Myeloperoxidase deficiency (PT)	10074767
	Johanson-Blizzard syndrome (PT)	10074947
	Hypoplastic nasal cartilage (PT)	10074970
	Vascular malformation (PT)	10074979
	Congenital astigmatism (PT)	10074992
	Neonatal alloimmune thrombocytopenia (PT)	10075149
	Fryns syndrome (PT)	10075223
	Barakat syndrome (PT)	10075281
	Dentatorubral-pallidoluysian atrophy (PT)	10075298
	Hypomelanosis of Ito (PT)	10075301
	Laron syndrome (PT)	10075492
	Complement deficiency disease (PT)	10075551
	Parkes-Weber syndrome (PT)	10075554
	HER2 protein overexpression (PT)	10075638
	LDLR mutation (PT)	10075640
	Thiopurine methyltransferase polymorphism (PT)	10075641
	BLyS polymorphism (PT)	10075642
	Interleukin 28B polymorphism (PT)	10075643
	CYP2C9 polymorphism (PT)	10075647
	BRAF gene mutation (PT)	10075648
	CYP1A2 polymorphism (PT)	10075651
	HER2 gene amplification (PT)	10075653
	Platelet-derived growth factor receptor gene mutation (PT)	10075655
	Gaucher's disease type I (PT)	10075697
	Gaucher's disease type II (PT)	10075698
	Gaucher's disease type III (PT)	10075699
	UGT1A1 gene polymorphism (PT)	10075771
	NAT1 polymorphism (PT)	10075772

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Hypoxanthine-guanine phosphoribosyl transferase deficiency (PT)	10075774
	VKORC1 gene polymorphism (PT)	10075776
	Maxillonasal dysplasia (PT)	10075843
	Congenital disorder of glycosylation (PT)	10075892
	Lamin A/C gene mutation (PT)	10075979
	Cleidocranial dysostosis (PT)	10075994
	Mittendorf dot (PT)	10076031
	Progressive familial intrahepatic cholestasis (PT)	10076033
	Baraitser Rodeck Garner syndrome (PT)	10076038
	Ash leaf macule (PT)	10076367
	Kimmerle's anomaly (PT)	10076416
	Ellis-van Creveld syndrome (PT)	10076418
	Splenic hamartoma (PT)	10076586
	Carney complex (PT)	10076601
	Congenital thyroid disorder (PT)	10076602
	Right-to-left cardiac shunt (PT)	10076605
	Portal venous system anomaly (PT)	10076609
	Rib synostosis (PT)	10076624
	Primary familial hypomagnesaemia (PT)	10076626
	Enteric duplication (PT)	10076653
	Early onset primary dystonia (PT)	10076668
	Neuronal migration disorder (PT)	10076677
	Amegakaryocytic thrombocytopenia (PT)	10076744
	Labial tie (PT)	10076772
	XXX syndrome (PT)	10076910
	Alveolar capillary dysplasia (PT)	10077023
	Familial amyotrophic lateral sclerosis (PT)	10077024
	Lysosomal acid lipase deficiency (PT)	10077267
	Intracranial arterial fenestration (PT)	10077285
	Hereditary motor and sensory neuropathy (PT)	10077306

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital spinal stenosis (PT)	10077379
	Familial infantile bilateral striatal necrosis (PT)	10077450
	Ectopic posterior pituitary gland (PT)	10077557
	Congenital heart valve incompetence (PT)	10077594
	Thyroid hemiagenesis (PT)	10077609
	Bloch-Sulzberger syndrome (PT)	10077624
	Cornelia de Lange syndrome (PT)	10077707
	Rett syndrome (PT)	10077709
	Congenital thrombocytopenia (PT)	10077833
	Left-to-right cardiac shunt (PT)	10077834
	Multiple cutaneous and uterine leiomyomatosis (PT)	10077859
	Mismatch repair cancer syndrome (PT)	10077888
	Vein of Galen aneurysmal malformation (PT)	10077889
	Atrioventricular node dispersion (PT)	10077893
	Lecithin-cholesterol acyltransferase deficiency (PT)	10077917
	Supernumerary vertebra (PT)	10077919
	Tracheal web (PT)	10077940
	Hereditary hypophosphataemic rickets (PT)	10077943
	Pyruvate carboxylase deficiency (PT)	10077944
	GNE myopathy (PT)	10077945
	Adult polyglucosan body disease (PT)	10077946
	Citrate transporter deficiency (PT)	10077947
	Alternating hemiplegia of childhood (PT)	10077948
	Trifunctional protein deficiency (PT)	10077949
	Fatty acid oxidation disorder (PT)	10077951
	Epidermal naevus syndrome (PT)	10077952
	Primary hypercholesterolaemia (PT)	10077965
	Early onset familial Alzheimer's disease (PT)	10078036
	Welander distal myopathy (PT)	10078052

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Duplex appendix (PT)	10078212
	Hypothalamic hamartoma (PT)	10078217
	Activated PI3 kinase delta syndrome (PT)	10078281
	NUT gene mutation (PT)	10078296
	Camptomelia (PT)	10078297
	Wolfram syndrome (PT)	10078338
	Ureteric atresia (PT)	10078351
	Neonatal haemochromatosis (PT)	10078355
	Oral-facial-digital syndrome type II (PT)	10078419
	Proximal focal femoral deficiency (PT)	10078473
	Tornwaldt cyst (PT)	10078492
	Barth syndrome (PT)	10078537
	Acral peeling skin syndrome (PT)	10078538
	Congenital neoplasm (PT)	10078557
	Smith-Lemli-Opitz syndrome (PT)	10078573
	Joubert syndrome (PT)	10078574
	DNA mismatch repair protein gene mutation (PT)	10078672
	Glucose transporter type 1 deficiency syndrome (PT)	10078727
	Carnitine-acylcarnitine translocase deficiency (PT)	10078729
	Congenital chylothorax (PT)	10078770
	MLASA syndrome (PT)	10078801
	Allan-Herndon-Dudley syndrome (PT)	10078821
	Primary familial brain calcification (PT)	10078822
	Winchester syndrome (PT)	10078901
	2-Hydroxyglutaric aciduria (PT)	10078971
	Juvenile Paget's disease (PT)	10078977
	Left ventricular false tendon (PT)	10079017
	Gallbladder agenesis (PT)	10079018
	Hereditary multiple osteochondromas (PT)	10079019
	Oesophageal cyst (PT)	10079063

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Familial high density lipoprotein deficiency (PT)	10079119
	Aspartate-glutamate-transporter deficiency (PT)	10079140
	Emanuel syndrome (PT)	10079203
	Timothy syndrome (PT)	10079205
	Perry syndrome (PT)	10079207
	Non-compactio cardiomyopathy (PT)	10079253
	Morton's syndrome (PT)	10079320
	Glutathione synthetase deficiency (PT)	10079364
	Kleefstra syndrome (PT)	10079365
	Tilted disc syndrome (PT)	10079368
	Adams-Oliver syndrome (PT)	10079369
	Cystic angiomas (PT)	10079371
	Cystic fibrosis gastrointestinal disease (PT)	10079428
	Opitz-G/BBB syndrome (PT)	10079435
	MYH9-related disease (PT)	10079437
	Deficiency of the interleukin-36 receptor antagonist (PT)	10079451
	Ovarian hypoplasia (PT)	10079495
	Hepatic hamartoma (PT)	10079685
	Congenital midline defect (PT)	10079687
	Congenital amputation (PT)	10079701
	Tibial agenesis (PT)	10079730
	Gollop-Wolfgang complex (PT)	10079731
	Nail aplasia (PT)	10079732
	Delayed foetal renal development (PT)	10079753
	Ectrodactyly (PT)	10079827
	Acrodysostosis (PT)	10079856
	Curarino syndrome (PT)	10079857
	Congenital anosmia (PT)	10079876
	Popliteal pterygium syndrome (PT)	10079892
	Floating-Harbor syndrome (PT)	10079943

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Optic disc pit (PT)	10079967
	Urea cycle disorder (PT)	10080020
	Dopa-responsive dystonia (PT)	10080034
	Trisomy 4p (PT)	10080079
	Pachyonychia congenita (PT)	10080088
	Right ventricular false tendon (PT)	10080132
	Double outlet left ventricle (PT)	10080133
	Fraser syndrome (PT)	10080219
	Apparent mineralocorticoid excess (PT)	10080229
	Arterial tortuosity syndrome (PT)	10080250
	Pallister-Killian syndrome (PT)	10080297
	Dyke-Davidoff-Masson syndrome (PT)	10080312
	Frasier syndrome (PT)	10080313
	Bannayan-Riley-Ruvalcaba syndrome (PT)	10080314
	Shawl scrotum (PT)	10080319
	Congenital nipple inversion (PT)	10080355
	Congenital nipple anomaly (PT)	10080356
	Hereditary renal microhaematuria (PT)	10080385
	Pendred syndrome (PT)	10080398
	Familial acromegaly (PT)	10080509
	Tuberous sclerosis complex (PT)	10080584
	Pseudohypoaldosteronism (PT)	10080593
	Propionic acidaemia (PT)	10080607
	IPEX syndrome (PT)	10080631
	Microorchidism (PT)	10080650
	Vestibulocerebellar syndrome (PT)	10080748
	Familial isolated hyperparathyroidism (PT)	10080773
	Dyschromatosis (PT)	10080785
	Oxycephaly (PT)	10080833
	DOOR syndrome (PT)	10080835
	Von Willebrand's disease gene carrier (PT)	10080844
	Isocitrate dehydrogenase gene mutation (PT)	10080848

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital hypoplasia of depressor angularis oris muscle (PT)	10080879
	Hyperglycinaemia (PT)	10080883
	Hereditary angioedema with normal C1 esterase inhibitor (PT)	10080953
	Hereditary angioedema with C1 esterase inhibitor deficiency (PT)	10080955
	Congenital Zika syndrome (PT)	10081044
	Zika virus associated ocular birth defect (PT)	10081045
	Zika virus associated birth defect (PT)	10081047
	Zika virus associated microencephaly (PT)	10081048
	Bronchial atresia (PT)	10081164
	Epilepsy with myoclonic-atonic seizures (PT)	10081179
	Zhu-Tokita-Takenouchi-Kim syndrome (PT)	10081208
	Gatad2b associated neurodevelopmental disorder (PT)	10081209
	Familial gigantiform cementoma (PT)	10081225
	Diastrophic dysplasia (PT)	10081228
	PIK3CA-activated mutation (PT)	10081234
	Familial multiple lipomatosis (PT)	10081235
	PIK3CA related overgrowth spectrum (PT)	10081236
	BPES syndrome (PT)	10081258
	Monolid eyes (PT)	10081275
	Kommerell's diverticulum (PT)	10081282
	Loeys-Dietz syndrome (PT)	10081284
	Brachymetatarsia (PT)	10081308
	Benjamin syndrome (PT)	10081309
	Carpenter syndrome (PT)	10081310
	Hyperlysinaemia (PT)	10081311
	Kosaki overgrowth syndrome (PT)	10081313
	CARASIL syndrome (PT)	10081315
	Asymmetric thigh fold (PT)	10081340

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Reproductive toxicity	Persistent Muellerian duct syndrome (PT)	10081352
	Hypermucopolysaccharidosis (PT)	10081364
	Brunner syndrome (PT)	10081371
	Duplication of inferior vena cava (PT)	10081399
	Bergmeister's papilla (PT)	10081443
	Congenital dyserythropoietic anaemia (PT)	10081457
	Chorea-acanthocytosis (PT)	10081505
	Neuroacanthocytosis (PT)	10081506
	McLeod neuroacanthocytosis syndrome (PT)	10081507
	Fructose-1,6-bisphosphatase deficiency (PT)	10081516
	Griscelli syndrome (PT)	10081517
	ACAD9 deficiency (PT)	10081518
	CTLA4 deficiency (PT)	10081533
	Iris hamartoma (PT)	10081541
	Polyorchidism (PT)	10081542
	Emery-Dreifuss muscular dystrophy (PT)	10081544
	Morgagni-Stewart-Morel syndrome (PT)	10081545
	Unicuspid aortic valve (PT)	10081548
	Infantile fibromatosis (PT)	10081654
	Mucopolysaccharidosis IX (PT)	10081679
	Smith-Magenis syndrome (PT)	10081680
	Adenylosuccinate lyase deficiency (PT)	10081681
	Isodicentric chromosome 15 syndrome (PT)	10081682
	GRACILE syndrome (PT)	10081684
	Kniest dysplasia (PT)	10081685
	Mazabraud's syndrome (PT)	10081724
	NTRK gene fusion overexpression (PT)	10081769
	3M syndrome (PT)	10081775
	Coffin-Lowry syndrome (PT)	10081806
	TRPV4 gene mutation (PT)	10081831
	Brachyolmia (PT)	10081832
	PAPSS2 gene mutation (PT)	10081833

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Paroxysmal extreme pain disorder (PT)	10081856
	Laband syndrome (PT)	10081859
	Autosomal recessive megaloblastic anaemia (PT)	10081878
	Ring chromosome (PT)	10081894
	Donohue syndrome (PT)	10081896
	Tympanomeningeal fissure (PT)	10081914
	Checkpoint kinase 2 gene mutation (PT)	10081927
	Trisomy 16 (PT)	10081933
	Confined placental mosaicism (PT)	10081934
	PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome (PT)	10081947
	CHILD syndrome (PT)	10081963
	CYP3A4 polymorphism (PT)	10082012
	Grey matter heterotopia (PT)	10082084
	Short stature homeobox gene mutation (PT)	10082164
	Gap junction protein beta 2 gene mutation (PT)	10082218
	Congenital nasal septum deviation (PT)	10082221
	Shprintzen-Goldberg syndrome (PT)	10082234
	Pfeiffer syndrome (PT)	10082289
	Alpha-thalassaemia-intellectual deficit syndrome (PT)	10082291
	Congenital supraventricular tachycardia (PT)	10082343
	Ogden syndrome (PT)	10082376
	X-linked intellectual disability, Siderius type (PT)	10082377
	Schwartz Jampel syndrome (PT)	10082378
	Woodhouse-Sakati syndrome (PT)	10082379
	Aberrant aortic arch (PT)	10082380
	SADDAN syndrome (PT)	10082381
	Penta X syndrome (PT)	10082382
	Hyperpipecolic acidaemia (PT)	10082383
	1p36 deletion syndrome (PT)	10082398

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Phelan-McDermid syndrome (PT)	10082417
	Neutrophil Fc gamma RIIb deficiency (PT)	10082479
	Congenital arterial occlusion (PT)	10082546
	Plasminogen activator inhibitor type 1 deficiency (PT)	10082567
	Familial glucocorticoid deficiency (PT)	10082603
	Connective tissue dysplasia (PT)	10082604
	Uterine cervix canal atresia (PT)	10082605
	Neurodegeneration with brain iron accumulation disorder (PT)	10082633
	Apolipoprotein E e4 gene carrier (PT)	10082637
	Double inlet left ventricle (PT)	10082665
	Congenital bilateral perisylvian syndrome (PT)	10082716
	ROS1 gene rearrangement (PT)	10082790
	Anorectal malformation (PT)	10082798
	Cardiofaciocutaneous syndrome (PT)	10082805
	Papillon-Lefevre syndrome (PT)	10082856
	CFTR gene mutation (PT)	10082864
	RPE65 gene mutation (PT)	10082888
	Paranasal sinus hypoplasia (PT)	10082941
	Congenital LUMBAR syndrome (PT)	10082949
	TORCH infection (PT)	10082952
	Metatropic dysplasia (PT)	10082970
	Pycnodysostosis (PT)	10082973
	CDKL5 deficiency disorder (PT)	10083005
	Congenital ureteropelvic junction obstruction (PT)	10083021
	Glycogen storage disease type IX (PT)	10083034
	Alexander disease (PT)	10083059
	Hypotonia-cystinuria syndrome (PT)	10083099
	Aicardi-Goutieres syndrome (PT)	10083189
	Mannose-binding lectin deficiency (PT)	10083190

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Dacryocystocoele (PT)	10083192
	Systemic right ventricle (PT)	10083204
	Single atrium (PT)	10083205
	Fibromatosis colli of infancy (PT)	10083212
	Straddling tricuspid valve (PT)	10083223
	Bosch-Boonstra-Schaaf optic atrophy syndrome (PT)	10083269
	SATB2-associated syndrome (PT)	10083270
	Weaver syndrome (PT)	10083271
	Stahl's ear (PT)	10083305
	Galactosialidosis (PT)	10083306
	Saposin C deficiency (PT)	10083307
	Severe primary insulin like growth factor-1 deficiency (PT)	10083342
	Accessory renal artery (PT)	10083349
	OHVIRA syndrome (PT)	10083351
	Acquired chromosomal abnormality (PT)	10083362
	CYP3A5 polymorphism (PT)	10083372
	Transgenerational epigenetic inheritance (PT)	10083374
	Congenital dengue disease (PT)	10083386
	Odontoma (PT)	10083400
	Desmin myopathy (PT)	10083445
	Nievergelt-Pearlman syndrome (PT)	10083492
	Camptodactyly-arthropathy-coxa vara-pericarditis syndrome (PT)	10083494
	Congenital hyperinsulinaemic hypoglycaemia (PT)	10083495
	Congenital rubella syndrome (PT)	10083496
	Rapid-onset dystonia-parkinsonism (PT)	10083658
	Congenital Ebola virus infection (PT)	10083704
	CEC syndrome (PT)	10083749
	Abetalipoproteinaemia (PT)	10083851
	Isovaleric acidaemia (PT)	10083852

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Achard Thiers syndrome (PT)	10083853
	Acromicric dysplasia (PT)	10083854
	Alpha-mannosidosis (PT)	10083855
	ADNP syndrome (PT)	10083856
	Alpers disease (PT)	10083857
	Aniridia-cerebellar ataxia-mental deficiency (PT)	10083858
	Andersen-Tawil syndrome (PT)	10083859
	Ablepharon macrostomia syndrome (PT)	10083860
	ADCY5-related dyskinesia (PT)	10083861
	Antley-Bixler syndrome (PT)	10083864
	Acrocallosal syndrome (PT)	10083865
	Acromesomelic dysplasia (PT)	10083866
	AIDS dysmorphic syndrome (PT)	10083867
	Alpha-1 antitrypsin deficiency (PT)	10083869
	Ectonucleotide pyrophosphatase/phosphodiesterase 1 deficiency (PT)	10083910
	Congenital hypotransferrinaemia (PT)	10083911
	Sarcoglycanopathy (PT)	10083931
	Congenital hypogonadotropic hypogonadism (PT)	10083932
	GM2 gangliosidosis (PT)	10083933
	Congenital growth hormone deficiency (PT)	10083935
	Leukocyte adhesion deficiency type I (PT)	10083936
	Pro-opiomelanocortin deficiency (PT)	10083937
	Cone dystrophy (PT)	10083940
	Coffin Siris syndrome (PT)	10083941
	Congenital myasthenic syndrome (PT)	10083942
	Filippi syndrome (PT)	10083943
	Femoral facial syndrome (PT)	10083944
	Fountain syndrome (PT)	10083946
	De Barsy syndrome (PT)	10083947
	COPA syndrome (PT)	10083948

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Catel Manzke syndrome (PT)	10083949
	Schmid Fraccaro syndrome (PT)	10083957
	CARD9 deficiency (PT)	10083959
	ASAH1 related disorder (PT)	10083960
	Campomelic syndrome (PT)	10083962
	Baller-Gerold syndrome (PT)	10083963
	Opitz trigonocephaly syndrome (PT)	10083975
	Elbow synostosis (PT)	10084070
	Senior-Loken syndrome (PT)	10084074
	Transcobalamin deficiency (PT)	10084086
	Brown-Vialetto-Van Laere syndrome (PT)	10084089
	Creatine deficiency syndrome (PT)	10084104
	Leptin receptor deficiency (PT)	10084105
	Hyperphenylalaninaemia (PT)	10084106
	Primary coenzyme Q10 deficiency (PT)	10084107
	Inborn error of amino acid metabolism (PT)	10084108
	Pyruvate dehydrogenase complex deficiency (PT)	10084109
	Aromatic L-amino acid decarboxylase deficiency (PT)	10084110
	Primary hyperoxaluria (PT)	10084111
	Supernumerary rib (PT)	10084170
	Platelet storage pool deficiency (PT)	10084190
	ADSL gene mutation (PT)	10084193
	Hyperornithinaemia-hyperammonaemia-homocitrullinuria syndrome (PT)	10084220
	Pallister W syndrome (PT)	10084236
	Cryptotia (PT)	10084250
	Congenital viral hepatitis (PT)	10084251
	Congenital hepatitis C infection (PT)	10084252
	Asymmetric crying facies (PT)	10084253
	Haemoglobin Lepore trait (PT)	10084259
	Piebaldism (PT)	10084262

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Autoinflammation with infantile enterocolitis (PT)	10084306
	Congenital lymphatic dysplasia (PT)	10084317
	Robinow syndrome (PT)	10084325
	Roberts syndrome (PT)	10084326
	Swyer syndrome (PT)	10084327
	22q11.2 deletion syndrome (PT)	10084363
	Mitochondrial cardiomyopathy (PT)	10084364
	Split hand nystagmus syndrome (PT)	10084376
	Otospondylomegaepiphyseal dysplasia (PT)	10084407
	Otopalatodigital spectrum disorder (PT)	10084408
	Schinzel syndrome (PT)	10084409
	Nager syndrome (PT)	10084410
	KBG syndrome (PT)	10084411
	Riedel lobe (PT)	10084530
	Block vertebra (PT)	10084531
	DDX3X syndrome (PT)	10084534
	Myoclonic dystonia (PT)	10084572
	Melanocortin 4 receptor deficiency (PT)	10084582
	CBL gene mutation (PT)	10084604
	KMT2A gene mutation (PT)	10084605
	CALR gene mutation (PT)	10084606
	PRPF8 gene mutation (PT)	10084607
	SRSF2 gene mutation (PT)	10084608
	TP53 gene mutation (PT)	10084609
	ZRSR2 gene mutation (PT)	10084610
	ASXL1 gene mutation (PT)	10084611
	DNMT3A gene mutation (PT)	10084612
	EZH2 gene mutation (PT)	10084613
	MPL gene mutation (PT)	10084614
	NPM1 gene mutation (PT)	10084615
	STAG2 gene mutation (PT)	10084616

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	U2AF1 gene mutation (PT)	10084617
	FLT3 gene mutation (PT)	10084619
	RUNX1 gene mutation (PT)	10084620
	SF3B1 gene mutation (PT)	10084621
	TET2 gene mutation (PT)	10084622
	WT1 gene mutation (PT)	10084623
	PTPN11 gene mutation (PT)	10084624
	BCOR gene mutation (PT)	10084625
	CEBPA gene mutation (PT)	10084626
	Labrune syndrome (PT)	10084766
	Zeichi-Ceide syndrome (PT)	10084780
	NR5A1 gene mutation (PT)	10084823
	Abnormal DNA methylation (PT)	10084827
	Bifid ureter (PT)	10085056
	Loose anagen syndrome (PT)	10085066
	Congenital COVID-19 (PT)	10085080
	Stiff skin syndrome (PT)	10085085
	Dolichocephaly (PT)	10085104
	JAG1 gene mutation (PT)	10085239
	Heritable pulmonary arterial hypertension (PT)	10085244
	Lacrime-auriculo-dento-digital syndrome (PT)	10085252
	Inherited otosclerosis (PT)	10085362
	Cayler cardiofacial syndrome (PT)	10085379
	Cone-rod dystrophy (PT)	10085521
	Simpson-Golabi-Behmel syndrome (PT)	10085695
	CHAPPLE syndrome (PT)	10085728
	Disseminated superficial actinic porokeratosis (PT)	10085766
	Congenital arachnoid cyst (PT)	10085780
	VEXAS syndrome (PT)	10085860
	PURA syndrome (PT)	10085882
	Hereditary microcytic anaemia (PT)	10085905

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Haemochromatosis carrier (PT)	10085972
	Chronic atrial and intestinal dysrhythmia syndrome (PT)	10086078
	Epilepsy of infancy with migrating focal seizures (PT)	10086114
	Acatalasaemia (PT)	10086141
	Glycoprotein metabolism disorder (PT)	10086143
	Congenital lactase deficiency (PT)	10086148
	Primary bilateral macronodular adrenal hyperplasia (PT)	10086163
	Maternally inherited diabetes and deafness (PT)	10086189
	Vallecular cyst (PT)	10086190
	Histiocytosis-lymphadenopathy plus syndrome (PT)	10086258
	BARD 1 gene mutation (PT)	10086271
	Small patella syndrome (PT)	10086423
	Progressive encephalopathy, hypersarrhythmia and optic atrophy syndrome (PT)	10086607
	Geniospasm (PT)	10086622
	Oculo-digito-oesophageal-duodenal syndrome (PT)	10086623
	Hereditary persistence of foetal haemoglobin (PT)	10086664
	Purine nucleoside phosphorylase deficiency (PT)	10086665
	Inborn error of steroid synthesis (PT)	10086685
	Congenital connective tissue disorder (PT)	10086687
	Congenital musculoskeletal disorder of limbs (PT)	10086689
	Congenital musculoskeletal disorder of head and neck (PT)	10086691
	Congenital musculoskeletal disorder of spine (PT)	10086692
	Lysosomal storage disorder (PT)	10086694
	Congenital musculoskeletal disorder of skull	10086695

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Safety topic	MedDRA term selection of adverse events	MedDRA code
	(PT)	
	Congenital musculoskeletal disorder of trunk	10086699
	(PT)	
	Congenital musculoskeletal disorder (PT)	10086700
	GATA2 deficiency (PT)	10086705
	Congenital Chagas disease (PT)	10086708
	Congenital parvovirus B19 infection (PT)	10086713
	CRIA syndrome (PT)	10086727
	Familial chondrocalcinosis (PT)	10086739
	Congenital anisocoria (PT)	10086805
	Congenital viral infection (PT)	10086942
	Foetal tobacco syndrome (PT)	10086945
	Congenital lip pits (PT)	10086976
	Benign recurrent intrahepatic cholestasis (PT)	10087038
	Congenital leptin deficiency (PT)	10087061
	Myofibrillar myopathy (PT)	10087101
	Macrophthalmos (PT)	10087144
	Congenital female reproductive tract disorder	10087145
	(PT)	
	Congenital female genital tract fistula (PT)	10087146
	Progressive diaphyseal dysplasia (PT)	10087147
	Congenital alopecia (PT)	10087148
	Congenital subglottic stenosis (PT)	10087149
	Chondrodysplasia punctata (PT)	10087150
	Osteochondrodysplasia (PT)	10087151
	Congenital laryngeal malformation (PT)	10087152
	Athelia (PT)	10087153
	Congenital vena cava stenosis (PT)	10087154
	Pleural malformation (PT)	10087155
	Aphallia (PT)	10087156
	Arhinencephaly (PT)	10087157
	De la Chapelle syndrome (PT)	10087158

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Congenital vocal cord paralysis (PT)	10087175
	Heparin cofactor II deficiency (PT)	10087332
	Familial partial lipodystrophy (PT)	10087377
	PCDH19 gene mutation (PT)	10087458
	Congenital ectopic spleen (PT)	10087500
	Marfanoid habitus (PT)	10087588
	Vertebral artery fenestration (PT)	10087592
	Nakajo-Nishimura syndrome (PT)	10087602
	Congenital pulmonary airway malformation (PT)	10087693
	Alpha-1 antitrypsin deficiency carrier (PT)	10087740
	Anisomelia (PT)	10087742
	Odontoid process hypoplasia (PT)	10087748
	Taurodontism (PT)	10087780
	Drug resistance mutation (PT)	10087795
	Beaver tail liver (PT)	10087843
	Lymphatic malformation (PT)	10087901
	Foetal alcohol spectrum disorder (PT)	10087902
	Jansen's metaphyseal chondrodysplasia (PT)	10087907
	Raine syndrome (PT)	10087908
	Brooke-Spiegler syndrome (PT)	10087912
	RBM20 mutation (PT)	10087916
	Hereditary alpha tryptasaemia (PT)	10087980
	Spondylocostal dysostosis (PT)	10088002
	Congenital umbilico-enteric fistula (PT)	10088009
	Congenital trigeminal anaesthesia (PT)	10088099
	Congenital vaccinia virus infection (PT)	10088114
	WNT4 deficiency (PT)	10088125
	Familial dilated cardiomyopathy (PT)	10088172
	Glutaric acidaemia type I (PT)	10088192
	Infantile neuroaxonal dystrophy (PT)	10088200
	Macular hypoplasia (PT)	10088203
	Fumarase deficiency (PT)	10088204

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Vascular rings and slings (PT)	10088205
	Hereditary gingival fibromatosis (PT)	10088210
	Cerebral folate deficiency (PT)	10088217
	Gestational alloimmune liver disease (PT)	10088236
	Benign macrocrania of infancy (PT)	10088237
	Oligodontia (PT)	10088239
	Enameloma (PT)	10088243
	Cerebrocostomandibular syndrome (PT)	10088264
	Bile acid synthesis disorder (PT)	10088265
	Familial atrial fibrillation (PT)	10088317
	Paramyotonia congenita (PT)	10088318
	Galloway Mowat syndrome (PT)	10088355
	Nail dysplasia (PT)	10088402
	Poirier-Bienvenu neurodevelopmental syndrome (PT)	10088424
	Oculocerebrocutaneous syndrome (PT)	10088432
	Megalencephaly (PT)	10088459
	Mainzer-Saldino syndrome (PT)	10088468
	Diamine oxidase deficiency (PT)	10088485
	Ampullary renal pelvis (PT)	10088562
	PCSK9 gene mutation (PT)	10088568
	ApoB gene mutation (PT)	10088569
	Methylmalonic acidaemia (PT)	10088602
	Pituitary stalk interruption syndrome (PT)	10088621
	H63D mutation (PT)	10088628
	Overgrowth syndrome (PT)	10088693
	Ataxia with vitamin E deficiency (PT)	10088735
	Rabson Mendenhall syndrome (PT)	10088742
	FGFR3 gene mutation (PT)	10088779
	Muenke syndrome (PT)	10088781
	NTRK gene amplification (PT)	10088796
	STING-associated vasculopathy with onset in	10088833

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Safety topic	MedDRA term selection of adverse events	MedDRA code
	infancy (PT)	
	Abnormal gene carrier (PT)	10088840
	ALG8 gene mutation carrier (PT)	10088841
	Perlman syndrome (PT)	10088870
	Haber's syndrome (PT)	10088871
	Chromosomal microduplication (PT)	10088883
	Rapadilino syndrome (PT)	10088963
	Mitral valve dysplasia (PT)	10089005
	Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) (broad)	20000186
	Abnormal labour (PT)	10000153
	Abnormal labour affecting foetus (PT)	10000154
	Acute fatty liver of pregnancy (PT)	10000746
	Amniocentesis abnormal (PT)	10001959
	Amnioscopy abnormal (PT)	10001965
	Antiphospholipid syndrome (PT)	10002817
	Arrested labour (PT)	10003118
	Artificial rupture of membranes (PT)	10003440
	Bacteriuria in pregnancy (PT)	10004058
	Benign hydatidiform mole (PT)	10004272
	Breech delivery (PT)	10006346
	Breech extraction (PT)	10006348
	Breech presentation (PT)	10006356
	Brief psychotic disorder, with postpartum onset (PT)	10006362
	Caesarean section (PT)	10006924
	Cephalo-pelvic disproportion (PT)	10008020
	Cervical incompetence (PT)	10008267
	Chloasma (PT)	10008570
	Delayed delivery (PT)	10012186
	Diabetes complicating pregnancy (PT)	10012596

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Drug dependence, antepartum (PT)	10013675
	Drug dependence, postpartum (PT)	10013676
	Eclampsia (PT)	10014129
	Ectopic pregnancy (PT)	10014166
	Ectopic pregnancy termination (PT)	10014168
	Elderly primigravida (PT)	10014349
	Face presentation (PT)	10016035
	Failed forceps delivery (PT)	10016116
	Failed induction of labour (PT)	10016123
	Failed trial of labour (PT)	10016142
	False labour (PT)	10016194
	Foetal arm prolapse (PT)	10016846
	Foetal malposition (PT)	10016863
	Forceps delivery (PT)	10016991
	Gestational diabetes (PT)	10018209
	Glucose tolerance impaired in pregnancy (PT)	10018430
	Glycosuria during pregnancy (PT)	10018475
	Haemorrhage in pregnancy (PT)	10018981
	Herpes gestationis (PT)	10019939
	High foetal head (PT)	10020065
	Hyperemesis gravidarum (PT)	10020614
	Impetigo herpetiformis (PT)	10021534
	Incoordinate uterine action (PT)	10021648
	Induced labour (PT)	10021718
	Large for dates baby (PT)	10023789
	Locked twins (PT)	10024787
	Malignant hydatidiform mole (PT)	10025598
	Malignant neoplasm of placenta (PT)	10026350
	Mastitis postpartum (PT)	10026889
	Morning sickness (PT)	10027975
	Multiple pregnancy (PT)	10028243
	Obstetrical pulmonary embolism (PT)	10029925

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Obstructed labour (PT)	10029934
	Oligohydramnios (PT)	10030289
	Pelvic haematoma obstetric (PT)	10034248
	Perineal haematoma (PT)	10034520
	Perineal repair breakdown (PT)	10034528
	Pituitary infarction (PT)	10035092
	Placenta praevia (PT)	10035119
	Placenta praevia haemorrhage (PT)	10035121
	Placental disorder (PT)	10035132
	Placental insufficiency (PT)	10035138
	Placental necrosis (PT)	10035139
	Placental polyp (PT)	10035142
	Placental transfusion syndrome (PT)	10035146
	Polyhydramnios (PT)	10036079
	Postpartum hypopituitarism (PT)	10036297
	Postpartum venous thrombosis (PT)	10036300
	Postpartum haemorrhage (PT)	10036417
	Postpartum neurosis (PT)	10036419
	Postpartum sepsis (PT)	10036422
	Postpartum uterine subinvolution (PT)	10036423
	Pre-eclampsia (PT)	10036485
	Precipitate labour (PT)	10036519
	Pregnancy in habitual aborter (PT)	10036562
	Pregnancy with advanced maternal age (PT)	10036582
	Premature delivery (PT)	10036595
	Premature labour (PT)	10036600
	Premature rupture of membranes (PT)	10036603
	Premature separation of placenta (PT)	10036608
	Previous caesarean section (PT)	10036656
	Prolonged labour (PT)	10036872
	Prolonged pregnancy (PT)	10036877
	Puerperal pyrexia (PT)	10037294

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Reproductive toxicity	Retained placenta or membranes (PT)	10038758
	Retained products of conception (PT)	10038773
	Rubella in pregnancy (PT)	10039264
	Shoulder dystocia (PT)	10040613
	Third stage postpartum haemorrhage (PT)	10043449
	Threatened labour (PT)	10043508
	Transverse presentation (PT)	10044456
	Traumatic delivery (PT)	10044520
	Twin pregnancy (PT)	10045188
	Ultrasound antenatal screen abnormal (PT)	10045400
	Umbilical cord around neck (PT)	10045447
	Umbilical cord compression (PT)	10045451
	Umbilical cord prolapse (PT)	10045452
	Umbilical cord short (PT)	10045453
	Umbilical cord vascular disorder (PT)	10045454
	Unstable foetal lie (PT)	10046255
	Uterine atony (PT)	10046763
	Uterine hypertonus (PT)	10046790
	Uterine hypotonus (PT)	10046792
	Uterine inversion (PT)	10046796
	Uterine malposition (PT)	10046800
	Uterine rupture (PT)	10046820
	Vacuum extractor delivery (PT)	10046868
	Vasa praevia (PT)	10047036
	Ruptured ectopic pregnancy (PT)	10048407
	Biopsy chorionic villous abnormal (PT)	10048537
	Umbilical cord abnormality (PT)	10048596
	Tocolysis (PT)	10048773
	Cholestasis of pregnancy (PT)	10049055
	HELLP syndrome (PT)	10049058
	Peripartum cardiomyopathy (PT)	10049430
	Gestational trophoblastic detachment (PT)	10049469

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Afterbirth pain (PT)	10049589
	Metastases to placenta (PT)	10049725
	Uterine contractions during pregnancy (PT)	10049975
	Amniotic infection syndrome of Blane (PT)	10051407
	Amniorrhexis (PT)	10051641
	High risk pregnancy (PT)	10052744
	Brow presentation (PT)	10052848
	Oblique presentation (PT)	10052849
	Labour stimulation (PT)	10052855
	Labour induction (PT)	10052856
	Obstetric infection (PT)	10053636
	Retroplacental haematoma (PT)	10054798
	Placental dysplasia (PT)	10054810
	Cervix dystocia (PT)	10054939
	Cervix cerclage procedure (PT)	10054992
	Intrauterine infection (PT)	10056254
	Maternal distress during labour (PT)	10056391
	Postpartum stress disorder (PT)	10056394
	Renal disorder in pregnancy (PT)	10056505
	Thyroid dysfunction in pregnancy (PT)	10056525
	Placental chorioangioma (PT)	10056718
	Foetal malpresentation (PT)	10058013
	Maternal therapy to enhance foetal lung maturity (PT)	10058340
	Missed labour (PT)	10059107
	Amniotic cavity disorder (PT)	10060936
	Amniotic cavity infection (PT)	10060937
	Labour complication (PT)	10061050
	Obstetric procedure complication (PT)	10061315
	Placental neoplasm (PT)	10061349
	Uterine contractions abnormal (PT)	10061400
	Complication of pregnancy (PT)	10061452

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Postpartum disorder (PT)	10061469
	Assisted delivery (PT)	10061661
	Complication of delivery (PT)	10061781
	Placenta accreta (PT)	10062936
	Amniotic fluid volume decreased (PT)	10063356
	Amniotic fluid volume increased (PT)	10063357
	Gestational oedema (PT)	10063412
	Rhesus incompatibility (PT)	10063676
	Lymphocytic hypophysitis (PT)	10063685
	Heterotopic pregnancy (PT)	10064228
	Omphalorrhexis (PT)	10064270
	Umbilical cord haemorrhage (PT)	10064534
	Placental infarction (PT)	10064620
	Symphysiotomy (PT)	10064625
	Amniotic fluid erythropoietin level increased (PT)	10064845
	Drug exposure before pregnancy (PT)	10064998
	Prophylaxis of abortion (PT)	10065000
	Maternal alcohol use (PT)	10065158
	Varicose veins vaginal (PT)	10066002
	Polymorphic eruption of pregnancy (PT)	10066100
	Lochial infection (PT)	10066103
	Uterine hyperstimulation (PT)	10066288
	Prophylaxis against Rh isoimmunisation (PT)	10066359
	Anaemia of pregnancy (PT)	10066468
	Amniorrhoea (PT)	10066470
	Anaphylactoid syndrome of pregnancy (PT)	10067010
	Venous thrombosis in pregnancy (PT)	10067030
	Amniotic fluid index abnormal (PT)	10067079
	Tubal rupture (PT)	10067553
	Intrapartum haemorrhage (PT)	10067703
	Shortened cervix (PT)	10067726

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Uterine cervix stenosis (PT)	10067732
	Placental hypertrophy (PT)	10068326
	Decidual cast (PT)	10068735
	Mirror syndrome (PT)	10068875
	Discordant twin (PT)	10069150
	Prenatal screening test abnormal (PT)	10069151
	Pregnancy with young maternal age (PT)	10069615
	Uterine dehiscence (PT)	10070301
	Gestational hypertension (PT)	10070538
	External cephalic version (PT)	10070636
	Inferior vena cava syndrome (PT)	10070911
	Subchorionic haemorrhage (PT)	10071010
	Vulvovaginal injury (PT)	10071212
	Exposure via father (PT)	10071403
	Foetal exposure during pregnancy (PT)	10071404
	Foetal exposure timing unspecified (PT)	10071405
	Maternal exposure before pregnancy (PT)	10071406
	Maternal exposure during pregnancy (PT)	10071408
	Foetal exposure during delivery (PT)	10071409
	Maternal exposure timing unspecified (PT)	10071415
	Foetal monitoring abnormal (PT)	10071507
	Umbilical cord thrombosis (PT)	10071652
	Small size placenta (PT)	10072038
	Chronic villitis of unknown etiology (PT)	10072271
	Delivery outside health facility (PT)	10072446
	Kleihauer-Betke test positive (PT)	10072577
	Subchorionic haematoma (PT)	10072596
	Puerperal infection (PT)	10072652
	Peripartum haemorrhage (PT)	10072693
	Pregnancy of unknown location (PT)	10072811
	Preterm premature rupture of membranes (PT)	10073024
	Prolonged rupture of membranes (PT)	10073027

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Induction of cervix ripening (PT)	10073175
	Postponement of preterm delivery (PT)	10073177
	Reversible cerebral vasoconstriction syndrome (PT)	10073240
	Perineal injury (PT)	10073329
	Exposure during pregnancy (PT)	10073513
	Ectopic pregnancy under hormonal contraception (PT)	10073727
	Uterine adhesions (PT)	10074333
	Ectopic pregnancy with contraceptive device (PT)	10074497
	Uterine scar (PT)	10074527
	Endometritis bacterial (PT)	10074861
	Hyperreactio luteinalis (PT)	10074866
	Amniotic fluid index decreased (PT)	10075866
	Amniotic fluid index increased (PT)	10075867
	Uterine scar diverticulum (PT)	10076608
	Postpartum thrombosis (PT)	10077022
	Tracheloplasty (PT)	10077464
	Retained placenta operation (PT)	10078243
	Risk of future pregnancy miscarriage (PT)	10078342
	Uterine compression sutures (PT)	10078738
	Amniotic membrane rupture test positive (PT)	10078834
	Blood type incompatibility (PT)	10078985
	Silent thyroiditis (PT)	10079012
	Umbilical cord cyst (PT)	10079122
	Uterine irritability (PT)	10079224
	Short interpregnancy interval (PT)	10079272
	Drug use disorder, antepartum (PT)	10079382
	Drug use disorder, postpartum (PT)	10079383
	Angiotensin II receptor type 1 antibody positive (PT)	10079737
	Labour augmentation (PT)	10079807

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Maternal cancer in pregnancy (PT)	10079877
	Uterine tachysystole (PT)	10080022
	Paternal exposure during pregnancy (PT)	10080091
	Paternal exposure timing unspecified (PT)	10080092
	Paternal exposure before pregnancy (PT)	10080093
	Chorioamniotic separation (PT)	10080381
	Threatened uterine rupture (PT)	10080427
	Bimanual uterine compression (PT)	10080950
	Placental lake (PT)	10081737
	Placental calcification (PT)	10082008
	Uterine hypokinesia (PT)	10082029
	Placenta duplex (PT)	10082173
	Postpartum anxiety (PT)	10082233
	Asynclitic presentation (PT)	10082614
	Placental cyst (PT)	10083196
	Pelvic girdle pain (PT)	10083336
	Foetal dystocia (PT)	10083545
	Umbilical artery vascular resistance increased (PT)	10084637
	Superimposed pre-eclampsia (PT)	10084825
	Abnormal cord insertion (PT)	10084854
	Uterine diverticulum (PT)	10084900
	Maternal exposure via partner during pregnancy (PT)	10084938
	Cervix scarring (PT)	10085368
	Foetal vascular malperfusion (PT)	10085689
	Lochiostasis (PT)	10085701
	Uterine artery embolisation (PT)	10085781
	Genital scarring (PT)	10086046
	Vaginal tamponade (PT)	10086574
	Reproductive tract procedural infection (PT)	10086679
	Perineal swelling (PT)	10086719

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Maternal death (PT)	10086743
	Obstetrical tetanus (PT)	10086748
	Pregnancy related infection (PT)	10086854
	Medically induced preterm birth (PT)	10086969
	Maternal body mass index decreased (PT)	10087008
	Maternal body mass index increased (PT)	10087009
	Excessive maternal gestational weight gain (PT)	10087010
	Maternal pre-pregnancy underweight (PT)	10087011
	Maternal pre-pregnancy obesity (PT)	10087013
	Placental oedema (PT)	10088054
	Prurigo of pregnancy (PT)	10088604
	Maternal disease complicating pregnancy (PT)	10088758
	Lactation related topics (incl neonatal exposure through breast milk) (SMQ) (broad)	20000187
	Functional lactation disorders (SMQ) (broad)	20000188
	Galactocele (PT)	10017590
	Lactation puerperal increased (PT)	10023671
	Mastitis (PT)	10026883
	Nipple infection (PT)	10029419
	Retracted nipple (PT)	10038944
	Breast milk discolouration (PT)	10058665
	Galactostasis (PT)	10060710
	Lactation disorder (PT)	10061261
	Nipple inflammation (PT)	10064043
	Mastitis fungal (PT)	10065211
	Mastitis bacterial (PT)	10065212
	Lactation inhibition therapy (PT)	10069058
	Neonatal insufficient breast milk syndrome (PT)	10072188
	Viral mastitis (PT)	10074560
	Lactation stimulation therapy (PT)	10079806
	Breast milk odour abnormal (PT)	10080335
	Delayed onset of lactation (PT)	10088878

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Lactation insufficiency (PT)	10088879
	Neonatal exposures via breast milk (SMQ) (broad)	20000189
	Intoxication by breast feeding (PT)	10049999
	Exposure via breast milk (PT)	10080751
	Maternal exposure during breast feeding (PT)	10080752
	Foetal disorders (SMQ) (broad)	20000190
	Alpha 1 foetoprotein abnormal (PT)	10001773
	Alpha 1 foetoprotein amniotic fluid abnormal (PT)	10001776
	Alpha 1 foetoprotein amniotic fluid increased (PT)	10001778
	Alpha 1 foetoprotein decreased (PT)	10001780
	Alpha 1 foetoprotein increased (PT)	10001781
	Bradycardia foetal (PT)	10006094
	Cerebral infarction foetal (PT)	10008119
	Foetal arrhythmia (PT)	10016847
	Foetal damage (PT)	10016852
	Foetal distress syndrome (PT)	10016855
	Foetal malnutrition (PT)	10016862
	Foetal-maternal haemorrhage (PT)	10016871
	Hydrops foetalis (PT)	10020529
	Maternal death affecting foetus (PT)	10026912
	Maternal drugs affecting foetus (PT)	10026923
	Maternal hypertension affecting foetus (PT)	10026924
	Meconium increased (PT)	10027059
	Tachycardia foetal (PT)	10043074
	Cerebral haemorrhage foetal (PT)	10050157
	Foetal acidosis (PT)	10050347
	Paternal drugs affecting foetus (PT)	10050425
	Meconium in amniotic fluid (PT)	10051133
	Foetal heart rate decreased (PT)	10051136
	Foetal heart rate increased (PT)	10051138

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Foetal heart rate abnormal (PT)	10051139
	Foetal cardiac disorder (PT)	10052088
	Anaesthetic complication foetal (PT)	10052850
	Foetal cerebrovascular disorder (PT)	10053601
	Radiation injury affecting foetus (PT)	10053602
	Foetal macrosomia (PT)	10053700
	Meconium stain (PT)	10057028
	Foetal therapeutic procedure (PT)	10057294
	Maternal condition affecting foetus (PT)	10057673
	Meconium peritonitis (PT)	10058113
	Biopsy foetal abnormal (PT)	10058370
	Alpha 1 foetoprotein amniotic fluid decreased (PT)	10060746
	Foetal disorder (PT)	10061157
	Foetal heart rate disorder (PT)	10061158
	Haemorrhage foetal (PT)	10061191
	Cordocentesis (PT)	10066447
	Vesicoamniotic shunt (PT)	10068236
	Foetal hypokinesia (PT)	10068461
	Foetal growth restriction (PT)	10070531
	Foetal non-stress test abnormal (PT)	10071516
	Gestational age test abnormal (PT)	10072479
	Foetal heart rate deceleration abnormality (PT)	10074636
	Baseline foetal heart rate variability disorder (PT)	10074638
	Nonreassuring foetal heart rate pattern (PT)	10074641
	Foetal heart rate acceleration abnormality (PT)	10074642
	Sinusoidal foetal heart rate pattern (PT)	10074643
	Umbilical cord occlusion (PT)	10076714
	Foetal tachyarrhythmia (PT)	10077575
	Foetal movement disorder (PT)	10077576
	Foetal anaemia (PT)	10077577

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Ultrasound foetal abnormal (PT)	10077578
	Foetal gastrointestinal tract imaging abnormal (PT)	10077579
	Foetal musculoskeletal imaging abnormal (PT)	10077580
	Foetal renal imaging abnormal (PT)	10077581
	Foetal growth abnormality (PT)	10077582
	Foetal compartment fluid collection (PT)	10077628
	Foetal biophysical profile score equivocal (PT)	10078123
	Foetal biophysical profile score abnormal (PT)	10078124
	Foetal renal impairment (PT)	10078987
	Foetal heart rate indeterminate (PT)	10079882
	Foetal surgery (PT)	10080563
	Enlarged foetal cisterna magna (PT)	10081422
	Foetal cardiac arrest (PT)	10084280
	Increased foetal movements (PT)	10086915
	Foetal cardiac function test abnormal (PT)	10087476
	Foetal brain scan abnormal (PT)	10087477
	Drug administered to foetus (PT)	10087864
	Maternal-foetal therapy (PT)	10088442
	Neonatal disorders (SMQ) (broad)	20000191
	ABO incompatibility (PT)	10000206
	Acne infantile (PT)	10000507
	Adrenocortical insufficiency neonatal (PT)	10001391
	Agitation neonatal (PT)	10001500
	Anaemia neonatal (PT)	10002068
	Apgar score low (PT)	10002944
	Arrhythmia neonatal (PT)	10003124
	Atelectasis neonatal (PT)	10003599
	Atrial septal defect repair (PT)	10003667
	Birth trauma (PT)	10004954
	Blood loss anaemia neonatal (PT)	10005644
	Breast engorgement in newborn (PT)	10006241

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Bronchopulmonary dysplasia (PT)	10006475
	Cardiac arrest neonatal (PT)	10007516
	Cardio-respiratory arrest neonatal (PT)	10007618
	Cephalhaematoma (PT)	10008014
	Cerebral haemorrhage neonatal (PT)	10008112
	Circulatory failure neonatal (PT)	10009196
	Cleft palate repair (PT)	10009272
	Coagulation disorder neonatal (PT)	10009732
	Coxsackie viral disease of the newborn (PT)	10011260
	Cranial nerve injury secondary to birth trauma (PT)	10011308
	Cyanosis neonatal (PT)	10011705
	Death neonatal (PT)	10011912
	Diarrhoea infectious neonatal (PT)	10012744
	Disseminated intravascular coagulation in newborn (PT)	10013443
	Drug withdrawal syndrome neonatal (PT)	10013756
	Dyskinesia neonatal (PT)	10013922
	Eczema infantile (PT)	10014198
	Encephalopathy neonatal (PT)	10014633
	Endocardial cushion defect repair (PT)	10014657
	Extraocular retinoblastoma (PT)	10015831
	Facial nerve injury due to birth trauma (PT)	10016056
	Failure to thrive (PT)	10016165
	Fever neonatal (PT)	10016562
	Fontanelle bulging (PT)	10016945
	Fracture of clavicle due to birth trauma (PT)	10017107
	Gangrene neonatal (PT)	10017717
	Granulocytopenia neonatal (PT)	10018688
	Grey syndrome neonatal (PT)	10018723
	Haemorrhagic disease of newborn (PT)	10019008
	Hepatitis neonatal (PT)	10019785

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Hepatocellular damage neonatal (PT)	10019834
	Hepatosplenomegaly neonatal (PT)	10019848
	Hyperbilirubinaemia neonatal (PT)	10020580
	Hyperkinesia neonatal (PT)	10020652
	Hypoglycaemia neonatal (PT)	10020994
	Hypokinesia neonatal (PT)	10021022
	Hypotonia neonatal (PT)	10021119
	Hypoventilation neonatal (PT)	10021134
	Immature respiratory system (PT)	10021412
	Infantile colic (PT)	10021746
	Infantile scurvy (PT)	10021749
	Infantile spasms (PT)	10021750
	Injury to brachial plexus due to birth trauma (PT)	10022158
	Injury to spinal cord secondary to birth trauma (PT)	10022343
	Intraventricular haemorrhage neonatal (PT)	10022841
	Isoimmune haemolytic disease (PT)	10023052
	Jaundice neonatal (PT)	10023138
	Kernicterus (PT)	10023376
	Late metabolic acidosis of newborn (PT)	10024004
	Lymphocytopenia neonatal (PT)	10025279
	Meconium ileus (PT)	10027058
	Myasthenia gravis neonatal (PT)	10028419
	Neonatal alveolar aeration excessive (PT)	10028918
	Neonatal anoxia (PT)	10028921
	Neonatal asphyxia (PT)	10028923
	Neonatal candida infection (PT)	10028924
	Neonatal diabetes mellitus (PT)	10028933
	Neonatal disorder (PT)	10028934
	Neonatal exchange blood transfusion (PT)	10028937
	Neonatal infective mastitis (PT)	10028950

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Neonatal intestinal obstruction (PT)	10028951
	Neonatal respiratory acidosis (PT)	10028966
	Neonatal respiratory alkalosis (PT)	10028967
	Neonatal respiratory arrest (PT)	10028968
	Neonatal respiratory depression (PT)	10028970
	Neonatal respiratory distress (PT)	10028973
	Neonatal respiratory distress syndrome (PT)	10028974
	Neonatal respiratory failure (PT)	10028975
	Neonatal thyrotoxicosis (PT)	10028976
	Neuroblastoma (PT)	10029260
	Neutropenia neonatal (PT)	10029358
	Omphalitis (PT)	10030306
	Ophthalmia neonatorum (PT)	10030861
	Patent ductus arteriosus repair (PT)	10034131
	Postmature baby (PT)	10036392
	Premature baby (PT)	10036590
	Purpura neonatal (PT)	10037557
	Pyloromyotomy (PT)	10037626
	Rash neonatal (PT)	10037871
	Renal failure neonatal (PT)	10038447
	Repair of imperforate rectum (PT)	10038570
	Respiratory tract haemorrhage neonatal (PT)	10038728
	Retinopathy of prematurity (PT)	10038933
	Sepsis neonatal (PT)	10040049
	Small for dates baby (PT)	10041092
	Somnolence neonatal (PT)	10041350
	Subarachnoid haemorrhage neonatal (PT)	10042317
	Subdural haemorrhage neonatal (PT)	10042365
	Sudden infant death syndrome (PT)	10042440
	Tetanus neonatorum (PT)	10043378
	Thrombocytopenia neonatal (PT)	10043557
	Thrombophlebitis neonatal (PT)	10043586

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Transient hypogammaglobulinaemia of infancy (PT)	10044388
	Transient tachypnoea of the newborn (PT)	10044403
	Tremor neonatal (PT)	10044575
	Umbilical sepsis (PT)	10045470
	Urinary tract infection neonatal (PT)	10046573
	Ventricular septal defect repair (PT)	10047301
	Vision abnormal neonatal (PT)	10047511
	Weight decrease neonatal (PT)	10047894
	Hypertonia neonatal (PT)	10048615
	Immature larynx (PT)	10048855
	Neonatal hyponatraemia (PT)	10049222
	Neonatal hypotension (PT)	10049223
	Herpes simplex virus conjunctivitis neonatal (PT)	10049458
	Neonatal tachycardia (PT)	10049775
	Renal impairment neonatal (PT)	10049776
	Melaena neonatal (PT)	10049777
	Neonatal anuria (PT)	10049778
	Peripheral oedema neonatal (PT)	10049779
	Neonatal cardiac failure (PT)	10049780
	Hypertension neonatal (PT)	10049781
	Neonatal neuroblastoma (PT)	10049793
	Neonatal hepatomegaly (PT)	10049995
	Hypothermia neonatal (PT)	10050080
	Neonatal hypoxia (PT)	10050081
	Poor weight gain neonatal (PT)	10050086
	Cardiomyopathy neonatal (PT)	10050111
	Haemolysis neonatal (PT)	10050190
	Hygroma colli (PT)	10050249
	Neonatal oversedation (PT)	10050395
	Neonatal multi-organ failure (PT)	10050401
	Pulmonary oedema neonatal (PT)	10050459

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Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Leukopenia neonatal (PT)	10050504
	Floppy infant (PT)	10051004
	Meconium abnormal (PT)	10051132
	High-pitched crying (PT)	10052286
	Periventricular leukomalacia (PT)	10052594
	Systemic-pulmonary artery shunt (PT)	10052717
	Anaesthetic complication neonatal (PT)	10052851
	Fontanelle depressed (PT)	10053214
	Neonatal pneumonia (PT)	10053584
	Meningoencephalitis herpes simplex neonatal (PT)	10053586
	Neonatal mucocutaneous herpes simplex (PT)	10053587
	Group B streptococcus neonatal sepsis (PT)	10053588
	Pulmonary dysmaturity syndrome (PT)	10053766
	Inclusion conjunctivitis neonatal (PT)	10053991
	Delayed closure of cranial sutures (PT)	10054008
	Delayed fontanelle closure (PT)	10054034
	Neonatal respiratory distress syndrome	10054933
	prophylaxis (PT)	
	Necrotising enterocolitis neonatal (PT)	10055667
	Erythema toxicum neonatorum (PT)	10056274
	Caput succedaneum (PT)	10056311
	Perinatal brain damage (PT)	10056392
	Bradycardia neonatal (PT)	10056471
	Neonatal cholestasis (PT)	10056528
	Neonatal warming therapy (PT)	10056585
	Incubator therapy (PT)	10056613
	Apgar score abnormal (PT)	10056850
	Neonatal hypoparathyroidism (PT)	10056974
	Cleft lip repair (PT)	10056999
	Neonatal tetany (PT)	10057037
	Meconium plug syndrome (PT)	10057075
	Neonatal tachypnoea (PT)	10057183

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Cranial sutures widening (PT)	10058604
	Poor sucking reflex (PT)	10058605
	Meningitis neonatal (PT)	10058780
	Neonatal intestinal dilatation (PT)	10058934
	Neonatal aspiration (PT)	10059033
	Overfeeding of infant (PT)	10059260
	Coma neonatal (PT)	10059497
	Head circumference abnormal (PT)	10060043
	Polycythaemia neonatorum (PT)	10060476
	Alloimmunisation (PT)	10060935
	Neonatal infection (PT)	10061308
	Oedema neonatal (PT)	10061317
	Respiratory disorder neonatal (PT)	10061484
	Neonatal complications of substance abuse (PT)	10061862
	Haemorrhage neonatal (PT)	10061993
	Infantile spitting up (PT)	10063338
	Balloon atrial septostomy (PT)	10064200
	Funisitis (PT)	10064502
	Venous thrombosis neonatal (PT)	10064602
	Thymus enlargement (PT)	10065588
	Arterial switch operation (PT)	10066129
	Aorticopulmonary window repair (PT)	10066834
	Tetralogy of Fallot repair (PT)	10067017
	Low birth weight baby (PT)	10067508
	Umbilical granuloma (PT)	10067731
	Pulmonary air leakage (PT)	10067826
	Norwood procedure (PT)	10068098
	Atrial switch operation (PT)	10068964
	Gaspings syndrome (PT)	10069162
	Subgaleal haematoma (PT)	10069510
	Perinatal HIV infection (PT)	10071049
	Growth failure (PT)	10071095

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Maternal exposure during delivery (PT)	10071407
	Early infantile epileptic encephalopathy with burst-suppression (PT)	10071545
	Breast milk substitute intolerance (PT)	10072187
	Umbilical discharge (PT)	10072595
	Neonatal behavioural syndrome (PT)	10072605
	Transient neonatal pustular melanosis (PT)	10072688
	Neuroendocrine cell hyperplasia of infancy (PT)	10072968
	Lenticulostriatal vasculopathy (PT)	10073774
	Perinatal stroke (PT)	10073945
	Parenteral nutrition associated liver disease (PT)	10074151
	Disturbance of thermoregulation of newborn (PT)	10074158
	Neonatal gastrointestinal haemorrhage (PT)	10074159
	Neonatal intestinal perforation (PT)	10074160
	Dry lung syndrome (PT)	10074163
	Meconium cyst (PT)	10074182
	Fixed bowel loop (PT)	10074216
	Junctional ectopic tachycardia (PT)	10074640
	Perinatal HBV infection (PT)	10075233
	Infantile vomiting (PT)	10075315
	Poor feeding infant (PT)	10075316
	Infantile haemangioma (PT)	10075378
	Neonatal testicular torsion (PT)	10075380
	Feeding intolerance (PT)	10076042
	Neonatal gastrointestinal disorder (PT)	10076388
	Meconium aspiration syndrome (PT)	10076496
	Periventricular haemorrhage neonatal (PT)	10076706
	Infantile back arching (PT)	10077276
	Infantile apnoea (PT)	10077321
	Epileptic encephalopathy (PT)	10077380
	Sporadic infantile bilateral striatal necrosis	10077451

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
	(PT)	
	Neonatal toxicity (PT)	10078986
	Neonatal hypocalcaemia (PT)	10079306
	Posthaemorrhagic hydrocephalus (PT)	10079859
	Neonatal deafness (PT)	10080897
	Subgaleal haemorrhage (PT)	10080900
	Neonatal hypoacusis (PT)	10080902
	Birth defect correction (PT)	10081218
	Truncus arteriosus repair (PT)	10081508
	Neonatal bradyarrhythmia (PT)	10082054
	Neonatal tachyarrhythmia (PT)	10082055
	Neonatal pneumothorax (PT)	10082056
	Neonatal seizure (PT)	10082067
	Neonatal epileptic seizure (PT)	10082068
	Infant sedation (PT)	10082187
	Neonatal sinus bradycardia (PT)	10082188
	Infant irritability (PT)	10082189
	Constipation neonatal (PT)	10082190
	Neonatal sinus tachycardia (PT)	10082191
	Administration site reaction neonatal (PT)	10082193
	Pulmonary haemorrhage neonatal (PT)	10082194
	Infant dyschezia (PT)	10082228
	Small fontanelle (PT)	10082319
	Neonatal deformity (PT)	10082494
	Infantile acropustulosis (PT)	10083179
	Postnatal growth restriction (PT)	10083523
	Neonatal Crohn's disease (PT)	10084237
	Neonatal dyspnoea (PT)	10084238
	Midline head position (PT)	10084324
	Finnegan score increased (PT)	10085520
	Brief resolved unexplained event (PT)	10086181
	Delayed umbilical cord clamping (PT)	10086215

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Suck-swallow breathing coordination disturbance (PT)	10086396
	Neonatal hyperglycaemia (PT)	10086425
	Neonatal bacteraemia (PT)	10086931
	Scalp injury due to birth trauma (PT)	10086941
	Hypoxic ischaemic encephalopathy neonatal (PT)	10086943
	Intracranial haemorrhage neonatal (PT)	10086946
	Infantile postural asymmetry (PT)	10087210
	Subaponeurotic cerebrospinal fluid collection of infancy (PT)	10087497
	Neonatal bacterial pneumonia (PT)	10087867
	Transient neonatal hyperthyrotropinaemia (PT)	10087924
	High risk infant (PT)	10088619
	Delayed passage of meconium (PT)	10088625
	Infantile diarrhoea (PT)	10088652
	Gastrooesophageal reflux in neonate (PT)	10088653
	Neonatal pulmonary hypertension (PT)	10088909
	Termination of pregnancy and risk of abortion (SMQ) (broad)	20000192
	Aborted pregnancy (PT)	10000209
	Abortion (PT)	10000210
	Abortion complete complicated (PT)	10000212
	Abortion incomplete (PT)	10000217
	Abortion incomplete complicated (PT)	10000218
	Abortion induced (PT)	10000220
	Abortion induced complete complicated (PT)	10000221
	Abortion induced complicated (PT)	10000223
	Abortion induced incomplete complicated (PT)	10000225
	Abortion infected (PT)	10000228
	Abortion missed (PT)	10000230
	Abortion spontaneous (PT)	10000234
	Abortion spontaneous complete complicated (PT)	10000236

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Abortion spontaneous complicated (PT)	10000238
	Abortion spontaneous incomplete complicated (PT)	10000239
	Abortion threatened (PT)	10000242
	Evacuation of retained products of conception (PT)	10015550
	Mycoplasmal postabortal fever (PT)	10028479
	Post abortion complication (PT)	10036244
	Post abortion haemorrhage (PT)	10036246
	Stillbirth (PT)	10042062
	Imminent abortion (PT)	10051459
	Induced abortion haemorrhage (PT)	10052844
	Induced abortion infection (PT)	10052845
	Abortion early (PT)	10052846
	Abortion late (PT)	10052847
	Induced abortion failed (PT)	10053191
	Abortion induced incomplete (PT)	10053984
	Foetal death (PT)	10055690
	Abnormal product of conception (PT)	10060927
	Abortion induced complete (PT)	10060928
	Post abortion infection (PT)	10061467
	Abortion complete (PT)	10061614
	Abortion complicated (PT)	10061615
	Abortion spontaneous complete (PT)	10061616
	Abortion spontaneous incomplete (PT)	10061617
	Habitual abortion (PT)	10062935
	Biochemical pregnancy (PT)	10063639
	Molar abortion (PT)	10065942
	Abortion of ectopic pregnancy (PT)	10066266
	Selective abortion (PT)	10067499
	Vanishing twin syndrome (PT)	10071398
	Foeticide (PT)	10075033
	Premature baby death (PT)	10076700

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Anembryonic gestation (PT)	10079814
	Lithopedion (PT)	10082976
	Vacuum aspiration (PT)	10083276
	Normal pregnancy conditions and outcomes (SMQ) (broad)	20000193
	Alpha 1 foetoprotein amniotic fluid normal (PT)	10001779
	Alpha 1 foetoprotein normal (PT)	10001782
	Amniocentesis normal (PT)	10001963
	Amnioscopy normal (PT)	10001966
	Breast engorgement (PT)	10006240
	Multigravida (PT)	10028160
	Multiparous (PT)	10028163
	Normal labour (PT)	10029767
	Normal newborn (PT)	10029769
	Nulliparous (PT)	10029827
	Parity (PT)	10033997
	Pregnancy (PT)	10036556
	Pregnancy on oral contraceptive (PT)	10036567
	Pregnancy test positive (PT)	10036575
	Pregnancy test urine positive (PT)	10036578
	Primigravida (PT)	10036757
	Primiparous (PT)	10036758
	Ultrasound antenatal screen normal (PT)	10045401
	Unintended pregnancy (PT)	10045542
	Unwanted pregnancy (PT)	10046267
	Postpartum state (PT)	10048738
	Normal fetus (PT)	10049081
	Live birth (PT)	10049550
	Pregnancy of partner (PT)	10050192
	Foetal heart rate normal (PT)	10051140
	First trimester pregnancy (PT)	10052395
	Second trimester pregnancy (PT)	10052396

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Case retrieval strategy

Safety topic	MedDRA term selection of adverse events	MedDRA code
Reproductive toxicity	Third trimester pregnancy (PT)	10052397
	Prenatal care (PT)	10052859
	Pregnancy with injectable contraceptive (PT)	10053394
	Biopsy foetal normal (PT)	10058398
	Labour pain (PT)	10059204
	Pregnancy with implant contraceptive (PT)	10063122
	Pregnancy with contraceptive device (PT)	10063130
	False negative pregnancy test (PT)	10063476
	Pregnancy after post coital contraception (PT)	10063671
	Pregnancy with contraceptive patch (PT)	10067082
	Delivery (PT)	10067647
	Pregnancy on contraceptive (PT)	10067667
	Human chorionic gonadotropin increased (PT)	10071332
	Human chorionic gonadotropin positive (PT)	10071335
	Term birth (PT)	10072953
	Planning to become pregnant (PT)	10076056
	Caesarean delivery on maternal request (PT)	10076983
	Newborn head moulding (PT)	10077984
	Birth weight normal (PT)	10078661
	Cervical dilatation (PT)	10079273
	Term baby (PT)	10080681
	Amniotic fluid index normal (PT)	10086422
	Spontaneous rupture of membranes (PT)	10087390

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
Age (years)			
n	157	76	233
Mean (SD)	51.0 (13.48)	51.0 (13.95)	51.0 (13.61)
Median	52.0	52.0	52.0
Min-Max	24-83	19-77	19-83
Race -n (%)			
Asian	22 (14.0)	11 (14.5)	33 (14.2)
Caucasian	119 (75.8)	57 (75.0)	176 (75.5)
Others	16 (10.2)	8 (10.5)	24 (10.3)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
Ethnicity -n (%)			
Hispanic or Latino	15 (9.6)	17 (22.4)	32 (13.7)
Not Hispanic or Latino	102 (65.0)	43 (56.6)	145 (62.2)
Not Reported	23 (14.6)	11 (14.5)	34 (14.6)
Unknown	17 (10.8)	5 (6.6)	22 (9.4)
Weight (Kg)			
n	154	76	230
Mean (SD)	79.1 (18.33)	76.9 (20.82)	78.4 (19.17)
Median	78.2	75.0	76.4
Min-Max	46-184	42-194	42-194
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
Height (cm)			
n	153	76	229
Mean (SD)	168.3 (10.74)	167.4 (10.13)	168.0 (10.53)
Median	168.0	167.0	168.0
Min-Max	141-195	148-191	141-195
Body mass index (kg/m2)			
n	153	76	229
Mean (SD)	27.9 (6.56)	27.4 (7.16)	27.8 (6.76)
Median	26.9	25.8	26.3
Min-Max	18-74	18-68	18-74
ECOG performance status -n (%)			
0	126 (80.3)	62 (81.6)	188 (80.7)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
1	28 (17.8)	14 (18.4)	42 (18.0)
2	2 (1.3)	0	2 (0.9)
3	0	0	0
4	0	0	0
Missing	1 (0.6)	0	1 (0.4)
Stratification factor by IRT - n (%)			
Major Cytogenetic Response	46 (29.3)	22 (28.9)	68 (29.2)
No Major Cytogenetic Response	111 (70.7)	54 (71.1)	165 (70.8)
Stratification factor by CRF - n (%)			
Major Cytogenetic Response	58 (36.9)	25 (32.9)	83 (35.6)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1
Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
No Major Cytogenetic Response	99 (63.1)	51 (67.1)	150 (64.4)
Reason for discontinuation of the last prior TKI -n (%)			
Failure	95 (60.5)	54 (71.1)	149 (63.9)
Intolerance	59 (37.6)	22 (28.9)	81 (34.8)
Missing	3 (1.9)	0	3 (1.3)
Number of prior TKI therapies -n (%)			
2	89 (56.7)	33 (43.4)	122 (52.4)
3	54 (34.4)	33 (43.4)	87 (37.3)
≥4	14 (8.9)	10 (13.2)	24 (10.3)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
Line of therapy of randomized treatment -n (%)			
3	82 (52.2)	30 (39.5)	112 (48.1)
4	44 (28.0)	29 (38.2)	73 (31.3)
>=5	31 (19.7)	17 (22.4)	48 (20.6)
With or without Week1 Day 1 BCR-ABL1 mutation -n (%)			
Wild type	125 (79.6)	63 (82.9)	188 (80.7)
Mutant	17 (10.8)	8 (10.5)	25 (10.7)
Missing	15 (9.6)	5 (6.6)	20 (8.6)
BCR-ABL ratio at baseline -n (%)			
>= 1%	142 (90.4)	72 (94.7)	214 (91.8)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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Demographic variable	Asciminib N=157	Bosutinib N=76	All subjects N=233
< 1%	15 (9.6)	4 (5.3)	19 (8.2)
Geographic region -n (%)			
Europe	90 (57.3)	45 (59.2)	135 (57.9)
Others	67 (42.7)	31 (40.8)	98 (42.1)
All percentages based on Full Analysis Set			
Rate of concordance between stratum reported per IRT (randomization data) and stratum based on values collected on eCRF is 84.5%			

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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	Asciminib N=157	Bosutinib N=76	All subjects N=233
Age category n(%)			
18 - <65 years	128 (81.5)	61 (80.3)	189 (81.1)
65 - <75 years	25 (15.9)	13 (17.1)	38 (16.3)
>=75 years	4 (2.5)	2 (2.6)	6 (2.6)
Age category n(%)			
18 - 65 years	128 (81.5)	61 (80.3)	189 (81.1)
>=65 years	29 (18.5)	15 (19.7)	44 (18.9)
Sex n(%)			
Female	75 (47.8)	45 (59.2)	120 (51.5)
Male	82 (52.2)	31 (40.8)	113 (48.5)
Time since initial diagnosis of CML (years)			
n	157	76	233
Mean (SD)	6.2 (5.75)	7.0 (5.63)	6.5 (5.71)
Median	3.8	5.1	4.2
Min-Max	1- 28	1- 21	1- 28
Any extramedullary involvement n(%)			
No	149 (94.9)	72 (94.7)	221 (94.8)
Yes	8 (5.1)	4 (5.3)	12 (5.2)

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Data cut-off: EOT (23MAR2023)

All percentages based on Full Analysis Set

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
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	Asciminib N=157	Bosutinib N=76	All subjects N=233
Localisation of extramedullary involvement n(%)			
Spleen	8 (5.1)	4 (5.3)	12 (5.2)
Liver	1 (0.6)	1 (1.3)	2 (0.9)
Blasts (%) in bone marrow			
n	139	69	208
Mean (SD)	1.4 (1.70)	1.8 (2.19)	1.5 (1.88)
Median	1.0	1.0	1.0
Min-Max	0.0-11.0	0.0-14.8	0.0-14.8
Blasts (%) in bone marrow, categorized n(%)			
Missing	18 (11.5)	7 (9.2)	25 (10.7)
=0%	34 (21.7)	9 (11.8)	43 (18.5)
>0% - <5%	97 (61.8)	56 (73.7)	153 (65.7)
>=5% - <15%	8 (5.1)	4 (5.3)	12 (5.2)
Promyelocytes (%) in bone marrow			
n	134	68	202
Mean (SD)	3.5 (4.17)	2.8 (2.99)	3.3 (3.83)
Median	2.0	2.0	2.0
Min-Max	0.0-26.0	0.0-11.0	0.0-26.0

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All percentages based on Full Analysis Set

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Table 1-1 Demographics and baseline characteristics
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	Asciminib N=157	Bosutinib N=76	All subjects N=233
Blasts and promyelocytes (%) in bone marrow			
n	140	71	211
Mean (SD)	4.8 (4.56)	4.4 (3.93)	4.7 (4.35)
Median	4.0	3.0	3.8
Min-Max	0.0-29.0	0.0-16.8	0.0-29.0
Other abnormalities in PH+ metaphases n(%)			
Missing	12 (7.6)	1 (1.3)	13 (5.6)
No	129 (82.2)	59 (77.6)	188 (80.7)
Yes	16 (10.2)	16 (21.1)	32 (13.7)
Other abnormalities in PH- metaphases n(%)			
Missing	12 (7.6)	2 (2.6)	14 (6.0)
No	134 (85.4)	65 (85.5)	199 (85.4)
Yes	11 (7.0)	9 (11.8)	20 (8.6)
Ph+-metaphases (%) in bone marrow			
n	122	67	189
Mean (SD)	61.0 (39.48)	64.4 (38.75)	62.2 (39.15)
Median	75.0	85.0	75.0
Min-Max	0.0- 100	0.0- 100	0.0- 100

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Data cut-off: EOT (23MAR2023)

All percentages based on Full Analysis Set

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Full Analysis Set
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	Asciminib N=157	Bosutinib N=76	All subjects N=233
Ph+-metaphases (%) in bone marrow, categorized n(%)			
Missing	35 (22.3)	9 (11.8)	44 (18.9)
=0%	19 (12.1)	5 (6.6)	24 (10.3)
>0% - 35%	26 (16.6)	16 (21.1)	42 (18.0)
>35% - 65%	11 (7.0)	8 (10.5)	19 (8.2)
>65% - 95%	26 (16.6)	13 (17.1)	39 (16.7)
>95%	40 (25.5)	25 (32.9)	65 (27.9)
MCyR in bone marrow n(%)			
Missing	35 (22.3)	9 (11.8)	44 (18.9)
No	77 (49.0)	46 (60.5)	123 (52.8)
Yes	45 (28.7)	21 (27.6)	66 (28.3)
MCyR n(%)			
With MCyR per IRT	46 (29.3)	22 (28.9)	68 (29.2)
Without MCyR per IRT	111 (70.7)	54 (71.1)	165 (70.8)
MCyR per IRT and CRF n(%)			
With MCyR per IRT -With MCyR per CRF	40 (25.5)	18 (23.7)	58 (24.9)
With MCyR per IRT -Without MCyR per CRF	6 (3.8)	4 (5.3)	10 (4.3)
Without MCyR per IRT -With MCyR per CRF	18 (11.5)	7 (9.2)	25 (10.7)

(Continued)

Data cut-off: EOT (23MAR2023)

All percentages based on Full Analysis Set

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Table 1-1 Demographics and baseline characteristics
Full Analysis Set
(Page 12 of 12)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Without MCyR per IRT -Without MCyR per CRF	93 (59.2)	47 (61.8)	140 (60.1)
Prior TKI n(%)			
Dasatinib	131 (83.4)	65 (85.5)	196 (84.1)
Imatinib	129 (82.2)	63 (82.9)	192 (82.4)
Nilotinib	103 (65.6)	56 (73.7)	159 (68.2)
Ponatinib	23 (14.6)	18 (23.7)	41 (17.6)
Radotinib	4 (2.5)	2 (2.6)	6 (2.6)
Other	4 (2.5)	3 (3.9)	7 (3.0)
Prior non-TKI therapy n(%)			
No	101 (64.3)	51 (67.1)	152 (65.2)
Yes	56 (35.7)	25 (32.9)	81 (34.8)

Data cut-off: EOT (23MAR2023)

All percentages based on Full Analysis Set

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Table 1-1a Organisation for Economic Co-operation and Development (OECD) country patients
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157 n (%)	Bosutinib N=76 n (%)	All subjects N=233 n (%)
Organisation for Economic Co-operation and Development (OECD)			
Yes	106 (67.5)	50 (65.8)	156 (67.0)
No	51 (32.5)	26 (34.2)	77 (33.0)
all percentages based on Full Analysis Set			
OECD countries:Australia, Canada, Czech Republic, France, Germany, Hungary, Israel, Italy, Japan, Korea, Mexico, Netherlands, Spain , Switzerland, Turkey, United Kingdom and the United States.			

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Table 1-1b Eligibility criteria for treatment with Nilotinib and Dasatinib
Full Analysis Set
(Page 1 of 2)

	Asciminib N=157	Bosutinib N=76
Prior antineoplastic therapy with Dasatinib, n(%)		
Yes	131 (83.4)	65 (85.5)
No	26 (16.6)	11 (14.5)
Prior antineoplastic therapy with Nilotinib, n(%)		
Yes	104 (66.2)	56 (73.7)
No	53 (33.8)	20 (26.3)
Prior antineoplastic therapy with Nilotinib and Dasatinib, n(%)		
Yes	80 (51.0)	45 (59.2)
No	77 (49.0)	31 (40.8)
Relevant BCR-ABL1 mutation associated with CML in Disease history, n(%)		
Yes	9 (5.7)	5 (6.6)
No	148 (94.3)	71 (93.4)
BCR-ABL1 mutation, n(%)		
E255K	1 (0.6)	1 (1.3)
E255V	0	1 (1.3)
F317L	1 (0.6)	2 (2.6)
F359I	1 (0.6)	0
F359V	2 (1.3)	1 (1.3)
Y253H	5 (3.2)	2 (2.6)

Data cut-off: 25MAY2020

All percentages based on Full Analysis Set

Table 1-1b Eligibility criteria for treatment with Nilotinib and Dasatinib
Full Analysis Set
(Page 2 of 2)

	Asciminib N=157	Bosutinib N=76
ESC-Score, n(%)		
Very high risk	24 (15.3)	14 (18.4)
Low to high risk	133 (84.7)	62 (81.6)
Relevant Medical History (SOC), n(%)		
Cardiac disorders	31 (19.7)	8 (10.5)
Eye disorders	9 (5.7)	6 (7.9)
Metabolism and nutrition disorders	40 (25.5)	20 (26.3)
Nervous system disorders	7 (4.5)	5 (6.6)
Respiratory, thoracic and mediastinal disorders	22 (14.0)	11 (14.5)
Surgical and medical procedures	2 (1.3)	1 (1.3)
Vascular disorders	9 (5.7)	3 (3.9)
Eligible for treatment with Nilotinib or Dasatinib, n(%)		
No	119 (75.8)	64 (84.2)
Yes	38 (24.2)	12 (15.8)

Data cut-off: 25MAY2020

All percentages based on Full Analysis Set

Table 1-1c Eligibility criteria for treatment with Dasatinib in patients with no Dasatinib as prior antineoplastic therapy
Full Analysis Set
(Page 1 of 1)

	Asciminib N=26	Bosutinib N=11
Relevant BCR-ABL1 mutation associated with CML in Disease history, n(%)		
Yes	0	2 (18.2)
No	26 (100.0)	9 (81.8)
BCR-ABL1 mutation, n(%)		
F317L	0	2 (18.2)
Relevant Medical History (SOC), n(%)		
Cardiac disorders	2 (7.7)	2 (18.2)
Eye disorders	3 (11.5)	1 (9.1)
Metabolism and nutrition disorders	7 (26.9)	4 (36.4)
Respiratory, thoracic and mediastinal disorders	1 (3.8)	2 (18.2)
Vascular disorders	0	1 (9.1)
Eligible for treatment with Dasatinib, n(%)		
No	10 (38.5)	7 (63.6)
Yes	16 (61.5)	4 (36.4)

Data cut-off: 25MAY2020

All percentages based on Number of patients with no Dasatinib as prior antineoplastic therapy in the FAS

Table 1-1d Eligibility criteria for treatment with Nilotinib in patients with no Nilotinib as prior antineoplastic therapy
Full Analysis Set
(Page 1 of 1)

	Asciminib N=53	Bosutinib N=20
Relevant BCR-ABL1 mutation associated with CML in Disease history, n(%)		
Yes	2 (3.8)	1 (5.0)
No	51 (96.2)	19 (95.0)
BCR-ABL1 mutation, n(%)		
E255K	1 (1.9)	1 (5.0)
F359V	0	1 (5.0)
Y253H	1 (1.9)	1 (5.0)
ESC-Score, n(%)		
High risk	11 (20.8)	8 (40.0)
Low risk	42 (79.2)	12 (60.0)
Relevant Medical History (SOC), n(%)		
Cardiac disorders	11 (20.8)	2 (10.0)
Eye disorders	3 (5.7)	1 (5.0)
Metabolism and nutrition disorders	17 (32.1)	6 (30.0)
Nervous system disorders	3 (5.7)	1 (5.0)
Surgical and medical procedures	1 (1.9)	1 (5.0)
Vascular disorders	4 (7.5)	1 (5.0)
Eligible for treatment with Nilotinib, n(%)		
No	31 (58.5)	12 (60.0)
Yes	22 (41.5)	8 (40.0)

Data cut-off: 25MAY2020

All percentages based on Number of patients with no Nilotinib as prior antineoplastic therapy in the FAS

Table 2-1.1 Overall survival: stratified as per IRT
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	14 (8.9)	5 (6.6)			
censored	143 (91.1)	71 (93.4)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.25	[0.45, 3.47]	0.671
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
[95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before					
the cut-off date, regardless of subsequent intake of treatment(s) after randomization.					
CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-1.1 Overall survival: stratified as per IRT
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 1	0.98 [0.94, 0.99]	0.99 [0.90, 1.00]			
Year 3	0.92 [0.87, 0.96]	0.97 [0.88, 0.99]			
Year 5	0.88 [0.79, 0.93]	0.90 [0.76, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

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Figure 2-1.1 Overall survival: Kaplan Meier plot of time to event

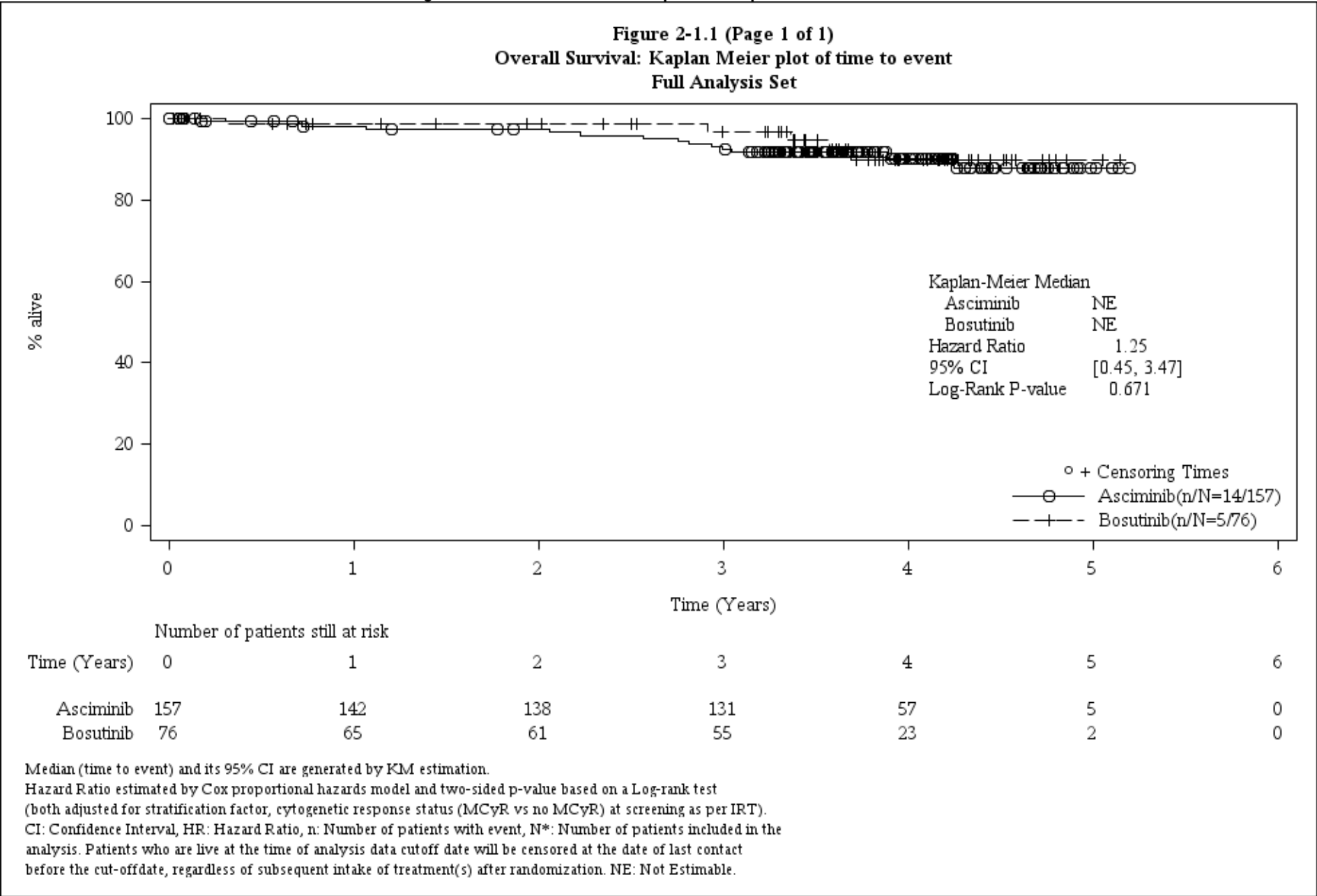


Table 2-1.1.1: Overall survival: stratified as per IRT
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	16 (10.2)	9 (11.8)			
censored	141 (89.8)	67 (88.2)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	6.31 [6.09, NE]			
median	NE [NE, NE]	NE [6.31, NE]	0.79	[0.35, 1.78]	0.564
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.97 [0.93, 0.99]	0.99 [0.90, 1.00]			
Year 3	0.92 [0.87, 0.96]	0.97 [0.88, 0.99]			
Year 5	0.89 [0.83, 0.93]	0.90 [0.79, 0.95]			
Year 7	0.88 [0.81, 0.93]	NE [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

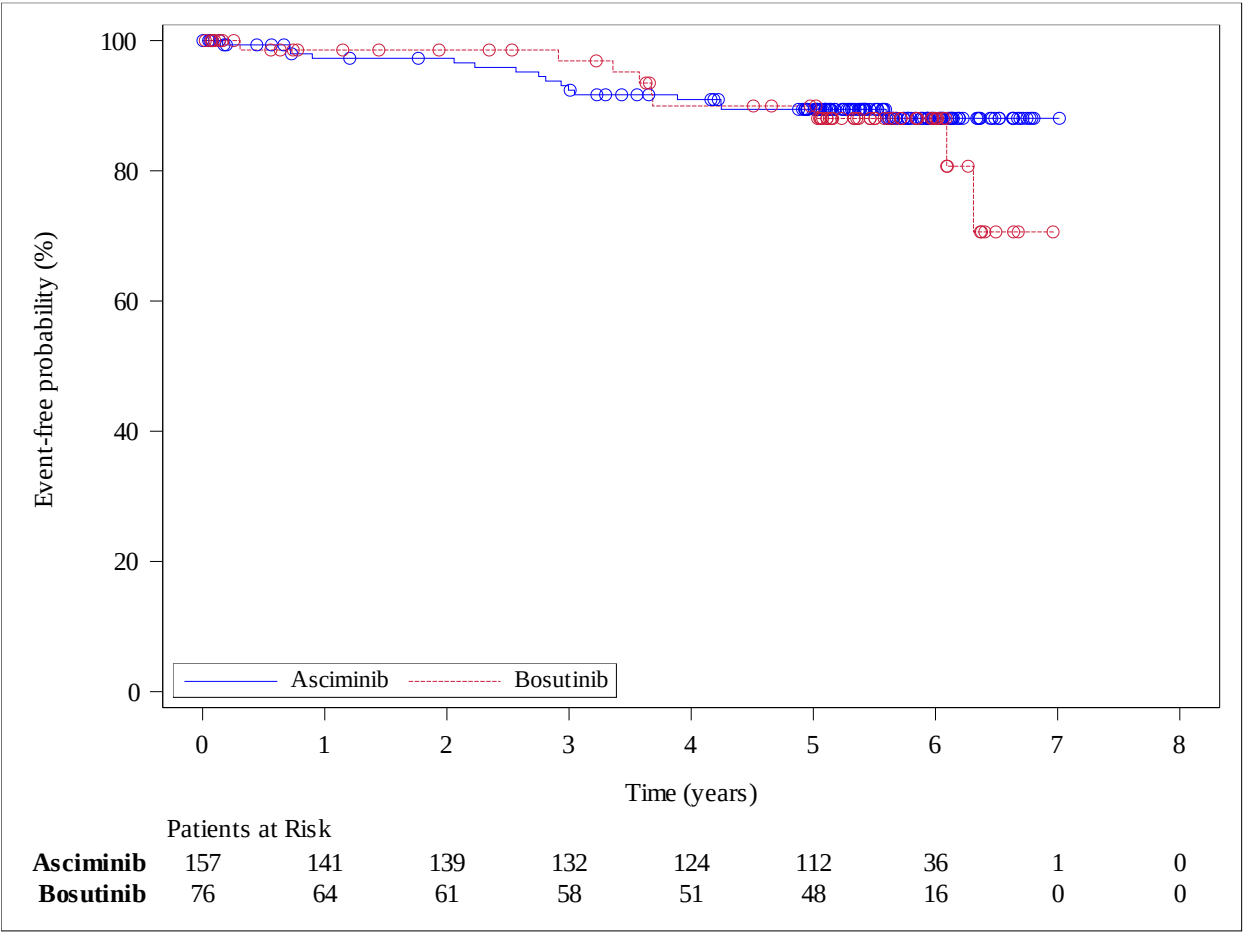
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Figure 2-1.1.1: Overall survival: stratified as per IRT - Kaplan-Meier plot (Full Analysis Set)



Note: o = Censored observations

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Table 2-1.1.2 Overall survival: censored for switch
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	14 (8.9)	3 (3.9)			
censored	143 (91.1)	73 (96.1)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	NE [3.69, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.36	[0.39, 4.74]	0.633
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
[95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.98 [0.94, 0.99]	0.99 [0.90, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time					
will be censored at the date of switch. CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-1.1.2 Overall survival: censored for switch
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 3	0.92 [0.87, 0.96]	0.99 [0.90, 1.00]			
Year 5	0.88 [0.79, 0.93]	0.90 [0.70, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch. CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Table 2-1.1.2.1: Overall survival: censored for switch
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	16 (10.2)	6 (7.9)			
censored	141 (89.8)	70 (92.1)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	6.31 [3.69, NE]			
median	NE [NE, NE]	NE [6.31, NE]	0.75	[0.29, 1.92]	0.546
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.97 [0.93, 0.99]	0.99 [0.90, 1.00]			
Year 3	0.92 [0.87, 0.96]	0.99 [0.90, 1.00]			
Year 5	0.89 [0.83, 0.93]	0.90 [0.74, 0.96]			
Year 7	0.88 [0.81, 0.93]	NE [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-1.2 Overall survival: Sensitivity – stratified as per CRF
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	14 (8.9)	5 (6.6)			
censored	143 (91.1)	71 (93.4)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.24	[0.44, 3.45]	0.681
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact					
before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.					
CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable. n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-1.2 Overall survival: Sensitivity – stratified as per CRF
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 1	0.98 [0.94, 0.99]	0.99 [0.90, 1.00]			
Year 3	0.92 [0.87, 0.96]	0.97 [0.88, 0.99]			
Year 5	0.88 [0.79, 0.93]	0.90 [0.76, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable. n: Number of patients with event,

N*: Number of patients included in the analysis.

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Table 2-1.2.1: Overall survival: Sensitivity - stratified as per CRF
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	16 (10.2)	9 (11.8)			
censored	141 (89.8)	67 (88.2)			
Percentiles (years) (95% CI)					
25th	NE [NE, NE]	6.31 [6.09, NE]			
median	NE [NE, NE]	NE [6.31, NE]	0.82	[0.36, 1.86]	0.639
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.97 [0.93, 0.99]	0.99 [0.90, 1.00]			
Year 3	0.92 [0.87, 0.96]	0.97 [0.88, 0.99]			
Year 5	0.89 [0.83, 0.93]	0.90 [0.79, 0.95]			
Year 7	0.88 [0.81, 0.93]	NE [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-2.1 Progression Free Survival: – stratified as per IRT
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	18 (11.5)	9 (11.8)			
censored	139 (88.5)	67 (88.2)			
Percentiles (years) (95% CI)					
25th	NE [3.89, NE]	3.58 [2.09, NE]			
median	NE [NE, NE]	NE [3.58, NE]	0.64	[0.28, 1.44]	0.276
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times					
will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the					
cut-off date, regardless of subsequent intake of treatment(s) after randomization. CI: Confidence Interval,					
HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-2.1 Progression Free Survival: – stratified as per IRT
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.92, 0.98]	0.91 [0.80, 0.96]			
Year 3	0.85 [0.77, 0.91]	0.84 [0.67, 0.93]			
Year 5	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization. CI: Confidence Interval,

HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

Figure 2-2.1 Progression Free Survival: Kaplan Meier plot of time to event

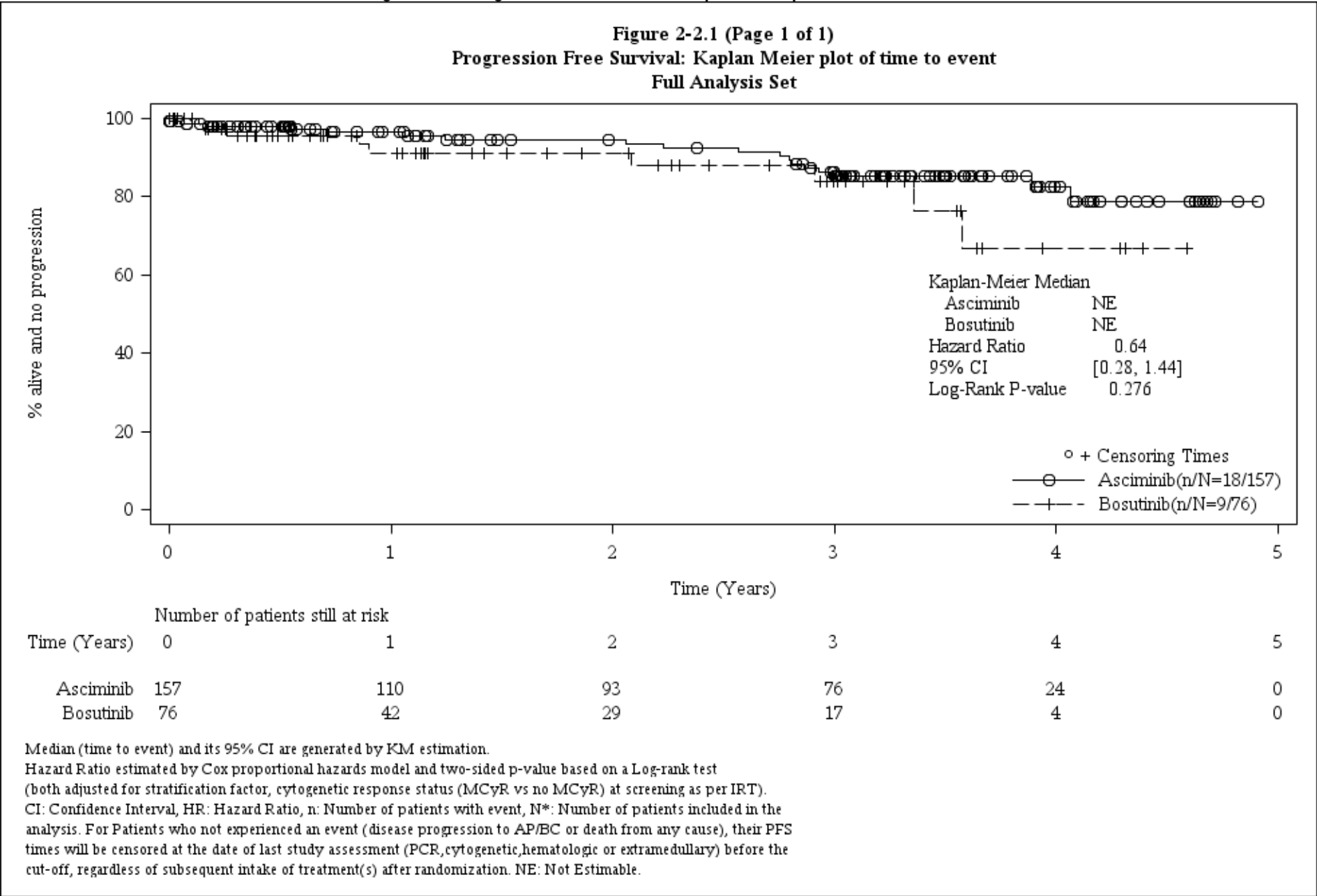


Table 2-2.1.1: Progression free survival: stratified as per IRT
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	22 (14.0)	13 (17.1)			
censored	135 (86.0)	63 (82.9)			
Percentiles (years) (95% CI)					
25th	4.65 [3.89, NE]	3.58 [2.09, 5.03]			
median	5.60 [4.65, NE]	5.03 [3.58, NE]	0.79	[0.37, 1.67]	0.531
75th	5.96 [5.60, NE]	6.05 [5.03, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.90, 0.98]	0.91 [0.80, 0.96]			
Year 3	0.86 [0.78, 0.91]	0.85 [0.70, 0.93]			
Year 5	0.69 [0.47, 0.83]	0.65 [0.38, 0.82]			
Year 7	0.00 [NE, NE]	0.00 [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

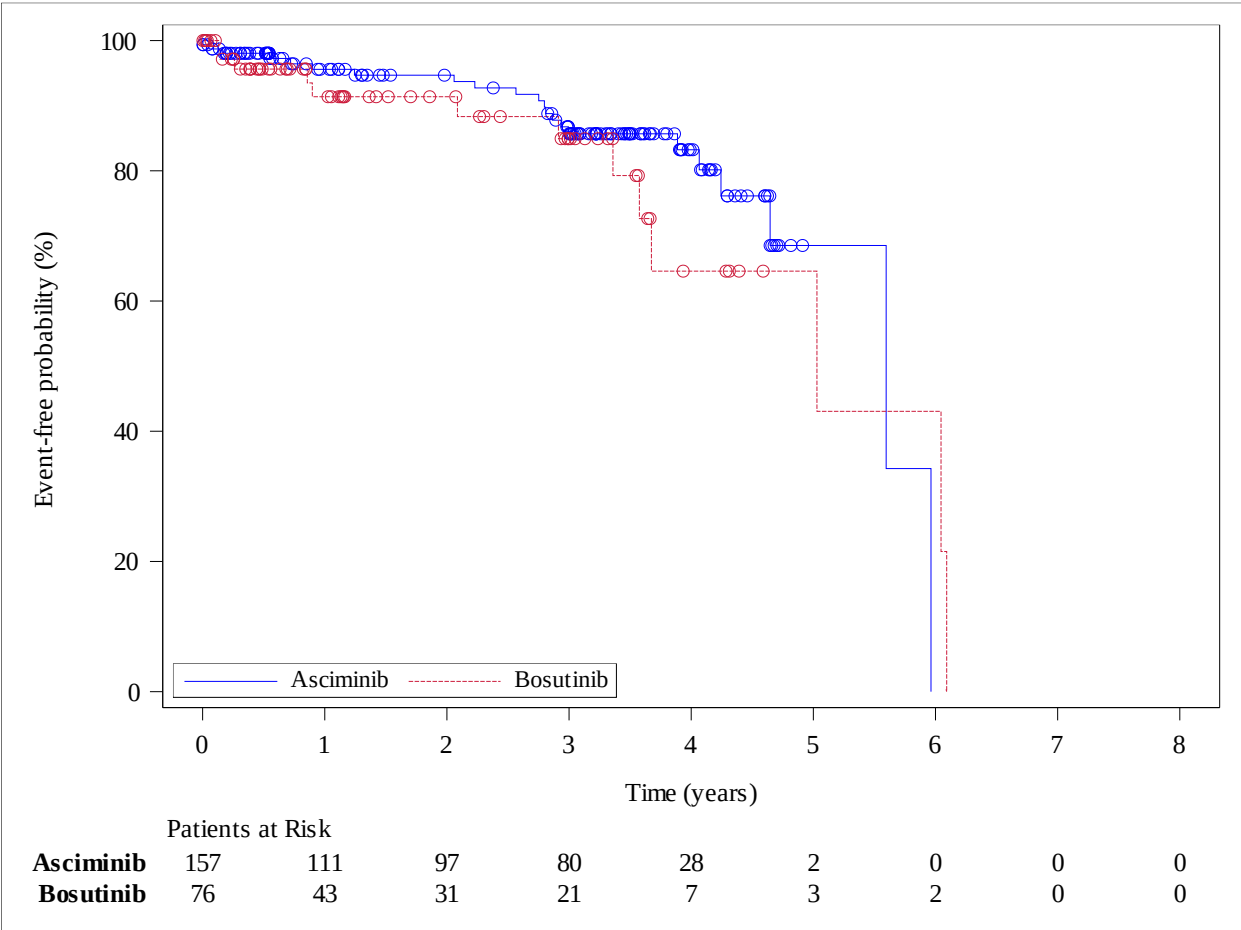
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Figure 2-2.1.1: Progression free survival: stratified as per IRT - Kaplan-Meier plot (Full Analysis Set)



Note: o = Censored observations

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Table 2-2.1.2 Progression Free Survival: censored for switch
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	18 (11.5)	6 (7.9)			
censored	139 (88.5)	70 (92.1)			
Percentiles (years) (95% CI)					
25th	NE [3.89, NE]	3.58 [2.09, NE]	0.71	[0.27, 1.83]	0.475
median	NE [NE, NE]	NE [3.58, NE]			
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
[95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.92, 0.98]	0.92 [0.77, 0.97]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time					
will be censored at the date of switch. CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-2.1.2 Progression Free Survival: censored for switch
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 3	0.85 [0.77, 0.91]	0.87 [0.67, 0.95]			
Year 5	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch. CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

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Table 2-2.1.2.1: Progression free survival: censored for switch
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	22 (14.0)	9 (11.8)			
censored	135 (86.0)	67 (88.2)			
Percentiles (years) (95% CI)					
25th	4.65 [3.89, NE]	3.67 [2.09, 5.03]			
median	5.60 [4.65, NE]	5.03 [3.58, NE]	0.80	[0.34, 1.87]	0.604
75th	5.96 [5.60, NE]	6.05 [5.03, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.90, 0.98]	0.92 [0.78, 0.97]			
Year 3	0.86 [0.78, 0.91]	0.87 [0.68, 0.95]			
Year 5	0.69 [0.47, 0.83]	0.65 [0.30, 0.85]			
Year 7	0.00 [NE, NE]	0.00 [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-2.2 Progression Free Survival: Sensitivity – stratified as per CRF
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	18 (11.5)	9 (11.8)			
censored	139 (88.5)	67 (88.2)			
Percentiles (years) (95% CI)					
25th	NE [3.89, NE]	3.58 [2.09, NE]			
median	NE [NE, NE]	NE [3.58, NE]	0.62	[0.28, 1.40]	0.250
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times					
will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the					
cut-off date, regardless of subsequent intake of treatment(s) after randomization. CI: Confidence Interval,					
HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-2.2 Progression Free Survival: Sensitivity – stratified as per CRF
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.92, 0.98]	0.91 [0.80, 0.96]			
Year 3	0.85 [0.77, 0.91]	0.84 [0.67, 0.93]			
Year 5	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization. CI: Confidence Interval,

HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

Table 2-2.2.1: Progression free survival: Sensitivity - stratified as per CRF
Full Analysis Set

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	22 (14.0)	13 (17.1)			
censored	135 (86.0)	63 (82.9)			
Percentiles (years) (95% CI)					
25th	4.65 [3.89, NE]	3.58 [2.09, 5.03]			
median	5.60 [4.65, NE]	5.03 [3.58, NE]	0.77	[0.36, 1.64]	0.501
75th	5.96 [5.60, NE]	6.05 [5.03, NE]			
Kaplan Meier event probability estimates (95% CI)					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Year 1	0.96 [0.90, 0.98]	0.91 [0.80, 0.96]			
Year 3	0.86 [0.78, 0.91]	0.85 [0.70, 0.93]			
Year 5	0.69 [0.47, 0.83]	0.65 [0.38, 0.82]			
Year 7	0.00 [NE, NE]	0.00 [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 1 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 4	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.90	[-0.24, 4.03]	0.224
Week 8	12 (7.6)	4 (5.3)	OR	1.50	[0.46, 4.93]	0.501
			RR	1.44	[0.49, 4.28]	0.501
			RD	2.34	[-4.08, 8.77]	0.501
Week 12	28 (17.8)	7 (9.2)	OR	2.17	[0.89, 5.26]	0.087
			RR	1.93	[0.89, 4.20]	0.083
			RD	8.58	[-0.18, 17.34]	0.083
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT. The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT. N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 2 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 16	36 (22.9)	8 (10.5)	OR	2.66	[1.14, 6.18]	0.023
			RR	2.17	[1.07, 4.42]	0.021
			RD	12.33	[2.90, 21.75]	0.021
Week 24	40 (25.5)	10 (13.2)	OR	2.35	[1.08, 5.12]	0.031
			RR	1.93	[1.03, 3.62]	0.029
			RD	12.24	[2.19, 22.30]	0.029
Week 36	41 (26.1)	9 (11.8)	OR	2.68	[1.22, 5.89]	0.015
			RR	2.20	[1.13, 4.27]	0.013
			RD	14.23	[4.33, 24.12]	0.013
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 3 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 48	46 (29.3)	10 (13.2)	OR	2.80	[1.31, 5.99]	0.008
			RR	2.22	[1.19, 4.16]	0.007
			RD	16.09	[5.69, 26.49]	0.007
Week 60	52 (33.1)	11 (14.5)	OR	2.96	[1.44, 6.12]	0.003
			RR	2.29	[1.27, 4.13]	0.003
			RD	18.61	[7.79, 29.43]	0.003
Week 72	52 (33.1)	12 (15.8)	OR	2.68	[1.32, 5.43]	0.006
			RR	2.09	[1.19, 3.69]	0.005
			RD	17.29	[6.22, 28.35]	0.005
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 4 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 84	50 (31.8)	10 (13.2)	OR	3.17	[1.49, 6.73]	0.003
			RR	2.42	[1.30, 4.50]	0.002
			RD	18.63	[8.12, 29.15]	0.002
Week 96	59 (37.6)	12 (15.8)	OR	3.29	[1.63, 6.65]	<0.001
			RR	2.38	[1.36, 4.16]	<0.001
			RD	21.74	[10.53, 32.95]	<0.001
Week 108	53 (33.8)	11 (14.5)	OR	3.13	[1.50, 6.53]	0.002
			RR	2.33	[1.29, 4.20]	0.002
			RD	19.22	[8.36, 30.07]	0.002
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 5 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	57 (36.3)	8 (10.5)	OR	5.05	[2.24, 11.40]	<0.001
			RR	3.44	[1.73, 6.86]	<0.001
			RD	25.72	[15.48, 35.97]	<0.001
Week 132	58 (36.9)	8 (10.5)	OR	5.50	[2.41, 12.60]	<0.001
			RR	3.50	[1.77, 6.93]	<0.001
			RD	26.33	[16.21, 36.45]	<0.001
Week 144	59 (37.6)	7 (9.2)	OR	6.64	[2.78, 15.84]	<0.001
			RR	4.07	[1.96, 8.42]	<0.001
			RD	28.28	[18.46, 38.11]	<0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 6 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	53 (33.8)	8 (10.5)	OR	4.64	[2.04, 10.56]	<0.001
			RR	3.20	[1.61, 6.36]	<0.001
			RD	23.16	[13.14, 33.18]	<0.001
Week 168	45 (28.7)	6 (7.9)	OR	4.85	[1.95, 12.08]	<0.001
			RR	3.62	[1.62, 8.11]	<0.001
			RD	20.72	[11.43, 30.00]	<0.001
Week 180	34 (21.7)	3 (3.9)	OR	6.89	[2.03, 23.38]	0.002
			RR	5.48	[1.72, 17.46]	<0.001
			RD	17.67	[9.78, 25.56]	<0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 7 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 192	30 (19.1)	3 (3.9)	OR	5.84	[1.72, 19.91]	0.005
			RR	4.84	[1.51, 15.50]	0.002
			RD	15.13	[7.49, 22.76]	0.002
Week 204	20 (12.7)	2 (2.6)	OR	5.41	[1.23, 23.81]	0.026
			RR	4.84	[1.16, 20.30]	0.014
			RD	10.10	[3.73, 16.46]	0.014
Week 216	18 (11.5)	3 (3.9)	OR	3.16	[0.90, 11.08]	0.073
			RR	2.91	[0.88, 9.56]	0.061
			RD	7.53	[0.89, 14.16]	0.061
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.1 MMR: Rate - at all scheduled time points
Full Analysis Set
(Page 8 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 228	16 (10.2)	3 (3.9)	OR	2.76	[0.78, 9.80]	0.116
			RR	2.58	[0.78, 8.58]	0.104
			RD	6.23	[-0.21, 12.67]	0.104
Week 240	10 (6.4)	1 (1.3)	OR	5.12	[0.64, 40.89]	0.123
			RR	4.84	[0.63, 37.42]	0.089
			RD	5.04	[0.43, 9.66]	0.089
Week 252	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.28	[-0.48, 3.04]	0.323

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
(Page 1 of 8)

	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 4	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.77	[-0.30, 3.83]	0.250
Week 8	12 (7.6)	4 (5.3)	OR	1.38	[0.41, 4.66]	0.599
			RR	1.32	[0.47, 3.74]	0.600
			RD	1.75	[-4.45, 7.96]	0.600
Week 12	28 (17.8)	7 (9.2)	OR	2.10	[0.85, 5.19]	0.106
			RR	1.83	[0.87, 3.85]	0.103
			RD	7.84	[-0.65, 16.33]	0.103
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF. The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF. N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 16	36 (22.9)	8 (10.5)	OR	2.56	[1.09, 6.00]	0.031
			RR	2.06	[1.04, 4.08]	0.028
			RD	11.41	[2.33, 20.49]	0.028
Week 24	40 (25.5)	10 (13.2)	OR	2.25	[1.03, 4.90]	0.041
			RR	1.85	[1.00, 3.41]	0.039
			RD	11.41	[1.58, 21.24]	0.039
Week 36	41 (26.1)	9 (11.8)	OR	2.62	[1.18, 5.81]	0.018
			RR	2.12	[1.11, 4.06]	0.016
			RD	13.52	[3.77, 23.27]	0.016
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 48	46 (29.3)	10 (13.2)	OR	2.75	[1.28, 5.94]	0.010
			RR	2.15	[1.16, 3.99]	0.008
			RD	15.25	[5.05, 25.45]	0.008
Week 60	52 (33.1)	11 (14.5)	OR	2.93	[1.41, 6.11]	0.004
			RR	2.23	[1.24, 4.00]	0.003
			RD	17.88	[7.21, 28.55]	0.003
Week 72	52 (33.1)	12 (15.8)	OR	2.66	[1.30, 5.45]	0.008
			RR	2.03	[1.16, 3.54]	0.007
			RD	16.43	[5.64, 27.22]	0.007
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 84	50 (31.8)	10 (13.2)	OR	3.12	[1.45, 6.68]	0.004
			RR	2.34	[1.27, 4.32]	0.003
			RD	17.84	[7.50, 28.17]	0.003
Week 96	59 (37.6)	12 (15.8)	OR	3.28	[1.60, 6.70]	0.001
			RR	2.31	[1.33, 3.99]	<0.001
			RD	20.86	[9.92, 31.80]	<0.001
Week 108	53 (33.8)	11 (14.5)	OR	3.05	[1.46, 6.38]	0.003
			RR	2.26	[1.26, 4.05]	0.002
			RD	18.39	[7.72, 29.05]	0.002
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	57 (36.3)	8 (10.5)	OR	5.01	[2.21, 11.36]	<0.001
			RR	3.34	[1.69, 6.61]	<0.001
			RD	24.92	[14.86, 34.98]	<0.001
Week 132	58 (36.9)	8 (10.5)	OR	5.33	[2.33, 12.23]	<0.001
			RR	3.39	[1.72, 6.68]	<0.001
			RD	25.36	[15.33, 35.39]	<0.001
Week 144	59 (37.6)	7 (9.2)	OR	6.44	[2.69, 15.38]	<0.001
			RR	3.92	[1.91, 8.08]	<0.001
			RD	27.31	[17.57, 37.06]	<0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF. The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF. N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	53 (33.8)	8 (10.5)	OR	4.52	[1.98, 10.35]	<0.001
			RR	3.08	[1.57, 6.05]	<0.001
			RD	22.26	[12.44, 32.08]	<0.001
Week 168	45 (28.7)	6 (7.9)	OR	4.84	[1.92, 12.18]	<0.001
			RR	3.50	[1.57, 7.78]	<0.001
			RD	19.90	[10.74, 29.07]	<0.001
Week 180	34 (21.7)	3 (3.9)	OR	6.76	[1.99, 23.01]	0.002
			RR	5.34	[1.68, 16.98]	<0.001
			RD	17.14	[9.38, 24.90]	<0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 192	30 (19.1)	3 (3.9)	OR	5.74	[1.68, 19.64]	0.005
			RR	4.71	[1.47, 15.07]	0.002
			RD	14.64	[7.12, 22.15]	0.002
Week 204	20 (12.7)	2 (2.6)	OR	5.31	[1.20, 23.52]	0.028
			RR	4.66	[1.12, 19.41]	0.016
			RD	9.73	[3.46, 16.01]	0.016
Week 216	18 (11.5)	3 (3.9)	OR	3.11	[0.89, 10.93]	0.076
			RR	2.84	[0.88, 9.23]	0.065
			RD	7.41	[0.76, 14.07]	0.065
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response. NE: Not Estimable.						

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Table 2-3.1.1.2 MMR: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 228	16 (10.2)	3 (3.9)	OR	2.71	[0.76, 9.63]	0.123
			RR	2.51	[0.77, 8.24]	0.111
			RD	6.08	[-0.36, 12.53]	0.111
Week 240	10 (6.4)	1 (1.3)	OR	4.93	[0.62, 39.53]	0.133
			RR	4.53	[0.61, 33.40]	0.100
			RD	4.83	[0.28, 9.38]	0.100
Week 252	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.25	[-0.49, 3.00]	0.331

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 8	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.26	[-0.48, 3.01]	0.324
Week 12	7 (4.5)	1 (1.3)	OR	3.54	[0.42, 29.65]	0.243
			RR	3.36	[0.43, 26.32]	0.217
			RD	3.12	[-0.95, 7.19]	0.217
Week 16	16 (10.2)	3 (3.9)	OR	2.83	[0.79, 10.20]	0.111
			RR	2.57	[0.78, 8.41]	0.100
			RD	6.20	[-0.13, 12.53]	0.100

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 24	17 (10.8)	4 (5.3)	OR	2.20	[0.71, 6.84]	0.172
			RR	2.05	[0.71, 5.90]	0.165
			RD	5.54	[-1.46, 12.53]	0.165
Week 36	14 (8.9)	2 (2.6)	OR	3.63	[0.80, 16.40]	0.094
			RR	3.39	[0.78, 14.64]	0.077
			RD	6.28	[0.52, 12.03]	0.077
Week 48	17 (10.8)	3 (3.9)	OR	2.98	[0.84, 10.54]	0.091
			RR	2.74	[0.83, 9.05]	0.079

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.86	[0.33, 13.39]	0.079
Week 60	19 (12.1)	4 (5.3)	OR	2.48	[0.81, 7.59]	0.111
			RR	2.30	[0.81, 6.53]	0.102
			RD	6.82	[-0.34, 13.99]	0.102
Week 72	21 (13.4)	6 (7.9)	OR	1.81	[0.69, 4.69]	0.225
			RR	1.69	[0.71, 4.01]	0.222
			RD	5.46	[-2.59, 13.51]	0.222
Week 84	19 (12.1)	5 (6.6)	OR	1.97	[0.70, 5.52]	0.199
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.						

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Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 96	27 (17.2)	8 (10.5)	RR	1.83	[0.71, 4.71]	0.194
			RD	5.49	[-2.02, 13.01]	0.194
			OR	1.77	[0.76, 4.12]	0.185
			RR	1.63	[0.78, 3.43]	0.183
			RD	6.64	[-2.46, 15.74]	0.183
Week 108	25 (15.9)	8 (10.5)	OR	1.61	[0.69, 3.78]	0.271
			RR	1.51	[0.71, 3.20]	0.270
			RD	5.37	[-3.61, 14.35]	0.270

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	25 (15.9)	5 (6.6)	OR	2.70	[0.99, 7.39]	0.053
			RR	2.42	[0.96, 6.09]	0.047
			RD	9.32	[1.30, 17.34]	0.047
Week 132	30 (19.1)	5 (6.6)	OR	3.38	[1.25, 9.14]	0.016
			RR	2.90	[1.17, 7.16]	0.012
			RD	12.50	[4.24, 20.77]	0.012
Week 144	29 (18.5)	5 (6.6)	OR	3.27	[1.20, 8.88]	0.020
			RR	2.80	[1.13, 6.93]	0.016
			RD	11.86	[3.66, 20.05]	0.016

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	30 (19.1)	5 (6.6)	OR	3.38	[1.25, 9.14]	0.016
			RR	2.90	[1.17, 7.16]	0.012
			RD	12.50	[4.24, 20.77]	0.012
Week 168	31 (19.7)	4 (5.3)	OR	4.45	[1.51, 13.14]	0.007
			RR	3.75	[1.37, 10.25]	0.004
			RD	14.46	[6.46, 22.47]	0.004
Week 180	19 (12.1)	2 (2.6)	OR	5.10	[1.15, 22.48]	0.032
			RR	4.60	[1.10, 19.34]	0.019

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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Treatment Groups		Comparison			
Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
		RD	9.46	[3.20, 15.72]	0.019
Week 204	15 (9.6)	OR	3.91	[0.87, 17.57]	0.075
		RR	3.63	[0.85, 15.57]	0.058
		RD	6.92	[1.06, 12.77]	0.058
Week 216	12 (7.6)	OR	3.07	[0.67, 14.10]	0.149
		RR	2.91	[0.67, 12.68]	0.132
		RD	5.02	[-0.47, 10.51]	0.132
Week 228	13 (8.3)	OR	3.34	[0.73, 15.21]	0.119

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

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Table 2-3.1.1.3 MR4: Rate - at all scheduled time points
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Treatment Groups		Comparison			
Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 240	7 (4.5)	RR	3.15	[0.73, 13.64]	0.101
			5.65	[0.04, 11.27]	0.101
		OR	3.51	[0.42, 29.19]	0.245
			3.38	[0.42, 27.30]	0.219
			3.13	[-1.01, 7.27]	0.219
			1.28	[-0.48, 3.04]	0.323
Week 252	2 (1.3)	OR	NE	[NE, NE]	NE
		RR	NE	[NE, NE]	NE
		RD	1.28	[-0.48, 3.04]	0.323

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

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Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 8	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.18	[-0.51, 2.87]	0.350
Week 12	7 (4.5)	1 (1.3)	OR	3.30	[0.39, 27.99]	0.273
			RR	3.07	[0.40, 23.63]	0.251
			RD	2.83	[-1.18, 6.84]	0.251
Week 16	16 (10.2)	3 (3.9)	OR	2.69	[0.74, 9.84]	0.134
			RR	2.37	[0.75, 7.53]	0.124
			RD	5.63	[-0.55, 11.81]	0.124

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 24	17 (10.8)	4 (5.3)	OR	2.11	[0.67, 6.72]	0.204
			RR	1.90	[0.70, 5.20]	0.199
			RD	4.93	[-1.77, 11.63]	0.199
Week 36	14 (8.9)	2 (2.6)	OR	3.53	[0.76, 16.25]	0.106
			RR	3.13	[0.76, 12.87]	0.089
			RD	5.82	[0.25, 11.38]	0.089
Week 48	17 (10.8)	3 (3.9)	OR	2.91	[0.80, 10.59]	0.106
			RR	2.52	[0.80, 7.93]	0.095

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.22	[-0.03, 12.46]	0.095
Week 60	19 (12.1)	4 (5.3)	OR	2.41	[0.78, 7.48]	0.127
			RR	2.17	[0.78, 6.03]	0.120
			RD	6.33	[-0.67, 13.33]	0.120
Week 72	21 (13.4)	6 (7.9)	OR	1.74	[0.66, 4.61]	0.265
			RR	1.60	[0.69, 3.73]	0.263
			RD	4.85	[-3.00, 12.70]	0.263
Week 84	19 (12.1)	5 (6.6)	OR	1.89	[0.67, 5.36]	0.230

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 96	27 (17.2)	8 (10.5)	RR	1.75	[0.70, 4.38]	0.226
			RD	5.04	[-2.37, 12.45]	0.226
			OR	1.72	[0.73, 4.03]	0.211
			RR	1.58	[0.76, 3.29]	0.209
			RD	6.19	[-2.79, 15.16]	0.209
Week 108	25 (15.9)	8 (10.5)	OR	1.57	[0.66, 3.69]	0.306
			RR	1.46	[0.70, 3.07]	0.305
			RD	4.93	[-3.93, 13.80]	0.305

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval,
MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

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Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	25 (15.9)	5 (6.6)	OR	2.64	[0.96, 7.29]	0.061
			RR	2.32	[0.93, 5.75]	0.055
			RD	8.80	[0.95, 16.66]	0.055
Week 132	30 (19.1)	5 (6.6)	OR	3.31	[1.22, 8.98]	0.019
			RR	2.80	[1.15, 6.86]	0.015
			RD	12.05	[3.85, 20.25]	0.015
Week 144	29 (18.5)	5 (6.6)	OR	3.17	[1.17, 8.64]	0.024
			RR	2.70	[1.10, 6.63]	0.019
			RD	11.39	[3.26, 19.52]	0.019

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points,sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	30 (19.1)	5 (6.6)	OR	3.32	[1.22, 9.04]	0.019
			RR	2.79	[1.14, 6.83]	0.015
			RD	11.98	[3.81, 20.15]	0.015
Week 168	31 (19.7)	4 (5.3)	OR	4.39	[1.48, 13.03]	0.008
			RR	3.64	[1.34, 9.89]	0.005
			RD	14.01	[6.08, 21.94]	0.005
Week 180	19 (12.1)	2 (2.6)	OR	5.00	[1.13, 22.18]	0.034
			RR	4.44	[1.06, 18.54]	0.021

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	9.14	[2.95, 15.33]	0.021
Week 204	15 (9.6)	2 (2.6)	OR	3.81	[0.84, 17.22]	0.082
			RR	3.50	[0.82, 14.89]	0.065
			RD	6.63	[0.85, 12.42]	0.065
Week 216	12 (7.6)	2 (2.6)	OR	3.00	[0.65, 13.78]	0.158
			RR	2.83	[0.65, 12.29]	0.142
			RD	4.87	[-0.61, 10.35]	0.142
Week 228	13 (8.3)	2 (2.6)	OR	3.29	[0.72, 14.97]	0.124

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.4 MR4: Rate - at all scheduled time points,sensitivity - stratified as per CRF
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 240	7 (4.5)	1 (1.3)	RR	3.08	[0.72, 13.25]	0.107
			RD	5.53	[-0.08, 11.14]	0.107
			OR	3.33	[0.40, 27.91]	0.268
Week 252	2 (1.3)	0	RR	3.13	[0.41, 24.01]	0.244
			RD	2.91	[-1.15, 6.96]	0.244
			OR	NE	[NE, NE]	NE
Week 252	2 (1.3)	0	RR	NE	[NE, NE]	NE
			RD	1.25	[-0.49, 3.00]	0.331

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval,

MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 8	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.63	[-0.61, 1.87]	0.489
Week 12	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.27	[-0.48, 3.02]	0.326
Week 16	10 (6.4)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	6.35	[2.53, 10.16]	0.024
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 24	14 (8.9)	1 (1.3)	OR	7.50	[0.96, 58.56]	0.055
			RR	6.77	[0.90, 51.05]	0.026
			RD	7.58	[2.41, 12.74]	0.026
Week 36	9 (5.7)	2 (2.6)	OR	2.25	[0.47, 10.73]	0.308
			RR	2.18	[0.48, 9.94]	0.298
			RD	3.09	[-2.06, 8.24]	0.298
Week 48	12 (7.6)	1 (1.3)	OR	6.31	[0.80, 49.79]	0.080
			RR	5.80	[0.76, 44.27]	0.048

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.30	[1.40, 11.21]	0.048
Week 60	14 (8.9)	2 (2.6)	OR	3.67	[0.81, 16.67]	0.093
			RR	3.38	[0.79, 14.40]	0.076
			RD	6.26	[0.57, 11.96]	0.076
Week 72	17 (10.8)	2 (2.6)	OR	4.55	[1.02, 20.35]	0.047
			RR	4.10	[0.98, 17.22]	0.032
			RD	8.17	[2.16, 14.19]	0.032
Week 84	14 (8.9)	2 (2.6)	OR	3.67	[0.81, 16.67]	0.093
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.						

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Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 96	17 (10.8)	4 (5.3)	RR	3.38	[0.78, 14.70]	0.076
			RD	6.26	[0.48, 12.04]	0.076
			OR	2.20	[0.71, 6.84]	0.172
			RR	2.05	[0.71, 5.90]	0.165
			RD	5.54	[-1.46, 12.53]	0.165
Week 108	14 (8.9)	5 (6.6)	OR	1.39	[0.48, 4.07]	0.543
			RR	1.35	[0.51, 3.59]	0.544
			RD	2.31	[-4.78, 9.39]	0.544

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	16 (10.2)	3 (3.9)	OR	2.81	[0.78, 10.05]	0.113
			RR	2.57	[0.77, 8.56]	0.102
			RD	6.21	[-0.22, 12.64]	0.102
Week 132	18 (11.5)	4 (5.3)	OR	2.36	[0.76, 7.30]	0.136
			RR	2.17	[0.77, 6.15]	0.129
			RD	6.17	[-0.84, 13.17]	0.129
Week 144	17 (10.8)	3 (3.9)	OR	3.02	[0.85, 10.79]	0.088
			RR	2.73	[0.84, 8.90]	0.077
			RD	6.84	[0.41, 13.28]	0.077

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	14 (8.9)	4 (5.3)	OR	1.78	[0.56, 5.68]	0.330
			RR	1.69	[0.58, 4.90]	0.327
			RD	3.62	[-3.02, 10.26]	0.327
Week 168	13 (8.3)	3 (3.9)	OR	2.21	[0.61, 8.06]	0.229
			RR	2.09	[0.61, 7.11]	0.221
			RD	4.31	[-1.82, 10.44]	0.221
Week 180	13 (8.3)	1 (1.3)	OR	6.77	[0.87, 52.78]	0.068
			RR	6.30	[0.84, 47.47]	0.037
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.96	[1.94, 11.98]	0.037
Week 204	7 (4.5)	2 (2.6)	OR	1.73	[0.35, 8.51]	0.503
			RR	1.69	[0.36, 8.02]	0.500
			RD	1.82	[-3.02, 6.67]	0.500
Week 216	6 (3.8)	2 (2.6)	OR	1.48	[0.29, 7.52]	0.639
			RR	1.46	[0.30, 7.03]	0.638
			RD	1.20	[-3.47, 5.87]	0.638
Week 228	6 (3.8)	2 (2.6)	OR	1.47	[0.29, 7.47]	0.641
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.						

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Table 2-3.1.1.5 MR4.5: Rate - at all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 240	5 (3.2)	1 (1.3)	RR	1.45	[0.30, 7.06]	0.641
			RD	1.19	[-3.49, 5.88]	0.641
			OR	2.47	[0.28, 21.48]	0.414
			RR	2.42	[0.29, 20.48]	0.401
			RD	1.87	[-1.89, 5.63]	0.401
Week 252	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.64	[-0.61, 1.89]	0.486

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 8	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.59	[-0.61, 1.79]	0.512
Week 12	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.18	[-0.51, 2.87]	0.350
Week 16	10 (6.4)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	5.97	[2.25, 9.69]	0.028
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

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Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 24	14 (8.9)	1 (1.3)	OR	7.27	[0.92, 57.45]	0.060
			RR	6.20	[0.86, 44.57]	0.031
			RD	7.11	[2.12, 12.10]	0.031
Week 36	9 (5.7)	2 (2.6)	OR	2.12	[0.43, 10.44]	0.357
			RR	1.97	[0.46, 8.48]	0.351
			RD	2.64	[-2.28, 7.57]	0.351
Week 48	12 (7.6)	1 (1.3)	OR	6.09	[0.76, 48.85]	0.089
			RR	5.28	[0.73, 38.42]	0.057

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points,sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	5.85	[1.13, 10.58]	0.057
Week 60	14 (8.9)	2 (2.6)	OR	3.53	[0.76, 16.25]	0.106
			RR	3.13	[0.76, 12.87]	0.089
			RD	5.82	[0.25, 11.38]	0.089
Week 72	17 (10.8)	2 (2.6)	OR	4.44	[0.98, 20.11]	0.054
			RR	3.80	[0.94, 15.39]	0.038
			RD	7.66	[1.80, 13.52]	0.038
Week 84	14 (8.9)	2 (2.6)	OR	3.53	[0.76, 16.25]	0.106

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 96	17 (10.8)	4 (5.3)	RR	3.13	[0.76, 12.87]	0.089
			RD	5.82	[0.25, 11.38]	0.089
			OR	2.11	[0.67, 6.63]	0.199
			RR	1.94	[0.69, 5.44]	0.193
			RD	5.08	[-1.75, 11.91]	0.193
Week 108	14 (8.9)	5 (6.6)	OR	1.30	[0.43, 3.90]	0.638
			RR	1.25	[0.49, 3.24]	0.639
			RD	1.72	[-5.15, 8.59]	0.639

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval,
MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

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Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points,sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 120	16 (10.2)	3 (3.9)	OR	2.68	[0.74, 9.74]	0.133
			RR	2.39	[0.75, 7.62]	0.123
			RD	5.70	[-0.53, 11.94]	0.123
Week 132	18 (11.5)	4 (5.3)	OR	2.26	[0.73, 7.03]	0.158
			RR	2.07	[0.74, 5.76]	0.151
			RD	5.74	[-1.20, 12.68]	0.151
Week 144	17 (10.8)	3 (3.9)	OR	2.89	[0.80, 10.45]	0.105
			RR	2.54	[0.80, 8.02]	0.095
			RD	6.29	[-0.01, 12.59]	0.095

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points,sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 156	14 (8.9)	4 (5.3)	OR	1.68	[0.52, 5.42]	0.385
			RR	1.59	[0.55, 4.54]	0.383
			RD	3.16	[-3.38, 9.70]	0.383
Week 168	13 (8.3)	3 (3.9)	OR	2.13	[0.59, 7.77]	0.251
			RR	2.04	[0.59, 7.01]	0.244
			RD	4.09	[-2.02, 10.20]	0.244
Week 180	13 (8.3)	1 (1.3)	OR	6.60	[0.84, 51.63]	0.072
			RR	5.94	[0.82, 42.82]	0.041
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

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Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.75	[1.77, 11.72]	0.041
Week 204	7 (4.5)	2 (2.6)	OR	1.67	[0.34, 8.28]	0.530
			RR	1.64	[0.35, 7.69]	0.528
			RD	1.69	[-3.12, 6.51]	0.528
Week 216	6 (3.8)	2 (2.6)	OR	1.43	[0.28, 7.30]	0.664
			RR	1.42	[0.29, 6.82]	0.664
			RD	1.10	[-3.58, 5.78]	0.664
Week 228	6 (3.8)	2 (2.6)	OR	1.43	[0.28, 7.30]	0.664
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.						

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Table 2-3.1.1.6 MR4.5: Rate - at all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 240	5 (3.2)	1 (1.3)	RR	1.42	[0.29, 6.82]	0.664
			RD	1.10	[-3.58, 5.78]	0.664
			OR	2.35	[0.27, 20.65]	0.441
			RR	2.27	[0.28, 18.26]	0.430
			RD	1.73	[-2.01, 5.47]	0.430
Week 252	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.66	[-0.61, 1.94]	0.473

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	74 (47.1)	19 (25.0)	OR	2.77	[1.49, 5.15]	0.001
			RR	1.88	[1.23, 2.87]	0.001
			RD	22.06	[9.64, 34.49]	0.001
by week 4	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.90	[-0.24, 4.03]	0.224
by week 8	12 (7.6)	4 (5.3)	OR	1.50	[0.46, 4.93]	0.501
			RR	1.44	[0.49, 4.28]	0.501
			RD	2.34	[-4.08, 8.77]	0.501
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT. The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT. N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 12	30 (19.1)	7 (9.2)	OR	2.38	[0.98, 5.78]	0.055
			RR	2.07	[0.96, 4.46]	0.051
			RD	9.85	[1.00, 18.69]	0.051
by week 16	39 (24.8)	8 (10.5)	OR	2.93	[1.27, 6.76]	0.012
			RR	2.35	[1.16, 4.76]	0.010
			RD	14.25	[4.68, 23.81]	0.010
by week 24	43 (27.4)	11 (14.5)	OR	2.30	[1.09, 4.83]	0.028
			RR	1.89	[1.04, 3.43]	0.027
			RD	12.85	[2.40, 23.29]	0.027
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 36	51 (32.5)	13 (17.1)	OR	2.37	[1.19, 4.74]	0.014
			RR	1.90	[1.10, 3.25]	0.013
			RD	15.33	[4.23, 26.42]	0.013
by week 48	55 (35.0)	15 (19.7)	OR	2.23	[1.15, 4.32]	0.018
			RR	1.77	[1.08, 2.92]	0.017
			RD	15.24	[3.65, 26.83]	0.017
by week 60	60 (38.2)	16 (21.1)	OR	2.35	[1.23, 4.48]	0.009
			RR	1.81	[1.12, 2.92]	0.009
			RD	17.11	[5.24, 28.99]	0.009
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 72	60 (38.2)	17 (22.4)	OR	2.17	[1.15, 4.09]	0.017
			RR	1.71	[1.07, 2.71]	0.016
			RD	15.80	[3.74, 27.86]	0.016
by week 84	63 (40.1)	17 (22.4)	OR	2.37	[1.25, 4.46]	0.008
			RR	1.79	[1.13, 2.84]	0.007
			RD	17.70	[5.60, 29.80]	0.007
by week 96	67 (42.7)	18 (23.7)	OR	2.45	[1.31, 4.58]	0.005
			RR	1.80	[1.16, 2.80]	0.005
			RD	18.93	[6.61, 31.25]	0.005
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	67 (42.7)	18 (23.7)	OR	2.45	[1.31, 4.58]	0.005
			RR	1.80	[1.16, 2.80]	0.005
			RD	18.93	[6.61, 31.25]	0.005
by week 120	68 (43.3)	18 (23.7)	OR	2.51	[1.35, 4.69]	0.004
			RR	1.83	[1.17, 2.84]	0.003
			RD	19.57	[7.24, 31.90]	0.003
by week 132	70 (44.6)	18 (23.7)	OR	2.67	[1.43, 5.00]	0.002
			RR	1.88	[1.21, 2.92]	0.002
			RD	20.83	[8.49, 33.18]	0.002
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	71 (45.2)	18 (23.7)	OR	2.76	[1.47, 5.18]	0.002
			RR	1.91	[1.23, 2.96]	0.001
			RD	21.47	[9.11, 33.82]	0.001
by week 156	71 (45.2)	18 (23.7)	OR	2.76	[1.47, 5.18]	0.002
			RR	1.91	[1.23, 2.96]	0.001
			RD	21.47	[9.11, 33.82]	0.001
by week 168	72 (45.9)	18 (23.7)	OR	2.83	[1.51, 5.30]	0.001
			RR	1.93	[1.25, 3.00]	<0.001
			RD	22.10	[9.74, 34.46]	<0.001

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 180	72 (45.9)	18 (23.7)	OR	2.83	[1.51, 5.30]	0.001
			RR	1.93	[1.25, 3.00]	<0.001
			RD	22.10	[9.74, 34.46]	<0.001
by week 192	72 (45.9)	18 (23.7)	OR	2.83	[1.51, 5.30]	0.001
			RR	1.93	[1.25, 3.00]	<0.001
			RD	22.10	[9.74, 34.46]	<0.001
by week 204	72 (45.9)	18 (23.7)	OR	2.83	[1.51, 5.30]	0.001
			RR	1.93	[1.25, 3.00]	<0.001
			RD	22.10	[9.74, 34.46]	<0.001

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	74 (47.1)	19 (25.0)	OR	2.77	[1.49, 5.15]	0.001
			RR	1.88	[1.23, 2.87]	0.001
			RD	22.06	[9.64, 34.49]	0.001
by week 228	74 (47.1)	19 (25.0)	OR	2.77	[1.49, 5.15]	0.001
			RR	1.88	[1.23, 2.87]	0.001
			RD	22.06	[9.64, 34.49]	0.001
by week 240	74 (47.1)	19 (25.0)	OR	2.77	[1.49, 5.15]	0.001
			RR	1.88	[1.23, 2.87]	0.001
			RD	22.06	[9.64, 34.49]	0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.1 MMR: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 252	74 (47.1)	19 (25.0)	OR	2.77	[1.49, 5.15]	0.001
			RR	1.88	[1.23, 2.87]	0.001
			RD	22.06	[9.64, 34.49]	0.001

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	74 (47.1)	19 (25.0)	OR	2.79	[1.47, 5.28]	0.002
			RR	1.82	[1.22, 2.74]	0.001
			RD	20.89	[8.96, 32.82]	0.001
by week 4	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.77	[-0.30, 3.83]	0.250
by week 8	12 (7.6)	4 (5.3)	OR	1.38	[0.41, 4.66]	0.599
			RR	1.32	[0.47, 3.74]	0.600
			RD	1.75	[-4.45, 7.96]	0.600

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 12	30 (19.1)	7 (9.2)	OR	2.32	[0.94, 5.71]	0.068
			RR	1.95	[0.93, 4.08]	0.064
			RD	9.02	[0.49, 17.54]	0.064
by week 16	39 (24.8)	8 (10.5)	OR	2.86	[1.23, 6.66]	0.015
			RR	2.24	[1.13, 4.42]	0.013
			RD	13.33	[4.11, 22.56]	0.013
by week 24	43 (27.4)	11 (14.5)	OR	2.22	[1.05, 4.69]	0.037
			RR	1.82	[1.01, 3.26]	0.035
			RD	12.04	[1.82, 22.26]	0.035
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 36	51 (32.5)	13 (17.1)	OR	2.32	[1.15, 4.67]	0.018
			RR	1.84	[1.08, 3.12]	0.017
			RD	14.55	[3.64, 25.47]	0.017
by week 48	55 (35.0)	15 (19.7)	OR	2.19	[1.12, 4.27]	0.022
			RR	1.72	[1.06, 2.81]	0.021
			RD	14.40	[3.03, 25.77]	0.021
by week 60	60 (38.2)	16 (21.1)	OR	2.32	[1.21, 4.46]	0.012
			RR	1.77	[1.10, 2.82]	0.011
			RD	16.29	[4.62, 27.95]	0.011
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 72	60 (38.2)	17 (22.4)	OR	2.14	[1.12, 4.08]	0.021
			RR	1.66	[1.06, 2.61]	0.020
			RD	14.92	[3.16, 26.68]	0.020
by week 84	63 (40.1)	17 (22.4)	OR	2.34	[1.23, 4.47]	0.010
			RR	1.74	[1.11, 2.73]	0.009
			RD	16.76	[4.99, 28.53]	0.009
by week 96	67 (42.7)	18 (23.7)	OR	2.44	[1.29, 4.62]	0.006
			RR	1.75	[1.14, 2.68]	0.006
			RD	17.90	[6.03, 29.78]	0.006
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	67 (42.7)	18 (23.7)	OR	2.44	[1.29, 4.62]	0.006
			RR	1.75	[1.14, 2.68]	0.006
			RD	17.90	[6.03, 29.78]	0.006
by week 120	68 (43.3)	18 (23.7)	OR	2.50	[1.32, 4.73]	0.005
			RR	1.77	[1.16, 2.72]	0.004
			RD	18.57	[6.66, 30.48]	0.004
by week 132	70 (44.6)	18 (23.7)	OR	2.67	[1.40, 5.07]	0.003
			RR	1.82	[1.19, 2.79]	0.002
			RD	19.75	[7.88, 31.62]	0.002
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	71 (45.2)	18 (23.7)	OR	2.76	[1.45, 5.26]	0.002
			RR	1.85	[1.21, 2.82]	0.002
			RD	20.34	[8.49, 32.18]	0.002
by week 156	71 (45.2)	18 (23.7)	OR	2.76	[1.45, 5.26]	0.002
			RR	1.85	[1.21, 2.82]	0.002
			RD	20.34	[8.49, 32.18]	0.002
by week 168	72 (45.9)	18 (23.7)	OR	2.86	[1.49, 5.46]	0.002
			RR	1.87	[1.23, 2.85]	0.001
			RD	20.93	[9.10, 32.75]	0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 180	72 (45.9)	18 (23.7)	OR	2.86	[1.49, 5.46]	0.002
			RR	1.87	[1.23, 2.85]	0.001
			RD	20.93	[9.10, 32.75]	0.001
by week 192	72 (45.9)	18 (23.7)	OR	2.86	[1.49, 5.46]	0.002
			RR	1.87	[1.23, 2.85]	0.001
			RD	20.93	[9.10, 32.75]	0.001
by week 204	72 (45.9)	18 (23.7)	OR	2.86	[1.49, 5.46]	0.002
			RR	1.87	[1.23, 2.85]	0.001
			RD	20.93	[9.10, 32.75]	0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	74 (47.1)	19 (25.0)	OR	2.79	[1.47, 5.28]	0.002
			RR	1.82	[1.22, 2.74]	0.001
			RD	20.89	[8.96, 32.82]	0.001
by week 228	74 (47.1)	19 (25.0)	OR	2.79	[1.47, 5.28]	0.002
			RR	1.82	[1.22, 2.74]	0.001
			RD	20.89	[8.96, 32.82]	0.001
by week 240	74 (47.1)	19 (25.0)	OR	2.79	[1.47, 5.28]	0.002
			RR	1.82	[1.22, 2.74]	0.001
			RD	20.89	[8.96, 32.82]	0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.						

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Table 2-3.1.2.2 MMR: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 252	74 (47.1)	19 (25.0)	OR	2.79	[1.47, 5.28]	0.002
			RR	1.82	[1.22, 2.74]	0.001
			RD	20.89	[8.96, 32.82]	0.001

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	45 (28.7)	11 (14.5)	OR	2.39	[1.15, 4.96]	0.019
			RR	1.98	[1.09, 3.61]	0.018
			RD	14.15	[3.53, 24.78]	0.018
by week 8	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.26	[-0.48, 3.01]	0.324
by week 12	8 (5.1)	1 (1.3)	OR	4.12	[0.50, 33.98]	0.189
			RR	3.84	[0.50, 29.48]	0.159
			RD	3.76	[-0.46, 7.98]	0.159

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 16	16 (10.2)	3 (3.9)	OR	2.83	[0.79, 10.20]	0.111
			RR	2.57	[0.78, 8.41]	0.100
			RD	6.20	[-0.13, 12.53]	0.100
by week 24	17 (10.8)	5 (6.6)	OR	1.74	[0.61, 4.95]	0.301
			RR	1.64	[0.63, 4.26]	0.299
			RD	4.22	[-3.13, 11.56]	0.299
by week 36	20 (12.7)	5 (6.6)	OR	2.08	[0.75, 5.82]	0.161
			RR	1.93	[0.76, 4.93]	0.155

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.13	[-1.46, 13.73]	0.155
by week 48	22 (14.0)	5 (6.6)	OR	2.32	[0.84, 6.42]	0.104
			RR	2.13	[0.84, 5.38]	0.098
			RD	7.41	[-0.34, 15.16]	0.098
by week 60	22 (14.0)	6 (7.9)	OR	1.91	[0.74, 4.93]	0.184
			RR	1.77	[0.75, 4.18]	0.180
			RD	6.10	[-2.03, 14.22]	0.180
by week 72	23 (14.6)	9 (11.8)	OR	1.28	[0.56, 2.93]	0.562
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.						

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Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 84	25 (15.9)	9 (11.8)	RR	1.23	[0.60, 2.53]	0.563
			RD	2.78	[-6.33, 11.89]	0.563
			OR	1.41	[0.62, 3.21]	0.410
			RR	1.34	[0.66, 2.73]	0.411
			RD	4.05	[-5.17, 13.27]	0.411
by week 96	31 (19.7)	10 (13.2)	OR	1.63	[0.75, 3.54]	0.218
			RR	1.50	[0.78, 2.89]	0.218
			RD	6.56	[-3.26, 16.37]	0.218

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

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Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	33 (21.0)	10 (13.2)	OR	1.76	[0.81, 3.82]	0.150
			RR	1.59	[0.83, 3.06]	0.148
			RD	7.83	[-2.08, 17.74]	0.148
by week 120	35 (22.3)	10 (13.2)	OR	1.90	[0.88, 4.09]	0.101
			RR	1.69	[0.89, 3.23]	0.099
			RD	9.11	[-0.89, 19.11]	0.099
by week 132	36 (22.9)	10 (13.2)	OR	1.97	[0.92, 4.25]	0.082
			RR	1.74	[0.91, 3.32]	0.080
			RD	9.74	[-0.30, 19.78]	0.080

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	37 (23.6)	11 (14.5)	OR	1.83	[0.87, 3.83]	0.111
			RR	1.63	[0.88, 3.01]	0.109
			RD	9.06	[-1.27, 19.40]	0.109
by week 156	39 (24.8)	11 (14.5)	OR	1.96	[0.94, 4.09]	0.074
			RR	1.71	[0.93, 3.16]	0.072
			RD	10.34	[-0.07, 20.75]	0.072
by week 168	41 (26.1)	11 (14.5)	OR	2.10	[1.01, 4.37]	0.048
			RR	1.80	[0.98, 3.31]	0.046

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	11.61	[1.13, 22.10]	0.046
by week 180	41 (26.1)	11 (14.5)	OR	2.10	[1.01, 4.37]	0.048
			RR	1.80	[0.98, 3.31]	0.046
			RD	11.61	[1.13, 22.10]	0.046
by week 192	42 (26.8)	11 (14.5)	OR	2.17	[1.04, 4.52]	0.038
			RR	1.85	[1.01, 3.38]	0.036
			RD	12.24	[1.72, 22.77]	0.036
by week 204	43 (27.4)	11 (14.5)	OR	2.25	[1.08, 4.68]	0.031

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	43 (27.4)	11 (14.5)	RR	1.89	[1.03, 3.46]	0.029
			RD	12.88	[2.32, 23.44]	0.029
			OR	2.25	[1.08, 4.68]	0.031
			RR	1.89	[1.03, 3.46]	0.029
			RD	12.88	[2.32, 23.44]	0.029
by week 228	45 (28.7)	11 (14.5)	OR	2.39	[1.15, 4.96]	0.019
			RR	1.98	[1.09, 3.61]	0.018
			RD	14.15	[3.53, 24.78]	0.018
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%. NE: Not Estimable.						

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Table 2-3.1.2.3 MR4: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 240	45 (28.7)	11 (14.5)	OR	2.39	[1.15, 4.96]	0.019
			RR	1.98	[1.09, 3.61]	0.018
			RD	14.15	[3.53, 24.78]	0.018
by week 252	45 (28.7)	11 (14.5)	OR	2.39	[1.15, 4.96]	0.019
			RR	1.98	[1.09, 3.61]	0.018
			RD	14.15	[3.53, 24.78]	0.018

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	45 (28.7)	11 (14.5)	OR	2.36	[1.12, 4.94]	0.023
			RR	1.92	[1.06, 3.46]	0.021
			RD	13.45	[3.04, 23.86]	0.021
by week 8	2 (1.3)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.18	[-0.51, 2.87]	0.350
by week 12	8 (5.1)	1 (1.3)	OR	3.83	[0.46, 32.00]	0.215
			RR	3.50	[0.46, 26.51]	0.188
			RD	3.42	[-0.74, 7.58]	0.188

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 16	16 (10.2)	3 (3.9)	OR	2.69	[0.74, 9.84]	0.134
			RR	2.37	[0.75, 7.53]	0.124
			RD	5.63	[-0.55, 11.81]	0.124
by week 24	17 (10.8)	5 (6.6)	OR	1.65	[0.56, 4.82]	0.362
			RR	1.52	[0.61, 3.77]	0.361
			RD	3.56	[-3.50, 10.62]	0.361
by week 36	20 (12.7)	5 (6.6)	OR	2.01	[0.70, 5.75]	0.191
			RR	1.80	[0.74, 4.41]	0.187

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	5.48	[-1.85, 12.80]	0.187
by week 48	22 (14.0)	5 (6.6)	OR	2.27	[0.80, 6.41]	0.123
			RR	1.99	[0.82, 4.81]	0.117
			RD	6.73	[-0.73, 14.20]	0.117
by week 60	22 (14.0)	6 (7.9)	OR	1.84	[0.70, 4.87]	0.218
			RR	1.67	[0.73, 3.82]	0.215
			RD	5.44	[-2.42, 13.30]	0.215
by week 72	23 (14.6)	9 (11.8)	OR	1.22	[0.52, 2.84]	0.653

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 84	25 (15.9)	9 (11.8)	RR	1.17	[0.58, 2.35]	0.654
			RD	2.08	[-6.76, 10.92]	0.654
			OR	1.36	[0.59, 3.13]	0.476
			RR	1.28	[0.64, 2.56]	0.477
			RD	3.41	[-5.59, 12.42]	0.477
by week 96	31 (19.7)	10 (13.2)	OR	1.58	[0.72, 3.47]	0.254
			RR	1.45	[0.76, 2.75]	0.253
			RD	5.96	[-3.67, 15.59]	0.253

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

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Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	33 (21.0)	10 (13.2)	OR	1.72	[0.79, 3.74]	0.174
			RR	1.55	[0.82, 2.93]	0.172
			RD	7.29	[-2.47, 17.06]	0.172
by week 120	35 (22.3)	10 (13.2)	OR	1.86	[0.86, 4.02]	0.118
			RR	1.64	[0.87, 3.09]	0.116
			RD	8.54	[-1.30, 18.39]	0.116
by week 132	36 (22.9)	10 (13.2)	OR	1.93	[0.89, 4.18]	0.097
			RR	1.68	[0.90, 3.16]	0.095
			RD	9.13	[-0.73, 19.00]	0.095

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	37 (23.6)	11 (14.5)	OR	1.78	[0.84, 3.78]	0.130
			RR	1.58	[0.86, 2.88]	0.129
			RD	8.43	[-1.71, 18.57]	0.129
by week 156	39 (24.8)	11 (14.5)	OR	1.92	[0.91, 4.05]	0.087
			RR	1.66	[0.91, 3.03]	0.085
			RD	9.69	[-0.53, 19.90]	0.085
by week 168	41 (26.1)	11 (14.5)	OR	2.06	[0.98, 4.33]	0.057
			RR	1.75	[0.96, 3.17]	0.055

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	10.94	[0.66, 21.22]	0.055
by week 180	41 (26.1)	11 (14.5)	OR	2.06	[0.98, 4.33]	0.057
			RR	1.75	[0.96, 3.17]	0.055
			RD	10.94	[0.66, 21.22]	0.055
by week 192	42 (26.8)	11 (14.5)	OR	2.13	[1.01, 4.49]	0.046
			RR	1.79	[0.99, 3.23]	0.044
			RD	11.53	[1.23, 21.83]	0.044
by week 204	43 (27.4)	11 (14.5)	OR	2.21	[1.05, 4.65]	0.037

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	43 (27.4)	11 (14.5)	RR	1.83	[1.01, 3.30]	0.035
			RD	12.12	[1.81, 22.43]	0.035
			OR	2.21	[1.05, 4.65]	0.037
			RR	1.83	[1.01, 3.30]	0.035
			RD	12.12	[1.81, 22.43]	0.035
			OR	2.36	[1.12, 4.94]	0.023
by week 228	45 (28.7)	11 (14.5)	RR	1.92	[1.06, 3.46]	0.021
			RD	13.45	[3.04, 23.86]	0.021
			OR	2.36	[1.12, 4.94]	0.023

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%, NE: Not Estimable.

Table 2-3.1.2.4 MR4: Rate - by all scheduled time points, sensitivity - stratified as per CRF
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 240	45 (28.7)	11 (14.5)	OR	2.36	[1.12, 4.94]	0.023
			RR	1.92	[1.06, 3.46]	0.021
			RD	13.45	[3.04, 23.86]	0.021
by week 252	45 (28.7)	11 (14.5)	OR	2.36	[1.12, 4.94]	0.023
			RR	1.92	[1.06, 3.46]	0.021
			RD	13.45	[3.04, 23.86]	0.021
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4: BCR-ABL1 ratio <=0.01%. NE: Not Estimable.						

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Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	29 (18.5)	7 (9.2)	OR	2.23	[0.93, 5.37]	0.072
			RR	2.00	[0.92, 4.37]	0.068
			RD	9.25	[0.36, 18.14]	0.068
by week 8	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.63	[-0.61, 1.87]	0.489
by week 12	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.90	[-0.23, 4.04]	0.227

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 16	10 (6.4)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	6.35	[2.53, 10.16]	0.024
by week 24	15 (9.6)	1 (1.3)	OR	8.17	[1.05, 63.64]	0.045
			RR	7.25	[0.96, 54.48]	0.019
			RD	8.21	[2.91, 13.50]	0.019
by week 36	15 (9.6)	2 (2.6)	OR	3.98	[0.88, 18.04]	0.073
			RR	3.62	[0.84, 15.66]	0.056

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.89	[0.99, 12.79]	0.056
by week 48	15 (9.6)	2 (2.6)	OR	3.98	[0.88, 18.04]	0.073
			RR	3.62	[0.84, 15.66]	0.056
			RD	6.89	[0.99, 12.79]	0.056
by week 60	16 (10.2)	3 (3.9)	OR	2.81	[0.78, 10.05]	0.113
			RR	2.57	[0.77, 8.56]	0.102
			RD	6.21	[-0.22, 12.64]	0.102
by week 72	19 (12.1)	3 (3.9)	OR	3.38	[0.96, 11.88]	0.057

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
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Treatment Groups			Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 84	19 (12.1)	3 (3.9)	RR	3.06	[0.93, 10.01]	0.046
			RD	8.13	[1.42, 14.84]	0.046
			OR	3.38	[0.96, 11.88]	0.057
			RR	3.06	[0.93, 10.01]	0.046
			RD	8.13	[1.42, 14.84]	0.046
by week 96	20 (12.7)	5 (6.6)	OR	2.09	[0.75, 5.86]	0.160
			RR	1.93	[0.76, 4.93]	0.154
			RD	6.13	[-1.46, 13.71]	0.154
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT. The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT. Timepoints with all observations as Non-responders are excluded from output. N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

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Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	21 (13.4)	5 (6.6)	OR	2.21	[0.79, 6.16]	0.128
			RR	2.03	[0.80, 5.15]	0.123
			RD	6.76	[-0.90, 14.43]	0.123
by week 120	22 (14.0)	5 (6.6)	OR	2.33	[0.84, 6.46]	0.103
			RR	2.12	[0.84, 5.38]	0.097
			RD	7.40	[-0.34, 15.15]	0.097
by week 132	22 (14.0)	6 (7.9)	OR	1.91	[0.74, 4.95]	0.183
			RR	1.77	[0.75, 4.18]	0.179
			RD	6.09	[-2.03, 14.21]	0.179

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	22 (14.0)	6 (7.9)	OR	1.91	[0.74, 4.95]	0.183
			RR	1.77	[0.75, 4.18]	0.179
			RD	6.09	[-2.03, 14.21]	0.179
by week 156	22 (14.0)	6 (7.9)	OR	1.91	[0.74, 4.95]	0.183
			RR	1.77	[0.75, 4.18]	0.179
			RD	6.09	[-2.03, 14.21]	0.179
by week 168	22 (14.0)	7 (9.2)	OR	1.61	[0.65, 3.97]	0.301
			RR	1.52	[0.68, 3.40]	0.300

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	4.78	[-3.69, 13.25]	0.300
by week 180	23 (14.6)	7 (9.2)	OR	1.70	[0.69, 4.16]	0.249
			RR	1.59	[0.71, 3.54]	0.247
			RD	5.42	[-3.12, 13.95]	0.247
by week 192	25 (15.9)	7 (9.2)	OR	1.87	[0.77, 4.55]	0.168
			RR	1.73	[0.78, 3.81]	0.165
			RD	6.69	[-1.97, 15.35]	0.165
by week 204	26 (16.6)	7 (9.2)	OR	1.96	[0.81, 4.75]	0.137

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	28 (17.8)	7 (9.2)	RR	1.80	[0.82, 3.95]	0.133
			RD	7.33	[-1.39, 16.05]	0.133
			OR	2.14	[0.89, 5.16]	0.090
			RR	1.93	[0.89, 4.23]	0.086
			RD	8.61	[-0.23, 17.45]	0.086
by week 228	29 (18.5)	7 (9.2)	OR	2.23	[0.93, 5.37]	0.072
			RR	2.00	[0.92, 4.37]	0.068
			RD	9.25	[0.36, 18.14]	0.068

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
Timepoints with all observations as Non-responders are excluded from output.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

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Table 2-3.1.2.5 MR4.5: Rate - by all scheduled time points
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 240	29 (18.5)	7 (9.2)	OR	2.23	[0.93, 5.37]	0.072
			RR	2.00	[0.92, 4.37]	0.068
			RD	9.25	[0.36, 18.14]	0.068
by week 252	29 (18.5)	7 (9.2)	OR	2.23	[0.93, 5.37]	0.072
			RR	2.00	[0.92, 4.37]	0.068
			RD	9.25	[0.36, 18.14]	0.068

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	29 (18.5)	7 (9.2)	OR	2.19	[0.90, 5.31]	0.083
			RR	1.93	[0.90, 4.17]	0.079
			RD	8.73	[-0.04, 17.50]	0.079
by week 8	1 (0.6)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	0.59	[-0.61, 1.79]	0.512
by week 12	3 (1.9)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	1.77	[-0.30, 3.83]	0.250

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 16	10 (6.4)	0	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	5.97	[2.25, 9.69]	0.028
by week 24	15 (9.6)	1 (1.3)	OR	7.92	[1.01, 62.40]	0.049
			RR	6.63	[0.93, 47.46]	0.023
			RD	7.70	[2.60, 12.79]	0.023
by week 36	15 (9.6)	2 (2.6)	OR	3.86	[0.83, 17.83]	0.084
			RR	3.32	[0.81, 13.52]	0.068

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	6.33	[0.73, 11.93]	0.068
by week 48	15 (9.6)	2 (2.6)	OR	3.86	[0.83, 17.83]	0.084
			RR	3.32	[0.81, 13.52]	0.068
			RD	6.33	[0.73, 11.93]	0.068
by week 60	16 (10.2)	3 (3.9)	OR	2.69	[0.74, 9.84]	0.134
			RR	2.37	[0.75, 7.53]	0.124
			RD	5.63	[-0.55, 11.81]	0.124
by week 72	19 (12.1)	3 (3.9)	OR	3.30	[0.92, 11.81]	0.066
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.						

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Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 84	19 (12.1)	3 (3.9)	RR	2.84	[0.91, 8.91]	0.055
			RD	7.55	[1.07, 14.03]	0.055
			OR	3.30	[0.92, 11.81]	0.066
			RR	2.84	[0.91, 8.91]	0.055
			RD	7.55	[1.07, 14.03]	0.055
by week 96	20 (12.7)	5 (6.6)	OR	2.01	[0.71, 5.71]	0.189
			RR	1.82	[0.73, 4.53]	0.185
			RD	5.56	[-1.85, 12.96]	0.185
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

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Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 108	21 (13.4)	5 (6.6)	OR	2.13	[0.76, 6.01]	0.151
			RR	1.92	[0.77, 4.76]	0.146
			RD	6.22	[-1.28, 13.72]	0.146
by week 120	22 (14.0)	5 (6.6)	OR	2.26	[0.81, 6.31]	0.121
			RR	2.02	[0.82, 4.99]	0.115
			RD	6.89	[-0.71, 14.49]	0.115
by week 132	22 (14.0)	6 (7.9)	OR	1.85	[0.71, 4.83]	0.212
			RR	1.70	[0.73, 3.94]	0.209
			RD	5.59	[-2.39, 13.58]	0.209

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 144	22 (14.0)	6 (7.9)	OR	1.85	[0.71, 4.83]	0.212
			RR	1.70	[0.73, 3.94]	0.209
			RD	5.59	[-2.39, 13.58]	0.209
by week 156	22 (14.0)	6 (7.9)	OR	1.85	[0.71, 4.83]	0.212
			RR	1.70	[0.73, 3.94]	0.209
			RD	5.59	[-2.39, 13.58]	0.209
by week 168	22 (14.0)	7 (9.2)	OR	1.55	[0.62, 3.87]	0.343
			RR	1.46	[0.66, 3.23]	0.343

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	4.30	[-4.04, 12.64]	0.343
by week 180	23 (14.6)	7 (9.2)	OR	1.64	[0.66, 4.06]	0.283
			RR	1.53	[0.70, 3.37]	0.281
			RD	4.97	[-3.45, 13.39]	0.281
by week 192	25 (15.9)	7 (9.2)	OR	1.82	[0.74, 4.46]	0.192
			RR	1.67	[0.76, 3.64]	0.189
			RD	6.22	[-2.32, 14.76]	0.189
by week 204	26 (16.6)	7 (9.2)	OR	1.91	[0.78, 4.66]	0.156

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval,

MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 216	28 (17.8)	7 (9.2)	RR	1.74	[0.80, 3.78]	0.152
			RD	6.89	[-1.73, 15.50]	0.152
			OR	2.09	[0.86, 5.09]	0.103
			RR	1.87	[0.87, 4.05]	0.099
			RD	8.14	[-0.59, 16.87]	0.099
by week 228	29 (18.5)	7 (9.2)	OR	2.19	[0.90, 5.31]	0.083
			RR	1.93	[0.90, 4.17]	0.079
			RD	8.73	[-0.04, 17.50]	0.079
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.						
Timepoints with all observations as Non-responders are excluded from output.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%. NE: Not Estimable.						

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Table 2-3.1.2.6 MR4.5: Rate - by all scheduled time points, sensitivity - stratified as per CRF
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib (N=157) n(%)	Bosutinib (N=76) n(%)	Parameter	Estimate	[95% CI]	p-value
by week 240	29 (18.5)	7 (9.2)	OR	2.19	[0.90, 5.31]	0.083
			RR	1.93	[0.90, 4.17]	0.079
			RD	8.73	[-0.04, 17.50]	0.079
by week 252	29 (18.5)	7 (9.2)	OR	2.19	[0.90, 5.31]	0.083
			RR	1.93	[0.90, 4.17]	0.079
			RD	8.73	[-0.04, 17.50]	0.079

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per CRF.

The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per CRF.

Timepoints with all observations as Non-responders are excluded from output.

N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, MR4.5: BCR-ABL1 ratio <=0.0032%, NE: Not Estimable.

Table 2-3.2 MMR: Time to event - subdistribution hazard model
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		HR*	[95% CI]	p-value
	Asciminib (N=157)	Bosutinib (N=76)			
Number of patients, n (%)					
Number of subjects with MMR	74 (47.1)	19 (25.0)	2.26	[1.36, 3.76]	0.0018
Number of subjects with competing risks	75 (47.8)	56 (73.7)			
Treatment discontinuation	1 (0.6)	0			
Treatment Failure	74 (47.1)	56 (73.7)			
Number of subjects censored	8 (5.1)	1 (1.3)			
Estimated cumulative incidence [95% CI]					
12 weeks	8.9 [5.1, 14.0]	6.6 [2.4, 13.7]			
24 weeks	24.8 [18.4, 31.8]	11.8 [5.8, 20.3]			
48 weeks	32.5 [25.3, 39.9]	18.4 [10.6, 28.0]			
60 weeks	35.7 [28.2, 43.2]	19.7 [11.6, 29.5]			
72 weeks	38.2 [30.6, 45.8]	21.1 [12.6, 30.9]			
96 weeks	40.1 [32.4, 47.7]	22.4 [13.7, 32.4]			
120 weeks	42.7 [34.8, 50.3]	23.7 [14.7, 33.9]			
144 weeks	44.6 [36.7, 52.2]	23.7 [14.7, 33.9]			
168 weeks	46.0 [38.0, 53.6]	23.7 [14.7, 33.9]			
192 weeks	46.0 [38.0, 53.6]	23.7 [14.7, 33.9]			
216 weeks	49.0 [39.1, 58.3]	NE [NE, NE]			

*HR estimated and two sided P-value by sub-distribution hazard model, adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR).
CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.2 MMR: Time to event - subdistribution hazard model
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	Treatment Groups				HR*	[95% CI]	p-value
	Asciminib (N=157)		Bosutinib (N=76)				
240 weeks	NE	[NE, NE]	NE	[NE, NE]			
264 weeks	NE	[NE, NE]	NE	[NE, NE]			

*HR estimated and two sided P-value by sub-distribution hazard model, adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR).
CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable.

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Table 2-3.3.1 MMR: Duration of event
MMR Responder Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=74)	Bosutinib (N=19)	HR	[95% CI]	p-value
N*	74	19			
Number of patients, n (%)					
with events	2 (2.7)	1 (5.3)			
censored	72 (97.3)	18 (94.7)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [28.14, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.40	[0.03, 4.67]	0.453
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
[95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.90, 1.00]	1.00 [1.00, 1.00]			
Week 48	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-3.3.1 MMR: Duration of event
MMR Responder Set
 (Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=74)	Bosutinib (N=19)	HR	[95% CI]	p-value
Week 72	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 96	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 120	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 144	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 168	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 192	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 216	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 240	0.97 [0.89, 0.99]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

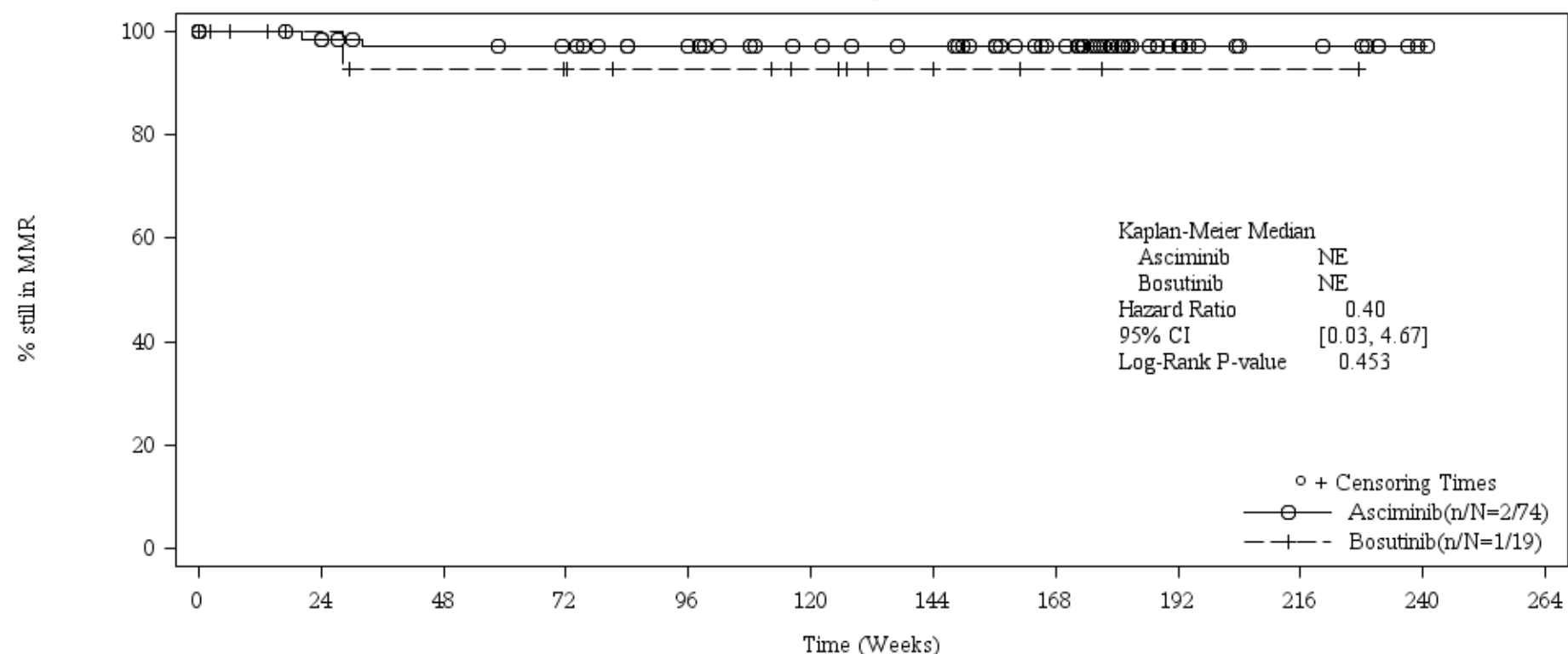
Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Figure 2-3.3.1 (Page 1 of 1)
MMR: Kaplan Meier plot of duration of event
MMR Responder Set



Number of patients still at risk												
Time (Weeks)	0	24	48	72	96	120	144	168	192	216	240	264
Asciminib	74	67	63	61	55	48	45	33	14	8	1	0
Bosutinib	19	14	12	11	9	7	4	2	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

MMR: Major molecular response, NE: Not Estimable.

Table 2-3.3.1.1 MMR: Duration of event - sensitivity: stratified as per CRF
MMR Responder Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=74)	Bosutinib (N=19)	HR	[95% CI]	p-value
N*	74	19			
Number of patients, n (%)					
with events	2 (2.7)	1 (5.3)			
censored	72 (97.3)	18 (94.7)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [28.14, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.43	[0.04, 4.79]	0.483
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.90, 1.00]	1.00 [1.00, 1.00]			
Week 48	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-3.3.1.1 MMR: Duration of event - sensitivity: stratified as per CRF
MMR Responder Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=74)	Bosutinib (N=19)	HR	[95% CI]	p-value
Week 72	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 96	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 120	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 144	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 168	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 192	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 216	0.97 [0.89, 0.99]	0.93 [0.59, 0.99]			
Week 240	0.97 [0.89, 0.99]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, MMR: Major molecular response, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

**Table 2-3.3.2 MR4: Duration of event
MMR Responder Set
(Page 1 of 2)**

	Treatment Groups		Comparison		
	Asciminib (N=45)	Bosutinib (N=11)	HR	[95% CI]	p-value
N*	45	11			
Number of patients, n (%)					
with events	0	1 (9.1)			
censored	45 (100)	10 (90.9)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [20.43, NE]	NE	[NE , NE]	NE
median	NE [NE, NE]	NE [20.43, NE]			
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 48	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, MR4: BCR-ABL1 <=0.01%, NE: Not Estimable,
n: Number of patients with event, N*: Number of patients included in the analysis.

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Table 2-3.3.2 MR4: Duration of event
MMR Responder Set
 (Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=45)	Bosutinib (N=11)	HR	[95% CI]	p-value
Week 72	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 96	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 120	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 144	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 168	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 192	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 216	1.00 [1.00, 1.00]	NE [NE, NE]			
Week 240	NE [NE, NE]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

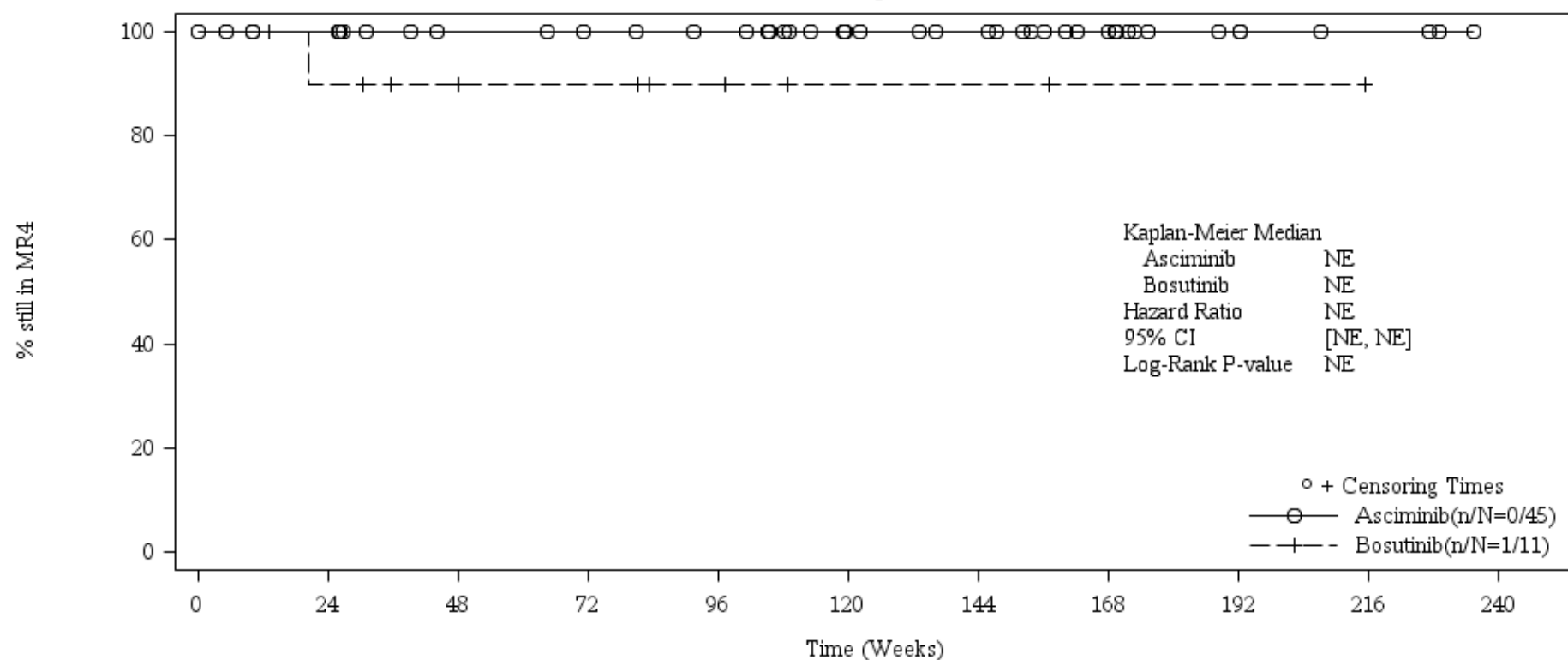
Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, MR4: BCR-ABL1 ≤0.01%, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Figure 2-3.3.2 (Page 1 of 1)
MR4: Kaplan Meier plot of duration of event
MMR Responder Set



Number of patients still at risk											
Time (Weeks)	0	24	48	72	96	120	144	168	192	216	240
Asciminib	45	41	35	33	31	23	20	13	6	3	0
Bosutinib	11	9	7	6	4	2	2	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

MR4: BCR-ABL1 ratio $\leq 0.01\%$, NE: Not Estimable.

**Table 2-3.3.2.1 MR4: Duration of event - sensitivity: stratified as per CRF
MMR Responder Set
(Page 1 of 2)**

	Treatment Groups		Comparison		
	Asciminib (N=45)	Bosutinib (N=11)	HR	[95% CI]	p-value
N*	45	11			
Number of patients, n (%)					
with events	0	1 (9.1)			
censored	45 (100)	10 (90.9)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [20.43, NE]			
median	NE [NE, NE]	NE [20.43, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 48	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, MR4: BCR-ABL1 <=0.01%, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-3.3.2.1 MR4: Duration of event - sensitivity: stratified as per CRF
MMR Responder Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=45)	Bosutinib (N=11)	HR	[95% CI]	p-value
Week 72	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 96	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 120	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 144	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 168	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 192	1.00 [1.00, 1.00]	0.90 [0.47, 0.99]			
Week 216	1.00 [1.00, 1.00]	NE [NE, NE]			
Week 240	NE [NE, NE]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, MR4: BCR-ABL1 ≤0.01%, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Table 2-3.3.3 MR4.5: Duration of event
MMR Responder Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=30)	Bosutinib (N=7)	HR	[95% CI]	p-value
N*	30	7			
Number of patients, n (%)					
with events	0	0			
censored	30 (100)	7 (100)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE , NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
[95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 48	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, MR4.5: BCR-ABL1 <=0.0032%, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-3.3.3 MR4.5: Duration of event
MMR Responder Set
 (Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=30)	Bosutinib (N=7)	HR	[95% CI]	p-value
Week 72	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 96	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 120	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 144	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 168	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 192	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 216	1.00 [1.00, 1.00]	NE [NE, NE]			
Week 240	NE [NE, NE]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, MR4.5: BCR-ABL1 ≤0.0032%, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Figure 2-3.3.3 MR4.5: Kaplan Meier plot of duration of event

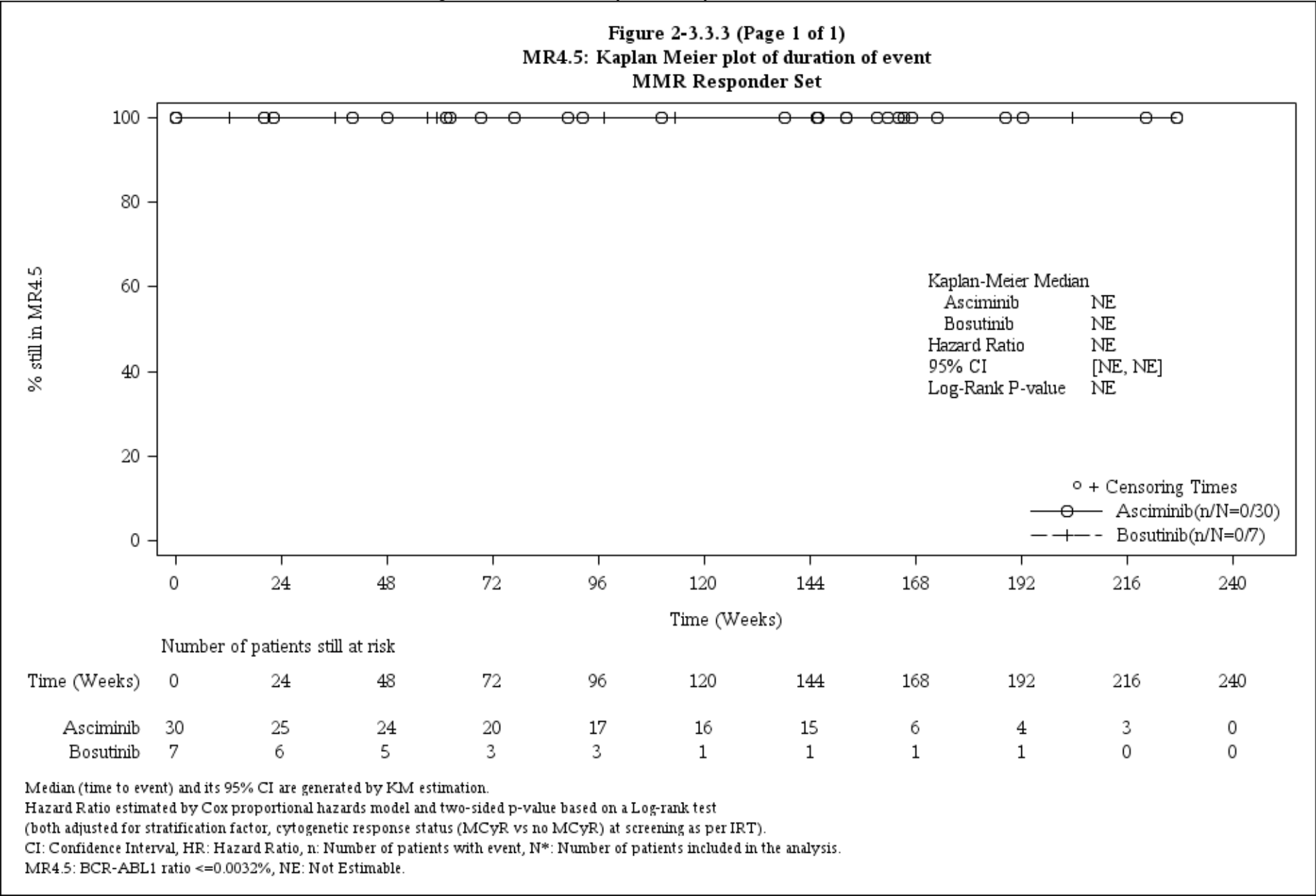


**Table 2-3.3.3.1 MR4.5: Duration of event - sensitivity : stratified as per CRF
MMR Responder Set
(Page 1 of 2)**

	Treatment Groups		Comparison		
	Asciminib (N=30)	Bosutinib (N=7)	HR	[95% CI]	p-value
N*	30	7			
Number of patients, n (%)					
with events	0	0			
censored	30 (100)	7 (100)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE , NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 48	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, MR4.5: BCR-ABL1 <=0.0032%, NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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**Table 2-3.3.3.1 MR4.5: Duration of event - sensitivity : stratified as per CRF
MMR Responder Set
(Page 2 of 2)**

	Treatment Groups		Comparison		
	Asciminib (N=30)	Bosutinib (N=7)	HR	[95% CI]	p-value
Week 72	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 96	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 120	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 144	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 168	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 192	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 216	1.00 [1.00, 1.00]	NE [NE, NE]			
Week 240	NE [NE, NE]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, MR4.5: BCR-ABL1 ≤0.0032%, NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Table 2-4.1 CCyR: Rate - at all scheduled time points
CCyR Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison			
	Asciminib (N=103) n(%)	Bosutinib (N=62) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 24	42 (40.8)	15 (24.2)	OR	2.41	[1.15, 5.05]	0.020
			RR	1.72	[1.06, 2.79]	0.019
			RD	17.30	[3.62, 30.99]	0.019
Week 48	41 (39.8)	13 (21.0)	OR	2.54	[1.22, 5.27]	0.013
			RR	1.90	[1.11, 3.27]	0.012
			RD	19.05	[4.87, 33.24]	0.012
Week 72	39 (37.9)	12 (19.4)	OR	2.60	[1.23, 5.52]	0.013
			RR	1.96	[1.11, 3.47]	0.012
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, CCyR: Complete cytogenetic response, NE: Not Estimable.						
Patients with MMR or better were counted as CCyR if no valid cytogenetic assessment was available at that specific time-point.						

Table 2-4.1 CCyR: Rate - at all scheduled time points
CCyR Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison			
	Asciminib (N=103) n(%)	Bosutinib (N=62) n(%)	Parameter	Estimate	[95% CI]	p-value
Week 96	41 (39.8)	10 (16.1)	RD	18.77	[4.87, 32.68]	0.012
			OR	3.50	[1.59, 7.69]	0.002
			RR	2.46	[1.32, 4.58]	0.001
			RD	23.87	[10.30, 37.43]	0.001
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, CCyR: Complete cytogenetic response, NE: Not Estimable.						
Patients with MMR or better were counted as CCyR if no valid cytogenetic assessment was available at that specific time-point.						

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Table 2-4.2 CCyR: Rate - by all scheduled time points
CCyR Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison			
	Asciminib (N=103) n(%)	Bosutinib (N=62) n(%)	Parameter	Estimate	[95% CI]	p-value
Overall	52 (50.5)	22 (35.5)	OR	1.94	[1.00, 3.77]	0.050
			RR	1.44	[0.98, 2.11]	0.050
			RD	15.51	[0.36, 30.66]	0.050
by week 24	42 (40.8)	15 (24.2)	OR	2.41	[1.15, 5.05]	0.020
			RR	1.72	[1.06, 2.79]	0.019
			RD	17.30	[3.62, 30.99]	0.019
by week 48	47 (45.6)	22 (35.5)	OR	1.59	[0.82, 3.08]	0.172
			RR	1.30	[0.88, 1.92]	0.174

The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, CCyR: Complete cytogenetic response, NE: Not Estimable.
Patients with MMR or better were counted as CCyR if no valid cytogenetic assessment was available at that specific time-point.

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Table 2-4.2 CCyR: Rate - by all scheduled time points
CCyR Analysis Set
(Page 2 of 2)

Treatment Groups			Comparison			
	Asciminib (N=103) n(%)	Bosutinib (N=62) n(%)	Parameter	Estimate	[95% CI]	p-value
			RD	10.66	[-4.47, 25.80]	0.174
by week 72	49 (47.6)	22 (35.5)	OR	1.73	[0.89, 3.37]	0.106
			RR	1.36	[0.92, 2.00]	0.107
			RD	12.65	[-2.48, 27.78]	0.107
by week 96	51 (49.5)	22 (35.5)	OR	1.87	[0.96, 3.64]	0.065
			RR	1.41	[0.96, 2.07]	0.065
			RD	14.56	[-0.59, 29.70]	0.065
The adjusted OR, 95% CI and p-value were obtained by a logistic regression model adjusted for stratification factor baseline MCyR response per IRT.						
The risk difference and risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.						
N: number of patients in the analysis; OR: Odds Ratio, RR: Risk Ratio, RD: Risk difference, CI: Confidence Interval, CCyR: Complete cytogenetic response, NE: Not Estimable.						
Patients with MMR or better were counted as CCyR if no valid cytogenetic assessment was available at that specific time-point.						

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Table 2-4.3.1 CCyR: Duration of event
CCyR Responder Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=52)	Bosutinib (N=22)	HR	[95% CI]	p-value
N*	52	22			
Number of patients, n (%)					
with events	2 (3.8)	2 (9.1)			
censored	50 (96.2)	20 (90.9)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [19.14, NE]			
median	NE [NE, NE]	NE [64.14, NE]	0.26	[0.03, 2.11]	0.181
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.98 [0.86, 1.00]	0.93 [0.59, 0.99]			
Week 48	0.96 [0.84, 0.99]	0.93 [0.59, 0.99]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, CCyR: Complete cytogenetic response., NE: Not Estimable,					
n: Number of patients with event, N*: Number of patients included in the analysis.					

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Table 2-4.3.1 CCyR: Duration of event
CCyR Responder Set
 (Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=52)	Bosutinib (N=22)	HR	[95% CI]	p-value
Week 72	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 96	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 120	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 144	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 168	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 192	0.96 [0.84, 0.99]	0.84 [0.48, 0.96]			
Week 216	0.96 [0.84, 0.99]	NE [NE, NE]			
Week 240	NE [NE, NE]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

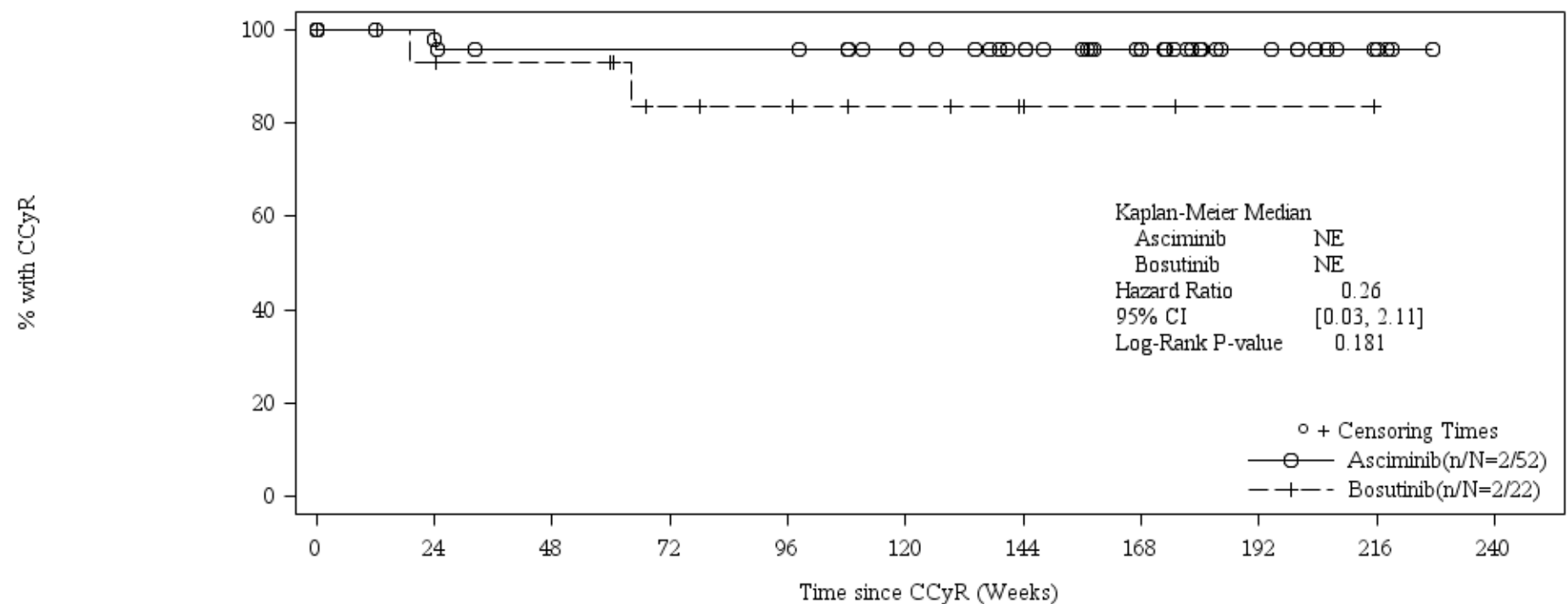
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, CCyR: Complete cytogenetic response., NE: Not Estimable,

n: Number of patients with event, N*: Number of patients included in the analysis.

Figure 2-4.3.1 CCyR: Kaplan Meier plot of duration of event

Figure 2-4.3.1 (Page 1 of 1)
CCyR: Kaplan Meier plot of Duration of event
CCyR Responder Set



Time since CCyR (Weeks)	Number of patients still at risk										
	0	24	48	72	96	120	144	168	192	216	240
Asciminib	52	45	42	42	42	37	30	21	11	4	0
Bosutinib	22	13	12	8	7	5	3	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

CCyR: Complete cytogenetic response, NE: Not Estimable.

Table 2-5.1.2.1 Progression to BC: time to event
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	5 (3.2)	4 (5.3)			
censored	152 (96.8)	72 (94.7)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.42	[0.11, 1.61]	0.193
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Week 48	0.99 [0.95, 1.00]	0.93 [0.81, 0.97]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, BC: Blast Crisis, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-5.1.2.1 Progression to BC: time to event
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Week 72	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 96	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 120	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 144	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 168	0.97 [0.91, 0.99]	0.93 [0.81, 0.97]			
Week 192	0.97 [0.91, 0.99]	0.93 [0.81, 0.97]			
Week 216	0.92 [0.77, 0.98]	0.93 [0.81, 0.97]			
Week 240	0.92 [0.77, 0.98]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, BC: Blast Crisis, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

Table 2-5.1.2.1 Progression to BC: Kaplan Meier plot of time to event

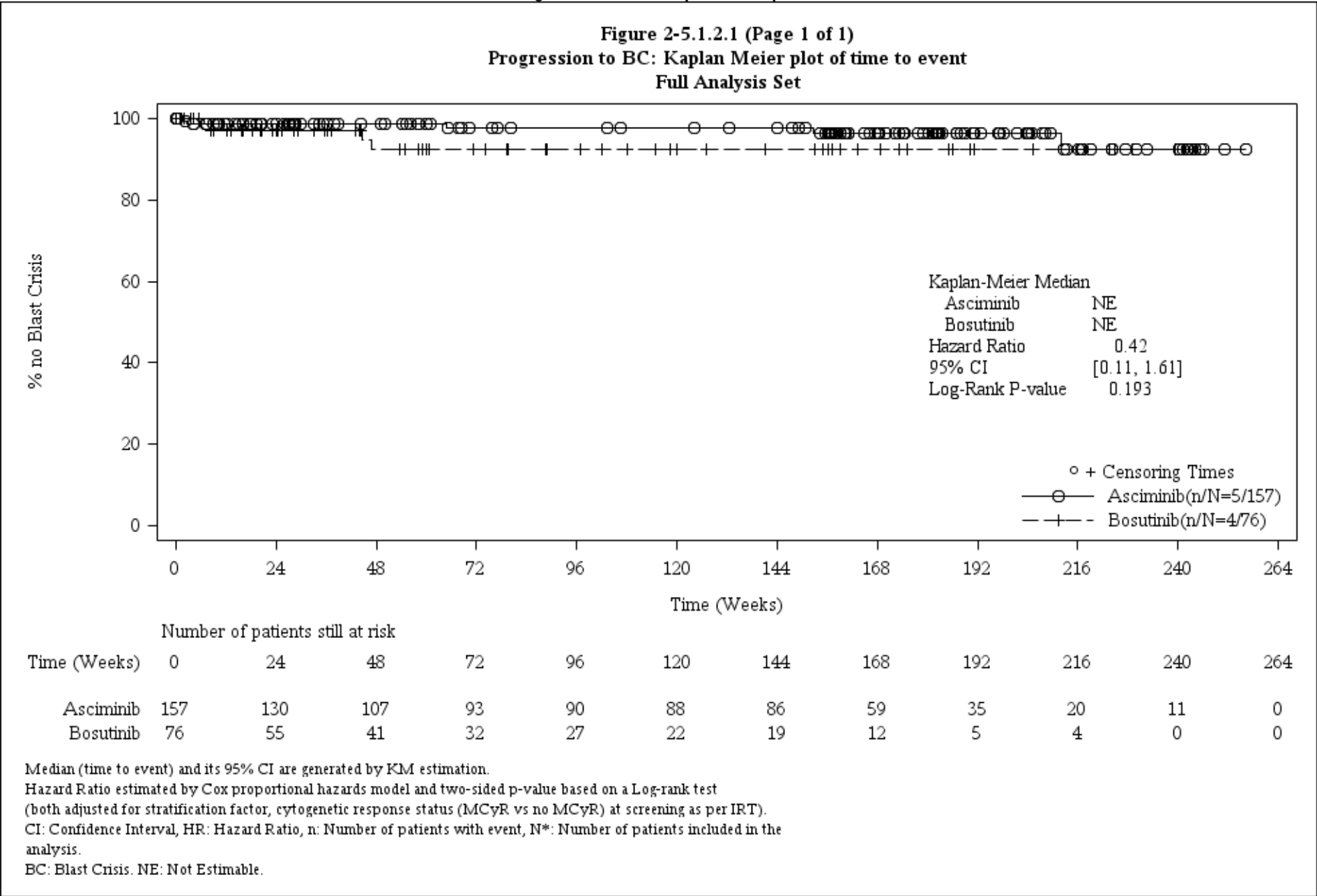


Table 2-5.1.2.1.1 Progression to BC: time to event -: stratified as per IRT
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	5 (3.2)	5 (6.6)			
censored	152 (96.8)	71 (93.4)			
Percentiles (weeks) (95% CI)					
25th	311.14 [NE, NE]	315.43 [NE, NE]			
median	311.14 [NE, NE]	315.43 [NE, NE]	0.37	[0.09, 1.50]	0.146
75th	311.14 [NE, NE]	315.43 [NE, NE]			
Kaplan Meier event probability estimates (95% CI)					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Week 48	0.99 [0.95, 1.00]	0.93 [0.81, 0.97]			
Week 72	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 96	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			

(Continued)

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-5.1.2.1.1 Progression to BC: time to event -: stratified as per IRT
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Week 120	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 144	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 168	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 192	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 216	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 240	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 264	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 288	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 312	0.00 [NE, NE]	0.93 [0.81, 0.97]			
Week 336	0.00 [NE, NE]	0.00 [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-5.1.2.1.1 Progression to BC: Kaplan Meier plot of time to event

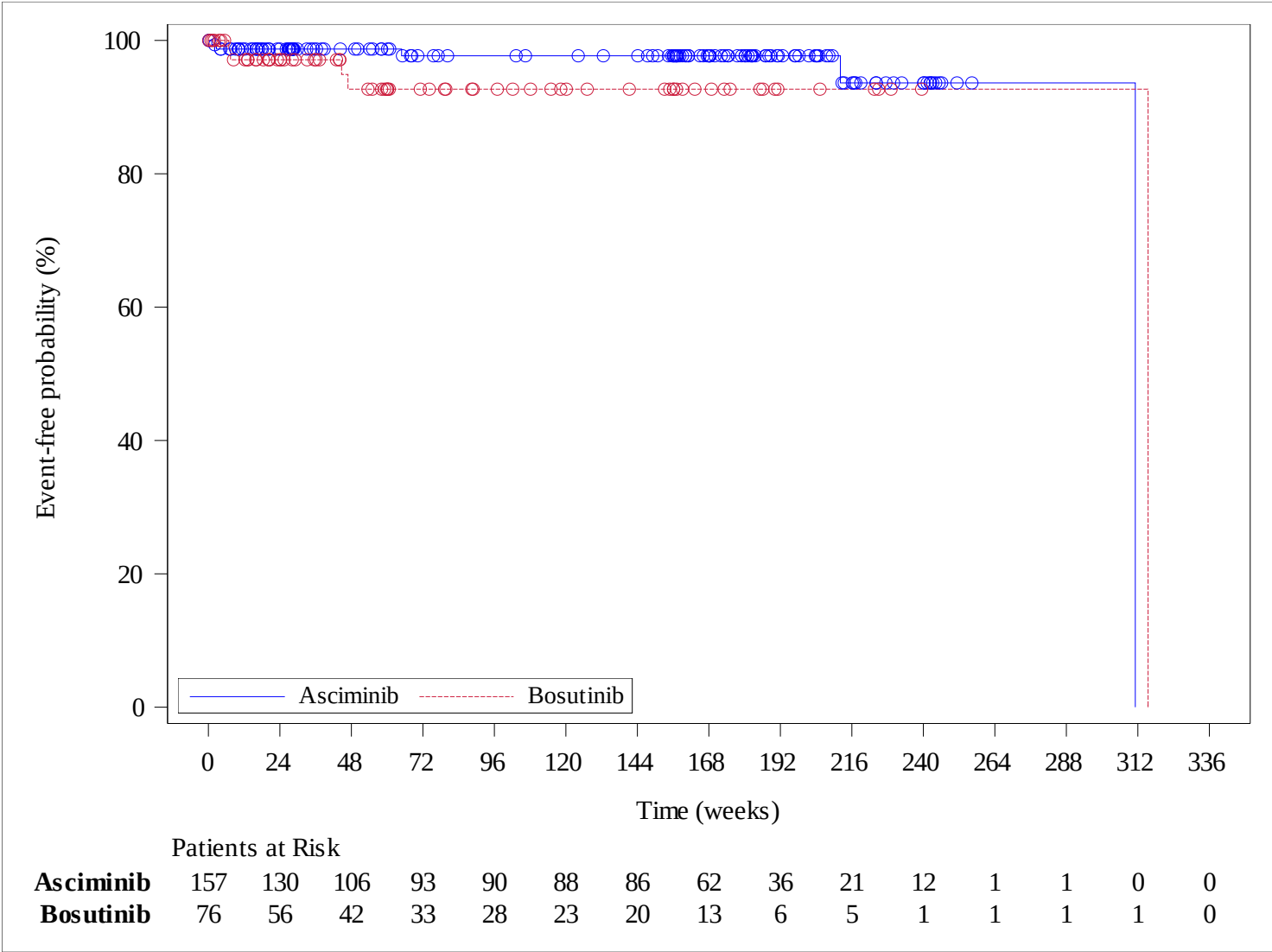


Table 2-5.1.2.2 Progression to BC: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	5 (3.2)	4 (5.3)			
censored	152 (96.8)	72 (94.7)			
Percentiles (Weeks) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.42	[0.11, 1.62]	0.197
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Week 48	0.99 [0.95, 1.00]	0.93 [0.81, 0.97]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, BC: Blast Crisis, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-5.1.2.2 Progression to BC: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Week 72	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 96	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 120	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 144	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 168	0.97 [0.91, 0.99]	0.93 [0.81, 0.97]			
Week 192	0.97 [0.91, 0.99]	0.93 [0.81, 0.97]			
Week 216	0.92 [0.77, 0.98]	0.93 [0.81, 0.97]			
Week 240	0.92 [0.77, 0.98]	NE [NE, NE]			
Week 264	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, BC: Blast Crisis, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

Table 2-5.1.2.2.1 Progression to BC: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Number of patients, n(%)					
with event	5 (3.2)	5 (6.6)			
censored	152 (96.8)	71 (93.4)			
Percentiles (weeks) (95% CI)					
25th	311.14 [NE, NE]	315.43 [NE, NE]			
median	311.14 [NE, NE]	315.43 [NE, NE]	0.37	[0.09, 1.50]	0.146
75th	311.14 [NE, NE]	315.43 [NE, NE]			
Kaplan Meier event probability estimates (95% CI)					
Week 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Week 24	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Week 48	0.99 [0.95, 1.00]	0.93 [0.81, 0.97]			
Week 72	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 96	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			

(Continued)

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-5.1.2.2.1 Progression to BC: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR	[95% CI]	p-value
Week 120	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 144	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 168	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 192	0.98 [0.93, 0.99]	0.93 [0.81, 0.97]			
Week 216	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 240	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 264	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 288	0.94 [0.78, 0.98]	0.93 [0.81, 0.97]			
Week 312	0.00 [NE, NE]	0.93 [0.81, 0.97]			
Week 336	0.00 [NE, NE]	0.00 [NE, NE]			

Data cut-off: 04DEC2024

Percentiles (time to event) and their 95% CIs are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event

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Table 2-6.1.2.1 Treatment Failure: time to event
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	86 (54.8)	69 (90.8)			
censored	71 (45.2)	7 (9.2)			
Percentiles (years) (95% CI)					
25th	0.46 [0.35, 0.47]	0.27 [0.16, 0.44]	0.41	[0.29, 0.56]	<0.001
median	2.40 [0.96, NE]	0.46 [0.46, 0.57]			
75th	NE [NE, NE]	1.15 [0.64, 2.35]			
Kaplan Meier event probability estimates [95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
For patients in the FAS who have not reached treatment failure, their TTFs will be censored at the time of their last					
study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date.					
CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-6.1.2.1 Treatment Failure: time to event
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 1	0.58 [0.50, 0.65]	0.25 [0.16, 0.35]			
Year 3	0.47 [0.39, 0.55]	0.11 [0.05, 0.19]			
Year 5	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients in the FAS who have not reached treatment failure, their TTFs will be censored at the time of their last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date.

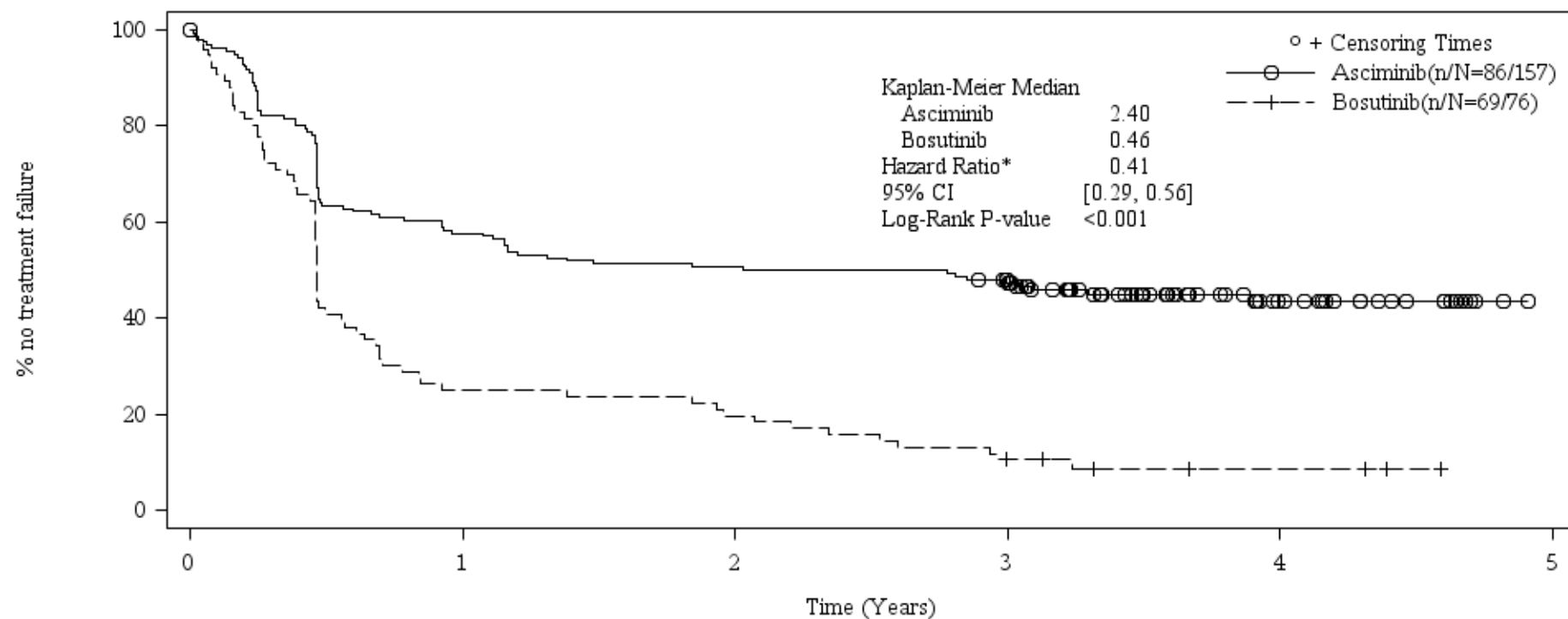
CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

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Figure 2-6.1.2.1 (Page 1 of 1)
Treatment Failure: Kaplan Meier plot of time to event
Full Analysis Set



Number of patients still at risk						
Time (Years)	0	1	2	3	4	5
Asciminib	157	90	79	69	22	0
Bosutinib	76	19	15	7	3	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). For patients in the FAS who have not reached treatment failure, their TTFs will be censored at the time of their last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

Table 2-6.1.2.2 Treatment Failure: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	157	76			
Number of patients, n (%)					
with events	86 (54.8)	69 (90.8)			
censored	71 (45.2)	7 (9.2)			
Percentiles (years) (95% CI)					
25th	0.46 [0.35, 0.47]	0.27 [0.16, 0.44]	0.41	[0.29, 0.56]	<0.001
median	2.40 [0.96, NE]	0.46 [0.46, 0.57]			
75th	NE [NE, NE]	1.15 [0.64, 2.35]			
Kaplan Meier event probability estimates					
[95% CI]					
Year 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
For patients in the FAS who have not reached treatment failure, their TTFs will be censored at the time of their last					
study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date.					
CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,					
N*: Number of patients included in the analysis.					

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Table 2-6.1.2.2 Treatment Failure: time to event - sensitivity: stratified as per CRF
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib (N=157)	Bosutinib (N=76)	HR	[95% CI]	p-value
Year 1	0.58 [0.50, 0.65]	0.25 [0.16, 0.35]			
Year 3	0.47 [0.39, 0.55]	0.11 [0.05, 0.19]			
Year 5	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

For patients in the FAS who have not reached treatment failure, their TTFs will be censored at the time of their last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date.

CI: Confidence Interval, HR: Hazard Ratio, NE: Not Estimable, n: Number of patients with event,

N*: Number of patients included in the analysis.

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Table 3-1.1 OS: Follow-up time by study treatment
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for OS (months)			
n	157	76	233
Mean (SD)	41.7 (14.94)	38.1 (17.13)	40.5 (15.74)
Median	44.2	43.0	43.9
Min-Max	0-62	0-62	0-62
-Follow-up time for OS [months] = (date of death or censoring date - date of randomization + 1)/30.4375			
-Censoring date = date of last contact before the cut-off date			
-Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.			

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**Table 3-1.1.1: OS: Follow-up time by study treatment
Full Analysis Set**

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for OS (months)			
n	157	76	233
Mean (SD)	57.7 (22.03)	52.0 (25.44)	55.8 (23.30)
Median	64.9	61.8	64.0
Min-Max	0-84	0-84	0-84

Data cut-off: 04DEC2024

Follow-up time for OS [months] = (date of death or censoring date - date of randomization + 1)/30.4375

Censoring date = date of last contact before the cut-off date

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

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Table 3-1.2 OS: Sensitivity Follow-up time by study treatment - censoring at treatment switch
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for OS (months)			
n	157	76	233
Mean (SD)	41.7 (14.94)	26.4 (20.36)	36.7 (18.33)
Median	44.2	23.7	42.7
Min-Max	0-62	0-62	0-62
-Follow-up time for OS [months]= (date of death or censoring date - date of randomization + 1)/30.4375			
-Censoring date = minimum (date of last contact before the cut-off date, date of switch)			
-Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date. If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.			

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Table 3-1.2.1: OS: Follow-up time by study treatment - censoring at treatment switch (Full Analysis Set)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for OS (months)			
n	157	76	233
Mean (SD)	57.7 (22.03)	36.4 (29.45)	50.7 (26.59)
Median	64.9	32.7	61.9
Min-Max	0-84	0-84	0-84

Data cut-off: 04DEC2024

Follow-up time for OS [months] = (date of death or censoring date - date of randomization + 1)/30.4375

Censoring date = minimum (date of last contact before the cut-off date, date of switch)

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date. If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.

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Table 3-2.1 PFS: Follow-up time by study treatment
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for PFS (months)			
n	157	76	233
Mean (SD)	28.4 (18.58)	19.5 (16.47)	25.5 (18.38)
Median	35.9	13.7	27.2
Min-Max	0-59	0-55	0-59
-Follow-up time for PFS [months] = (date of disease progression/death or censoring date - date of randomization + 1)/30.4375			
-Censoring date = date of last study assessment before the cut-off date			
-For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.			

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**Table 3-2.1.1: PFS: Follow-up time by study treatment
Full Analysis Set**

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for PFS (months)			
n	157	76	233
Mean (SD)	29.7 (19.09)	21.8 (19.10)	27.1 (19.42)
Median	36.1	13.8	33.7
Min-Max	0-72	0-73	0-73

Data cut-off: 04DEC2024

Follow-up time for PFS [months] = (date of disease progression/death or censoring date - date of randomization + 1)/30.4375

Censoring date = date of last study assessment before the cut-off date

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

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Table 3-2.2 PFS: Sensitivity Follow-up time by study treatment - censoring at treatment switch
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for PFS (months)			
n	157	76	233
Mean (SD)	28.4 (18.58)	14.0 (14.64)	23.7 (18.64)
Median	35.9	7.4	17.7
Min-Max	0-59	0-55	0-59
-Follow-up time for PFS [months] = (date of disease progression/death or censoring date - date of randomization + 1)/30.4375			
-Censoring date = minimum (date of last study assessment before the cut-off date, date of switch)			
-For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date. If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.			

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**Table 3-2.2.1: PFS: Follow-up time by study treatment - censoring at treatment switch
Full Analysis Set**

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for PFS (months)			
n	157	76	233
Mean (SD)	29.7 (19.09)	15.5 (17.02)	25.1 (19.58)
Median	36.1	7.5	24.7
Min-Max	0-72	0-73	0-73

Data cut-off: 04DEC2024

Follow-up time for PFS [months] = (date of disease progression/death or censoring date - date of randomization + 1)/30.4375

Censoring date = minimum (date of last study assessment before the cut-off date, date of switch)

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date. If a patient randomized to bosutinib crossed over to receive asciminib prior to observing an event, survival time will be censored at the date of switch.

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Table 3-3 MMR: Follow-up time by study treatment
Full Analysis Set
(Page 1 of 1)

	Asciminib N=157	Bosutinib N=76	All subjects N=233
Follow-up time for MMR (months)			
n	156	76	232
Mean (SD)	24.8 (19.91)	11.7 (14.25)	20.5 (19.24)
Median	22.5	5.6	8.3
Min-Max	0-59	0-55	0-59
Follow-up time for MMR [months] = (date of last follow-up for MMR – date of first administration of study treatment + 1)/30.4375			
Date of last follow-up for MMR = minimum (date of death, cut-off date, date of study treatment discontinuation or censoring date).			

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Table 3-4.1 AEs: Follow-up time for on-treatment period adverse events by study treatment
Safety Set
(Page 1 of 1)

	Asciminib N=156	Bosutinib N=76	All subjects N=232
Follow-up time AE (months)			
n	156	76	232
Mean (SD)	28.3 (19.12)	19.2 (16.20)	25.3 (18.68)
Median	36.9	13.4	21.3
Min-Max	1-60	1-56	1-60
-Follow-up time AE [months] = (date of last follow-up for AEs - date of first administ of study treatment + 1) / 30.4375			
-Date of last follow-up for AEs = minimum (date of death, cut-off date, last date of study treatment + 30 days)			

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Table 3-4.2 AEs: Switch Follow-up time for on-switched treatment period
Switch Analysis Set
(Page 1 of 1)

	Bosutinib N=25
Follow-up time AE (months)	
n	25
Mean (SD)	16.0 (12.99)
Median	11.1
Min-Max	3-43
-Follow-up time AE [months] = (date of last follow-up for AEs - date of first administ. of asciminib + 1) / 30.4375	
-Date of last follow-up for AEs= minimum (date of death, cut-off date, date of last actual administration of asciminib +30 days)	
-Follow-up time summarized in this table is for switched treatment:Asciminib.	
-Patients included in this table are randomized to Bosutinib and switched to Asciminib.	

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Table 3-4.3 AEs: Time until switch for on-treatment period
Switch Analysis Set
(Page 1 of 1)

	Bosutinib N=25
Follow-up time AE (months)	
n	25
Mean (SD)	8.5 (4.65)
Median	7.2
Min-Max	4-25
-Follow-up time AE [months] = (date of last follow-up for AEs - date of first administ of study treatment + 1) / 30.4375	
-Date of last follow-up for AEs = minimum (date of death, cut-off date, the day before the first administration of asciminib, date of last actual administration of bosutinib + 30 days).	
-Patients included in this table are randomized to Bosutinib and switched to Asciminib.	

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Table 4-1.1.1 Any AE: time to first event - stratified per IRT
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	142 (91.0)	74 (97.4)			
censored					
Discontinued from study treatment	14 (9.0)	2 (2.6)			
Percentiles (months) (95% CI)					
25th	0.03 [0.03, 0.10]	0.03 [NE, NE]	0.57	[0.43, 0.76]	<0.001
median	0.41 [0.26, 0.95]	0.08 [0.03, 0.20]			
75th	1.81 [1.18, 3.81]	0.44 [0.26, 0.82]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Table 4-1.1.1 Any AE: time to first event - stratified per IRT
Safety Set
(Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 3	0.19 [0.13, 0.25]	0.10 [0.05, 0.18]			
Month 6	0.15 [0.10, 0.21]	0.03 [0.01, 0.10]			
Month 9	0.13 [0.08, 0.18]	0.02 [0.00, 0.08]			
Month 12	0.10 [0.06, 0.16]	0.02 [0.00, 0.08]			
Month 15	0.08 [0.04, 0.13]	0.02 [0.00, 0.08]			
Month 18	0.08 [0.04, 0.13]	0.00 [NE, NE]			
Month 21	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 24	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 27	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 30	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 33	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 36	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 39	0.06 [0.02, 0.11]	0.00 [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-1.1.1 Any AE: time to first event - stratified per IRT
Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 42	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 45	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 48	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 51	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 54	NE [NE, NE]	0.00 [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

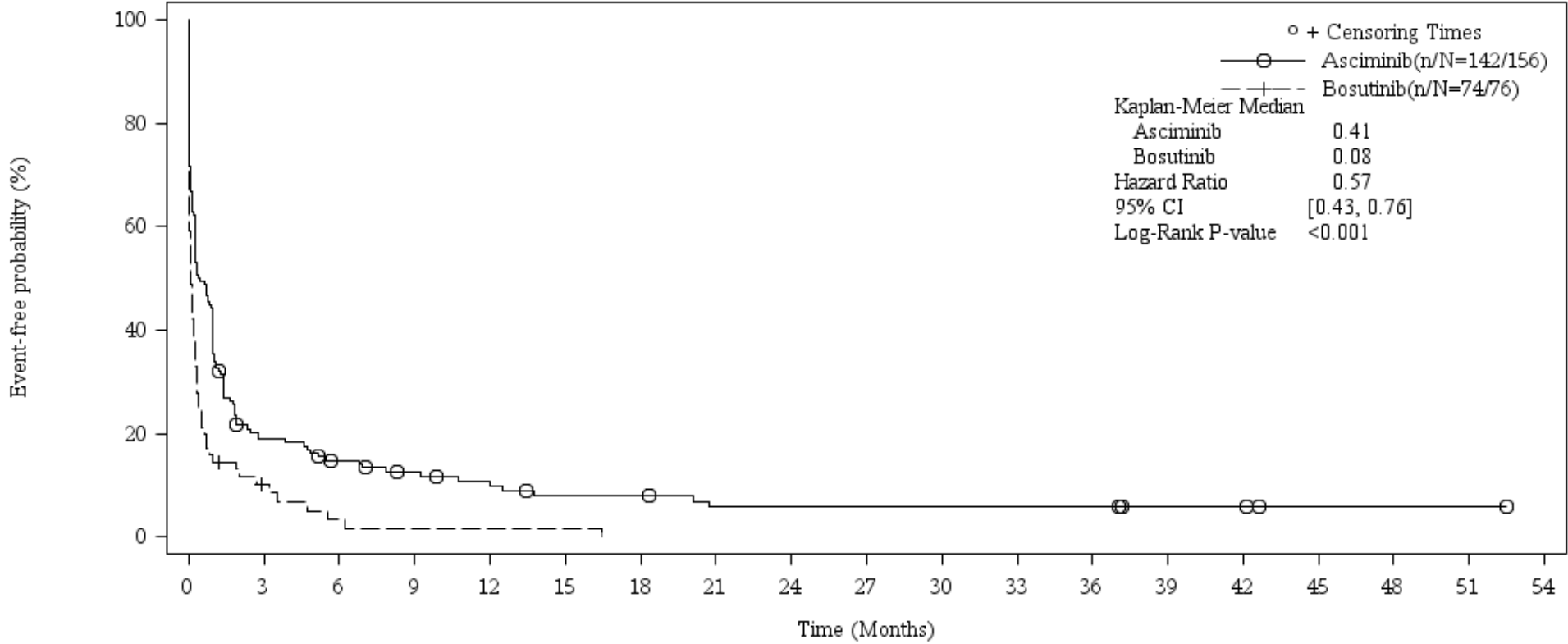
- NE: Not Estimable.

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Figure 4-1.1.1 Any AE: Kaplan Meier plot of time to first event

Figure 4-1.1.1 (Page 1 of 1)
Any AE: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set



Number of patients still at risk																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54
Asciminib	156	28	20	15	11	8	8	5	5	5	5	5	5	3	3	1	1	1	0
Bosutinib	76	6	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 4-1.1.2 Any AE: time to first event - stratified per CRF
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	142 (91.0)	74 (97.4)			
censored					
Discontinued from study treatment	14 (9.0)	2 (2.6)			
Percentiles (months) (95% CI)					
25th	0.03 [0.03, 0.10]	0.03 [NE, NE]	0.57	[0.42, 0.76]	<0.001
median	0.41 [0.26, 0.95]	0.08 [0.03, 0.20]			
75th	1.81 [1.18, 3.81]	0.44 [0.26, 0.82]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Table 4-1.1.2 Any AE: time to first event - stratified per CRF
Safety Set
(Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 3	0.19 [0.13, 0.25]	0.10 [0.05, 0.18]			
Month 6	0.15 [0.10, 0.21]	0.03 [0.01, 0.10]			
Month 9	0.13 [0.08, 0.18]	0.02 [0.00, 0.08]			
Month 12	0.10 [0.06, 0.16]	0.02 [0.00, 0.08]			
Month 15	0.08 [0.04, 0.13]	0.02 [0.00, 0.08]			
Month 18	0.08 [0.04, 0.13]	0.00 [NE, NE]			
Month 21	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 24	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 27	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 30	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 33	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 36	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 39	0.06 [0.02, 0.11]	0.00 [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-1.1.2 Any AE: time to first event - stratified per CRF
Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 42	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 45	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 48	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 51	0.06 [0.02, 0.11]	0.00 [NE, NE]			
Month 54	NE [NE, NE]	0.00 [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Table 4-1.1.3 Overview of AE: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 1 of 1)

Category	Bosutinib N=25	
	All grades n (%)	Grade >=3 n (%)
Adverse events	19 (76.0)	7 (28.0)
Treatment-related	10 (40.0)	5 (20.0)
SAEs	2 (8.0)	2 (8.0)
Treatment-related	1 (4.0)	1 (4.0)
Fatal SAEs	0	0
Treatment-related	0	0
AEs leading to discontinuation	1 (4.0)	1 (4.0)
Treatment-related	0	0
AEs leading to dose adjustment/interruption	8 (32.0)	5 (20.0)
AEs requiring additional therapy	10 (40.0)	3 (12.0)
Numbers (n) represent counts of subjects.		
A subject with multiple severity grades for an AE is only counted under the maximum grade.		
Patients included in this table are randomized to Bosutinib and switched to Asciminib.		
MedDRA version 26.0, CTCAE version 4.03		

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 1 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Blood and lymphatic system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	54 (34.6)	24 (31.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	99 (63.5)	37 (48.7)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	1.41 [0.95, 2.76]	3.68 [0.95, 19.35]			
median	NE [NE, NE]	NE [17.51, NE]	1.08	[0.67, 1.75]	0.774
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.68 [0.60, 0.74]	0.76 [0.64, 0.84]			
Month 6	0.67 [0.59, 0.74]	0.71 [0.58, 0.80]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 2 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.67 [0.59, 0.74]	0.71 [0.58, 0.80]			
Month 12	0.67 [0.59, 0.74]	0.67 [0.53, 0.78]			
Month 15	0.65 [0.57, 0.72]	0.67 [0.53, 0.78]			
Month 18	0.65 [0.57, 0.72]	0.63 [0.48, 0.75]			
Month 21	0.65 [0.57, 0.72]	0.59 [0.42, 0.72]			
Month 24	0.65 [0.57, 0.72]	0.59 [0.42, 0.72]			
Month 27	0.65 [0.57, 0.72]	0.59 [0.42, 0.72]			
Month 30	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 33	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 36	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 39	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 42	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 45	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 48	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 51	0.64 [0.56, 0.71]	0.59 [0.42, 0.72]			
Month 54	0.64 [0.56, 0.71]	NE [NE, NE]			
Month 57	0.64 [0.56, 0.71]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 3 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	7 (9.2)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	45 (59.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.57, NE]			
median	NE [NE, NE]	NE [32.69, NE]	0.80	[0.33, 1.97]	0.632
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.91 [0.80, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 4 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.95]	0.91 [0.80, 0.96]			
Month 12	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 15	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 18	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 21	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 24	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.81, 0.93]	0.76 [0.48, 0.91]			
Month 36	0.87 [0.79, 0.92]	0.76 [0.48, 0.91]			
Month 39	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 42	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 45	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 48	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 51	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 54	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 57	0.86 [0.77, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 5 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Eye disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	6 (7.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	44 (57.9)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [12.94, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.02	[0.40, 2.63]	0.967
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.92 [0.87, 0.96]	0.94 [0.84, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.96]	0.94 [0.84, 0.98]			
Month 12	0.91 [0.84, 0.94]	0.94 [0.84, 0.98]			
Month 15	0.90 [0.83, 0.94]	0.89 [0.72, 0.96]			
Month 18	0.88 [0.81, 0.93]	0.89 [0.72, 0.96]			
Month 21	0.88 [0.81, 0.93]	0.89 [0.72, 0.96]			
Month 24	0.88 [0.81, 0.93]	0.84 [0.62, 0.93]			
Month 27	0.88 [0.81, 0.93]	0.84 [0.62, 0.93]			
Month 30	0.88 [0.81, 0.93]	0.84 [0.62, 0.93]			
Month 33	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 36	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 39	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 42	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 45	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 48	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 51	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 54	0.87 [0.80, 0.92]	0.84 [0.62, 0.93]			
Month 57	0.87 [0.80, 0.92]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Gastrointestinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	69 (44.2)	61 (80.3)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	84 (53.8)	10 (13.2)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	2.04 [0.95, 7.29]	0.03 [0.03, 0.07]			
median	35.75 [13.77, NE]	0.26 [0.07, 0.36]	0.23	[0.16, 0.33]	<0.001
75th	NE [NE, NE]	0.99 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.74 [0.66, 0.80]	0.22 [0.13, 0.32]			
Month 6	0.71 [0.63, 0.77]	0.20 [0.12, 0.30]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.66 [0.57, 0.73]		0.18 [0.10, 0.28]			
Month 12	0.59 [0.50, 0.67]		0.18 [0.10, 0.28]			
Month 15	0.57 [0.48, 0.65]		0.18 [0.10, 0.28]			
Month 18	0.55 [0.46, 0.63]		0.18 [0.10, 0.28]			
Month 21	0.53 [0.43, 0.61]		0.18 [0.10, 0.28]			
Month 24	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 27	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 30	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 33	0.50 [0.41, 0.59]		0.18 [0.10, 0.28]			
Month 36	0.49 [0.39, 0.58]		0.18 [0.10, 0.28]			
Month 39	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 42	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 45	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 48	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 51	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 54	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 57	0.46 [0.36, 0.55]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
General disorders and administration site conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	52 (33.3)	25 (32.9)			
censored					
Death	2 (1.3)	0			
Discontinued from study treatment	102 (65.4)	31 (40.8)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	9.23 [3.71, 19.55]	6.21 [1.41, 15.44]			
median	50.17 [38.51, NE]	35.61 [15.44, NE]	0.73	[0.45, 1.19]	0.206
75th	NE [NE, NE]	NE [35.61, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.83 [0.76, 0.88]	0.78 [0.67, 0.86]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.78 [0.70, 0.84]		0.77 [0.65, 0.85]			
Month 9	0.76 [0.68, 0.82]		0.67 [0.53, 0.78]			
Month 12	0.72 [0.64, 0.79]		0.67 [0.53, 0.78]			
Month 15	0.70 [0.61, 0.77]		0.67 [0.53, 0.78]			
Month 18	0.69 [0.60, 0.76]		0.57 [0.40, 0.72]			
Month 21	0.65 [0.56, 0.73]		0.57 [0.40, 0.72]			
Month 24	0.63 [0.53, 0.71]		0.57 [0.40, 0.72]			
Month 27	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 30	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 33	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 36	0.60 [0.50, 0.69]		0.43 [0.22, 0.63]			
Month 39	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 42	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 45	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 48	0.56 [0.44, 0.66]		0.43 [0.22, 0.63]			
Month 51	0.50 [0.35, 0.63]		0.43 [0.22, 0.63]			
Month 54	0.50 [0.35, 0.63]		0.43 [0.22, 0.63]			
Month 57	0.50 [0.35, 0.63]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Infections and infestations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	76 (48.7)	22 (28.9)			
censored					
Death	2 (1.3)	0			
Discontinued from study treatment	78 (50.0)	38 (50.0)			
Treatment switched	0	16 (21.1)			
Percentiles (months) (95% CI)					
25th	3.78 [2.46, 5.22]	5.62 [3.48, 16.89]			
median	20.11 [10.81, 39.52]	33.12 [16.89, NE]	1.35	[0.84, 2.19]	0.216
75th	NE [42.87, NE]	NE [33.12, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.90 [0.81, 0.95]			
Month 6	0.67 [0.59, 0.74]	0.75 [0.62, 0.84]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.62 [0.53, 0.69]		0.70 [0.56, 0.80]			
Month 12	0.57 [0.48, 0.65]		0.66 [0.50, 0.77]			
Month 15	0.53 [0.44, 0.61]		0.66 [0.50, 0.77]			
Month 18	0.51 [0.42, 0.59]		0.60 [0.41, 0.74]			
Month 21	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 24	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 27	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 30	0.43 [0.34, 0.52]		0.60 [0.41, 0.74]			
Month 33	0.43 [0.34, 0.52]		0.52 [0.31, 0.70]			
Month 36	0.42 [0.33, 0.51]		0.44 [0.21, 0.64]			
Month 39	0.42 [0.33, 0.51]		0.44 [0.21, 0.64]			
Month 42	0.38 [0.28, 0.48]		0.44 [0.21, 0.64]			
Month 45	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 48	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 51	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 54	0.35 [0.25, 0.46]	NE	[NE, NE]			
Month 57	0.35 [0.25, 0.46]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Injury, poisoning and procedural complications					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	6 (7.9)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	124 (79.5)	45 (59.2)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	43.20 [20.96, NE]	NE [18.43, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.67	[0.69, 4.05]	0.254
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.90 [0.84, 0.94]		0.93 [0.83, 0.97]			
Month 9	0.89 [0.83, 0.94]		0.90 [0.77, 0.96]			
Month 12	0.87 [0.80, 0.91]		0.90 [0.77, 0.96]			
Month 15	0.85 [0.77, 0.90]		0.90 [0.77, 0.96]			
Month 18	0.85 [0.77, 0.90]		0.90 [0.77, 0.96]			
Month 21	0.83 [0.75, 0.88]		0.85 [0.68, 0.94]			
Month 24	0.82 [0.73, 0.87]		0.85 [0.68, 0.94]			
Month 27	0.80 [0.72, 0.87]		0.85 [0.68, 0.94]			
Month 30	0.79 [0.71, 0.86]		0.85 [0.68, 0.94]			
Month 33	0.79 [0.71, 0.86]		0.85 [0.68, 0.94]			
Month 36	0.78 [0.69, 0.85]		0.85 [0.68, 0.94]			
Month 39	0.77 [0.67, 0.84]		0.85 [0.68, 0.94]			
Month 42	0.77 [0.67, 0.84]		0.85 [0.68, 0.94]			
Month 45	0.74 [0.64, 0.82]		0.85 [0.68, 0.94]			
Month 48	0.72 [0.60, 0.80]		0.85 [0.68, 0.94]			
Month 51	0.68 [0.53, 0.78]		0.85 [0.68, 0.94]			
Month 54	0.68 [0.53, 0.78]		0.85 [0.68, 0.94]			
Month 57	0.68 [0.53, 0.78]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Investigations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	40 (52.6)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	98 (62.8)	24 (31.6)			
Treatment switched	0	11 (14.5)			
Percentiles (months) (95% CI)					
25th	4.63 [1.74, 10.18]	1.25 [0.95, 2.23]			
median	NE [33.38, NE]	6.60 [2.79, 25.10]	0.51	[0.34, 0.77]	0.001
75th	NE [NE, NE]	NE [25.10, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.59 [0.47, 0.70]			
Month 6	0.73 [0.65, 0.79]	0.53 [0.40, 0.64]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.71 [0.63, 0.78]		0.43 [0.30, 0.55]			
Month 12	0.68 [0.59, 0.75]		0.39 [0.25, 0.53]			
Month 15	0.66 [0.57, 0.73]		0.39 [0.25, 0.53]			
Month 18	0.63 [0.54, 0.71]		0.39 [0.25, 0.53]			
Month 21	0.63 [0.54, 0.71]		0.39 [0.25, 0.53]			
Month 24	0.62 [0.53, 0.70]		0.39 [0.25, 0.53]			
Month 27	0.62 [0.53, 0.70]		0.35 [0.21, 0.49]			
Month 30	0.62 [0.53, 0.70]		0.35 [0.21, 0.49]			
Month 33	0.61 [0.52, 0.69]		0.35 [0.21, 0.49]			
Month 36	0.59 [0.50, 0.67]		0.35 [0.21, 0.49]			
Month 39	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 42	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 45	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 48	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 51	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 54	0.57 [0.48, 0.66]	NE	[NE, NE]			
Month 57	0.57 [0.48, 0.66]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Metabolism and nutrition disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	14 (18.4)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	41 (53.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [7.39, NE]	19.09 [5.62, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.98	[0.52, 1.83]	0.939
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.88 [0.82, 0.92]	0.86 [0.76, 0.92]			
Month 6	0.85 [0.78, 0.89]	0.85 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]		0.83 [0.71, 0.90]			
Month 12	0.80 [0.72, 0.86]		0.83 [0.71, 0.90]			
Month 15	0.78 [0.70, 0.84]		0.83 [0.71, 0.90]			
Month 18	0.77 [0.69, 0.84]		0.83 [0.71, 0.90]			
Month 21	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 24	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 27	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 30	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 33	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 36	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 39	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 42	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 45	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 48	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 51	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 54	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 57	0.76 [0.68, 0.83]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Musculoskeletal and connective tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	18 (23.7)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	97 (62.2)	39 (51.3)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	4.60 [1.91, 10.12]	16.46 [2.33, 27.63]			
median	NE [20.70, NE]	NE [24.87, NE]	1.36	[0.80, 2.31]	0.260
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.77 [0.70, 0.83]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.72 [0.64, 0.79]		0.82 [0.71, 0.89]			
Month 9	0.69 [0.61, 0.76]		0.80 [0.68, 0.88]			
Month 12	0.65 [0.57, 0.73]		0.75 [0.60, 0.85]			
Month 15	0.65 [0.57, 0.73]		0.75 [0.60, 0.85]			
Month 18	0.61 [0.51, 0.69]		0.70 [0.52, 0.82]			
Month 21	0.59 [0.50, 0.68]		0.70 [0.52, 0.82]			
Month 24	0.59 [0.50, 0.68]		0.70 [0.52, 0.82]			
Month 27	0.58 [0.48, 0.66]		0.64 [0.43, 0.79]			
Month 30	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 33	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 36	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 39	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 42	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 45	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 48	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 51	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 54	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 57	0.57 [0.47, 0.65]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nervous system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	17 (22.4)			
censored					
Death	1 (0.6)	1 (1.3)			
Discontinued from study treatment	99 (63.5)	40 (52.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	7.16 [1.91, 12.91]	9.26 [3.02, NE]			
median	NE [26.84, NE]	NE [NE, NE]	1.35	[0.78, 2.34]	0.273
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.73, 0.85]	0.85 [0.75, 0.92]			
Month 6	0.76 [0.69, 0.82]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.71 [0.62, 0.78]		0.77 [0.65, 0.86]			
Month 12	0.68 [0.59, 0.75]		0.74 [0.59, 0.84]			
Month 15	0.65 [0.55, 0.72]		0.74 [0.59, 0.84]			
Month 18	0.62 [0.53, 0.70]		0.68 [0.51, 0.81]			
Month 21	0.62 [0.53, 0.70]		0.68 [0.51, 0.81]			
Month 24	0.61 [0.51, 0.69]		0.68 [0.51, 0.81]			
Month 27	0.60 [0.50, 0.68]		0.68 [0.51, 0.81]			
Month 30	0.57 [0.47, 0.66]		0.68 [0.51, 0.81]			
Month 33	0.57 [0.47, 0.66]		0.68 [0.51, 0.81]			
Month 36	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 39	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 42	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 45	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 48	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 51	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 54	0.53 [0.42, 0.63]	NE	[NE, NE]			
Month 57	0.53 [0.42, 0.63]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Psychiatric disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	22 (14.1)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	130 (83.3)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [30.39, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.35	[0.81, 6.83]	0.107
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.87, 0.95]	0.96 [0.88, 0.99]			
Month 6	0.90 [0.84, 0.94]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.89 [0.83, 0.93]	0.94 [0.86, 0.98]			
Month 12	0.86 [0.79, 0.91]	0.94 [0.86, 0.98]			
Month 15	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 18	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 21	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 24	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 27	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 30	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 33	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 36	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 39	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 42	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 45	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 48	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 51	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 54	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 57	0.83 [0.75, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Renal and urinary disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	5 (6.6)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	142 (91.0)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.72	[0.25, 2.09]	0.539
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.91, 0.98]		0.93 [0.83, 0.97]			
Month 12	0.94 [0.89, 0.97]		0.93 [0.83, 0.97]			
Month 15	0.92 [0.86, 0.96]		0.93 [0.83, 0.97]			
Month 18	0.92 [0.86, 0.96]		0.93 [0.83, 0.97]			
Month 21	0.91 [0.84, 0.95]		0.93 [0.83, 0.97]			
Month 24	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 27	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 30	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 33	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 36	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 39	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 42	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 45	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 48	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 51	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 54	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 57	0.88 [0.78, 0.94]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive system and breast disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	134 (85.9)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	41.30 [19.71, NE]			
median	NE [NE, NE]	NE [41.30, NE]	1.12	[0.40, 3.08]	0.833
75th	NE [NE, NE]	NE [41.30, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.99 [0.90, 1.00]			
Month 6	0.94 [0.89, 0.97]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.96]	0.95 [0.85, 0.98]			
Month 12	0.91 [0.85, 0.95]	0.95 [0.85, 0.98]			
Month 15	0.91 [0.85, 0.95]	0.95 [0.85, 0.98]			
Month 18	0.90 [0.84, 0.94]	0.95 [0.85, 0.98]			
Month 21	0.89 [0.82, 0.94]	0.89 [0.69, 0.97]			
Month 24	0.88 [0.81, 0.93]	0.89 [0.69, 0.97]			
Month 27	0.88 [0.81, 0.93]	0.89 [0.69, 0.97]			
Month 30	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 33	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 36	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 39	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 42	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 45	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 48	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 51	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 54	0.85 [0.76, 0.91]	NE [NE, NE]			
Month 57	0.85 [0.76, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	15 (19.7)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	116 (74.4)	37 (48.7)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	17.35 [7.39, NE]	13.63 [5.65, 48.99]			
median	NE [NE, NE]	48.99 [22.08, NE]	0.90	[0.49, 1.66]	0.736
75th	NE [NE, NE]	NE [48.99, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.91 [0.85, 0.94]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_2_1.sas@@/main/3 22NOV23:10:59

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.85 [0.78, 0.90]	0.86 [0.75, 0.93]			
Month 9	0.81 [0.73, 0.86]	0.86 [0.75, 0.93]			
Month 12	0.79 [0.71, 0.85]	0.78 [0.61, 0.88]			
Month 15	0.76 [0.68, 0.82]	0.73 [0.55, 0.85]			
Month 18	0.75 [0.66, 0.82]	0.73 [0.55, 0.85]			
Month 21	0.73 [0.64, 0.80]	0.73 [0.55, 0.85]			
Month 24	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 27	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 30	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 33	0.73 [0.64, 0.80]	0.60 [0.35, 0.77]			
Month 36	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 39	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 42	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 45	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 48	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 51	0.71 [0.62, 0.79]	0.40 [0.09, 0.70]			
Month 54	0.71 [0.62, 0.79]	NE [NE, NE]			
Month 57	0.71 [0.62, 0.79]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	58 (37.2)	33 (43.4)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	95 (60.9)	25 (32.9)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	2.83 [1.64, 6.21]	1.08 [0.39, 3.19]			
median	NE [41.07, NE]	22.14 [4.90, NE]	0.72	[0.47, 1.11]	0.134
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.74 [0.67, 0.81]	0.68 [0.56, 0.77]			
Month 6	0.69 [0.61, 0.76]	0.62 [0.49, 0.72]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.65 [0.57, 0.73]		0.56 [0.43, 0.67]			
Month 12	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 15	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 18	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 21	0.63 [0.54, 0.70]		0.51 [0.36, 0.64]			
Month 24	0.63 [0.54, 0.70]		0.46 [0.31, 0.61]			
Month 27	0.60 [0.51, 0.68]		0.46 [0.31, 0.61]			
Month 30	0.60 [0.51, 0.68]		0.46 [0.31, 0.61]			
Month 33	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 36	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 39	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 42	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 45	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 48	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 51	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 54	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 57	0.57 [0.48, 0.66]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vascular disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	6 (7.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	121 (77.6)	47 (61.8)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	24.87 [14.82, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.04	[0.85, 4.90]	0.104
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.96 [0.88, 0.99]			
Month 6	0.89 [0.83, 0.93]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.1 Any AE by SOC: time to first event - stratified per IRT
 Safety Set
 (Page 34 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.86 [0.79, 0.91]	0.93 [0.83, 0.97]			
Month 12	0.83 [0.76, 0.89]	0.89 [0.76, 0.95]			
Month 15	0.82 [0.75, 0.88]	0.89 [0.76, 0.95]			
Month 18	0.81 [0.74, 0.87]	0.89 [0.76, 0.95]			
Month 21	0.78 [0.70, 0.85]	0.89 [0.76, 0.95]			
Month 24	0.77 [0.68, 0.84]	0.89 [0.76, 0.95]			
Month 27	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 30	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 33	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 36	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 39	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 42	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 45	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 48	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 51	0.71 [0.59, 0.80]	0.89 [0.76, 0.95]			
Month 54	0.71 [0.59, 0.80]	0.89 [0.76, 0.95]			
Month 57	0.71 [0.59, 0.80]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

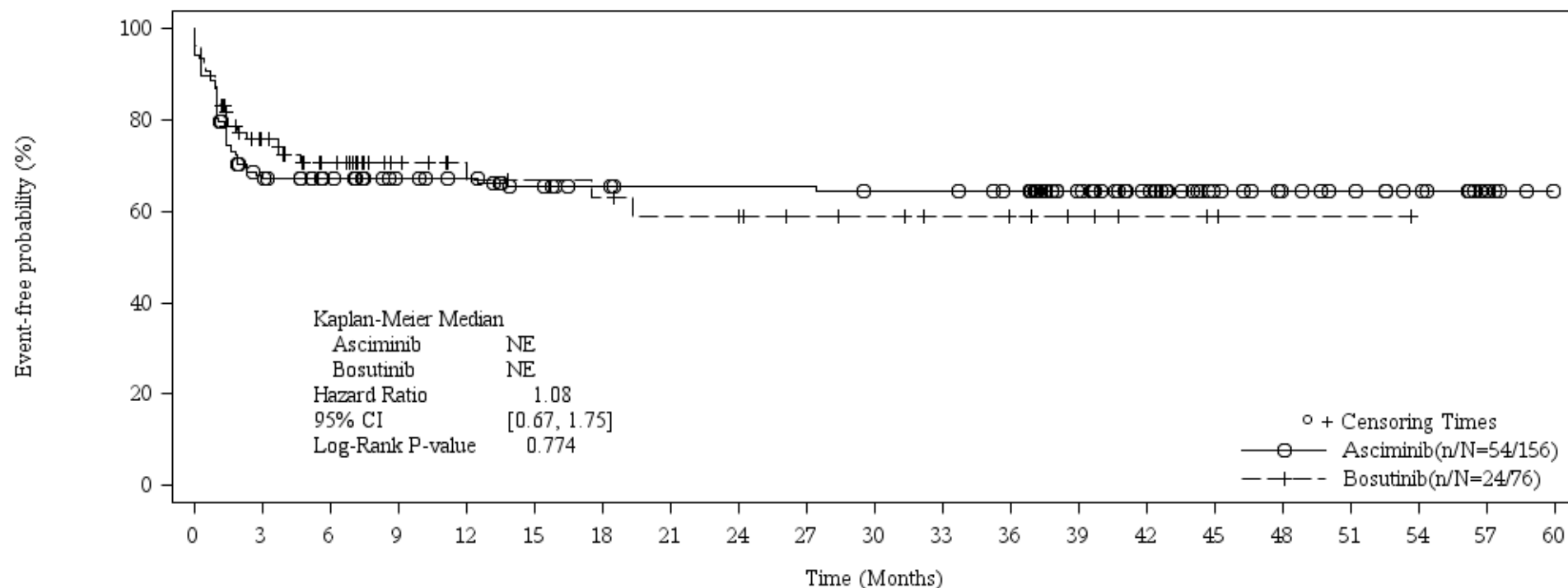
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Figure 4-1.2.1 (Page 1 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Blood and lymphatic system disorders



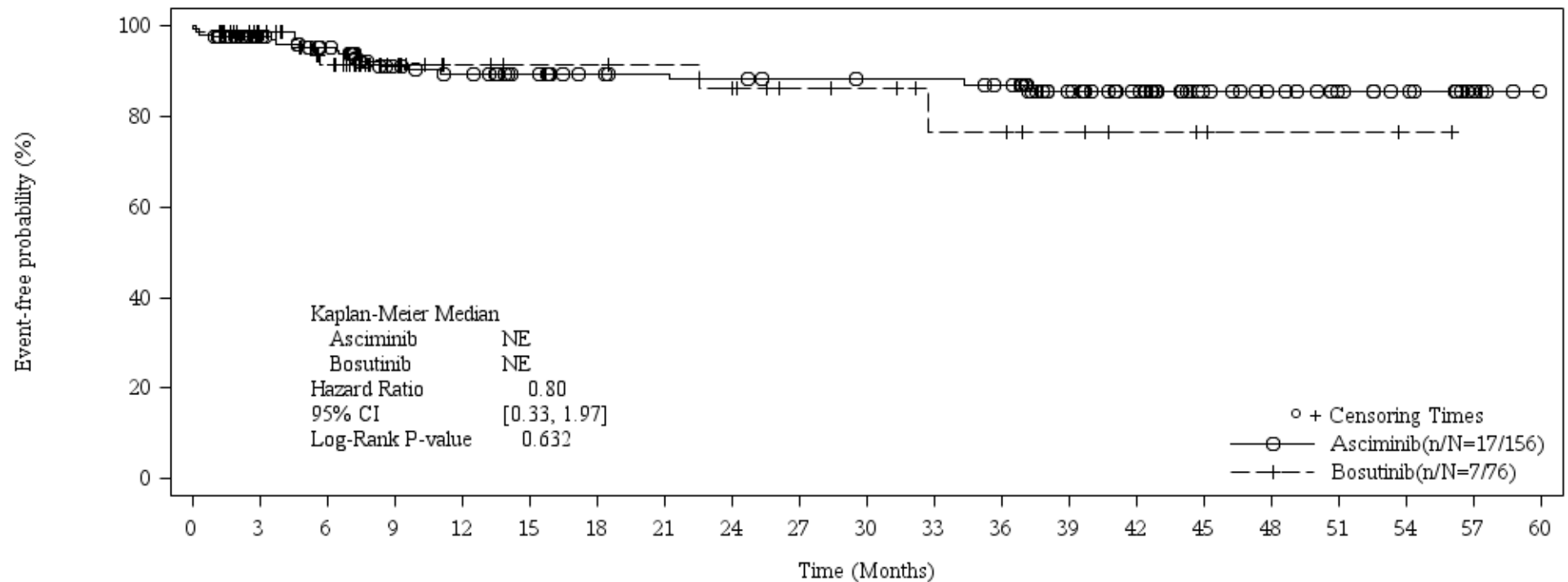
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	101	92	84	81	74	70	68	68	68	66	66	63	50	37	25	20	17	13	5	0
Bosutinib	76	47	35	24	18	17	16	14	14	11	10	8	7	5	3	2	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 2 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Cardiac disorders

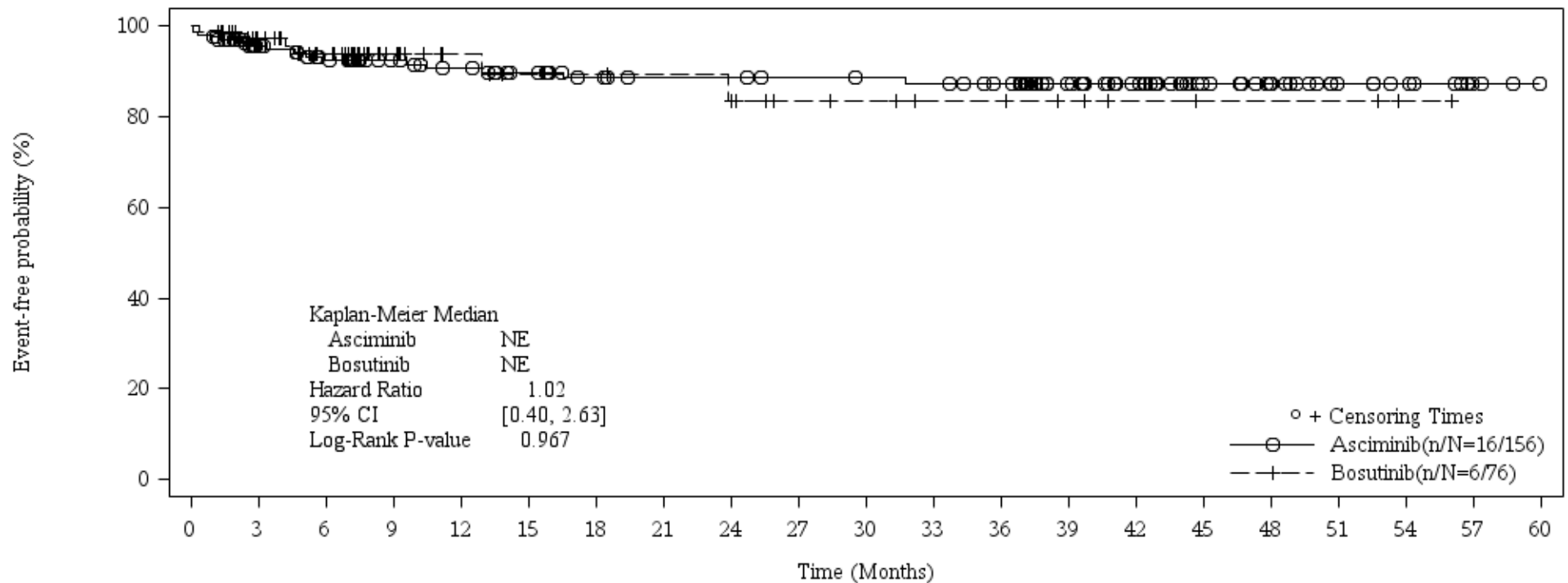


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	137	124	99	94	87	81	79	78	76	75	75	72	54	42	28	23	17	13	5	0
Bosutinib	76	62	46	28	20	18	18	17	16	12	11	8	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 3 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Eye disorders

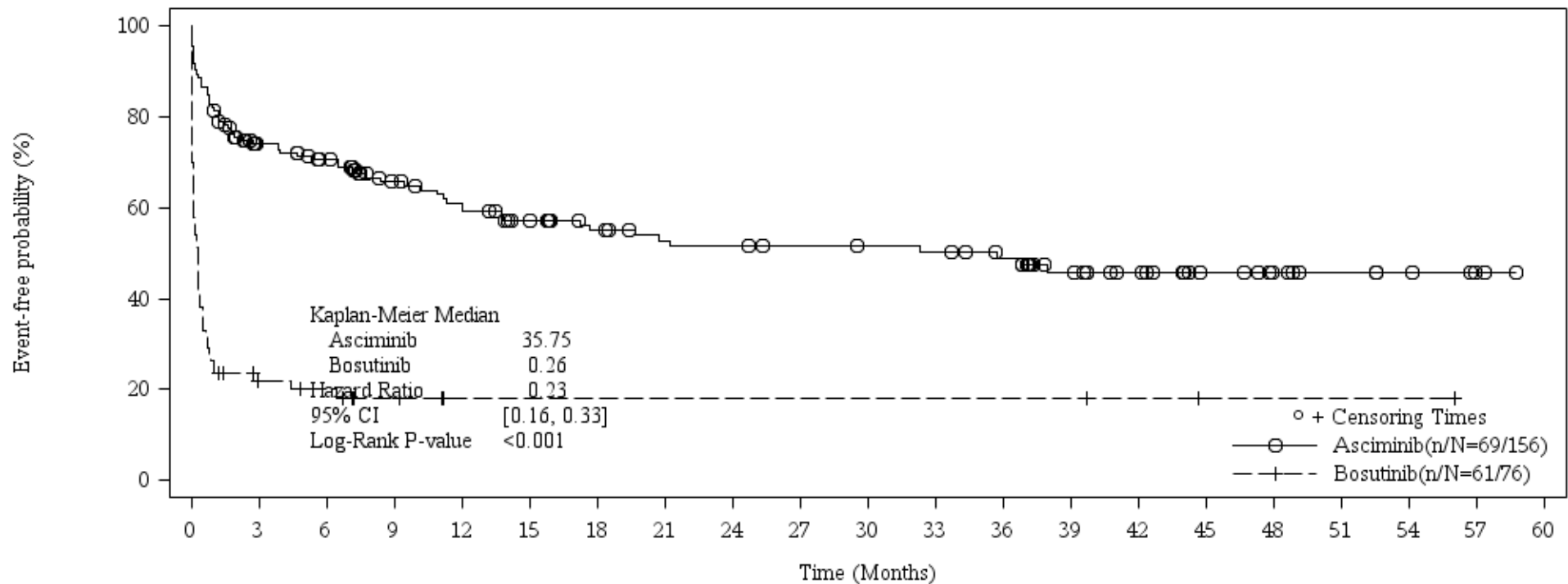


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	134	119	100	94	87	80	77	77	75	74	73	69	52	42	28	21	13	10	3	0
Bosutinib	76	61	47	28	20	17	17	16	15	11	10	8	8	6	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 4 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Gastrointestinal disorders

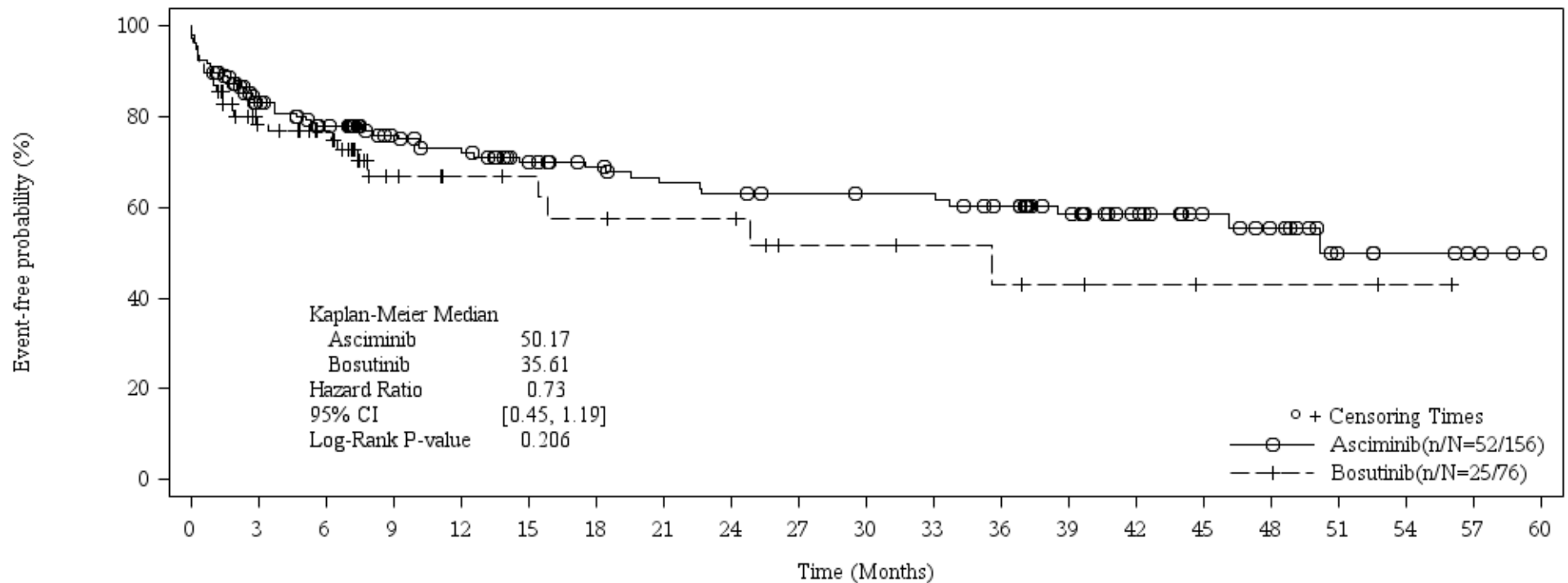


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	103	93	73	64	56	50	45	44	42	41	40	36	27	21	14	10	7	5	2	0
Bosutinib	76	12	10	6	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 5 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: General disorders and administration site conditions

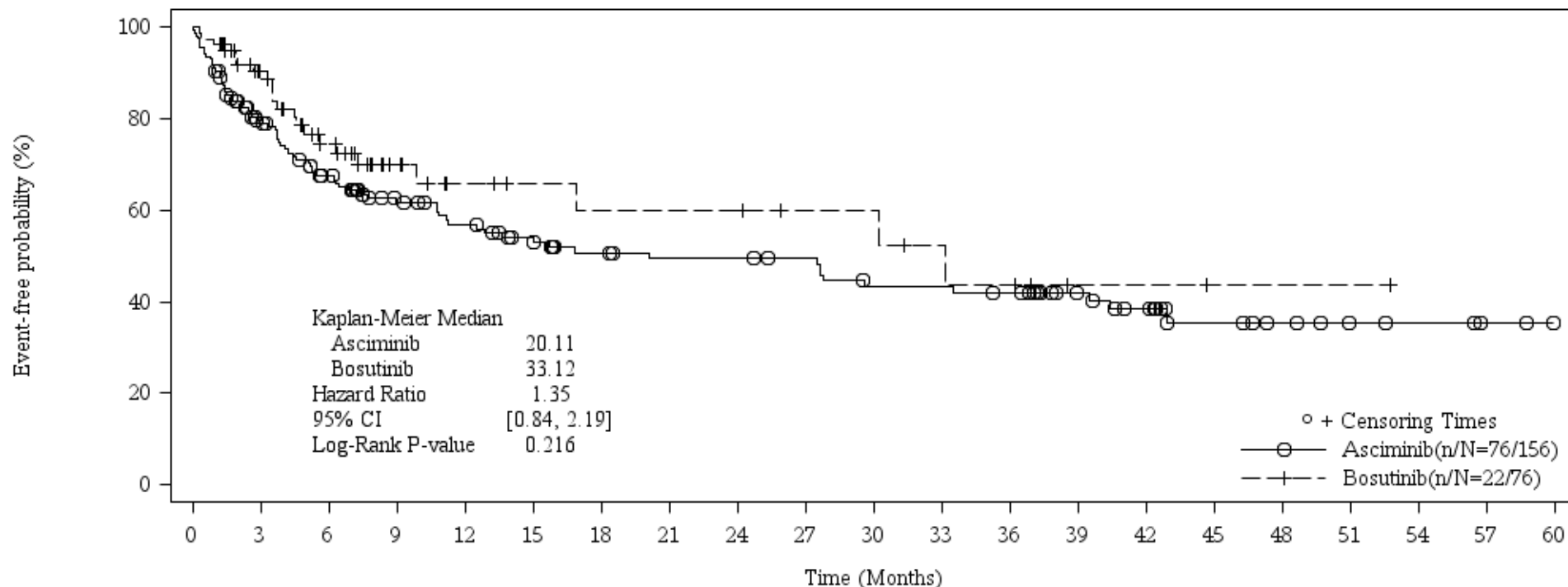


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	115	99	81	74	64	59	54	52	50	49	49	44	35	26	19	15	7	5	3	0
Bosutinib	76	48	39	19	15	14	12	11	11	7	7	6	5	4	3	2	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 6 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Infections and infestations



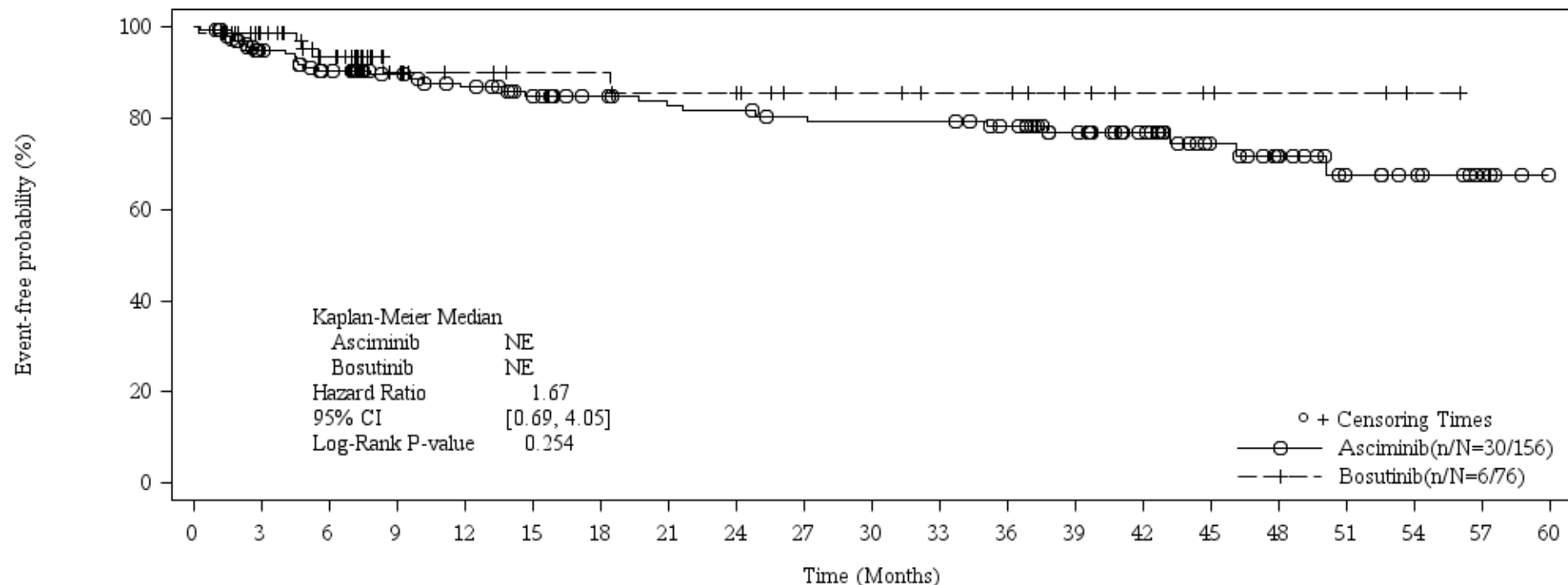
Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	111	88	68	60	50	45	42	42	40	34	34	32	23	18	11	8	5	4	2	0
Bosutinib	76	55	36	19	13	11	10	10	10	8	8	6	5	2	2	1	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 7 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Injury/ poisoning and procedural complications



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	134	119	101	94	85	79	75	74	71	70	70	65	53	41	28	21	14	11	5	0
Bosutinib	76	62	47	27	21	19	19	17	17	13	12	10	10	7	5	4	3	3	1	0	0

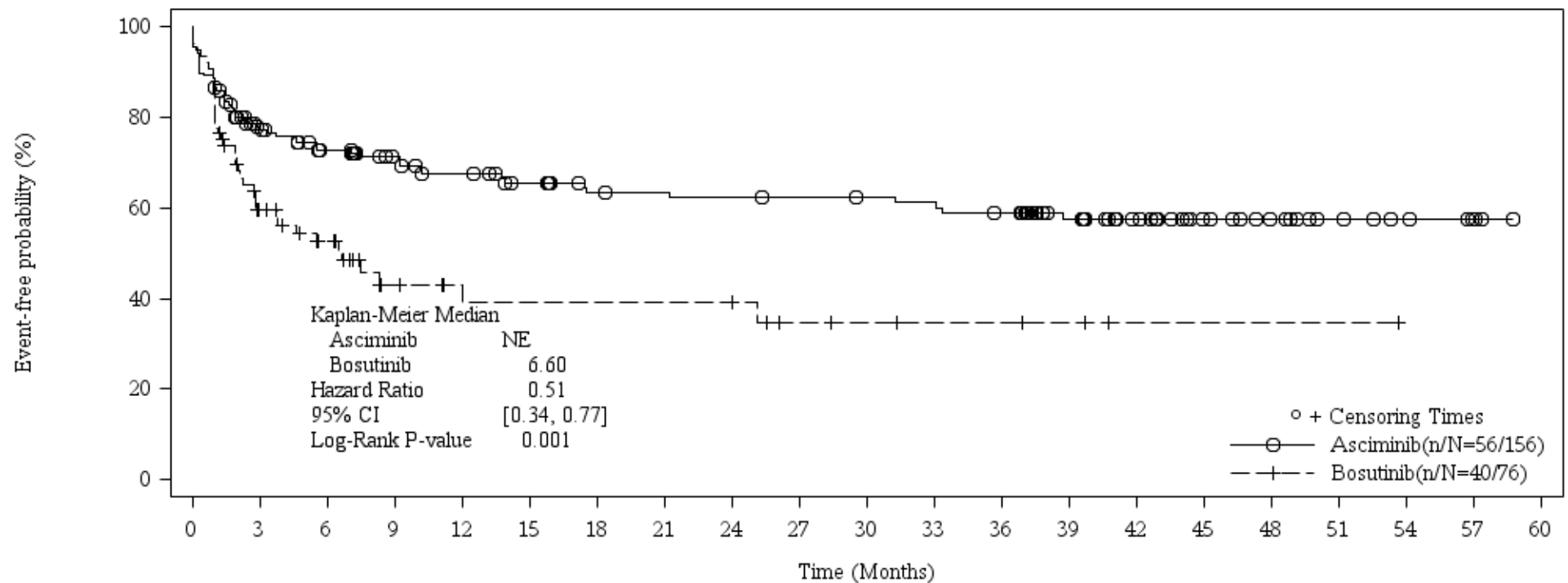
Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 8 of 17)

Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Investigations



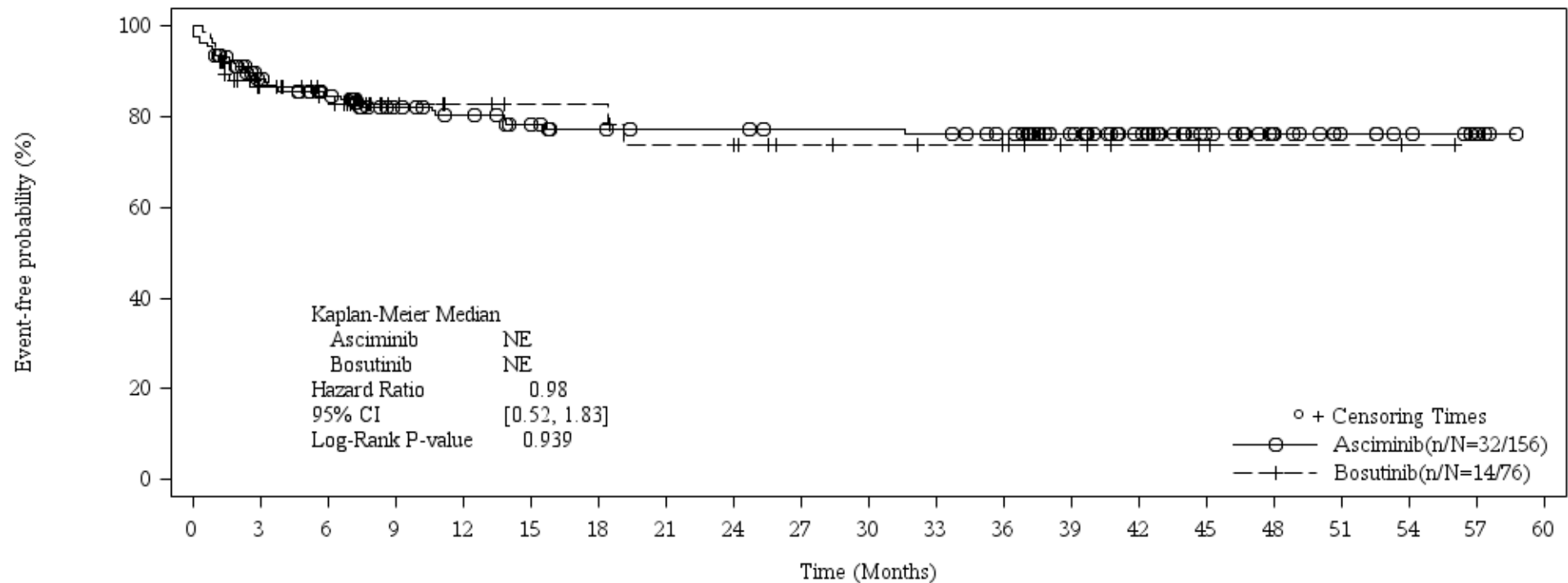
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	110	94	79	72	65	59	58	57	56	55	54	51	39	29	19	14	9	6	3	0
Bosutinib	76	38	27	14	10	10	10	10	10	6	5	4	4	3	1	1	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 9 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Metabolism and nutrition disorders

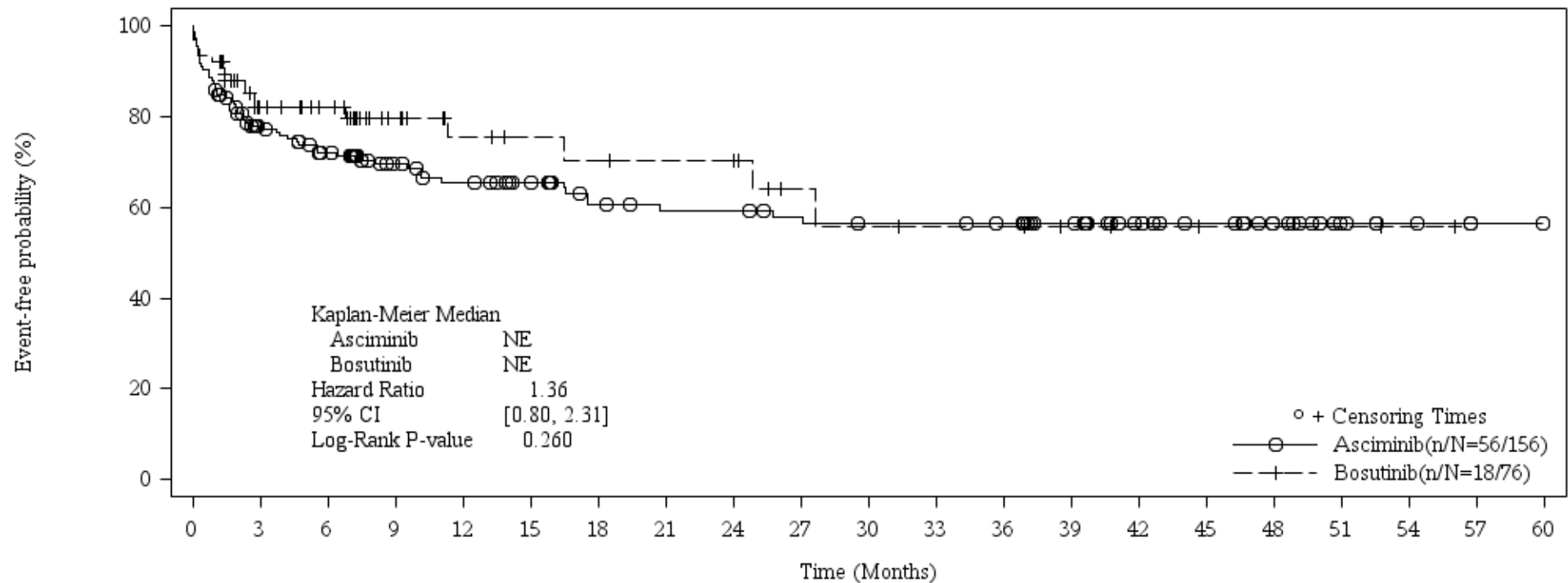


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	125	110	89	83	76	72	70	70	68	68	67	63	51	39	27	18	12	9	4	0
Bosutinib	76	53	43	25	21	19	19	16	16	12	11	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 10 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Musculoskeletal and connective tissue disorders



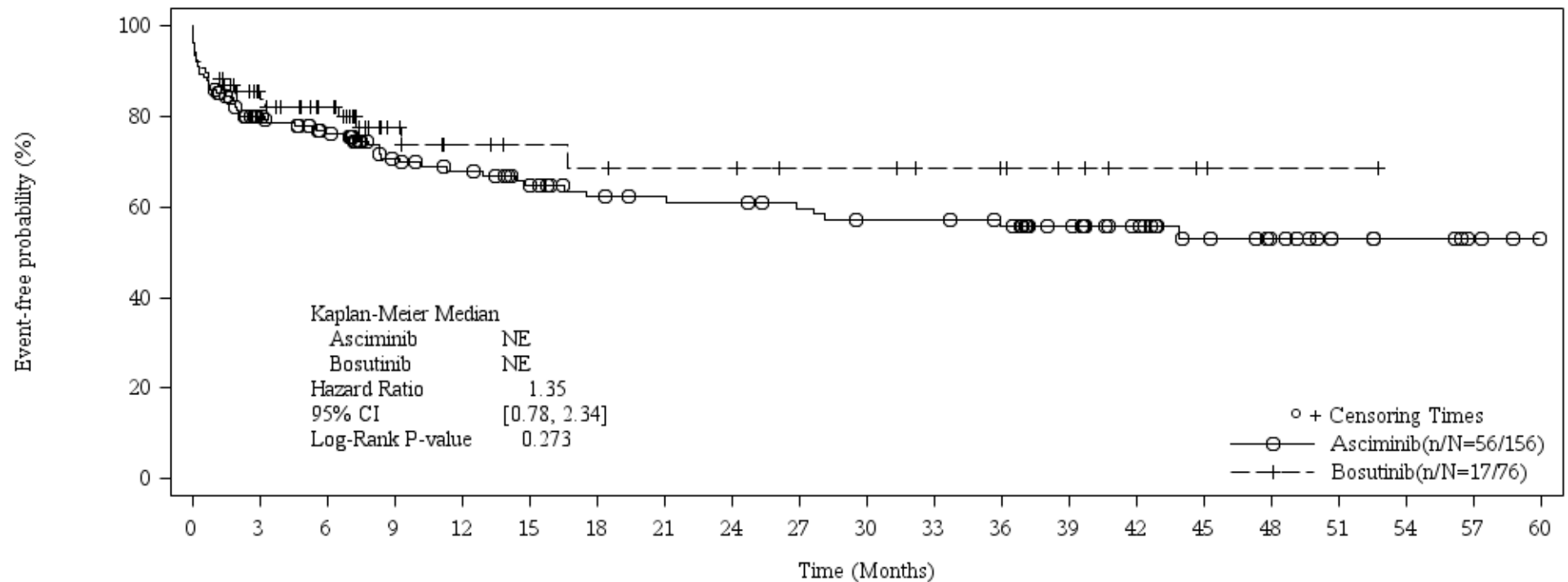
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	108	93	71	64	57	49	46	46	43	41	41	39	32	24	20	14	7	4	1	0
Bosutinib	76	49	40	23	17	15	14	13	13	8	7	6	6	4	3	2	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 11 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Nervous system disorders

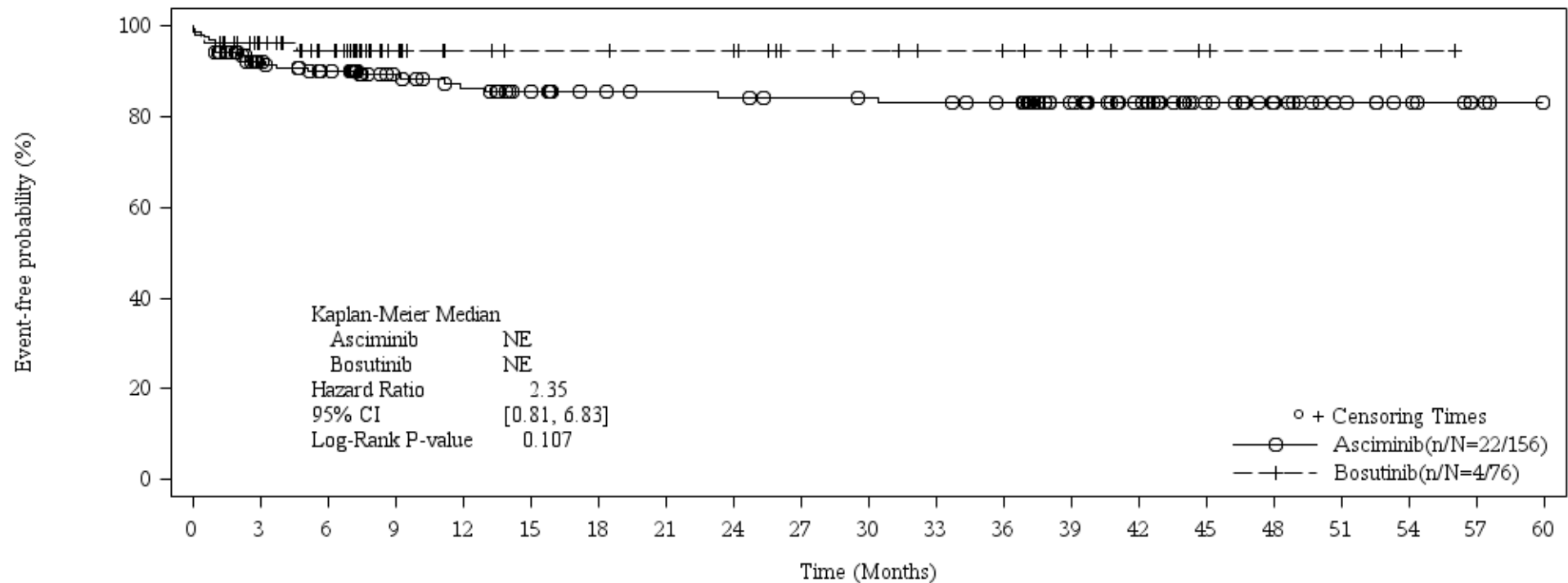


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	112	96	73	67	58	52	50	49	46	43	43	40	33	25	18	14	8	6	3	0
Bosutinib	76	53	40	22	16	14	13	12	12	10	10	8	7	5	3	2	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 12 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Psychiatric disorders

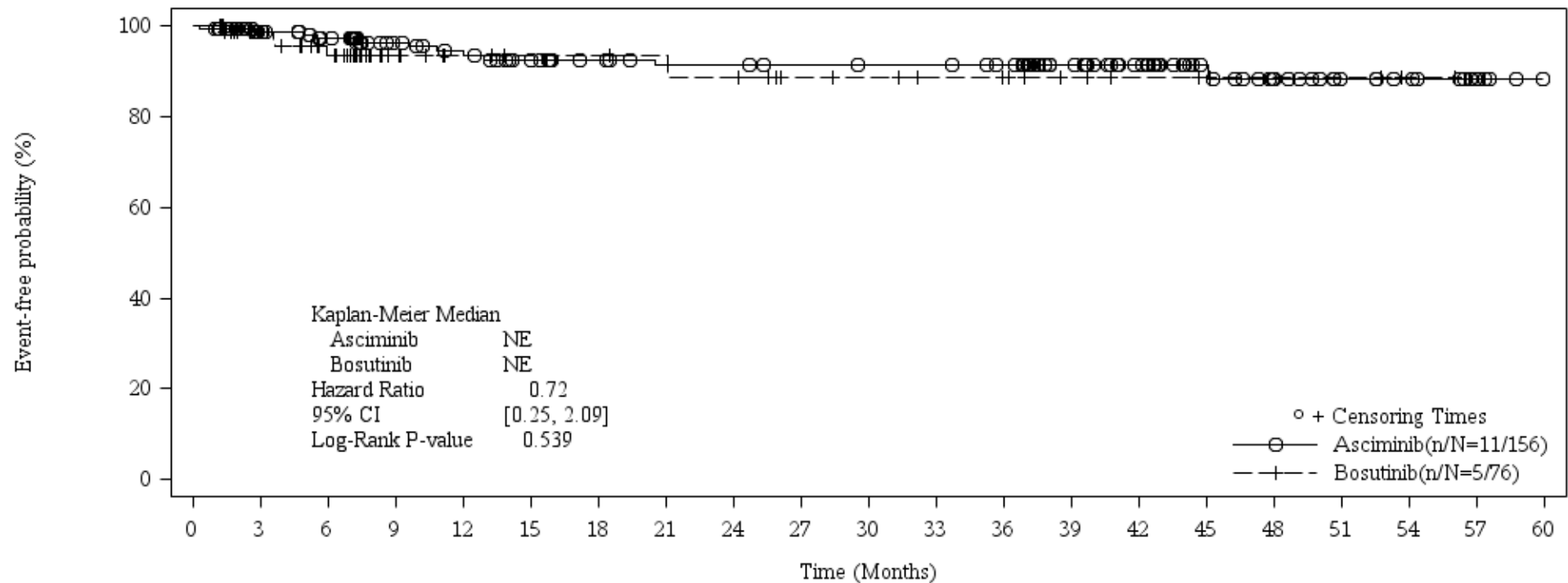


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	129	116	96	89	81	77	75	74	72	71	70	67	52	40	27	19	12	8	3	0
Bosutinib	76	61	48	28	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 13 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Renal and urinary disorders

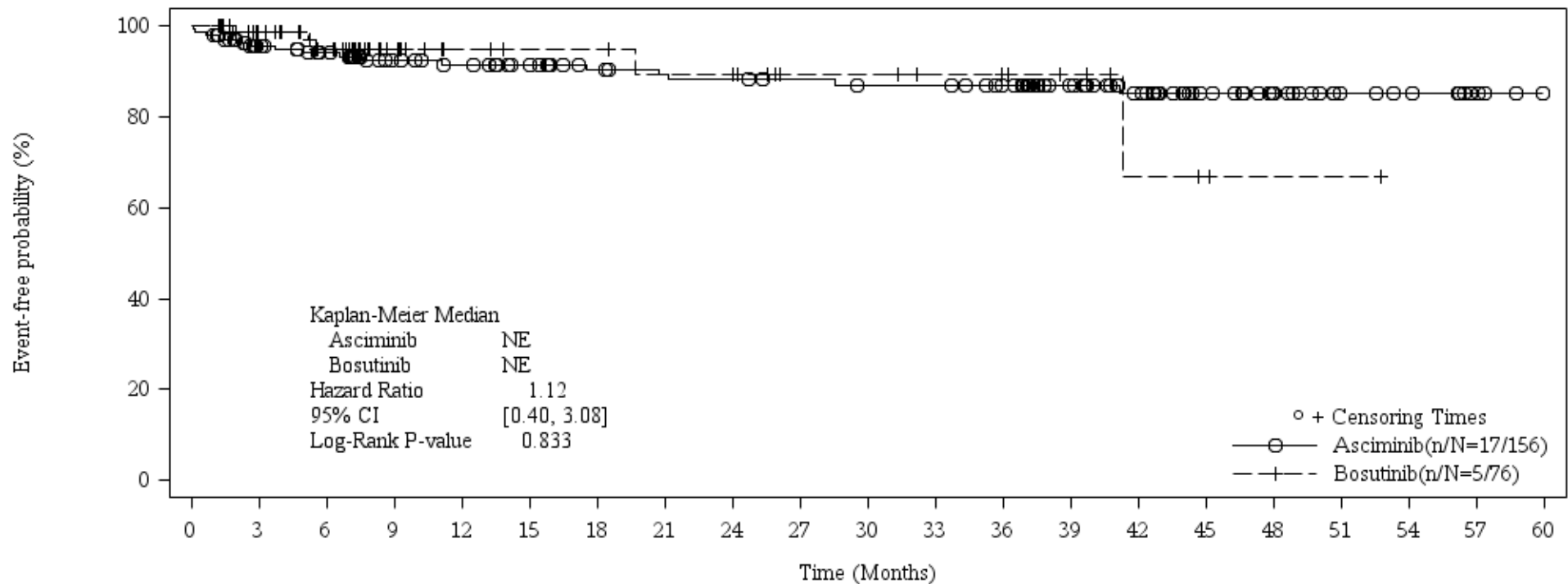


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	126	104	98	89	84	80	80	78	77	77	74	58	45	31	22	15	12	5	0
Bosutinib	76	61	48	28	22	20	20	19	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 14 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Reproductive system and breast disorders

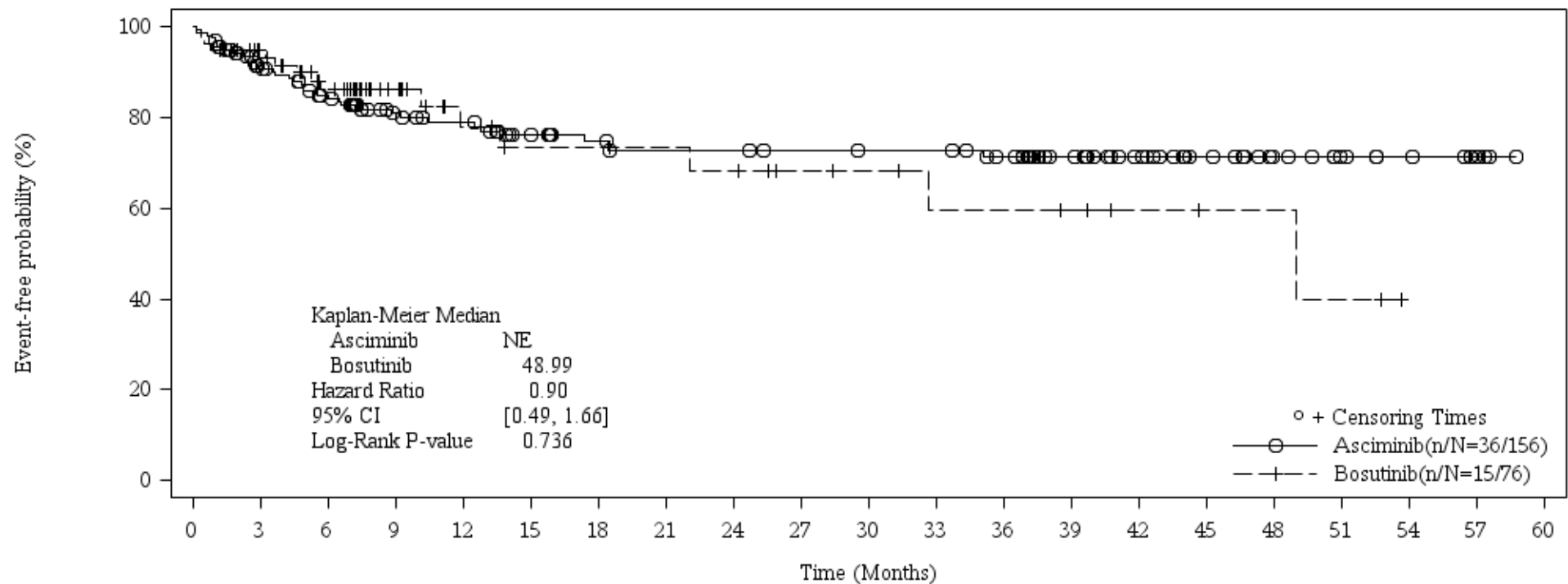


Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	124	102	97	90	83	80	79	77	75	75	70	54	42	29	20	12	10	4	0
Bosutinib	76	61	47	27	20	18	18	16	16	11	11	9	8	6	3	2	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 15 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Respiratory/ thoracic and mediastinal disorders

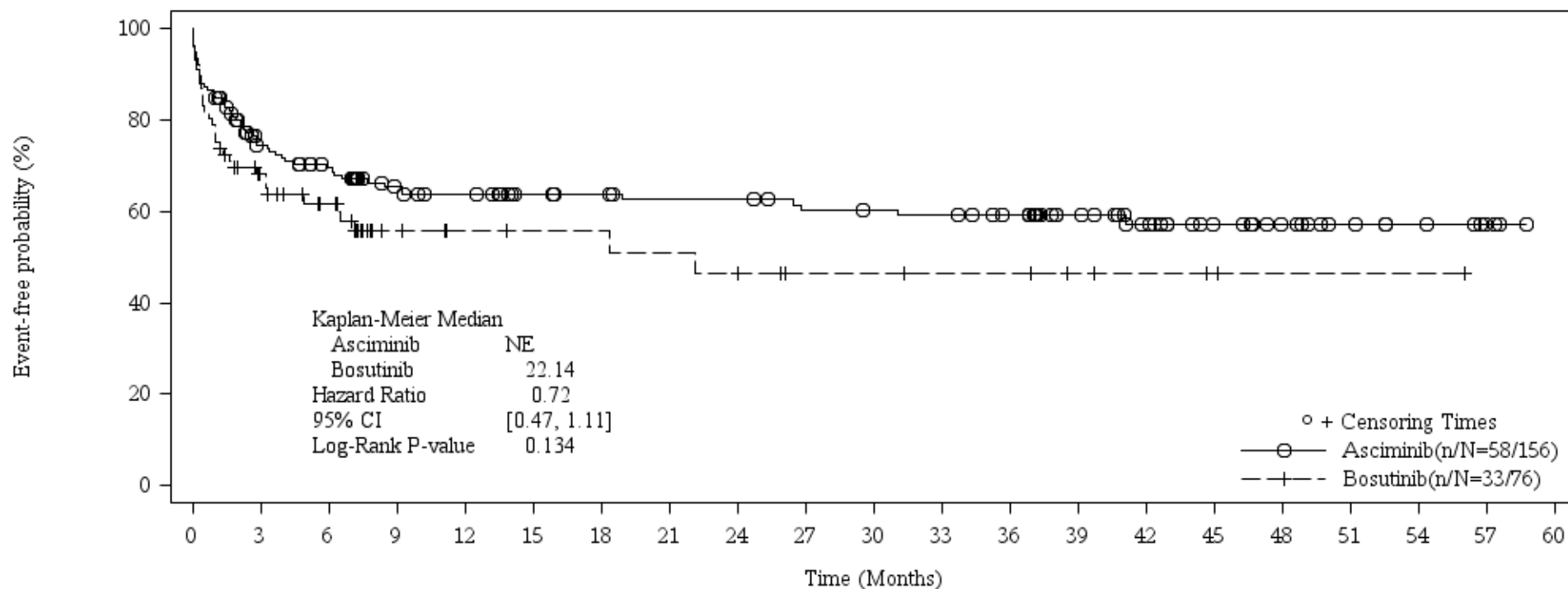


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	129	111	87	82	71	67	63	63	61	60	60	55	43	32	24	17	12	9	4	0
Bosutinib	76	59	44	27	18	15	15	14	13	10	9	7	7	6	4	3	3	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 16 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Skin and subcutaneous tissue disorders



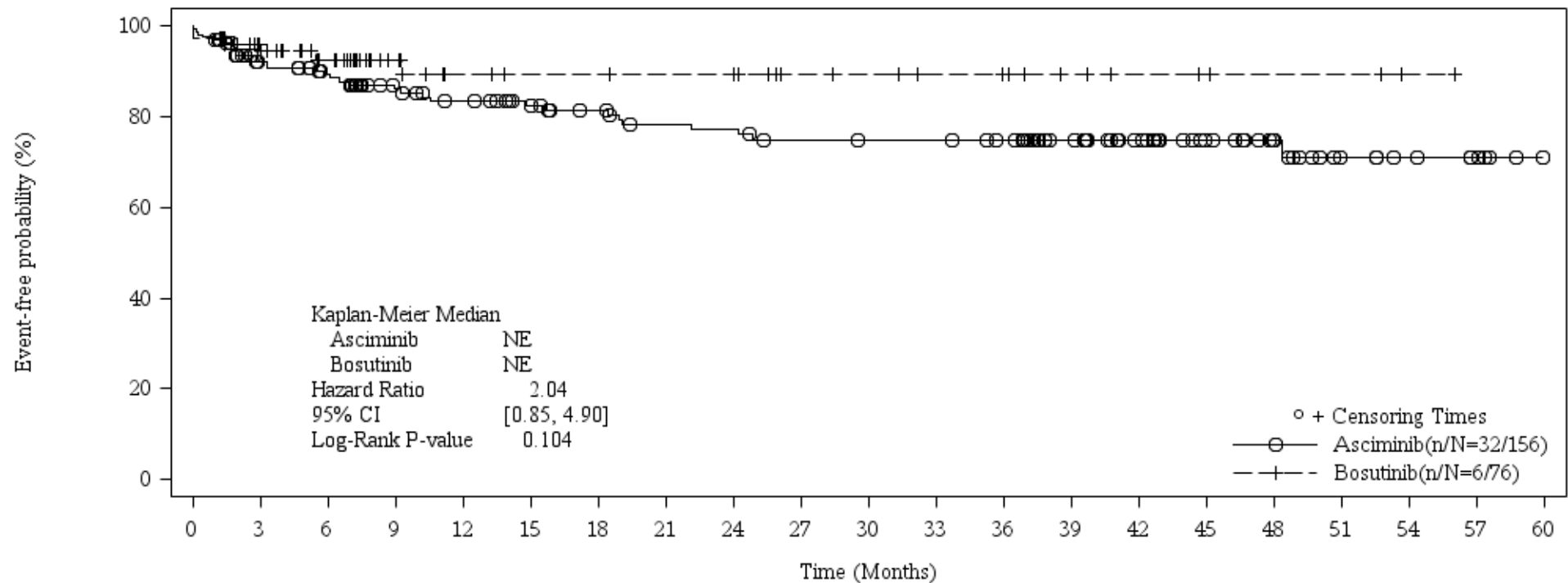
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	104	91	74	69	62	60	57	57	53	52	51	47	36	28	20	15	10	7	3	0
Bosutinib	76	44	33	17	13	12	12	11	10	7	7	6	6	4	3	2	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.2.1 (Page 17 of 17)
Any AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Vascular disorders



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	130	118	98	91	83	78	72	71	67	66	66	63	50	38	27	19	11	8	5	0
Bosutinib	76	60	47	29	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 1 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Blood and lymphatic system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	54 (34.6)	24 (31.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	99 (63.5)	37 (48.7)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	1.41 [0.95, 2.76]	3.68 [0.95, 19.35]			
median	NE [NE, NE]	NE [17.51, NE]	1.11	[0.68, 1.80]	0.695
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.68 [0.60, 0.74]	0.76 [0.64, 0.84]			
Month 6	0.67 [0.59, 0.74]	0.71 [0.58, 0.80]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

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Final

Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 34)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.67 [0.59, 0.74]		0.71 [0.58, 0.80]			
Month 12	0.67 [0.59, 0.74]		0.67 [0.53, 0.78]			
Month 15	0.65 [0.57, 0.72]		0.67 [0.53, 0.78]			
Month 18	0.65 [0.57, 0.72]		0.63 [0.48, 0.75]			
Month 21	0.65 [0.57, 0.72]		0.59 [0.42, 0.72]			
Month 24	0.65 [0.57, 0.72]		0.59 [0.42, 0.72]			
Month 27	0.65 [0.57, 0.72]		0.59 [0.42, 0.72]			
Month 30	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 33	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 36	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 39	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 42	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 45	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 48	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 51	0.64 [0.56, 0.71]		0.59 [0.42, 0.72]			
Month 54	0.64 [0.56, 0.71]	NE	[NE, NE]			
Month 57	0.64 [0.56, 0.71]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

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Final

Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 3 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	7 (9.2)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	45 (59.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.57, NE]			
median	NE [NE, NE]	NE [32.69, NE]	0.82	[0.33, 2.01]	0.662
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.91 [0.80, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_2_2.sas@@/main/3 22NOV23:11:00

Final

Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.95]	0.91 [0.80, 0.96]			
Month 12	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 15	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 18	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 21	0.89 [0.82, 0.94]	0.91 [0.80, 0.96]			
Month 24	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.81, 0.93]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.81, 0.93]	0.76 [0.48, 0.91]			
Month 36	0.87 [0.79, 0.92]	0.76 [0.48, 0.91]			
Month 39	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 42	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 45	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 48	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 51	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 54	0.86 [0.77, 0.91]	0.76 [0.48, 0.91]			
Month 57	0.86 [0.77, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_2_2.sas@@/main/3 22NOV23:11:00

Final

Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 5 of 34)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Eye disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	6 (7.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	44 (57.9)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [12.94, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.95	[0.37, 2.46]	0.922
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.92 [0.87, 0.96]	0.94 [0.84, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.96]		0.94 [0.84, 0.98]			
Month 12	0.91 [0.84, 0.94]		0.94 [0.84, 0.98]			
Month 15	0.90 [0.83, 0.94]		0.89 [0.72, 0.96]			
Month 18	0.88 [0.81, 0.93]		0.89 [0.72, 0.96]			
Month 21	0.88 [0.81, 0.93]		0.89 [0.72, 0.96]			
Month 24	0.88 [0.81, 0.93]		0.84 [0.62, 0.93]			
Month 27	0.88 [0.81, 0.93]		0.84 [0.62, 0.93]			
Month 30	0.88 [0.81, 0.93]		0.84 [0.62, 0.93]			
Month 33	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 36	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 39	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 42	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 45	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 48	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 51	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 54	0.87 [0.80, 0.92]		0.84 [0.62, 0.93]			
Month 57	0.87 [0.80, 0.92]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Gastrointestinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	69 (44.2)	61 (80.3)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	84 (53.8)	10 (13.2)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	2.04 [0.95, 7.29]	0.03 [0.03, 0.07]			
median	35.75 [13.77, NE]	0.26 [0.07, 0.36]	0.22	[0.15, 0.32]	<0.001
75th	NE [NE, NE]	0.99 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.74 [0.66, 0.80]	0.22 [0.13, 0.32]			
Month 6	0.71 [0.63, 0.77]	0.20 [0.12, 0.30]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.66 [0.57, 0.73]		0.18 [0.10, 0.28]			
Month 12	0.59 [0.50, 0.67]		0.18 [0.10, 0.28]			
Month 15	0.57 [0.48, 0.65]		0.18 [0.10, 0.28]			
Month 18	0.55 [0.46, 0.63]		0.18 [0.10, 0.28]			
Month 21	0.53 [0.43, 0.61]		0.18 [0.10, 0.28]			
Month 24	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 27	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 30	0.52 [0.42, 0.60]		0.18 [0.10, 0.28]			
Month 33	0.50 [0.41, 0.59]		0.18 [0.10, 0.28]			
Month 36	0.49 [0.39, 0.58]		0.18 [0.10, 0.28]			
Month 39	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 42	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 45	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 48	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 51	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 54	0.46 [0.36, 0.55]		0.18 [0.10, 0.28]			
Month 57	0.46 [0.36, 0.55]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
General disorders and administration site conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	52 (33.3)	25 (32.9)			
censored					
Death	2 (1.3)	0			
Discontinued from study treatment	102 (65.4)	31 (40.8)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	9.23 [3.71, 19.55]	6.21 [1.41, 15.44]			
median	50.17 [38.51, NE]	35.61 [15.44, NE]	0.74	[0.45, 1.20]	0.211
75th	NE [NE, NE]	NE [35.61, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.83 [0.76, 0.88]	0.78 [0.67, 0.86]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.78 [0.70, 0.84]		0.77 [0.65, 0.85]			
Month 9	0.76 [0.68, 0.82]		0.67 [0.53, 0.78]			
Month 12	0.72 [0.64, 0.79]		0.67 [0.53, 0.78]			
Month 15	0.70 [0.61, 0.77]		0.67 [0.53, 0.78]			
Month 18	0.69 [0.60, 0.76]		0.57 [0.40, 0.72]			
Month 21	0.65 [0.56, 0.73]		0.57 [0.40, 0.72]			
Month 24	0.63 [0.53, 0.71]		0.57 [0.40, 0.72]			
Month 27	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 30	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 33	0.63 [0.53, 0.71]		0.52 [0.32, 0.68]			
Month 36	0.60 [0.50, 0.69]		0.43 [0.22, 0.63]			
Month 39	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 42	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 45	0.59 [0.48, 0.67]		0.43 [0.22, 0.63]			
Month 48	0.56 [0.44, 0.66]		0.43 [0.22, 0.63]			
Month 51	0.50 [0.35, 0.63]		0.43 [0.22, 0.63]			
Month 54	0.50 [0.35, 0.63]		0.43 [0.22, 0.63]			
Month 57	0.50 [0.35, 0.63]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Infections and infestations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	76 (48.7)	22 (28.9)			
censored					
Death	2 (1.3)	0			
Discontinued from study treatment	78 (50.0)	38 (50.0)			
Treatment switched	0	16 (21.1)			
Percentiles (months) (95% CI)					
25th	3.78 [2.46, 5.22]	5.62 [3.48, 16.89]			
median	20.11 [10.81, 39.52]	33.12 [16.89, NE]	1.35	[0.84, 2.19]	0.214
75th	NE [42.87, NE]	NE [33.12, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.90 [0.81, 0.95]			
Month 6	0.67 [0.59, 0.74]	0.75 [0.62, 0.84]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.62 [0.53, 0.69]		0.70 [0.56, 0.80]			
Month 12	0.57 [0.48, 0.65]		0.66 [0.50, 0.77]			
Month 15	0.53 [0.44, 0.61]		0.66 [0.50, 0.77]			
Month 18	0.51 [0.42, 0.59]		0.60 [0.41, 0.74]			
Month 21	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 24	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 27	0.50 [0.40, 0.58]		0.60 [0.41, 0.74]			
Month 30	0.43 [0.34, 0.52]		0.60 [0.41, 0.74]			
Month 33	0.43 [0.34, 0.52]		0.52 [0.31, 0.70]			
Month 36	0.42 [0.33, 0.51]		0.44 [0.21, 0.64]			
Month 39	0.42 [0.33, 0.51]		0.44 [0.21, 0.64]			
Month 42	0.38 [0.28, 0.48]		0.44 [0.21, 0.64]			
Month 45	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 48	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 51	0.35 [0.25, 0.46]		0.44 [0.21, 0.64]			
Month 54	0.35 [0.25, 0.46]	NE	[NE, NE]			
Month 57	0.35 [0.25, 0.46]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Injury, poisoning and procedural complications					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	6 (7.9)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	124 (79.5)	45 (59.2)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	43.20 [20.96, NE]	NE [18.43, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.63	[0.67, 3.97]	0.274
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.90 [0.84, 0.94]		0.93 [0.83, 0.97]			
Month 9	0.89 [0.83, 0.94]		0.90 [0.77, 0.96]			
Month 12	0.87 [0.80, 0.91]		0.90 [0.77, 0.96]			
Month 15	0.85 [0.77, 0.90]		0.90 [0.77, 0.96]			
Month 18	0.85 [0.77, 0.90]		0.90 [0.77, 0.96]			
Month 21	0.83 [0.75, 0.88]		0.85 [0.68, 0.94]			
Month 24	0.82 [0.73, 0.87]		0.85 [0.68, 0.94]			
Month 27	0.80 [0.72, 0.87]		0.85 [0.68, 0.94]			
Month 30	0.79 [0.71, 0.86]		0.85 [0.68, 0.94]			
Month 33	0.79 [0.71, 0.86]		0.85 [0.68, 0.94]			
Month 36	0.78 [0.69, 0.85]		0.85 [0.68, 0.94]			
Month 39	0.77 [0.67, 0.84]		0.85 [0.68, 0.94]			
Month 42	0.77 [0.67, 0.84]		0.85 [0.68, 0.94]			
Month 45	0.74 [0.64, 0.82]		0.85 [0.68, 0.94]			
Month 48	0.72 [0.60, 0.80]		0.85 [0.68, 0.94]			
Month 51	0.68 [0.53, 0.78]		0.85 [0.68, 0.94]			
Month 54	0.68 [0.53, 0.78]		0.85 [0.68, 0.94]			
Month 57	0.68 [0.53, 0.78]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Investigations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	40 (52.6)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	98 (62.8)	24 (31.6)			
Treatment switched	0	11 (14.5)			
Percentiles (months) (95% CI)					
25th	4.63 [1.74, 10.18]	1.25 [0.95, 2.23]			
median	NE [33.38, NE]	6.60 [2.79, 25.10]	0.51	[0.34, 0.77]	0.001
75th	NE [NE, NE]	NE [25.10, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.59 [0.47, 0.70]			
Month 6	0.73 [0.65, 0.79]	0.53 [0.40, 0.64]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.71 [0.63, 0.78]		0.43 [0.30, 0.55]			
Month 12	0.68 [0.59, 0.75]		0.39 [0.25, 0.53]			
Month 15	0.66 [0.57, 0.73]		0.39 [0.25, 0.53]			
Month 18	0.63 [0.54, 0.71]		0.39 [0.25, 0.53]			
Month 21	0.63 [0.54, 0.71]		0.39 [0.25, 0.53]			
Month 24	0.62 [0.53, 0.70]		0.39 [0.25, 0.53]			
Month 27	0.62 [0.53, 0.70]		0.35 [0.21, 0.49]			
Month 30	0.62 [0.53, 0.70]		0.35 [0.21, 0.49]			
Month 33	0.61 [0.52, 0.69]		0.35 [0.21, 0.49]			
Month 36	0.59 [0.50, 0.67]		0.35 [0.21, 0.49]			
Month 39	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 42	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 45	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 48	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 51	0.57 [0.48, 0.66]		0.35 [0.21, 0.49]			
Month 54	0.57 [0.48, 0.66]	NE	[NE, NE]			
Month 57	0.57 [0.48, 0.66]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Metabolism and nutrition disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	14 (18.4)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	41 (53.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [7.39, NE]	19.09 [5.62, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.95	[0.50, 1.78]	0.868
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.88 [0.82, 0.92]	0.86 [0.76, 0.92]			
Month 6	0.85 [0.78, 0.89]	0.85 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]		0.83 [0.71, 0.90]			
Month 12	0.80 [0.72, 0.86]		0.83 [0.71, 0.90]			
Month 15	0.78 [0.70, 0.84]		0.83 [0.71, 0.90]			
Month 18	0.77 [0.69, 0.84]		0.83 [0.71, 0.90]			
Month 21	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 24	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 27	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 30	0.77 [0.69, 0.84]		0.74 [0.56, 0.85]			
Month 33	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 36	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 39	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 42	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 45	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 48	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 51	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 54	0.76 [0.68, 0.83]		0.74 [0.56, 0.85]			
Month 57	0.76 [0.68, 0.83]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Musculoskeletal and connective tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	18 (23.7)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	97 (62.2)	39 (51.3)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	4.60 [1.91, 10.12]	16.46 [2.33, 27.63]			
median	NE [20.70, NE]	NE [24.87, NE]	1.32	[0.77, 2.25]	0.308
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.77 [0.70, 0.83]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.72 [0.64, 0.79]		0.82 [0.71, 0.89]			
Month 9	0.69 [0.61, 0.76]		0.80 [0.68, 0.88]			
Month 12	0.65 [0.57, 0.73]		0.75 [0.60, 0.85]			
Month 15	0.65 [0.57, 0.73]		0.75 [0.60, 0.85]			
Month 18	0.61 [0.51, 0.69]		0.70 [0.52, 0.82]			
Month 21	0.59 [0.50, 0.68]		0.70 [0.52, 0.82]			
Month 24	0.59 [0.50, 0.68]		0.70 [0.52, 0.82]			
Month 27	0.58 [0.48, 0.66]		0.64 [0.43, 0.79]			
Month 30	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 33	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 36	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 39	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 42	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 45	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 48	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 51	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 54	0.57 [0.47, 0.65]		0.56 [0.32, 0.74]			
Month 57	0.57 [0.47, 0.65]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nervous system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	56 (35.9)	17 (22.4)			
censored					
Death	1 (0.6)	1 (1.3)			
Discontinued from study treatment	99 (63.5)	40 (52.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	7.16 [1.91, 12.91]	9.26 [3.02, NE]			
median	NE [26.84, NE]	NE [NE, NE]	1.36	[0.79, 2.35]	0.261
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.73, 0.85]	0.85 [0.75, 0.92]			
Month 6	0.76 [0.69, 0.82]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.71 [0.62, 0.78]		0.77 [0.65, 0.86]			
Month 12	0.68 [0.59, 0.75]		0.74 [0.59, 0.84]			
Month 15	0.65 [0.55, 0.72]		0.74 [0.59, 0.84]			
Month 18	0.62 [0.53, 0.70]		0.68 [0.51, 0.81]			
Month 21	0.62 [0.53, 0.70]		0.68 [0.51, 0.81]			
Month 24	0.61 [0.51, 0.69]		0.68 [0.51, 0.81]			
Month 27	0.60 [0.50, 0.68]		0.68 [0.51, 0.81]			
Month 30	0.57 [0.47, 0.66]		0.68 [0.51, 0.81]			
Month 33	0.57 [0.47, 0.66]		0.68 [0.51, 0.81]			
Month 36	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 39	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 42	0.56 [0.46, 0.65]		0.68 [0.51, 0.81]			
Month 45	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 48	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 51	0.53 [0.42, 0.63]		0.68 [0.51, 0.81]			
Month 54	0.53 [0.42, 0.63]	NE	[NE, NE]			
Month 57	0.53 [0.42, 0.63]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Psychiatric disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	22 (14.1)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	130 (83.3)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [30.39, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.32	[0.79, 6.76]	0.113
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.87, 0.95]	0.96 [0.88, 0.99]			
Month 6	0.90 [0.84, 0.94]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.89 [0.83, 0.93]	0.94 [0.86, 0.98]			
Month 12	0.86 [0.79, 0.91]	0.94 [0.86, 0.98]			
Month 15	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 18	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 21	0.85 [0.78, 0.90]	0.94 [0.86, 0.98]			
Month 24	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 27	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 30	0.84 [0.77, 0.89]	0.94 [0.86, 0.98]			
Month 33	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 36	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 39	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 42	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 45	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 48	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 51	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 54	0.83 [0.75, 0.89]	0.94 [0.86, 0.98]			
Month 57	0.83 [0.75, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Renal and urinary disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	5 (6.6)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	142 (91.0)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.70	[0.24, 2.05]	0.516
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.91, 0.98]		0.93 [0.83, 0.97]			
Month 12	0.94 [0.89, 0.97]		0.93 [0.83, 0.97]			
Month 15	0.92 [0.86, 0.96]		0.93 [0.83, 0.97]			
Month 18	0.92 [0.86, 0.96]		0.93 [0.83, 0.97]			
Month 21	0.91 [0.84, 0.95]		0.93 [0.83, 0.97]			
Month 24	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 27	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 30	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 33	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 36	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 39	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 42	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 45	0.91 [0.84, 0.95]		0.88 [0.71, 0.96]			
Month 48	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 51	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 54	0.88 [0.78, 0.94]		0.88 [0.71, 0.96]			
Month 57	0.88 [0.78, 0.94]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive system and breast disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	134 (85.9)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	41.30 [19.71, NE]			
median	NE [NE, NE]	NE [41.30, NE]	1.13	[0.41, 3.13]	0.815
75th	NE [NE, NE]	NE [41.30, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.99 [0.90, 1.00]			
Month 6	0.94 [0.89, 0.97]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.96]	0.95 [0.85, 0.98]			
Month 12	0.91 [0.85, 0.95]	0.95 [0.85, 0.98]			
Month 15	0.91 [0.85, 0.95]	0.95 [0.85, 0.98]			
Month 18	0.90 [0.84, 0.94]	0.95 [0.85, 0.98]			
Month 21	0.89 [0.82, 0.94]	0.89 [0.69, 0.97]			
Month 24	0.88 [0.81, 0.93]	0.89 [0.69, 0.97]			
Month 27	0.88 [0.81, 0.93]	0.89 [0.69, 0.97]			
Month 30	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 33	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 36	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 39	0.87 [0.79, 0.92]	0.89 [0.69, 0.97]			
Month 42	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 45	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 48	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 51	0.85 [0.76, 0.91]	0.67 [0.18, 0.91]			
Month 54	0.85 [0.76, 0.91]	NE [NE, NE]			
Month 57	0.85 [0.76, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	15 (19.7)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	116 (74.4)	37 (48.7)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	17.35 [7.39, NE]	13.63 [5.65, 48.99]			
median	NE [NE, NE]	48.99 [22.08, NE]	0.90	[0.49, 1.66]	0.745
75th	NE [NE, NE]	NE [48.99, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.91 [0.85, 0.94]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.85 [0.78, 0.90]	0.86 [0.75, 0.93]			
Month 9	0.81 [0.73, 0.86]	0.86 [0.75, 0.93]			
Month 12	0.79 [0.71, 0.85]	0.78 [0.61, 0.88]			
Month 15	0.76 [0.68, 0.82]	0.73 [0.55, 0.85]			
Month 18	0.75 [0.66, 0.82]	0.73 [0.55, 0.85]			
Month 21	0.73 [0.64, 0.80]	0.73 [0.55, 0.85]			
Month 24	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 27	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 30	0.73 [0.64, 0.80]	0.68 [0.48, 0.82]			
Month 33	0.73 [0.64, 0.80]	0.60 [0.35, 0.77]			
Month 36	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 39	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 42	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 45	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 48	0.71 [0.62, 0.79]	0.60 [0.35, 0.77]			
Month 51	0.71 [0.62, 0.79]	0.40 [0.09, 0.70]			
Month 54	0.71 [0.62, 0.79]	NE [NE, NE]			
Month 57	0.71 [0.62, 0.79]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	58 (37.2)	33 (43.4)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	95 (60.9)	25 (32.9)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	2.83 [1.64, 6.21]	1.08 [0.39, 3.19]			
median	NE [41.07, NE]	22.14 [4.90, NE]	0.70	[0.46, 1.08]	0.107
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.74 [0.67, 0.81]	0.68 [0.56, 0.77]			
Month 6	0.69 [0.61, 0.76]	0.62 [0.49, 0.72]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.65 [0.57, 0.73]		0.56 [0.43, 0.67]			
Month 12	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 15	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 18	0.64 [0.55, 0.71]		0.56 [0.43, 0.67]			
Month 21	0.63 [0.54, 0.70]		0.51 [0.36, 0.64]			
Month 24	0.63 [0.54, 0.70]		0.46 [0.31, 0.61]			
Month 27	0.60 [0.51, 0.68]		0.46 [0.31, 0.61]			
Month 30	0.60 [0.51, 0.68]		0.46 [0.31, 0.61]			
Month 33	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 36	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 39	0.59 [0.50, 0.67]		0.46 [0.31, 0.61]			
Month 42	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 45	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 48	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 51	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 54	0.57 [0.48, 0.66]		0.46 [0.31, 0.61]			
Month 57	0.57 [0.48, 0.66]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vascular disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	6 (7.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	121 (77.6)	47 (61.8)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	24.87 [14.82, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.00	[0.83, 4.82]	0.113
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.96 [0.88, 0.99]			
Month 6	0.89 [0.83, 0.93]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.2 Any AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.86 [0.79, 0.91]	0.93 [0.83, 0.97]			
Month 12	0.83 [0.76, 0.89]	0.89 [0.76, 0.95]			
Month 15	0.82 [0.75, 0.88]	0.89 [0.76, 0.95]			
Month 18	0.81 [0.74, 0.87]	0.89 [0.76, 0.95]			
Month 21	0.78 [0.70, 0.85]	0.89 [0.76, 0.95]			
Month 24	0.77 [0.68, 0.84]	0.89 [0.76, 0.95]			
Month 27	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 30	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 33	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 36	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 39	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 42	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 45	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 48	0.75 [0.66, 0.82]	0.89 [0.76, 0.95]			
Month 51	0.71 [0.59, 0.80]	0.89 [0.76, 0.95]			
Month 54	0.71 [0.59, 0.80]	0.89 [0.76, 0.95]			
Month 57	0.71 [0.59, 0.80]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.2.3 Overview of AE by SOC: Switched patients who do not have this event prior to switch
Switch Analysis Set
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	Bosutinib	
	N=25	
Primary system organ class	All grades n (%)	Grade ≥3 n (%)
Number of subjects with at least one event	19 (76.0)	7 (28.0)
Skin and subcutaneous tissue disorders	6 (24.0)	0
Blood and lymphatic system disorders	5 (20.0)	4 (16.0)
Infections and infestations	5 (20.0)	0
Nervous system disorders	5 (20.0)	0
General disorders and administration site conditions	4 (16.0)	1 (4.0)
Cardiac disorders	3 (12.0)	0
Gastrointestinal disorders	3 (12.0)	1 (4.0)
Injury, poisoning and procedural complications	3 (12.0)	0
Musculoskeletal and connective tissue disorders	3 (12.0)	1 (4.0)
Investigations	2 (8.0)	0
Metabolism and nutrition disorders	2 (8.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (8.0)	2 (8.0)
Numbers (n) represent counts of subjects.		
A subject with multiple severity grades for an AE is only counted under the maximum grade.		
Patients included in this table are randomized to Bosutinib and switched to Asciminib.		
MedDRA version 26.0, CTCAE version 4.03		

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Table 4-1.2.3 Overview of AE by SOC: Switched patients who do not have this event prior to switch
Switch Analysis Set
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	Bosutinib N=25	
Primary system organ class	All grades n (%)	Grade ≥3 n (%)
Respiratory, thoracic and mediastinal disorders	2 (8.0)	0
Ear and labyrinth disorders	1 (4.0)	0
Endocrine disorders	1 (4.0)	0
Eye disorders	1 (4.0)	0
Hepatobiliary disorders	1 (4.0)	1 (4.0)
Numbers (n) represent counts of subjects.		
A subject with multiple severity grades for an AE is only counted under the maximum grade.		
Patients included in this table are randomized to Bosutinib and switched to Asciminib.		
MedDRA version 26.0, CTCAE version 4.03		

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Abdominal pain					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	12 (15.8)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	137 (87.8)	42 (55.3)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.71, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.39	[0.18, 0.87]	0.017
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.91, 0.98]	0.88 [0.78, 0.94]			
Month 6	0.95 [0.90, 0.98]	0.85 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]		0.85 [0.74, 0.91]			
Month 12	0.94 [0.89, 0.97]		0.85 [0.74, 0.91]			
Month 15	0.93 [0.88, 0.97]		0.85 [0.74, 0.91]			
Month 18	0.93 [0.88, 0.97]		0.85 [0.74, 0.91]			
Month 21	0.91 [0.84, 0.95]		0.79 [0.63, 0.89]			
Month 24	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 27	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 30	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 33	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 36	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 39	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 42	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 45	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 48	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 51	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 54	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 57	0.88 [0.80, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Alanine aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	23 (30.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	143 (91.7)	38 (50.0)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	3.71 [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.11	[0.05, 0.26]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.78 [0.67, 0.86]			
Month 6	0.97 [0.93, 0.99]	0.68 [0.55, 0.78]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.97 [0.93, 0.99]		0.66 [0.53, 0.76]			
Month 12	0.96 [0.91, 0.98]		0.66 [0.53, 0.76]			
Month 15	0.96 [0.91, 0.98]		0.66 [0.53, 0.76]			
Month 18	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 21	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 24	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 27	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 30	0.94 [0.88, 0.97]		0.66 [0.53, 0.76]			
Month 33	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 36	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 39	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 42	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 45	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 48	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 51	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 54	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 57	0.93 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Anaemia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	6 (7.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	48 (63.2)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.23	[0.48, 3.15]	0.667
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.95 [0.86, 0.98]			
Month 6	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.84, 0.94]		0.93 [0.84, 0.97]			
Month 12	0.90 [0.84, 0.94]		0.93 [0.84, 0.97]			
Month 15	0.90 [0.84, 0.94]		0.93 [0.84, 0.97]			
Month 18	0.90 [0.84, 0.94]		0.93 [0.84, 0.97]			
Month 21	0.90 [0.84, 0.94]		0.88 [0.71, 0.95]			
Month 24	0.90 [0.84, 0.94]		0.88 [0.71, 0.95]			
Month 27	0.90 [0.84, 0.94]		0.88 [0.71, 0.95]			
Month 30	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 33	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 36	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 39	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 42	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 45	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 48	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 51	0.89 [0.83, 0.93]		0.88 [0.71, 0.95]			
Month 54	0.89 [0.83, 0.93]	NE	[NE, NE]			
Month 57	0.89 [0.83, 0.93]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arthralgia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	23 (14.7)	2 (2.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	128 (82.1)	50 (65.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [25.53, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.38	[1.02, 18.71]	0.030
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.87, 0.95]	0.97 [0.90, 0.99]			
Month 6	0.91 [0.85, 0.94]	0.97 [0.90, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.94]		0.97 [0.90, 0.99]			
Month 12	0.90 [0.83, 0.94]		0.97 [0.90, 0.99]			
Month 15	0.89 [0.82, 0.93]		0.97 [0.90, 0.99]			
Month 18	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 21	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 24	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 27	0.83 [0.75, 0.89]		0.97 [0.90, 0.99]			
Month 30	0.83 [0.75, 0.89]		0.97 [0.90, 0.99]			
Month 33	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 36	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 39	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 42	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 45	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 48	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 51	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 54	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 57	0.80 [0.70, 0.87]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Aspartate aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	16 (21.1)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	143 (91.7)	41 (53.9)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	7.33 [4.17, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.21	[0.09, 0.47]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.88 [0.77, 0.93]			
Month 6	0.97 [0.92, 0.99]	0.82 [0.71, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.91, 0.98]		0.74 [0.61, 0.84]			
Month 12	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 15	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 18	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 21	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 24	0.94 [0.88, 0.97]		0.74 [0.61, 0.84]			
Month 27	0.94 [0.88, 0.97]		0.74 [0.61, 0.84]			
Month 30	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 33	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 36	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 39	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 42	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 45	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 48	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 51	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 54	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 57	0.93 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Asthenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [46.09, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.63	[0.60, 35.64]	0.106
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.96 [0.91, 0.98]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.99 [0.91, 1.00]			
Month 12	0.94 [0.89, 0.97]	0.99 [0.91, 1.00]			
Month 15	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 18	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 21	0.91 [0.84, 0.95]	0.99 [0.91, 1.00]			
Month 24	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 27	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 30	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 33	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 36	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 39	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 42	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 45	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 48	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 51	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 54	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 57	0.85 [0.75, 0.92]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Back pain					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	3 (3.9)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	139 (89.1)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [16.46, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.47	[0.41, 5.29]	0.549
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.90, 1.00]			
Month 6	0.95 [0.89, 0.97]	0.99 [0.90, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.89, 0.97]	0.99 [0.90, 1.00]			
Month 12	0.93 [0.87, 0.96]	0.99 [0.90, 1.00]			
Month 15	0.92 [0.85, 0.95]	0.99 [0.90, 1.00]			
Month 18	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 21	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 24	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 27	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 30	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 33	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 36	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 39	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 42	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 45	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 48	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 51	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 54	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 57	0.90 [0.82, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
COVID-19					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [39.92, NE]	37.98 [18.04, NE]			
median	NE [NE, NE]	52.96 [37.98, NE]	0.46	[0.17, 1.27]	0.125
75th	NE [NE, NE]	NE [52.96, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.92, 1.00]		0.90 [0.65, 0.97]			
Month 24	0.96 [0.89, 0.98]		0.90 [0.65, 0.97]			
Month 27	0.95 [0.87, 0.98]		0.90 [0.65, 0.97]			
Month 30	0.92 [0.84, 0.96]		0.90 [0.65, 0.97]			
Month 33	0.90 [0.81, 0.95]		0.82 [0.53, 0.94]			
Month 36	0.86 [0.77, 0.92]		0.82 [0.53, 0.94]			
Month 39	0.85 [0.75, 0.91]		0.70 [0.36, 0.89]			
Month 42	0.81 [0.70, 0.88]		0.70 [0.36, 0.89]			
Month 45	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 48	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 51	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 54	0.76 [0.64, 0.85]	NE	[NE, NE]			
Month 57	0.76 [0.64, 0.85]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cough					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	138 (88.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [13.63, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.07	[0.38, 3.00]	0.891
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.94 [0.88, 0.97]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.87, 0.96]	0.93 [0.83, 0.97]			
Month 12	0.90 [0.84, 0.94]	0.93 [0.83, 0.97]			
Month 15	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 18	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 21	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 24	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 27	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 30	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 33	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 36	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 39	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 42	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 45	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 48	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 51	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 54	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 57	0.89 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Diarrhoea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	20 (12.8)	55 (72.4)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	132 (84.6)	14 (18.4)			
Treatment switched	0	6 (7.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	0.07 [0.03, 0.10]	0.09	[0.05, 0.15]	<0.001
median	NE [NE, NE]	0.28 [0.10, 0.72]			
75th	NE [NE, NE]	19.02 [0.76, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.91 [0.85, 0.95]	0.31 [0.21, 0.42]			
Month 6	0.89 [0.82, 0.93]	0.29 [0.20, 0.40]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 12	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 15	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 18	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 21	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 24	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 27	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 30	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 33	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 36	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 39	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 42	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 45	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 48	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 51	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 54	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 57	0.86 [0.78, 0.91]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Dizziness					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	2 (2.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.65	[0.60, 11.77]	0.183
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.97 [0.90, 0.99]			
Month 6	0.95 [0.91, 0.98]	0.97 [0.90, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]	0.97 [0.90, 0.99]			
Month 12	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 15	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 18	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 21	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 24	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 27	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 30	0.90 [0.83, 0.95]	0.97 [0.90, 0.99]			
Month 33	0.90 [0.83, 0.95]	0.97 [0.90, 0.99]			
Month 36	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 39	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 42	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 45	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 48	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 51	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 54	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 57	0.88 [0.80, 0.93]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Dyspepsia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.46	[0.40, 5.26]	0.564
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.97 [0.90, 0.99]			
Month 6	0.96 [0.91, 0.98]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 12	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 15	0.93 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 18	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 21	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 24	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 27	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 30	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 33	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 36	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 39	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 42	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 45	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 48	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 51	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 54	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 57	0.91 [0.85, 0.95]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Fatigue					
N*	156	76			
Number of patients, n (%)					
with events					
AE	24 (15.4)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	128 (82.1)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [20.07, NE]	NE [35.61, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.09	[0.48, 2.46]	0.833
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.93 [0.84, 0.97]			
Month 6	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.84, 0.94]		0.89 [0.77, 0.95]			
Month 12	0.88 [0.82, 0.93]		0.89 [0.77, 0.95]			
Month 15	0.87 [0.80, 0.92]		0.89 [0.77, 0.95]			
Month 18	0.85 [0.77, 0.90]		0.89 [0.77, 0.95]			
Month 21	0.83 [0.74, 0.88]		0.89 [0.77, 0.95]			
Month 24	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 27	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 30	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 33	0.80 [0.71, 0.86]		0.89 [0.77, 0.95]			
Month 36	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 39	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 42	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 45	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 48	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 51	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 54	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 57	0.80 [0.71, 0.86]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Headache					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	12 (15.8)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	NE [12.91, NE]	NE [7.29, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.99	[0.50, 1.95]	0.987
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.88 [0.82, 0.93]	0.89 [0.80, 0.95]			
Month 6	0.86 [0.80, 0.91]	0.89 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.84 [0.77, 0.89]		0.85 [0.73, 0.92]			
Month 12	0.83 [0.76, 0.89]		0.81 [0.66, 0.90]			
Month 15	0.80 [0.72, 0.86]		0.81 [0.66, 0.90]			
Month 18	0.78 [0.69, 0.84]		0.75 [0.57, 0.87]			
Month 21	0.78 [0.69, 0.84]		0.75 [0.57, 0.87]			
Month 24	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 27	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 30	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 33	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 36	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 39	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 42	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 45	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 48	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 51	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 54	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 57	0.77 [0.68, 0.83]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypertension					
N*	156	76			
Number of patients, n (%)					
with events					
AE	23 (14.7)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	129 (82.7)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [24.87, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.13	[0.73, 6.20]	0.156
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.97 [0.90, 0.99]			
Month 6	0.92 [0.86, 0.95]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.83, 0.94]		0.96 [0.87, 0.99]			
Month 12	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 15	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 18	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 21	0.86 [0.78, 0.91]		0.92 [0.79, 0.97]			
Month 24	0.85 [0.77, 0.90]		0.92 [0.79, 0.97]			
Month 27	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 30	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 33	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 36	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 39	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 42	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 45	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 48	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 51	0.79 [0.67, 0.87]		0.92 [0.79, 0.97]			
Month 54	0.79 [0.67, 0.87]		0.92 [0.79, 0.97]			
Month 57	0.79 [0.67, 0.87]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Insomnia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.60	[0.59, 35.82]	0.110
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			
Month 12	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 15	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 18	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 21	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 24	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 27	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 30	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 33	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 36	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 39	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 42	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 45	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 48	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 51	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 54	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 57	0.92 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myalgia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	10 (6.4)	3 (3.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	142 (91.0)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.37	[0.37, 5.04]	0.634
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.90, 0.99]			
Month 6	0.95 [0.91, 0.98]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.91, 0.98]		0.96 [0.87, 0.99]			
Month 12	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 15	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 18	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 21	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 24	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 27	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 30	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 33	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 36	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 39	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 42	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 45	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 48	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 51	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 54	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 57	0.92 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nasopharyngitis					
N*	156	76			
Number of patients, n (%)					
with events					
AE	18 (11.5)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [20.27, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.36	[0.69, 8.05]	0.157
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.90, 1.00]			
Month 6	0.92 [0.86, 0.95]	0.97 [0.88, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.89 [0.82, 0.93]	0.97 [0.88, 0.99]			
Month 12	0.89 [0.82, 0.93]	0.97 [0.88, 0.99]			
Month 15	0.88 [0.81, 0.93]	0.97 [0.88, 0.99]			
Month 18	0.88 [0.81, 0.93]	0.97 [0.88, 0.99]			
Month 21	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 24	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 27	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 30	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 33	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 36	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 39	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 42	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 45	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 48	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 51	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 54	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 57	0.84 [0.75, 0.90]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nausea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	18 (11.5)	35 (46.1)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	134 (85.9)	27 (35.5)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	0.33 [0.07, 0.95]			
median	NE [NE, NE]	NE [1.35, NE]	0.16	[0.09, 0.29]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.87, 0.96]	0.57 [0.45, 0.68]			
Month 6	0.92 [0.87, 0.95]	0.52 [0.40, 0.63]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.95]		0.52 [0.40, 0.63]			
Month 12	0.87 [0.80, 0.92]		0.52 [0.40, 0.63]			
Month 15	0.87 [0.80, 0.92]		0.52 [0.40, 0.63]			
Month 18	0.87 [0.80, 0.92]		0.52 [0.40, 0.63]			
Month 21	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 24	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 27	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 30	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 33	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 36	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 39	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 42	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 45	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 48	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 51	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 54	0.86 [0.79, 0.91]		0.52 [0.40, 0.63]			
Month 57	0.86 [0.79, 0.91]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_3_1.sas@@/main/3 22NOV23:11:01

Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Neutropenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	13 (17.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	121 (77.6)	42 (55.3)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [3.09, NE]	NE [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.07	[0.56, 2.06]	0.836
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.88]	0.85 [0.75, 0.91]			
Month 6	0.82 [0.75, 0.87]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]		0.82 [0.71, 0.89]			
Month 12	0.82 [0.75, 0.87]		0.82 [0.71, 0.89]			
Month 15	0.81 [0.74, 0.86]		0.82 [0.71, 0.89]			
Month 18	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 21	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 24	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 27	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 30	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 33	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 36	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 39	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 42	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 45	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 48	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 51	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 54	0.80 [0.72, 0.86]		0.82 [0.71, 0.89]			
Month 57	0.80 [0.72, 0.86]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Oedema peripheral					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	2 (2.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.34	[0.52, 10.56]	0.255
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.97 [0.89, 0.99]			
Month 6	0.94 [0.88, 0.97]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]		0.97 [0.89, 0.99]			
Month 12	0.94 [0.88, 0.97]		0.97 [0.89, 0.99]			
Month 15	0.93 [0.87, 0.96]		0.97 [0.89, 0.99]			
Month 18	0.93 [0.87, 0.96]		0.97 [0.89, 0.99]			
Month 21	0.92 [0.85, 0.95]		0.97 [0.89, 0.99]			
Month 24	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 27	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 30	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 33	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 36	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 39	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 42	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 45	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 48	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 51	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 54	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 57	0.91 [0.84, 0.95]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pain in extremity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	48 (63.2)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.18	[0.42, 3.28]	0.750
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.94 [0.86, 0.98]			
Month 6	0.93 [0.88, 0.96]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.88, 0.96]		0.92 [0.82, 0.97]			
Month 12	0.92 [0.87, 0.96]		0.92 [0.82, 0.97]			
Month 15	0.92 [0.87, 0.96]		0.92 [0.82, 0.97]			
Month 18	0.91 [0.85, 0.95]		0.92 [0.82, 0.97]			
Month 21	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 24	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 27	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 30	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 33	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 36	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 39	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 42	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 45	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 48	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 51	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 54	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 57	0.88 [0.80, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Platelet count decreased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	47 (61.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.39, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.00	[0.34, 2.88]	0.993
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.94 [0.86, 0.98]			
Month 6	0.93 [0.87, 0.96]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 12	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 15	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 18	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 21	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 24	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 27	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 30	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 33	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 36	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 39	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 42	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 45	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 48	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 51	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 54	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 57	0.93 [0.87, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

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Final

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Rash					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	18 (23.7)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	37 (48.7)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	7.10 [1.22, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.29	[0.14, 0.58]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.81 [0.71, 0.89]			
Month 6	0.93 [0.88, 0.96]	0.80 [0.69, 0.87]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 12	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 15	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 18	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 21	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 24	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 27	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 30	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 33	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 36	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 39	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 42	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 45	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 48	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 51	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 54	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 57	0.88 [0.81, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Thrombocytopenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	46 (60.5)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.41, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.59	[0.81, 3.12]	0.179
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.71, 0.84]	0.88 [0.78, 0.93]			
Month 6	0.77 [0.70, 0.83]	0.86 [0.76, 0.92]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.77 [0.70, 0.83]		0.86 [0.76, 0.92]			
Month 12	0.77 [0.70, 0.83]		0.82 [0.68, 0.90]			
Month 15	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 18	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 21	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 24	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 27	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 30	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 33	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 36	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 39	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 42	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 45	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 48	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 51	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 54	0.76 [0.69, 0.82]		0.82 [0.68, 0.90]			
Month 57	0.76 [0.69, 0.82]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Upper respiratory tract infection					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	49 (64.5)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [51.42, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.20	[0.39, 3.72]	0.749
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
(Page 52 of 54)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]		0.93 [0.82, 0.97]			
Month 12	0.94 [0.89, 0.97]		0.93 [0.82, 0.97]			
Month 15	0.94 [0.89, 0.97]		0.93 [0.82, 0.97]			
Month 18	0.92 [0.86, 0.96]		0.93 [0.82, 0.97]			
Month 21	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 24	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 27	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 30	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 33	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 36	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 39	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 42	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 45	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 48	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 51	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 54	0.82 [0.64, 0.92]		0.93 [0.82, 0.97]			
Month 57	0.82 [0.64, 0.92]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
Safety Set
(Page 53 of 54)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vomiting					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	20 (26.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	38 (50.0)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	3.55 [0.39, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.11, 0.46]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.76 [0.64, 0.84]			
Month 6	0.95 [0.90, 0.98]	0.72 [0.60, 0.81]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

Table 4-1.3.1 Any AE by PT: time to first event - stratified per IRT
 Safety Set
 (Page 54 of 54)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]		0.72 [0.60, 0.81]			
Month 12	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 15	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 18	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 21	0.91 [0.85, 0.95]		0.72 [0.60, 0.81]			
Month 24	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 27	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 30	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 33	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 36	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 39	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 42	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 45	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 48	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 51	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 54	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 57	0.90 [0.83, 0.94]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

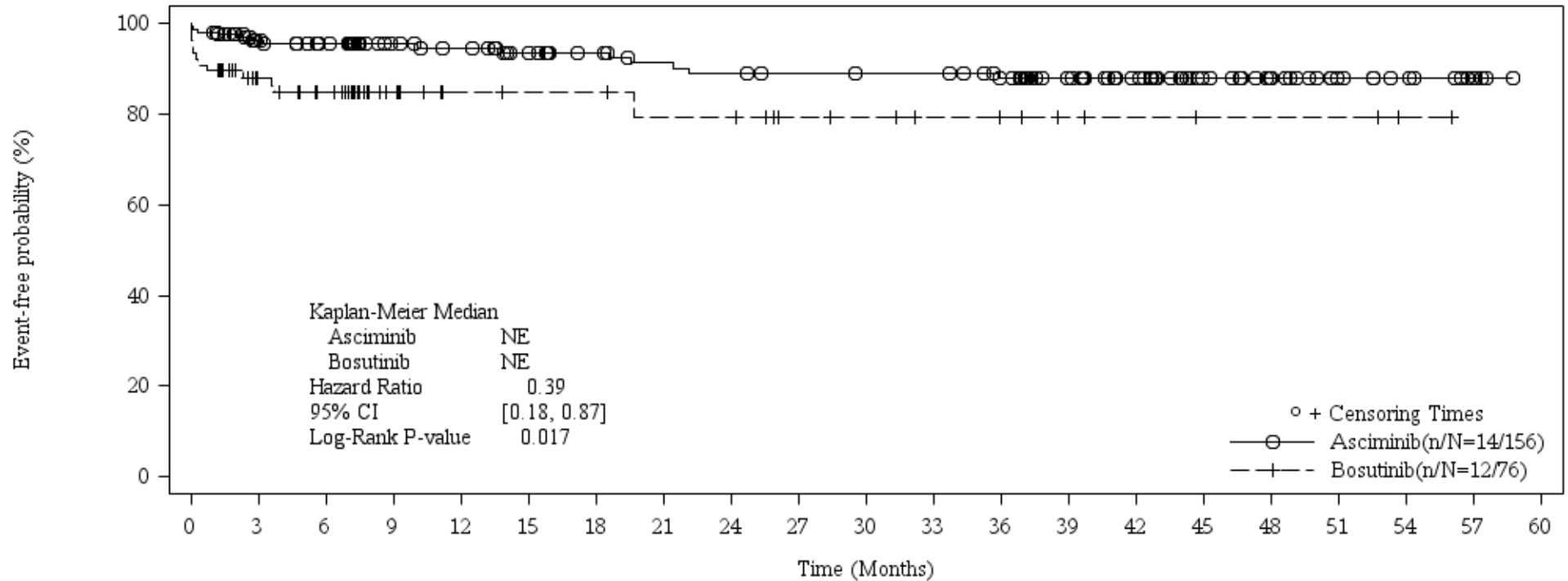
N*: Number of patients included in the analysis. - NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

Figure 4-1.3.1 (Page 1 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Abdominal pain



Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	126	106	101	92	87	82	80	78	77	77	71	57	45	31	23	15	11	4	0
Bosutinib	76	53	43	25	18	17	17	15	15	11	10	8	7	5	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

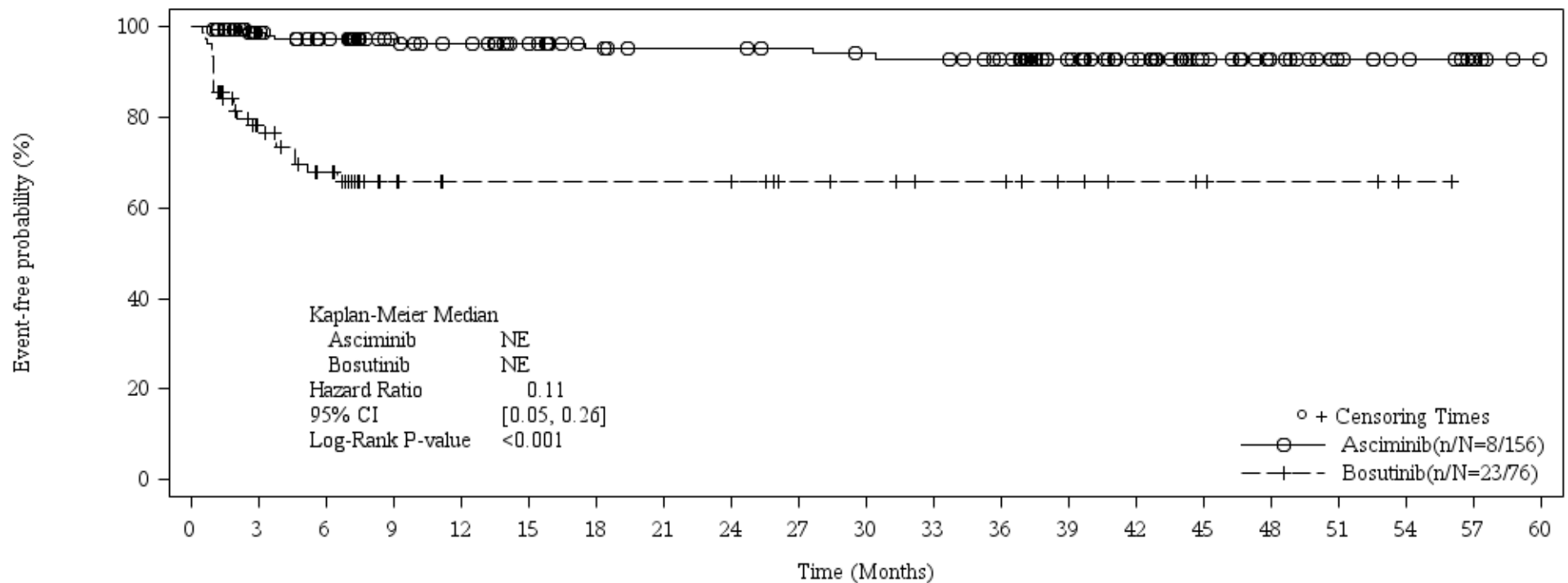
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 2 of 27)

Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

PT: Alanine aminotransferase increased



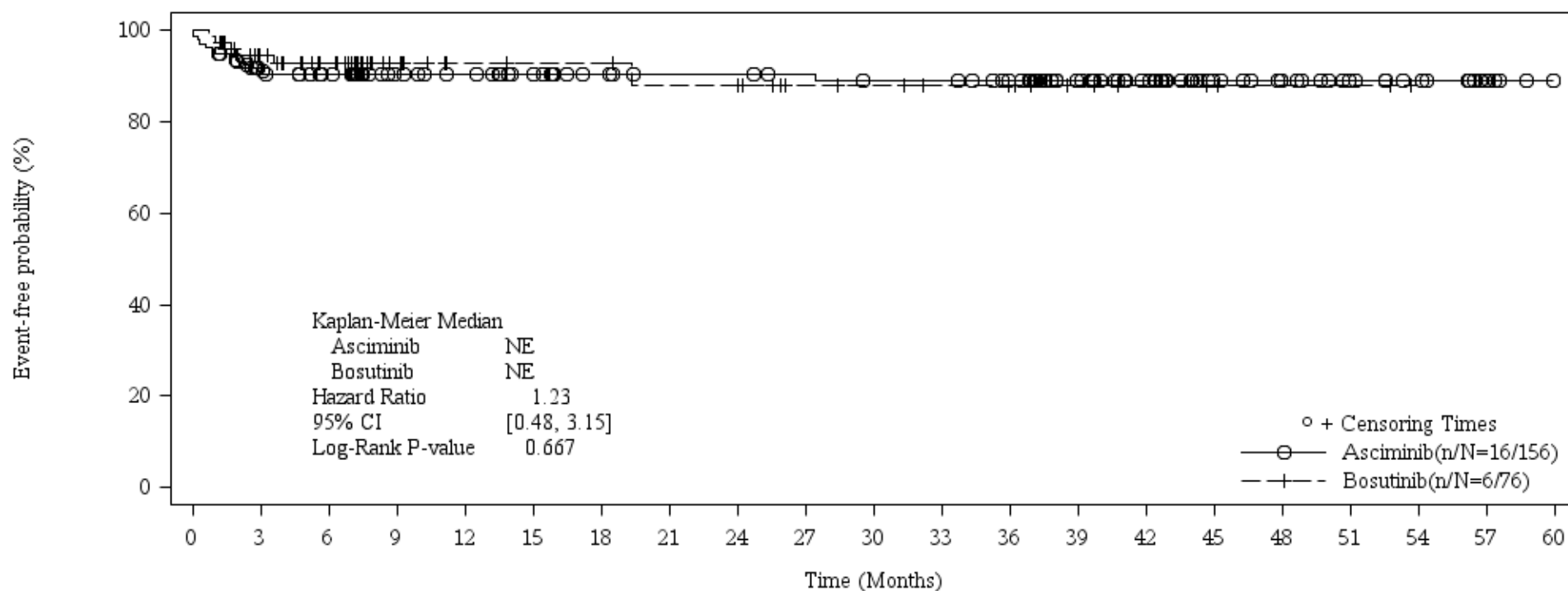
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	126	106	101	93	86	83	83	81	79	78	73	58	44	31	23	15	11	5	0
Bosutinib	76	48	35	21	17	17	17	17	17	13	12	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 3 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Anaemia



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	132	121	101	97	90	84	81	81	79	77	77	72	57	43	29	23	17	13	5	0
Bosutinib	76	58	45	28	21	20	20	18	18	13	12	10	9	6	4	3	2	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

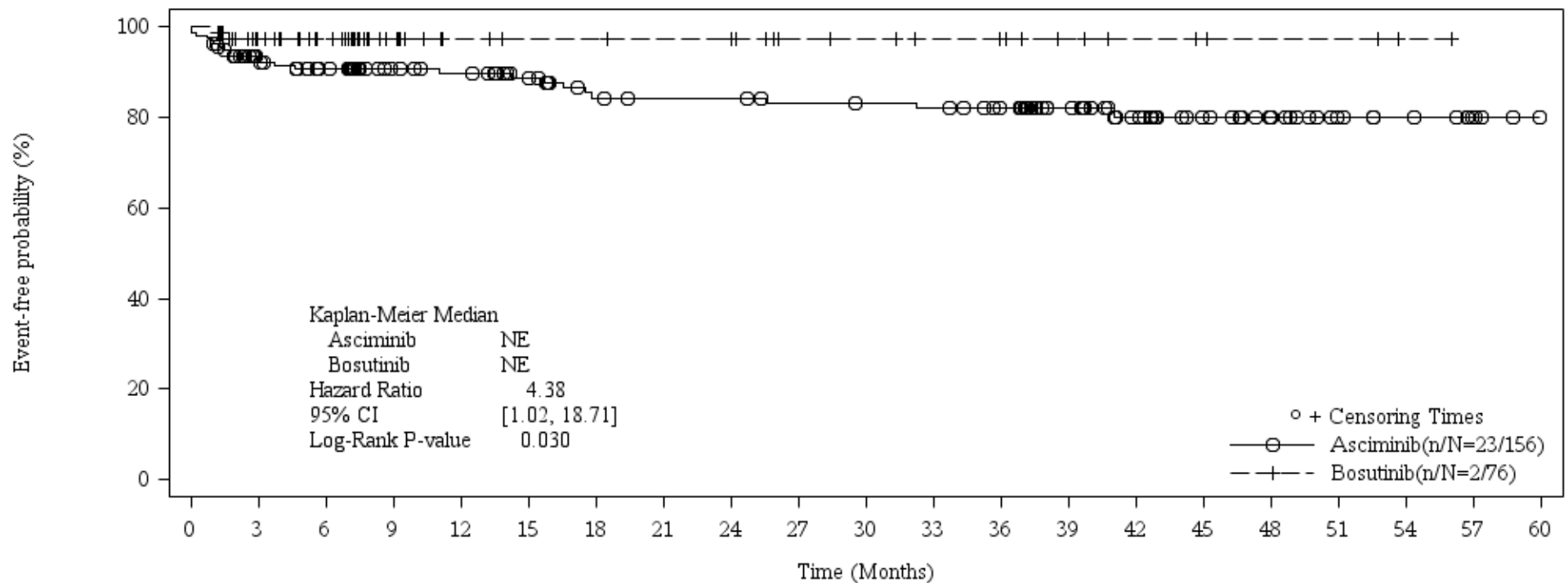
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 4 of 27)

Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

PT: Arthralgia



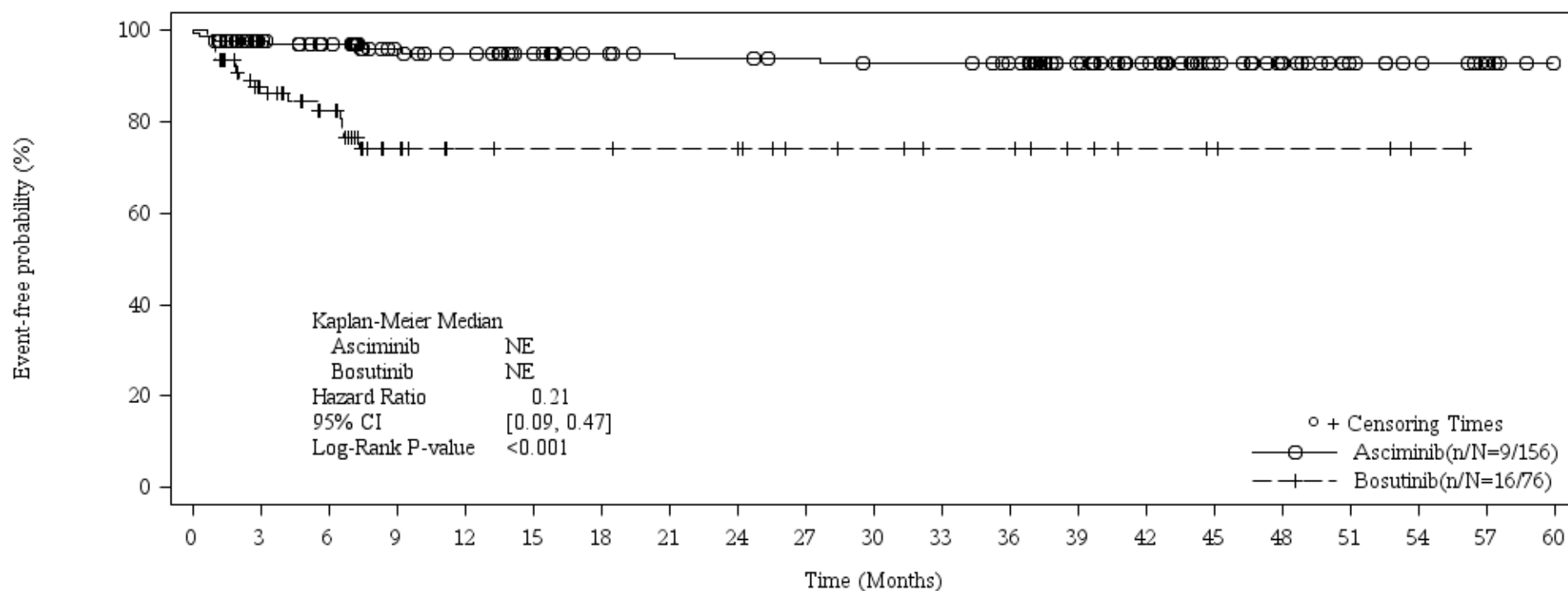
		Number of patients still at risk																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	130	117	97	93	84	75	73	73	70	69	68	63	50	37	27	19	12	9	4	0
Bosutinib	76	60	48	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 5 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Aspartate aminotransferase increased



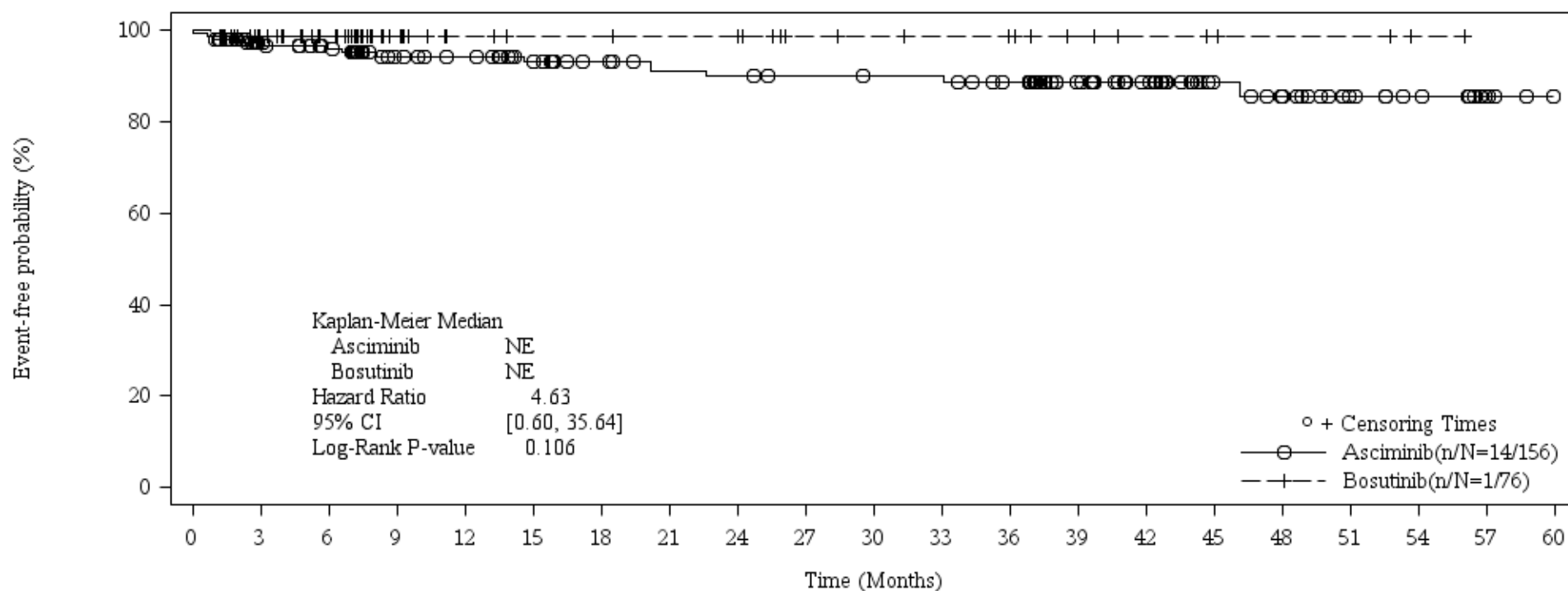
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	138	126	105	100	92	86	83	82	80	78	78	74	57	43	30	22	14	10	5	0
Bosutinib	76	55	43	25	19	18	18	17	17	13	12	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 6 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Asthenia



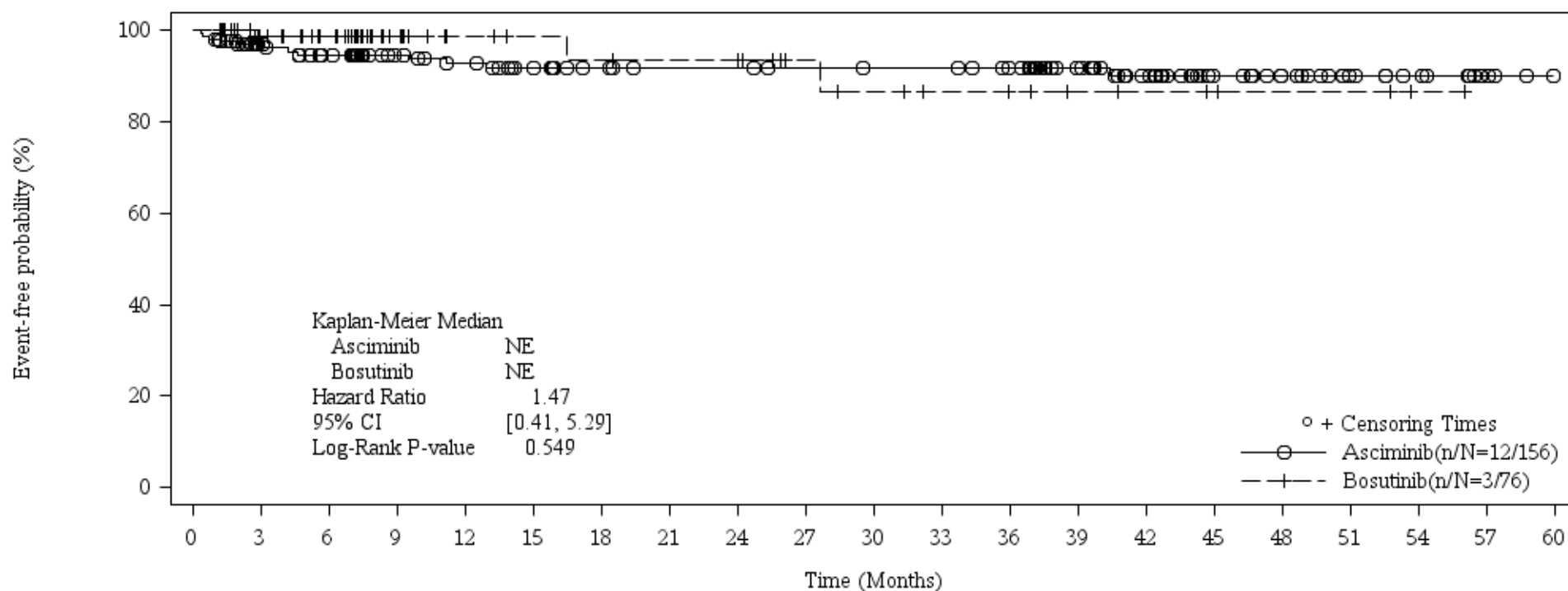
Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	137	124	104	100	91	85	80	79	77	76	76	71	55	42	28	23	15	11	4	0
Bosutinib	76	61	49	29	21	19	19	18	18	13	12	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 7 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Back pain



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	122	101	95	87	82	79	79	77	76	76	72	56	42	29	23	15	11	4	0
Bosutinib	76	61	50	30	22	20	19	18	18	13	11	9	8	6	5	4	3	3	1	0	0

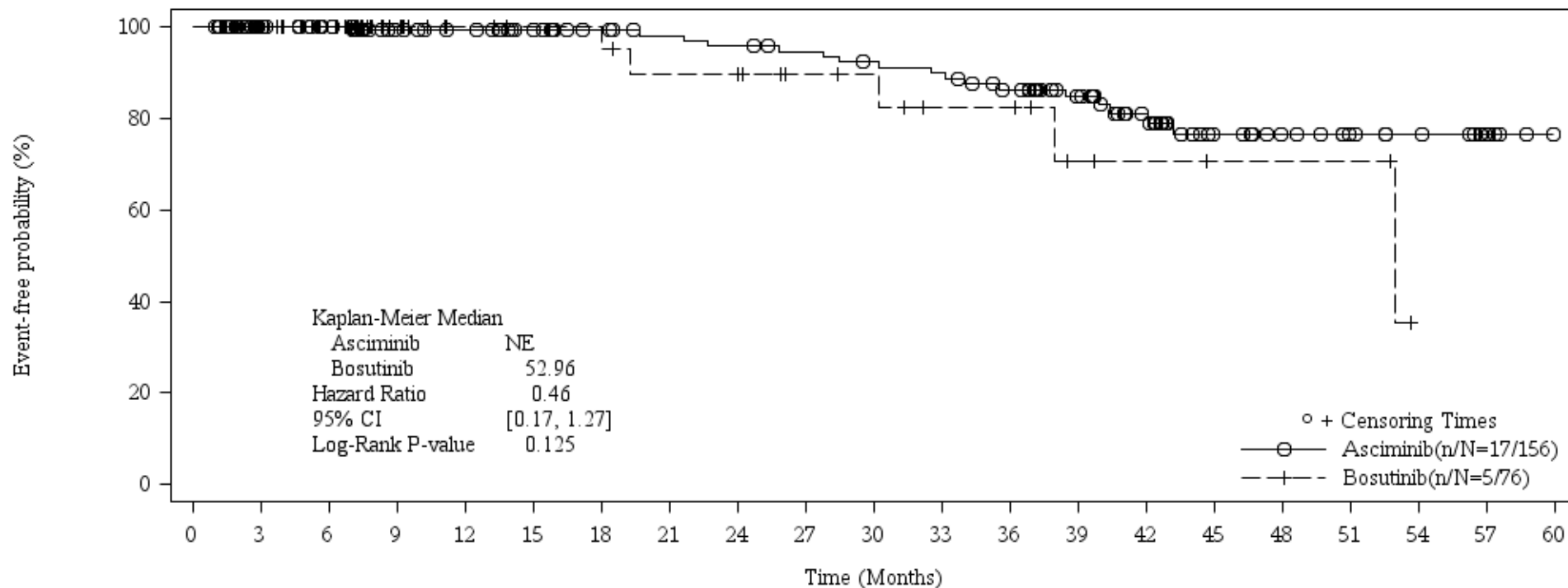
Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 8 of 27)

Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: COVID-19



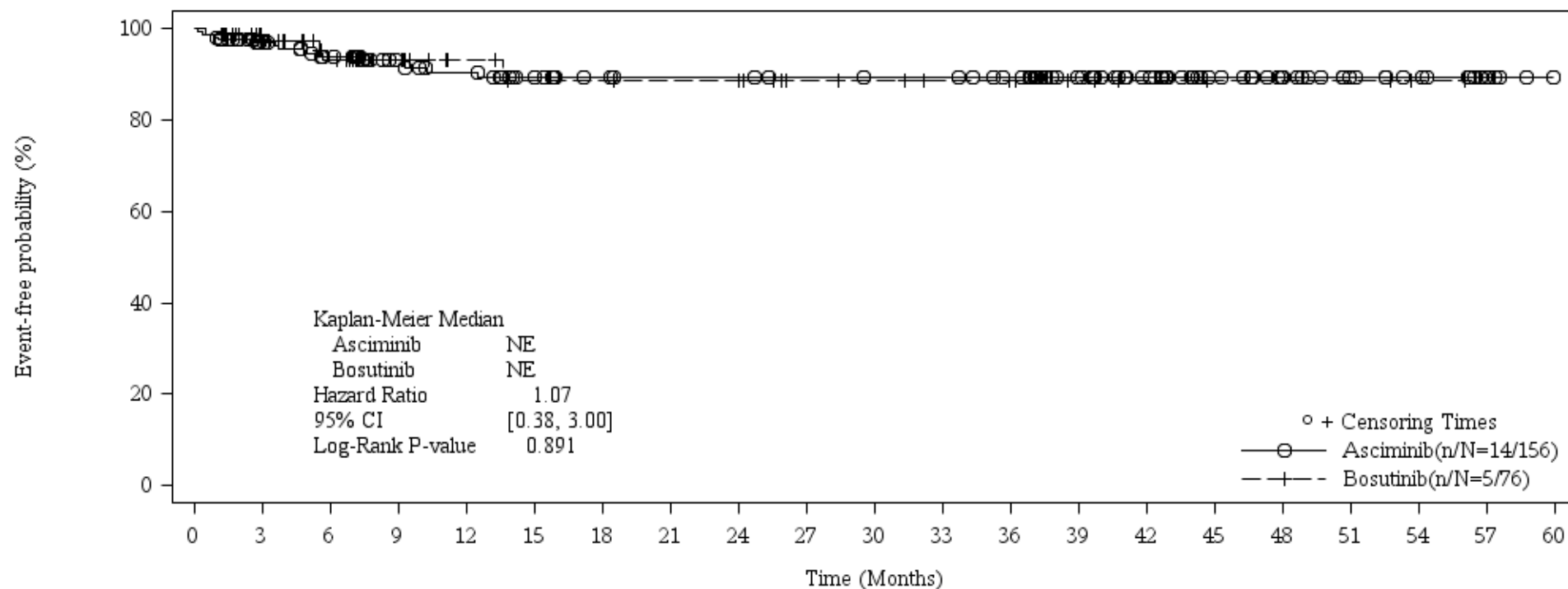
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	86	84	81	78	76	69	54	39	24	19	14	11	5	0
Bosutinib	76	62	50	30	22	20	20	17	17	13	12	9	9	5	4	3	3	3	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 9 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Cough



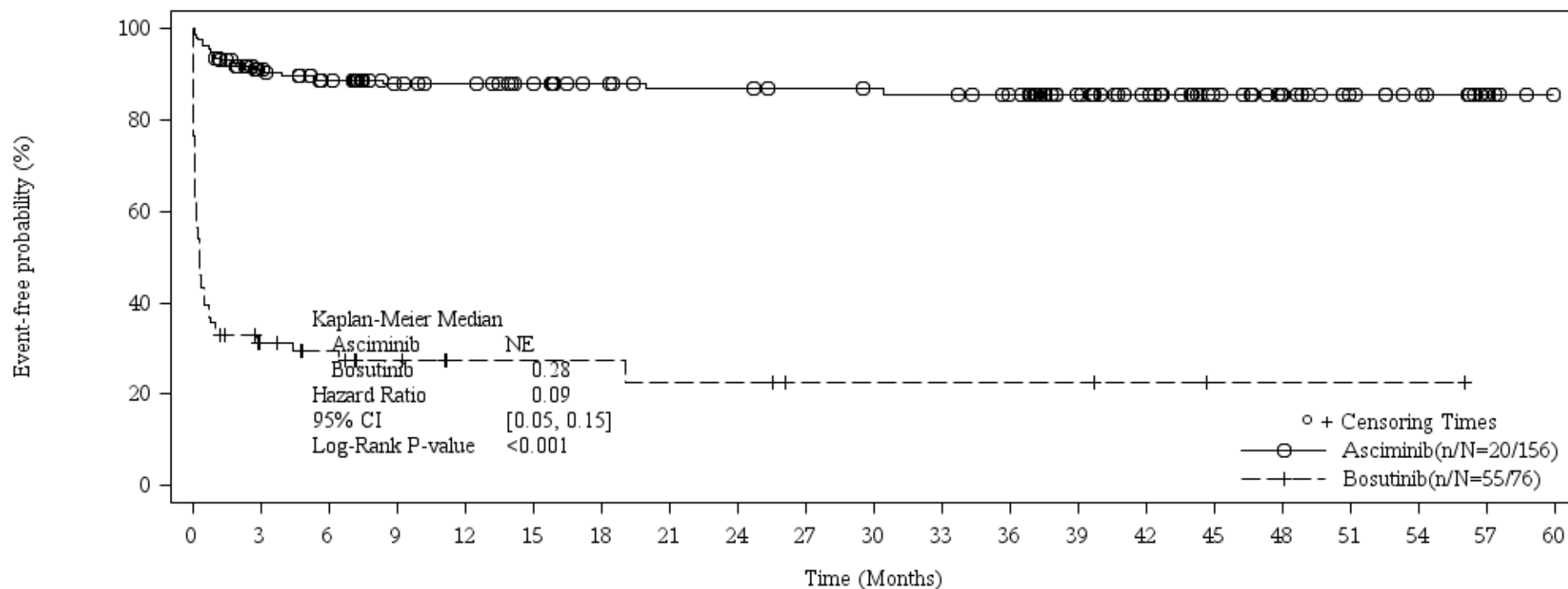
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	138	124	103	97	88	83	81	81	79	78	78	74	59	45	32	24	17	13	5	0
Bosutinib	76	61	46	29	21	18	18	17	17	12	11	9	8	6	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 10 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Diarrhoea



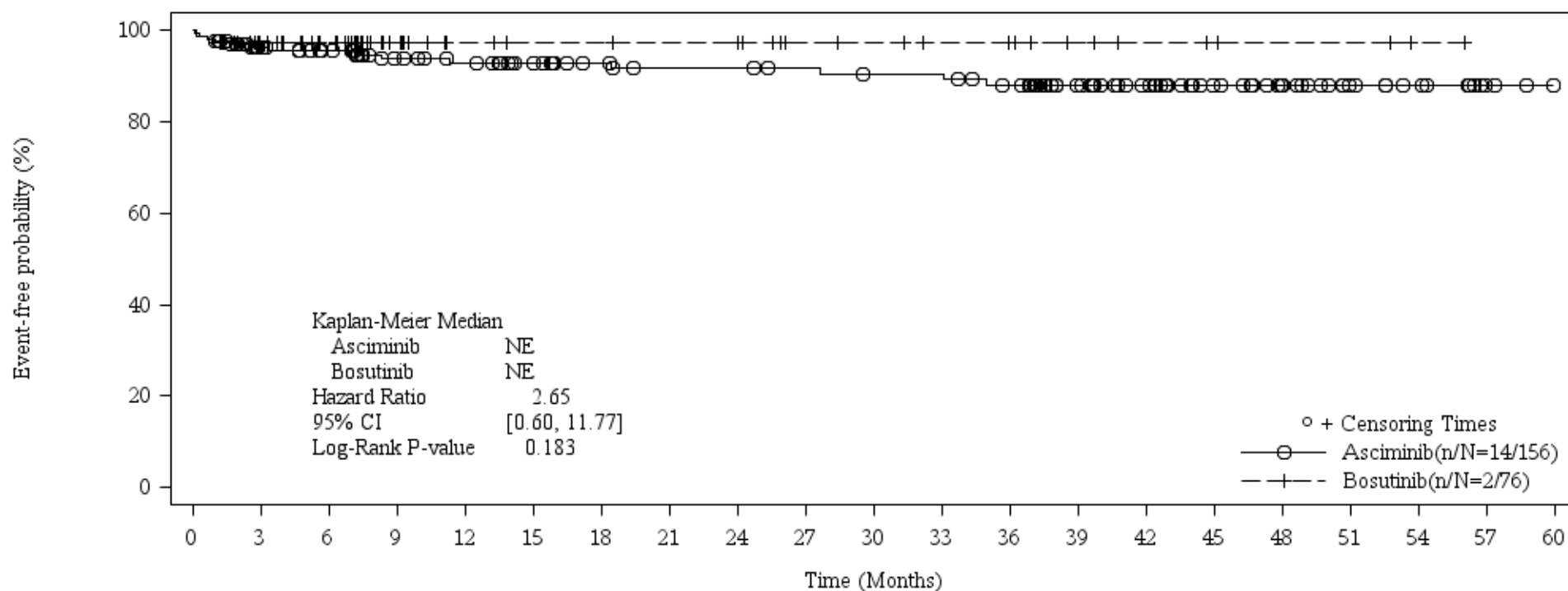
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	128	114	98	95	88	83	79	79	77	76	75	71	56	43	32	24	17	13	5	0
Bosutinib	76	18	13	9	6	6	6	5	5	3	3	3	3	3	2	1	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 11 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Dizziness



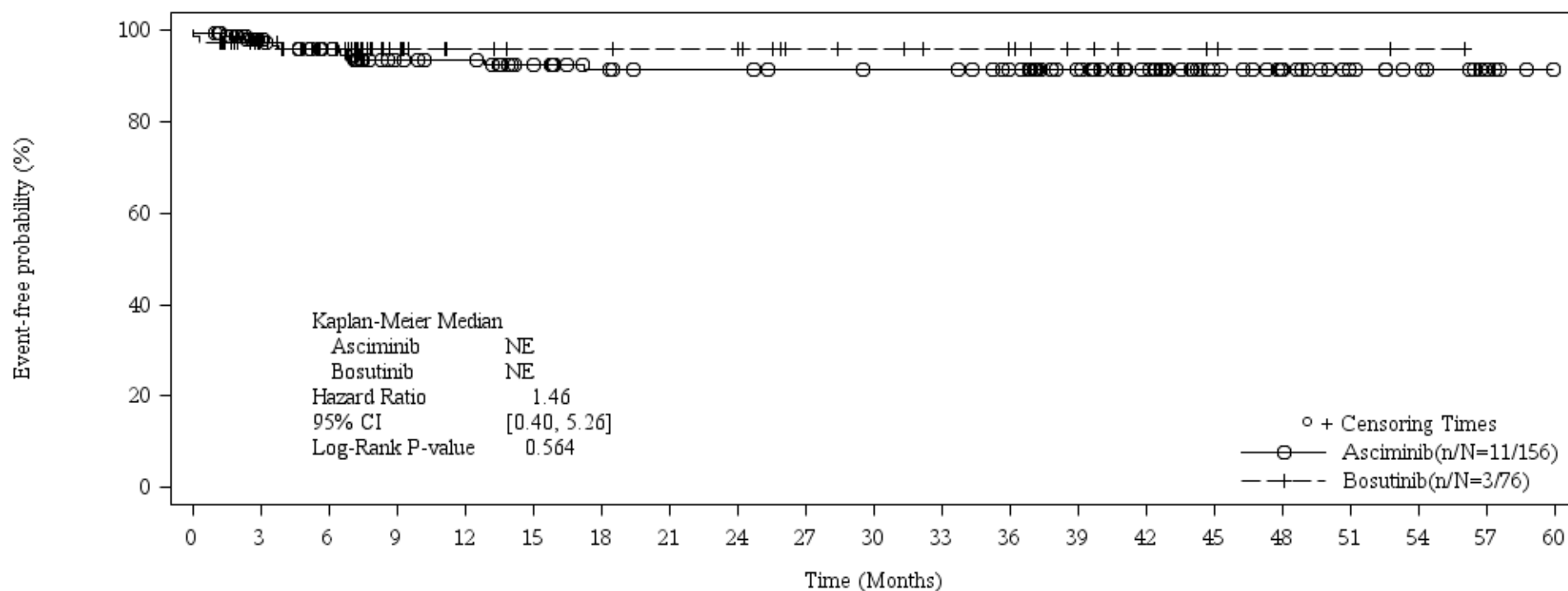
Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	135	123	103	98	90	84	80	80	78	76	76	71	55	42	30	22	14	10	3	0
Bosutinib	76	61	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 12 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Dyspepsia



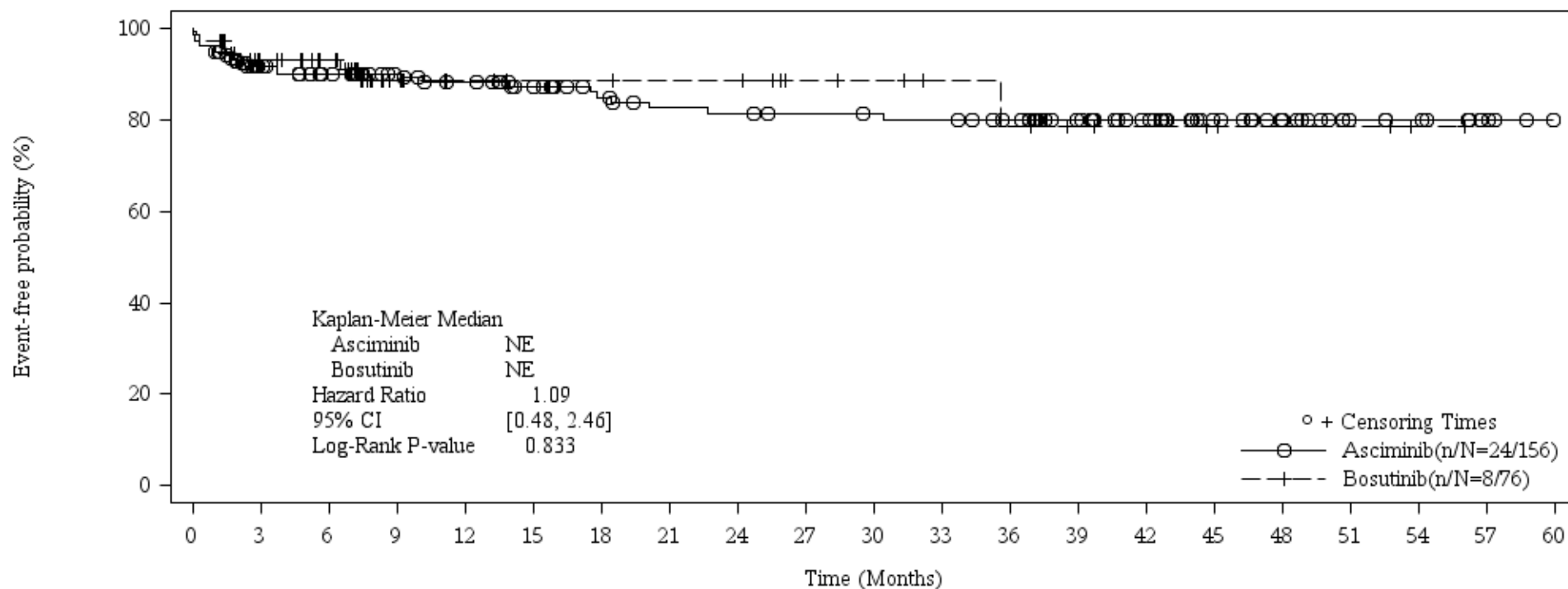
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	138	124	101	98	89	83	80	80	78	77	77	72	57	45	30	22	15	11	5	0
Bosutinib	76	60	47	28	21	19	19	18	18	13	12	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 13 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Fatigue



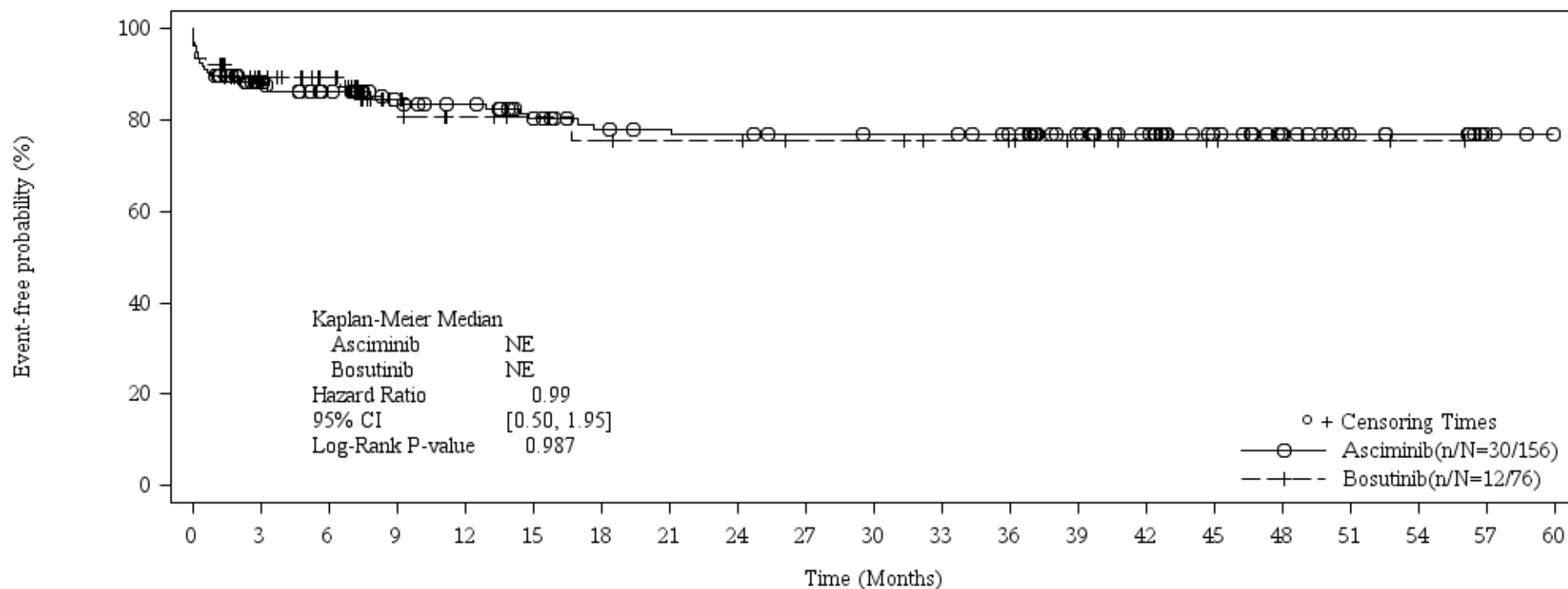
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	128	115	97	91	82	74	69	68	66	65	64	60	48	39	28	20	12	10	4	0
Bosutinib	76	57	47	25	19	17	17	16	16	12	11	9	8	6	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 14 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Headache



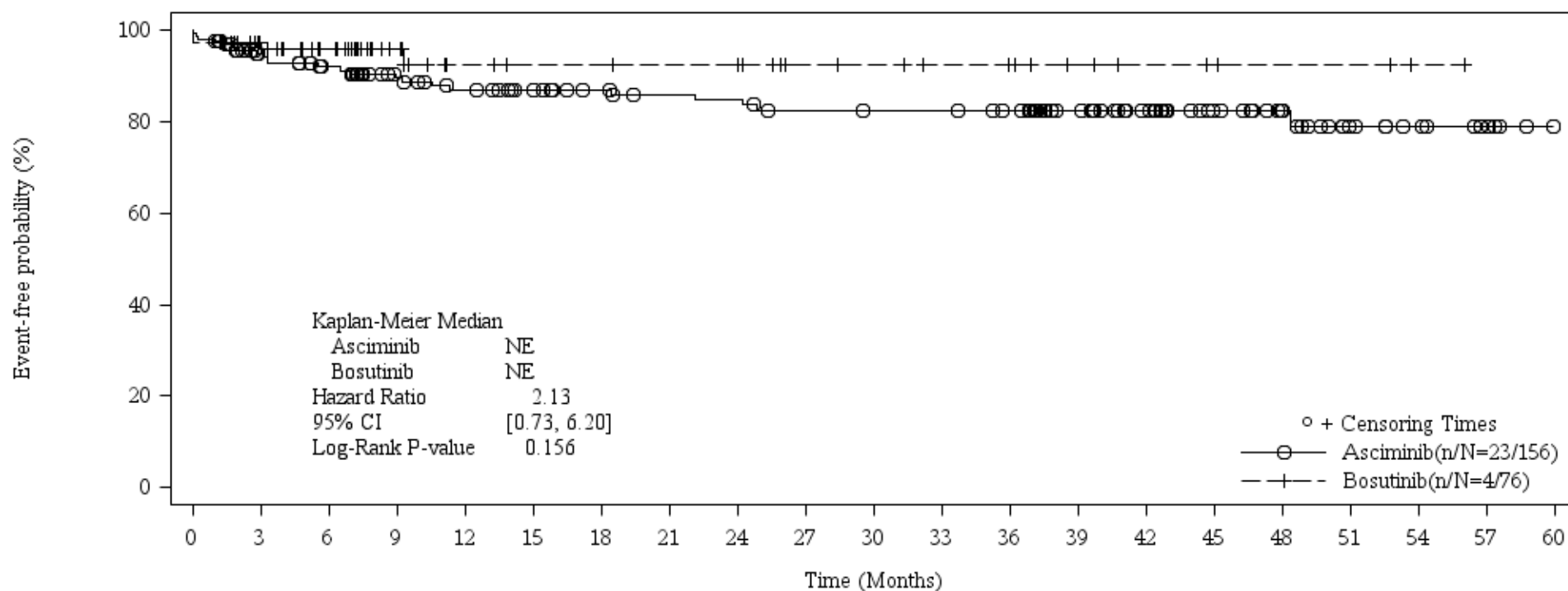
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	124	110	88	83	73	67	65	64	62	61	61	57	45	36	26	18	11	9	3	0
Bosutinib	76	54	43	24	17	15	14	13	13	11	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 15 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Hypertension



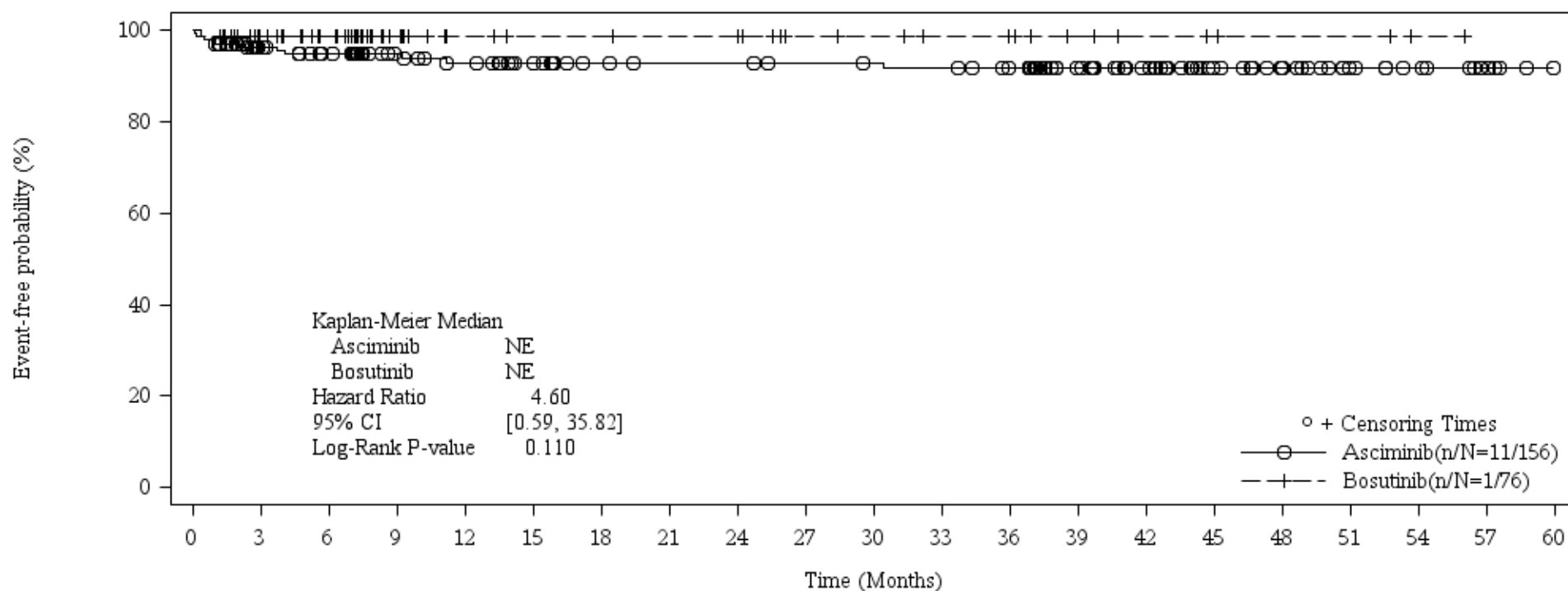
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	134	122	102	95	88	83	79	78	74	73	73	70	56	43	31	23	14	10	5	0
Bosutinib	76	61	48	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 16 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Insomnia



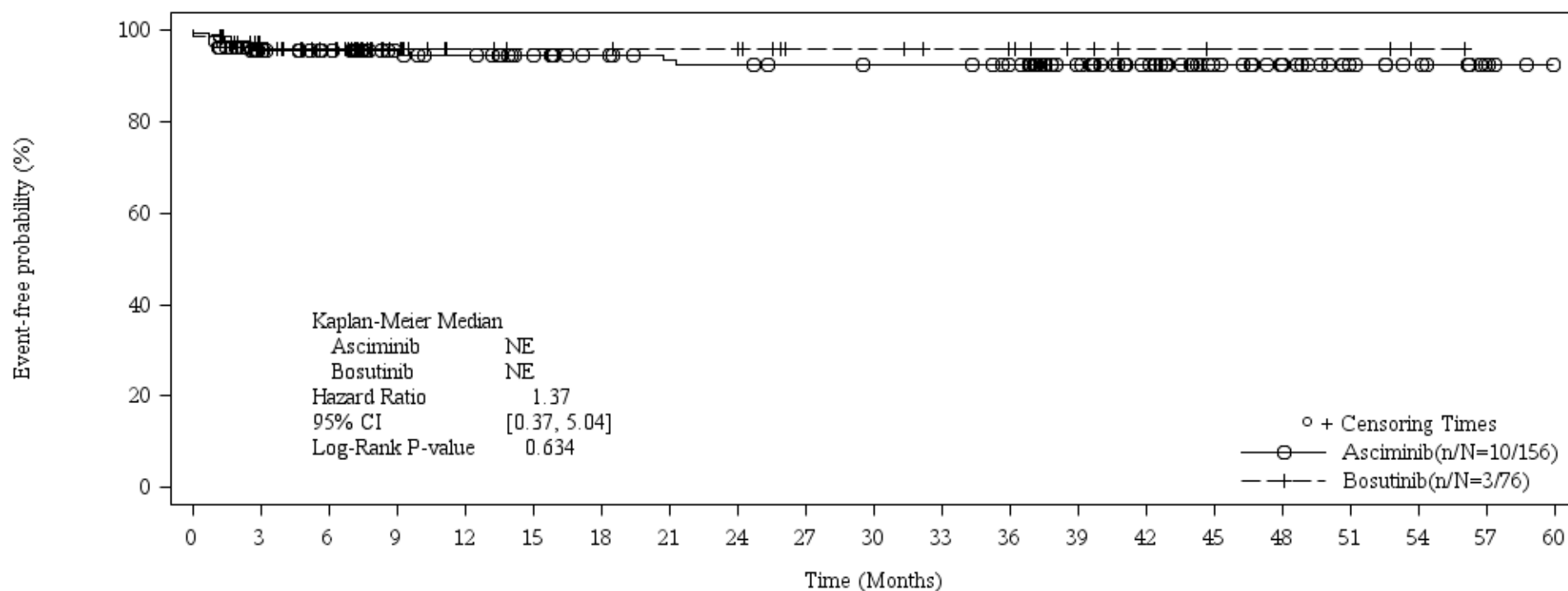
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	135	123	103	97	89	83	81	81	79	78	77	73	57	45	31	23	15	11	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 17 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Myalgia



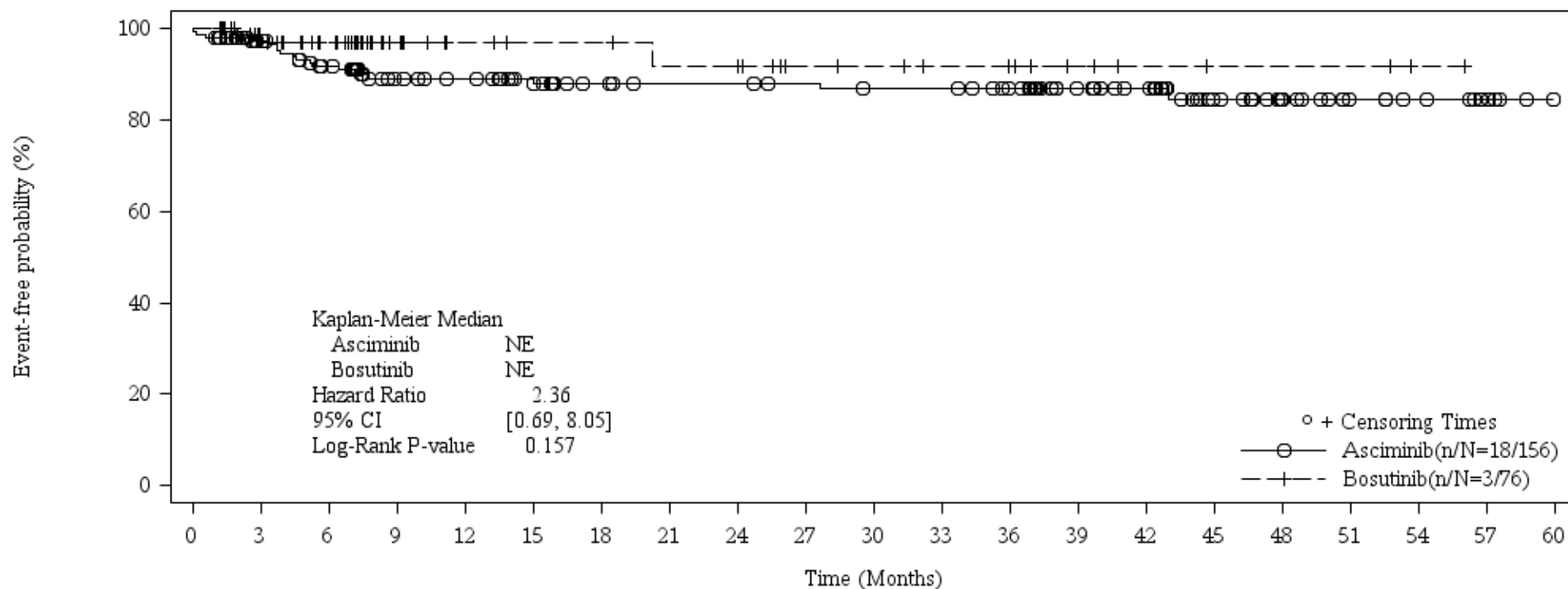
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	135	125	104	100	92	87	83	82	80	79	79	75	59	45	31	23	15	11	4	0
Bosutinib	76	60	48	28	20	18	18	17	17	12	12	10	9	6	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 18 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Nasopharyngitis



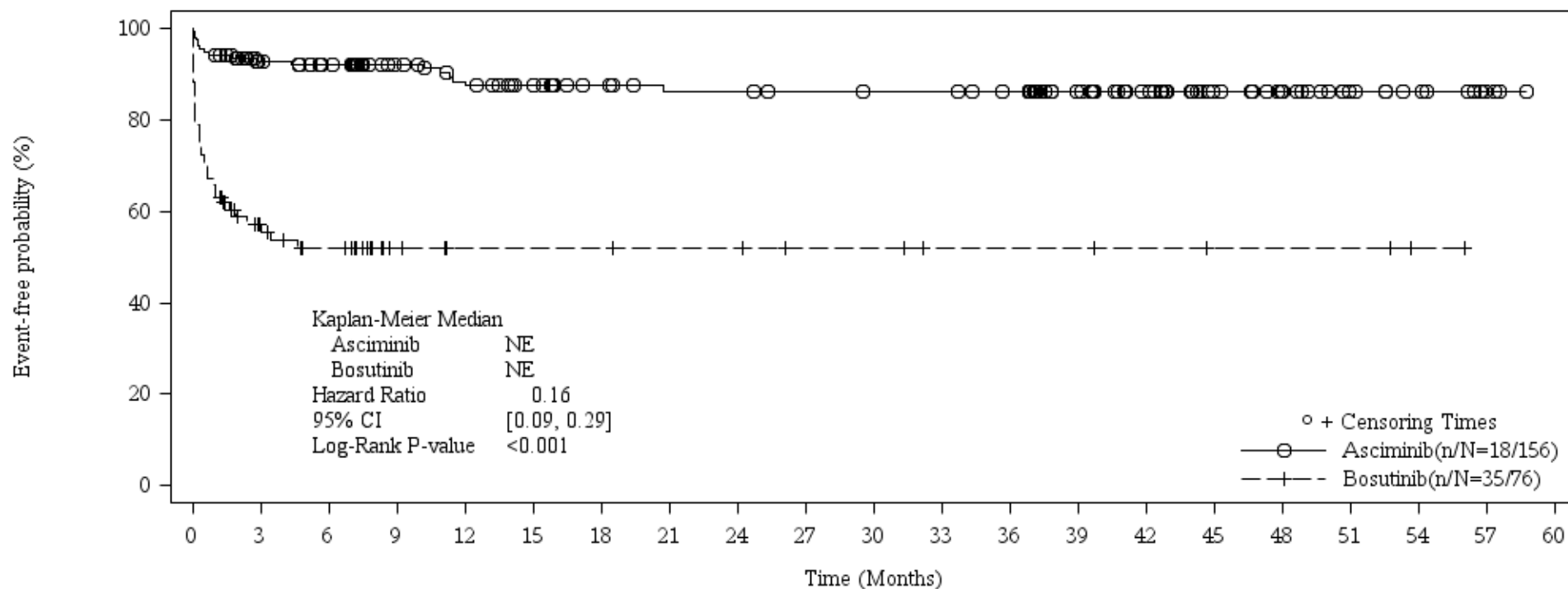
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	138	119	96	92	83	77	74	74	72	70	70	65	50	43	29	20	13	10	5	0
Bosutinib	76	61	48	29	22	20	20	18	18	13	12	10	9	6	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 19 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Nausea



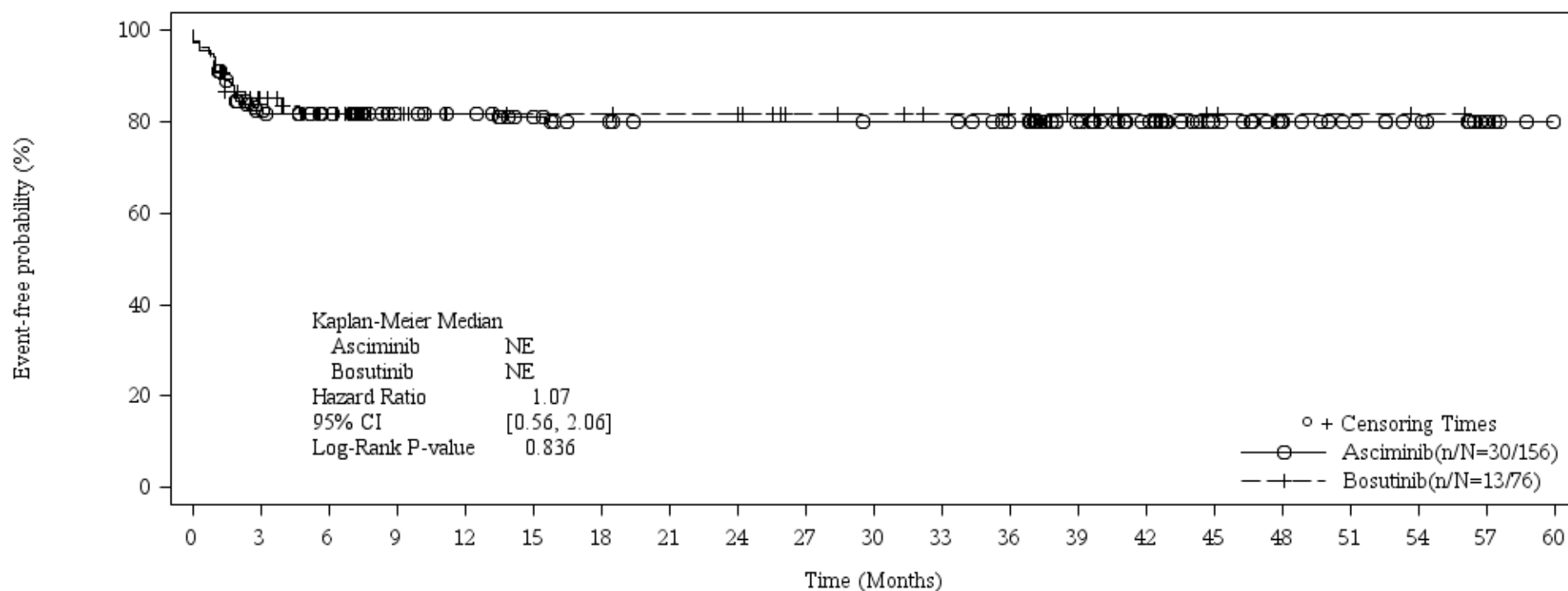
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	131	120	100	91	84	78	74	74	72	71	71	68	54	41	29	22	14	10	3	0
Bosutinib	76	33	25	13	10	10	10	9	9	7	7	5	5	5	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 20 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Neutropenia



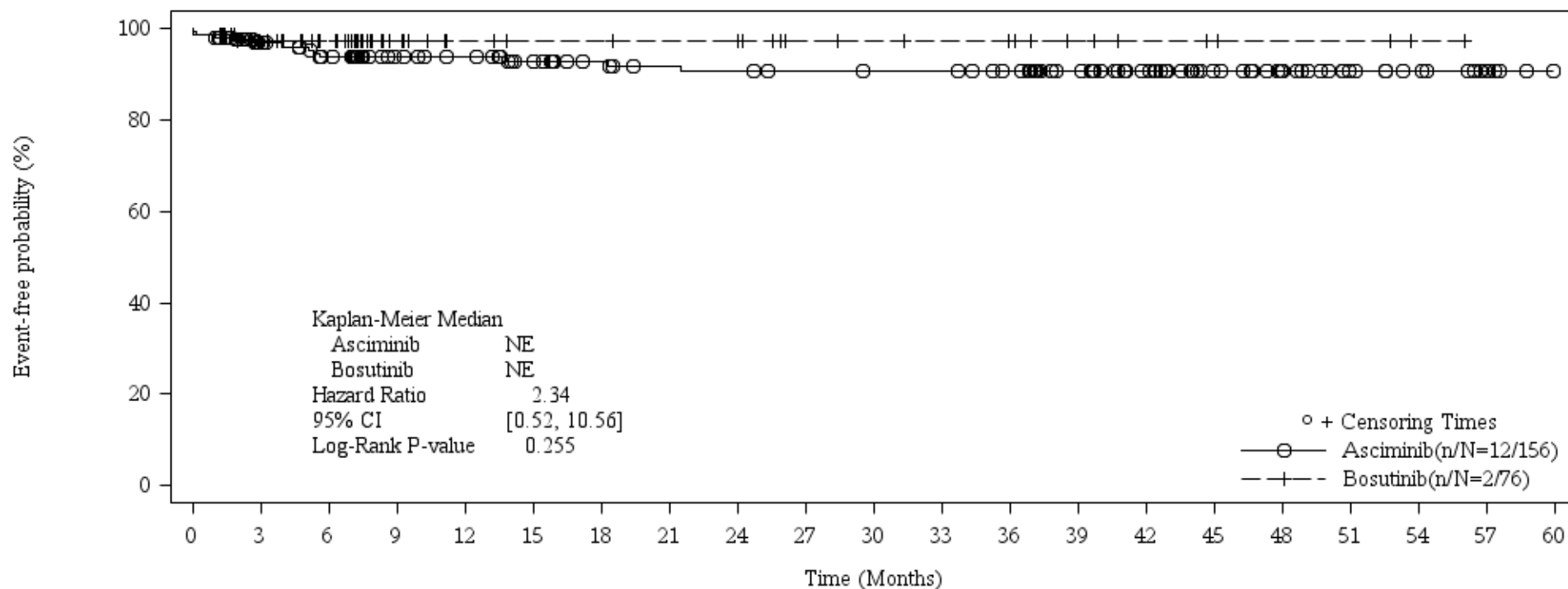
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	119	107	94	91	83	78	75	75	75	74	74	69	56	43	29	21	17	13	5	0
Bosutinib	76	54	42	27	20	18	18	17	17	12	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 21 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Oedema peripheral



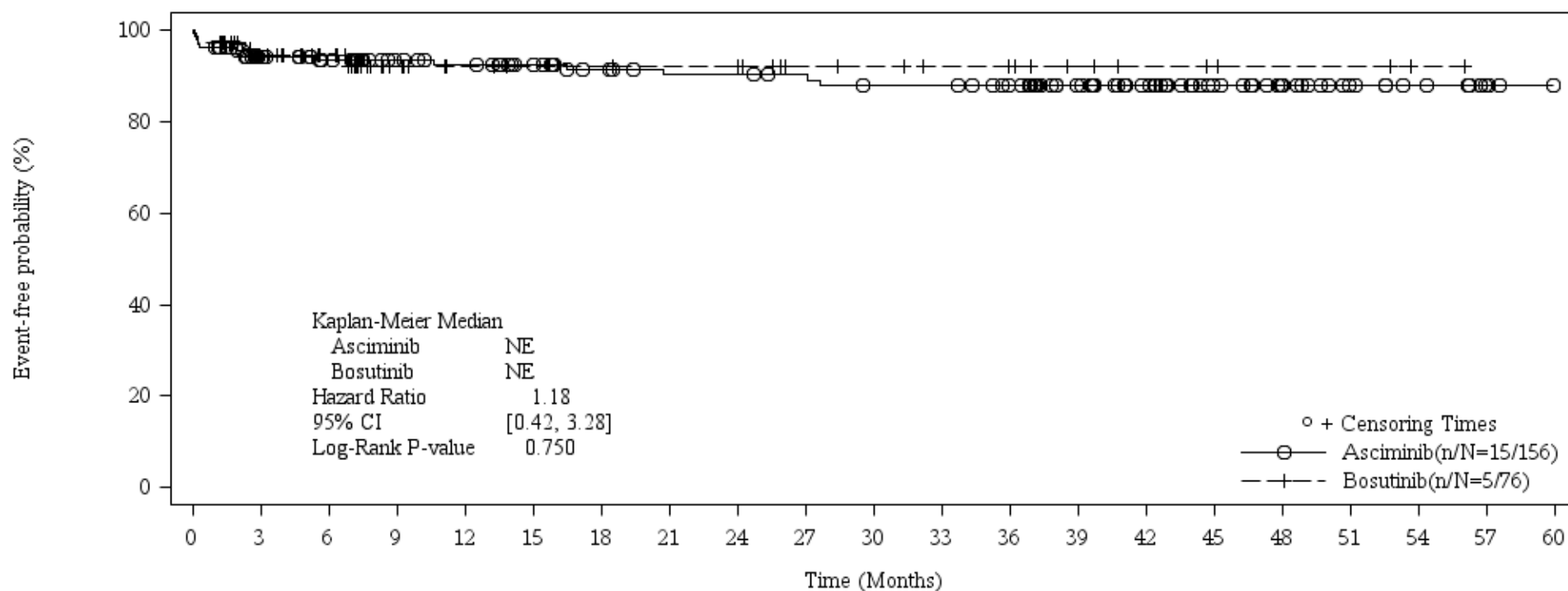
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	122	103	99	90	84	80	79	77	76	76	72	59	45	33	24	16	12	5	0
Bosutinib	76	60	48	28	21	19	19	18	18	13	12	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 22 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Pain in extremity



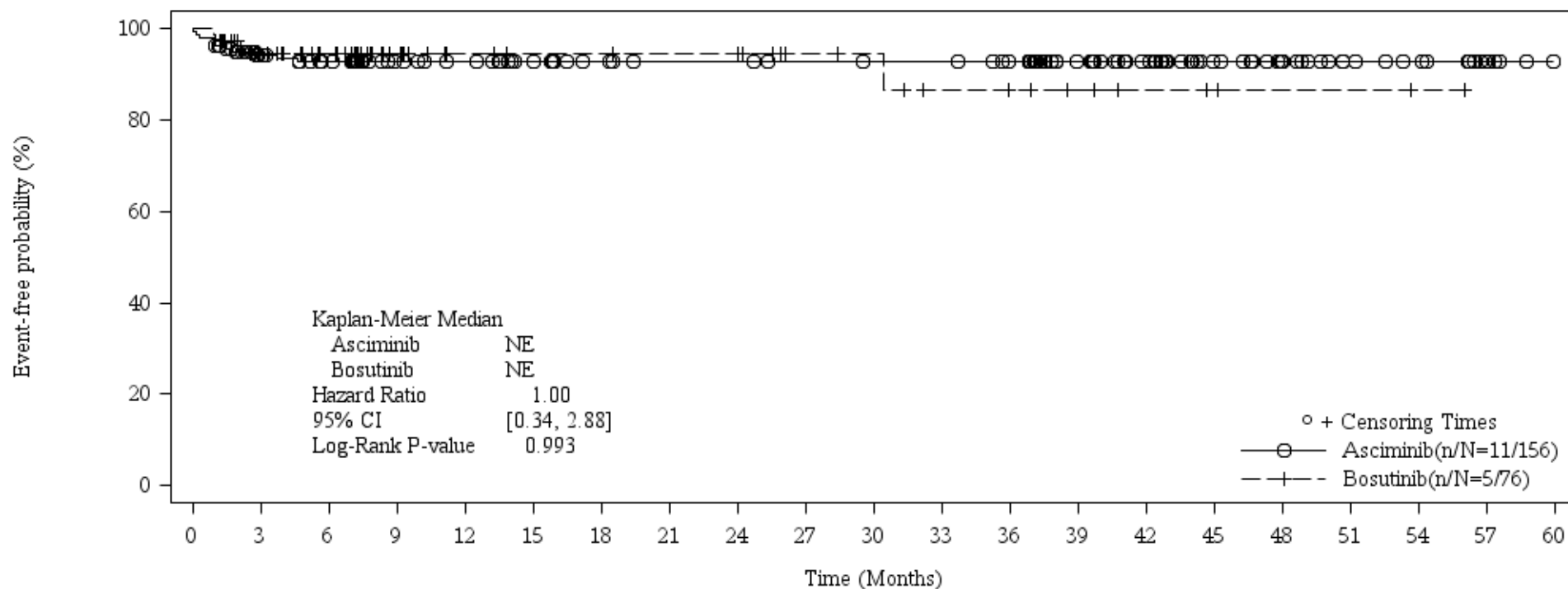
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	132	121	101	97	89	82	78	78	76	73	73	68	54	42	29	20	13	9	3	0
Bosutinib	76	58	46	27	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 23 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Platelet count decreased



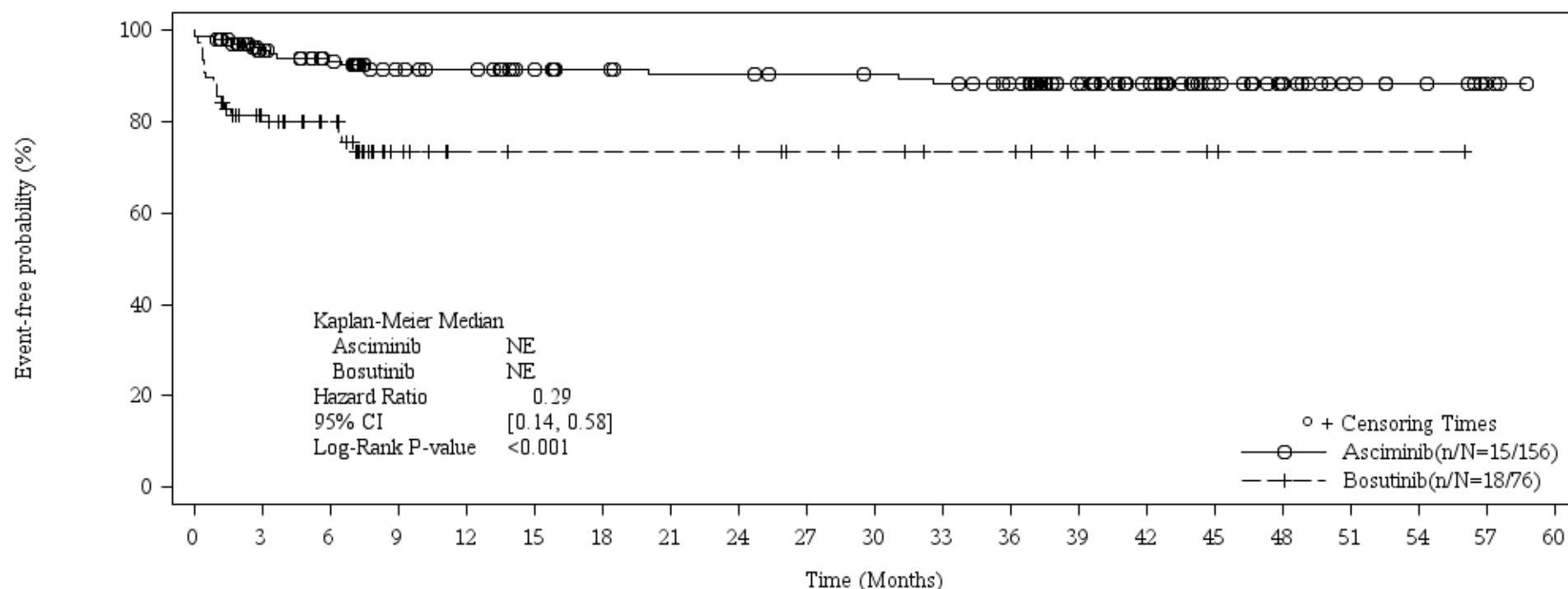
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	132	121	101	97	89	84	81	81	79	78	78	74	58	45	31	22	15	12	5	0
Bosutinib	76	58	46	29	21	19	19	18	18	13	12	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 24 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Rash



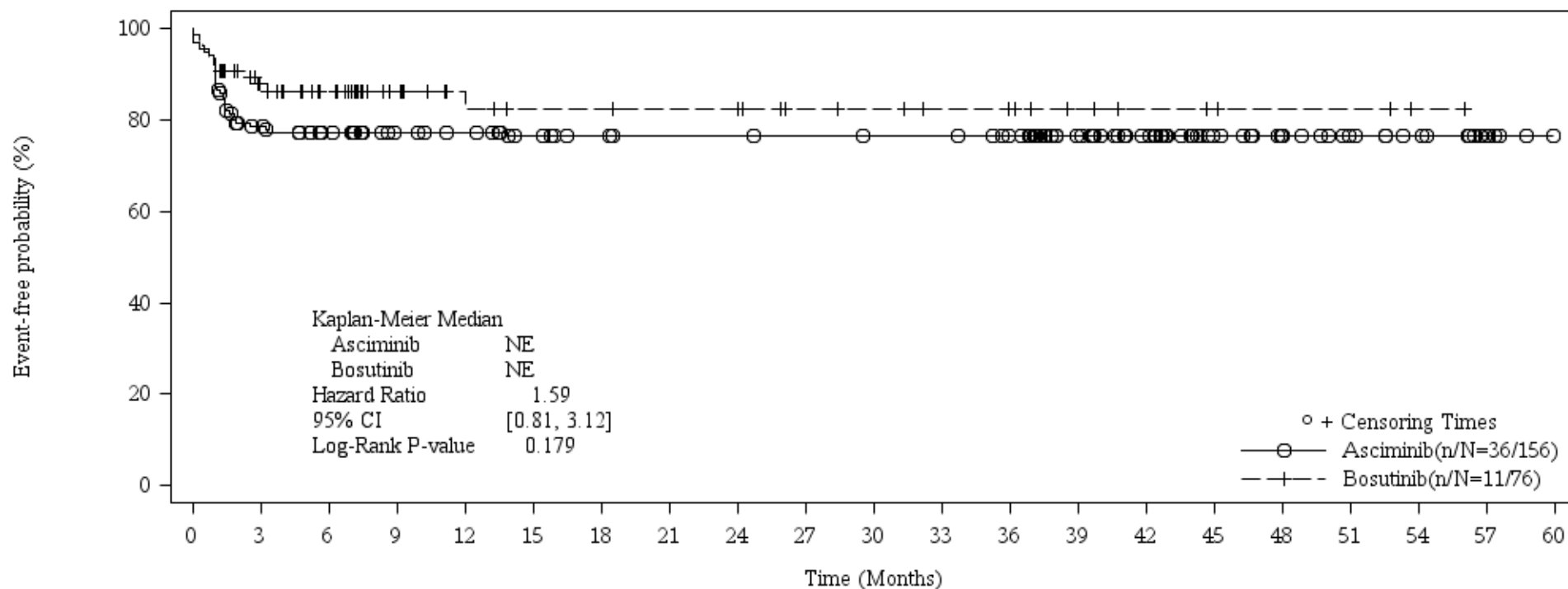
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	134	120	100	97	89	86	83	83	81	80	78	73	56	42	28	19	12	9	3	0
Bosutinib	76	50	39	20	14	13	13	13	13	10	9	7	7	4	3	2	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 25 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Thrombocytopenia



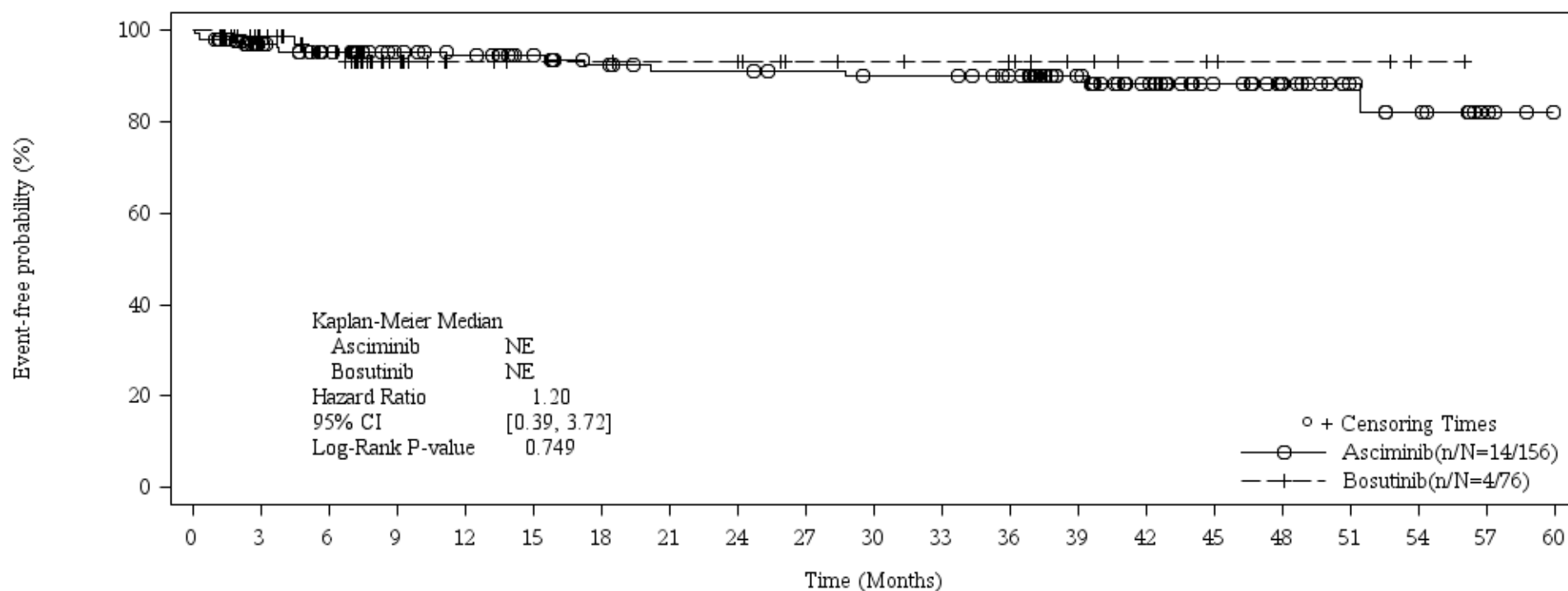
Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	116	104	94	91	84	80	78	78	77	76	76	72	58	44	30	22	17	13	5	0
Bosutinib	76	55	43	29	21	19	19	18	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 26 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Upper respiratory tract infection



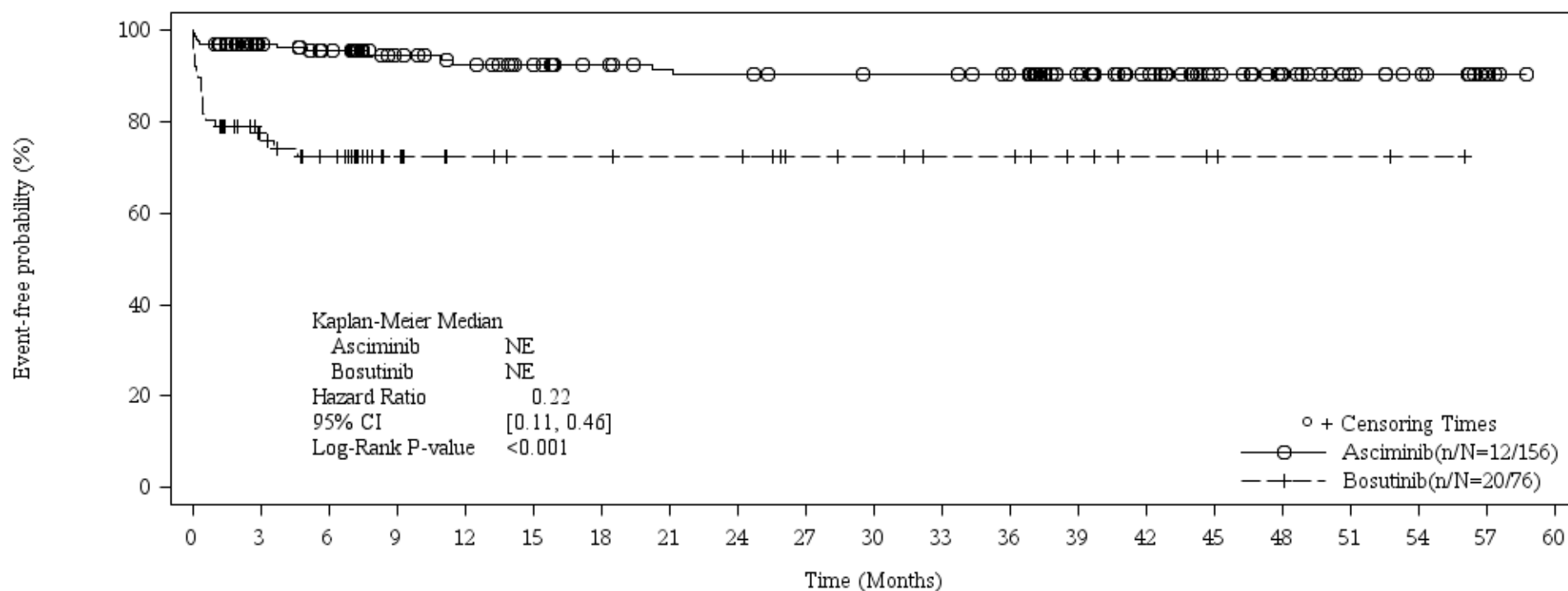
Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	124	105	100	92	86	82	82	80	78	78	73	57	43	31	23	15	11	4	0
Bosutinib	76	61	47	27	20	18	18	17	17	13	12	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Figure 4-1.3.1 (Page 27 of 27)
Any AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Vomiting



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	124	103	97	90	85	81	80	78	77	77	73	57	44	32	24	16	12	4	0
Bosutinib	76	46	38	24	19	17	17	16	16	12	11	9	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. MedDRA version 26.0

Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
Safety Set
(Page 1 of 54)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Abdominal pain					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	12 (15.8)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	137 (87.8)	42 (55.3)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.71, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.41	[0.19, 0.90]	0.023
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.91, 0.98]	0.88 [0.78, 0.94]			
Month 6	0.95 [0.90, 0.98]	0.85 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_3_2.sas@@/main/3 22NOV23:11:01

Final

Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 54)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]		0.85 [0.74, 0.91]			
Month 12	0.94 [0.89, 0.97]		0.85 [0.74, 0.91]			
Month 15	0.93 [0.88, 0.97]		0.85 [0.74, 0.91]			
Month 18	0.93 [0.88, 0.97]		0.85 [0.74, 0.91]			
Month 21	0.91 [0.84, 0.95]		0.79 [0.63, 0.89]			
Month 24	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 27	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 30	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 33	0.89 [0.82, 0.94]		0.79 [0.63, 0.89]			
Month 36	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 39	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 42	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 45	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 48	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 51	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 54	0.88 [0.80, 0.93]		0.79 [0.63, 0.89]			
Month 57	0.88 [0.80, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t41_3_2.sas@@/main/3 22NOV23:11:01

Final

Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
 Safety Set
 (Page 3 of 54)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Alanine aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	23 (30.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	143 (91.7)	38 (50.0)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	3.71 [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.12	[0.05, 0.27]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.78 [0.67, 0.86]			
Month 6	0.97 [0.93, 0.99]	0.68 [0.55, 0.78]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.97 [0.93, 0.99]		0.66 [0.53, 0.76]			
Month 12	0.96 [0.91, 0.98]		0.66 [0.53, 0.76]			
Month 15	0.96 [0.91, 0.98]		0.66 [0.53, 0.76]			
Month 18	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 21	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 24	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 27	0.95 [0.89, 0.98]		0.66 [0.53, 0.76]			
Month 30	0.94 [0.88, 0.97]		0.66 [0.53, 0.76]			
Month 33	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 36	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 39	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 42	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 45	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 48	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 51	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 54	0.93 [0.86, 0.96]		0.66 [0.53, 0.76]			
Month 57	0.93 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Anaemia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	6 (7.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	48 (63.2)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.23	[0.48, 3.15]	0.670
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.95 [0.86, 0.98]			
Month 6	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			
Month 12	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			
Month 15	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			
Month 18	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			
Month 21	0.90 [0.84, 0.94]	0.88 [0.71, 0.95]			
Month 24	0.90 [0.84, 0.94]	0.88 [0.71, 0.95]			
Month 27	0.90 [0.84, 0.94]	0.88 [0.71, 0.95]			
Month 30	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 33	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 36	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 39	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 42	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 45	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 48	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 51	0.89 [0.83, 0.93]	0.88 [0.71, 0.95]			
Month 54	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 57	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arthralgia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	23 (14.7)	2 (2.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	128 (82.1)	50 (65.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [25.53, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.29	[1.01, 18.32]	0.032
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.87, 0.95]	0.97 [0.90, 0.99]			
Month 6	0.91 [0.85, 0.94]	0.97 [0.90, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.94]		0.97 [0.90, 0.99]			
Month 12	0.90 [0.83, 0.94]		0.97 [0.90, 0.99]			
Month 15	0.89 [0.82, 0.93]		0.97 [0.90, 0.99]			
Month 18	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 21	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 24	0.84 [0.76, 0.90]		0.97 [0.90, 0.99]			
Month 27	0.83 [0.75, 0.89]		0.97 [0.90, 0.99]			
Month 30	0.83 [0.75, 0.89]		0.97 [0.90, 0.99]			
Month 33	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 36	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 39	0.82 [0.73, 0.88]		0.97 [0.90, 0.99]			
Month 42	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 45	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 48	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 51	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 54	0.80 [0.70, 0.87]		0.97 [0.90, 0.99]			
Month 57	0.80 [0.70, 0.87]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Aspartate aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	16 (21.1)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	143 (91.7)	41 (53.9)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	7.33 [4.17, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.09, 0.49]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.88 [0.77, 0.93]			
Month 6	0.97 [0.92, 0.99]	0.82 [0.71, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.91, 0.98]		0.74 [0.61, 0.84]			
Month 12	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 15	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 18	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 21	0.95 [0.90, 0.98]		0.74 [0.61, 0.84]			
Month 24	0.94 [0.88, 0.97]		0.74 [0.61, 0.84]			
Month 27	0.94 [0.88, 0.97]		0.74 [0.61, 0.84]			
Month 30	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 33	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 36	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 39	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 42	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 45	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 48	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 51	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 54	0.93 [0.86, 0.96]		0.74 [0.61, 0.84]			
Month 57	0.93 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Asthenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [46.09, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.73	[0.61, 36.45]	0.100
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.96 [0.91, 0.98]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.99 [0.91, 1.00]			
Month 12	0.94 [0.89, 0.97]	0.99 [0.91, 1.00]			
Month 15	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 18	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 21	0.91 [0.84, 0.95]	0.99 [0.91, 1.00]			
Month 24	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 27	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 30	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 33	0.90 [0.82, 0.94]	0.99 [0.91, 1.00]			
Month 36	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 39	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 42	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 45	0.89 [0.81, 0.93]	0.99 [0.91, 1.00]			
Month 48	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 51	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 54	0.85 [0.75, 0.92]	0.99 [0.91, 1.00]			
Month 57	0.85 [0.75, 0.92]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Back pain					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	3 (3.9)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	139 (89.1)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [16.46, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.41	[0.39, 5.06]	0.598
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.90, 1.00]			
Month 6	0.95 [0.89, 0.97]	0.99 [0.90, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.89, 0.97]	0.99 [0.90, 1.00]			
Month 12	0.93 [0.87, 0.96]	0.99 [0.90, 1.00]			
Month 15	0.92 [0.85, 0.95]	0.99 [0.90, 1.00]			
Month 18	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 21	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 24	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 27	0.92 [0.85, 0.95]	0.94 [0.72, 0.99]			
Month 30	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 33	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 36	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 39	0.92 [0.85, 0.95]	0.86 [0.59, 0.96]			
Month 42	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 45	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 48	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 51	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 54	0.90 [0.82, 0.94]	0.86 [0.59, 0.96]			
Month 57	0.90 [0.82, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
COVID-19					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [39.92, NE]	37.98 [18.04, NE]			
median	NE [NE, NE]	52.96 [37.98, NE]	0.50	[0.18, 1.39]	0.178
75th	NE [NE, NE]	NE [52.96, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.92, 1.00]		0.90 [0.65, 0.97]			
Month 24	0.96 [0.89, 0.98]		0.90 [0.65, 0.97]			
Month 27	0.95 [0.87, 0.98]		0.90 [0.65, 0.97]			
Month 30	0.92 [0.84, 0.96]		0.90 [0.65, 0.97]			
Month 33	0.90 [0.81, 0.95]		0.82 [0.53, 0.94]			
Month 36	0.86 [0.77, 0.92]		0.82 [0.53, 0.94]			
Month 39	0.85 [0.75, 0.91]		0.70 [0.36, 0.89]			
Month 42	0.81 [0.70, 0.88]		0.70 [0.36, 0.89]			
Month 45	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 48	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 51	0.76 [0.64, 0.85]		0.70 [0.36, 0.89]			
Month 54	0.76 [0.64, 0.85]	NE	[NE, NE]			
Month 57	0.76 [0.64, 0.85]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cough					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	138 (88.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [13.63, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.04	[0.37, 2.92]	0.936
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.94 [0.88, 0.97]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.87, 0.96]	0.93 [0.83, 0.97]			
Month 12	0.90 [0.84, 0.94]	0.93 [0.83, 0.97]			
Month 15	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 18	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 21	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 24	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 27	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 30	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 33	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 36	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 39	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 42	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 45	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 48	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 51	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 54	0.89 [0.83, 0.94]	0.88 [0.72, 0.96]			
Month 57	0.89 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Diarrhoea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	20 (12.8)	55 (72.4)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	132 (84.6)	14 (18.4)			
Treatment switched	0	6 (7.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	0.07 [0.03, 0.10]	0.09	[0.05, 0.15]	<0.001
median	NE [NE, NE]	0.28 [0.10, 0.72]			
75th	NE [NE, NE]	19.02 [0.76, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.91 [0.85, 0.95]	0.31 [0.21, 0.42]			
Month 6	0.89 [0.82, 0.93]	0.29 [0.20, 0.40]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 12	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 15	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 18	0.88 [0.81, 0.92]		0.27 [0.17, 0.38]			
Month 21	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 24	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 27	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 30	0.87 [0.80, 0.91]		0.23 [0.12, 0.35]			
Month 33	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 36	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 39	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 42	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 45	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 48	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 51	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 54	0.86 [0.78, 0.91]		0.23 [0.12, 0.35]			
Month 57	0.86 [0.78, 0.91]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Dizziness					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	2 (2.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.56	[0.58, 11.40]	0.200
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.97 [0.90, 0.99]			
Month 6	0.95 [0.91, 0.98]	0.97 [0.90, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]	0.97 [0.90, 0.99]			
Month 12	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 15	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 18	0.93 [0.87, 0.96]	0.97 [0.90, 0.99]			
Month 21	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 24	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 27	0.92 [0.85, 0.95]	0.97 [0.90, 0.99]			
Month 30	0.90 [0.83, 0.95]	0.97 [0.90, 0.99]			
Month 33	0.90 [0.83, 0.95]	0.97 [0.90, 0.99]			
Month 36	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 39	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 42	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 45	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 48	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 51	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 54	0.88 [0.80, 0.93]	0.97 [0.90, 0.99]			
Month 57	0.88 [0.80, 0.93]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Dyspepsia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.44	[0.40, 5.19]	0.577
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.97 [0.90, 0.99]			
Month 6	0.96 [0.91, 0.98]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 12	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 15	0.93 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 18	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 21	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 24	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 27	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 30	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 33	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 36	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 39	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 42	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 45	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 48	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 51	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 54	0.91 [0.85, 0.95]		0.96 [0.87, 0.99]			
Month 57	0.91 [0.85, 0.95]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Fatigue					
N*	156	76			
Number of patients, n (%)					
with events					
AE	24 (15.4)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	128 (82.1)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [20.07, NE]	NE [35.61, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.12	[0.50, 2.51]	0.793
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.93 [0.84, 0.97]			
Month 6	0.90 [0.84, 0.94]	0.93 [0.84, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.84, 0.94]		0.89 [0.77, 0.95]			
Month 12	0.88 [0.82, 0.93]		0.89 [0.77, 0.95]			
Month 15	0.87 [0.80, 0.92]		0.89 [0.77, 0.95]			
Month 18	0.85 [0.77, 0.90]		0.89 [0.77, 0.95]			
Month 21	0.83 [0.74, 0.88]		0.89 [0.77, 0.95]			
Month 24	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 27	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 30	0.81 [0.73, 0.87]		0.89 [0.77, 0.95]			
Month 33	0.80 [0.71, 0.86]		0.89 [0.77, 0.95]			
Month 36	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 39	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 42	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 45	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 48	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 51	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 54	0.80 [0.71, 0.86]		0.79 [0.51, 0.92]			
Month 57	0.80 [0.71, 0.86]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Headache					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	12 (15.8)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	NE [12.91, NE]	NE [7.29, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.96	[0.49, 1.90]	0.917
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.88 [0.82, 0.93]	0.89 [0.80, 0.95]			
Month 6	0.86 [0.80, 0.91]	0.89 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.84 [0.77, 0.89]		0.85 [0.73, 0.92]			
Month 12	0.83 [0.76, 0.89]		0.81 [0.66, 0.90]			
Month 15	0.80 [0.72, 0.86]		0.81 [0.66, 0.90]			
Month 18	0.78 [0.69, 0.84]		0.75 [0.57, 0.87]			
Month 21	0.78 [0.69, 0.84]		0.75 [0.57, 0.87]			
Month 24	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 27	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 30	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 33	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 36	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 39	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 42	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 45	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 48	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 51	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 54	0.77 [0.68, 0.83]		0.75 [0.57, 0.87]			
Month 57	0.77 [0.68, 0.83]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypertension					
N*	156	76			
Number of patients, n (%)					
with events					
AE	23 (14.7)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	129 (82.7)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [24.87, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.13	[0.73, 6.22]	0.156
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.97 [0.90, 0.99]			
Month 6	0.92 [0.86, 0.95]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.90 [0.83, 0.94]		0.96 [0.87, 0.99]			
Month 12	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 15	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 18	0.87 [0.80, 0.92]		0.92 [0.79, 0.97]			
Month 21	0.86 [0.78, 0.91]		0.92 [0.79, 0.97]			
Month 24	0.85 [0.77, 0.90]		0.92 [0.79, 0.97]			
Month 27	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 30	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 33	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 36	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 39	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 42	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 45	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 48	0.82 [0.74, 0.88]		0.92 [0.79, 0.97]			
Month 51	0.79 [0.67, 0.87]		0.92 [0.79, 0.97]			
Month 54	0.79 [0.67, 0.87]		0.92 [0.79, 0.97]			
Month 57	0.79 [0.67, 0.87]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Insomnia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	4.54	[0.58, 35.39]	0.114
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.97]	0.99 [0.91, 1.00]			
Month 12	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 15	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 18	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 21	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 24	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 27	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 30	0.93 [0.87, 0.96]	0.99 [0.91, 1.00]			
Month 33	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 36	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 39	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 42	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 45	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 48	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 51	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 54	0.92 [0.85, 0.95]	0.99 [0.91, 1.00]			
Month 57	0.92 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myalgia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	10 (6.4)	3 (3.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	142 (91.0)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.37	[0.37, 5.03]	0.634
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.90, 0.99]			
Month 6	0.95 [0.91, 0.98]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.91, 0.98]		0.96 [0.87, 0.99]			
Month 12	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 15	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 18	0.95 [0.89, 0.97]		0.96 [0.87, 0.99]			
Month 21	0.93 [0.88, 0.97]		0.96 [0.87, 0.99]			
Month 24	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 27	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 30	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 33	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 36	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 39	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 42	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 45	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 48	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 51	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 54	0.92 [0.86, 0.96]		0.96 [0.87, 0.99]			
Month 57	0.92 [0.86, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nasopharyngitis					
N*	156	76			
Number of patients, n (%)					
with events					
AE	18 (11.5)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [20.27, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.27	[0.66, 7.74]	0.180
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.90, 1.00]			
Month 6	0.92 [0.86, 0.95]	0.97 [0.88, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.89 [0.82, 0.93]	0.97 [0.88, 0.99]			
Month 12	0.89 [0.82, 0.93]	0.97 [0.88, 0.99]			
Month 15	0.88 [0.81, 0.93]	0.97 [0.88, 0.99]			
Month 18	0.88 [0.81, 0.93]	0.97 [0.88, 0.99]			
Month 21	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 24	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 27	0.88 [0.81, 0.93]	0.92 [0.72, 0.98]			
Month 30	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 33	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 36	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 39	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 42	0.87 [0.79, 0.92]	0.92 [0.72, 0.98]			
Month 45	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 48	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 51	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 54	0.84 [0.75, 0.90]	0.92 [0.72, 0.98]			
Month 57	0.84 [0.75, 0.90]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Nausea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	18 (11.5)	35 (46.1)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	134 (85.9)	27 (35.5)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	0.33 [0.07, 0.95]			
median	NE [NE, NE]	NE [1.35, NE]	0.16	[0.09, 0.28]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.87, 0.96]	0.57 [0.45, 0.68]			
Month 6	0.92 [0.87, 0.95]	0.52 [0.40, 0.63]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.92 [0.87, 0.95]	0.52 [0.40, 0.63]			
Month 12	0.87 [0.80, 0.92]	0.52 [0.40, 0.63]			
Month 15	0.87 [0.80, 0.92]	0.52 [0.40, 0.63]			
Month 18	0.87 [0.80, 0.92]	0.52 [0.40, 0.63]			
Month 21	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 24	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 27	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 30	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 33	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 36	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 39	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 42	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 45	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 48	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 51	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 54	0.86 [0.79, 0.91]	0.52 [0.40, 0.63]			
Month 57	0.86 [0.79, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Neutropenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	30 (19.2)	13 (17.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	121 (77.6)	42 (55.3)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [3.09, NE]	NE [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.11	[0.58, 2.13]	0.760
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.88]	0.85 [0.75, 0.91]			
Month 6	0.82 [0.75, 0.87]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]	0.82 [0.71, 0.89]			
Month 12	0.82 [0.75, 0.87]	0.82 [0.71, 0.89]			
Month 15	0.81 [0.74, 0.86]	0.82 [0.71, 0.89]			
Month 18	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 21	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 24	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 27	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 30	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 33	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 36	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 39	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 42	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 45	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 48	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 51	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 54	0.80 [0.72, 0.86]	0.82 [0.71, 0.89]			
Month 57	0.80 [0.72, 0.86]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Oedema peripheral					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	2 (2.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.37	[0.53, 10.69]	0.246
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.97 [0.89, 0.99]			
Month 6	0.94 [0.88, 0.97]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]		0.97 [0.89, 0.99]			
Month 12	0.94 [0.88, 0.97]		0.97 [0.89, 0.99]			
Month 15	0.93 [0.87, 0.96]		0.97 [0.89, 0.99]			
Month 18	0.93 [0.87, 0.96]		0.97 [0.89, 0.99]			
Month 21	0.92 [0.85, 0.95]		0.97 [0.89, 0.99]			
Month 24	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 27	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 30	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 33	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 36	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 39	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 42	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 45	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 48	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 51	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 54	0.91 [0.84, 0.95]		0.97 [0.89, 0.99]			
Month 57	0.91 [0.84, 0.95]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pain in extremity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	48 (63.2)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.15	[0.41, 3.20]	0.788
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.94 [0.86, 0.98]			
Month 6	0.93 [0.88, 0.96]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.88, 0.96]		0.92 [0.82, 0.97]			
Month 12	0.92 [0.87, 0.96]		0.92 [0.82, 0.97]			
Month 15	0.92 [0.87, 0.96]		0.92 [0.82, 0.97]			
Month 18	0.91 [0.85, 0.95]		0.92 [0.82, 0.97]			
Month 21	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 24	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 27	0.90 [0.83, 0.94]		0.92 [0.82, 0.97]			
Month 30	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 33	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 36	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 39	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 42	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 45	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 48	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 51	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 54	0.88 [0.80, 0.93]		0.92 [0.82, 0.97]			
Month 57	0.88 [0.80, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Platelet count decreased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	140 (89.7)	47 (61.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.39, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.03	[0.35, 2.98]	0.963
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.94 [0.86, 0.98]			
Month 6	0.93 [0.87, 0.96]	0.94 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 12	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 15	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 18	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 21	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 24	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 27	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 30	0.93 [0.87, 0.96]		0.94 [0.86, 0.98]			
Month 33	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 36	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 39	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 42	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 45	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 48	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 51	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 54	0.93 [0.87, 0.96]		0.87 [0.61, 0.96]			
Month 57	0.93 [0.87, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Rash					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	18 (23.7)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	37 (48.7)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	7.10 [1.22, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.30	[0.15, 0.60]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.81 [0.71, 0.89]			
Month 6	0.93 [0.88, 0.96]	0.80 [0.69, 0.87]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 12	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 15	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 18	0.91 [0.85, 0.95]		0.73 [0.60, 0.83]			
Month 21	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 24	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 27	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 30	0.90 [0.84, 0.94]		0.73 [0.60, 0.83]			
Month 33	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 36	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 39	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 42	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 45	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 48	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 51	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 54	0.88 [0.81, 0.93]		0.73 [0.60, 0.83]			
Month 57	0.88 [0.81, 0.93]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Thrombocytopenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	46 (60.5)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.41, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.66	[0.85, 3.27]	0.137
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.71, 0.84]	0.88 [0.78, 0.93]			
Month 6	0.77 [0.70, 0.83]	0.86 [0.76, 0.92]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.77 [0.70, 0.83]	0.86 [0.76, 0.92]			
Month 12	0.77 [0.70, 0.83]	0.82 [0.68, 0.90]			
Month 15	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 18	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 21	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 24	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 27	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 30	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 33	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 36	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 39	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 42	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 45	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 48	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 51	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 54	0.76 [0.69, 0.82]	0.82 [0.68, 0.90]			
Month 57	0.76 [0.69, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Upper respiratory tract infection					
N*	156	76			
Number of patients, n (%)					
with events					
AE	14 (9.0)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	49 (64.5)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [51.42, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.18	[0.38, 3.64]	0.771
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]		0.93 [0.82, 0.97]			
Month 12	0.94 [0.89, 0.97]		0.93 [0.82, 0.97]			
Month 15	0.94 [0.89, 0.97]		0.93 [0.82, 0.97]			
Month 18	0.92 [0.86, 0.96]		0.93 [0.82, 0.97]			
Month 21	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 24	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 27	0.91 [0.84, 0.95]		0.93 [0.82, 0.97]			
Month 30	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 33	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 36	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 39	0.90 [0.83, 0.94]		0.93 [0.82, 0.97]			
Month 42	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 45	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 48	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 51	0.88 [0.80, 0.93]		0.93 [0.82, 0.97]			
Month 54	0.82 [0.64, 0.92]		0.93 [0.82, 0.97]			
Month 57	0.82 [0.64, 0.92]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vomiting					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	20 (26.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	38 (50.0)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	3.55 [0.39, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.11, 0.47]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.76 [0.64, 0.84]			
Month 6	0.95 [0.90, 0.98]	0.72 [0.60, 0.81]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.2 Any AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]		0.72 [0.60, 0.81]			
Month 12	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 15	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 18	0.93 [0.86, 0.96]		0.72 [0.60, 0.81]			
Month 21	0.91 [0.85, 0.95]		0.72 [0.60, 0.81]			
Month 24	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 27	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 30	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 33	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 36	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 39	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 42	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 45	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 48	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 51	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 54	0.90 [0.83, 0.94]		0.72 [0.60, 0.81]			
Month 57	0.90 [0.83, 0.94]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-1.3.3 Overview of AE by PT: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 1 of 4)

	Bosutinib N=25	
Preferred term	All grades n (%)	Grade ≥3 n (%)
Number of subjects with at least one event	19 (76.0)	7 (28.0)
Headache	4 (16.0)	0
Neutropenia	4 (16.0)	3 (12.0)
Thrombocytopenia	3 (12.0)	2 (8.0)
Alopecia	2 (8.0)	0
Myalgia	2 (8.0)	0
Abdominal pain	1 (4.0)	1 (4.0)
Acne	1 (4.0)	0
Acute myeloid leukaemia	1 (4.0)	1 (4.0)
Back pain	1 (4.0)	1 (4.0)
Basal cell carcinoma	1 (4.0)	1 (4.0)
Blood creatinine increased	1 (4.0)	0
Bronchitis	1 (4.0)	0
Cholecystitis acute	1 (4.0)	1 (4.0)
Numbers (n) represent counts of subjects.		
A subject with multiple severity grades for an AE is only counted under the maximum grade.		
Patients included in this table are randomized to Bosutinib and switched to Asciminib.		
MedDRA version 26.0, CTCAE version 4.03		

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Table 4-1.3.3 Overview of AE by PT: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 2 of 4)

Preferred term	Bosutinib N=25	
	All grades n (%)	Grade ≥3 n (%)
Cough	1 (4.0)	0
Dermatitis acneiform	1 (4.0)	0
Diabetes mellitus	1 (4.0)	0
Dizziness	1 (4.0)	0
Dysphagia	1 (4.0)	0
Dyspnoea	1 (4.0)	0
Fall	1 (4.0)	0
Hair colour changes	1 (4.0)	0
Herpes virus infection	1 (4.0)	0
Hypoacusis	1 (4.0)	0
Hypocalcaemia	1 (4.0)	0
Hypokalaemia	1 (4.0)	0
Hypophosphataemia	1 (4.0)	0
Lactic acidosis	1 (4.0)	0

Numbers (n) represent counts of subjects.
A subject with multiple severity grades for an AE is only counted under the maximum grade.
Patients included in this table are randomized to Bosutinib and switched to Asciminib.
MedDRA version 26.0, CTCAE version 4.03

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Table 4-1.3.3 Overview of AE by PT: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 3 of 4)

Preferred term	Bosutinib N=25	
	All grades n (%)	Grade >=3 n (%)
Left ventricular hypertrophy	1 (4.0)	0
Ligament sprain	1 (4.0)	0
Macule	1 (4.0)	0
Mesenteric arterial occlusion	1 (4.0)	1 (4.0)
Mesenteric artery thrombosis	1 (4.0)	1 (4.0)
Muscle spasms	1 (4.0)	0
Nausea	1 (4.0)	0
Odynophagia	1 (4.0)	0
Oedema peripheral	1 (4.0)	0
Pain	1 (4.0)	1 (4.0)
Palpitations	1 (4.0)	0
Periorbital oedema	1 (4.0)	0
Peripheral swelling	1 (4.0)	0
Procedural pain	1 (4.0)	0

Numbers (n) represent counts of subjects.
A subject with multiple severity grades for an AE is only counted under the maximum grade.
Patients included in this table are randomized to Bosutinib and switched to Asciminib.
MedDRA version 26.0, CTCAE version 4.03

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Table 4-1.3.3 Overview of AE by PT: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 4 of 4)

Preferred term	Bosutinib N=25	
	All grades n (%)	Grade >=3 n (%)
Pyrexia	1 (4.0)	0
Rash	1 (4.0)	0
Rash maculo-papular	1 (4.0)	0
SARS-CoV-2 test negative	1 (4.0)	0
Sinus bradycardia	1 (4.0)	0
Suspected COVID-19	1 (4.0)	0
Thyroid mass	1 (4.0)	0
Upper respiratory tract infection	1 (4.0)	0
Viral infection	1 (4.0)	0
Vomiting	1 (4.0)	0
Weight decreased	1 (4.0)	0
Numbers (n) represent counts of subjects.		
A subject with multiple severity grades for an AE is only counted under the maximum grade.		
Patients included in this table are randomized to Bosutinib and switched to Asciminib.		
MedDRA version 26.0, CTCAE version 4.03		

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Table 4-2.1.1 Grade ≥3 AE: time to first event - stratified per IRT
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	93 (59.6)	52 (68.4)			
censored					
Discontinued from study treatment	63 (40.4)	15 (19.7)			
Treatment switched	0	9 (11.8)			
Percentiles (months) (95% CI)					
25th	1.41 [1.18, 1.87]	0.82 [0.36, 1.41]	0.69	[0.49, 0.98]	0.033
median	9.26 [3.25, 21.19]	3.48 [1.84, 8.31]			
75th	NE [46.55, NE]	27.24 [9.23, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Final

Table 4-2.1.1 Grade ≥3 AE: time to first event - stratified per IRT
Safety Set
(Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.59 [0.51, 0.67]	0.52 [0.40, 0.63]			
Month 6	0.55 [0.47, 0.63]	0.44 [0.32, 0.54]			
Month 9	0.51 [0.43, 0.59]	0.37 [0.26, 0.49]			
Month 12	0.46 [0.38, 0.54]	0.33 [0.21, 0.45]			
Month 15	0.46 [0.37, 0.54]	0.33 [0.21, 0.45]			
Month 18	0.44 [0.36, 0.52]	0.30 [0.19, 0.42]			
Month 21	0.42 [0.34, 0.50]	0.25 [0.14, 0.38]			
Month 24	0.41 [0.33, 0.49]	0.25 [0.14, 0.38]			
Month 27	0.40 [0.32, 0.48]	0.25 [0.14, 0.38]			
Month 30	0.40 [0.32, 0.48]	0.22 [0.11, 0.35]			
Month 33	0.38 [0.30, 0.46]	0.18 [0.08, 0.31]			
Month 36	0.38 [0.30, 0.46]	0.18 [0.08, 0.31]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-2.1.1 Grade ≥3 AE: time to first event - stratified per IRT
Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 39	0.36 [0.28, 0.44]	0.18 [0.08, 0.31]			
Month 42	0.36 [0.28, 0.44]	0.18 [0.08, 0.31]			
Month 45	0.34 [0.26, 0.43]	0.18 [0.08, 0.31]			
Month 48	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 51	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 54	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 57	0.32 [0.23, 0.41]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

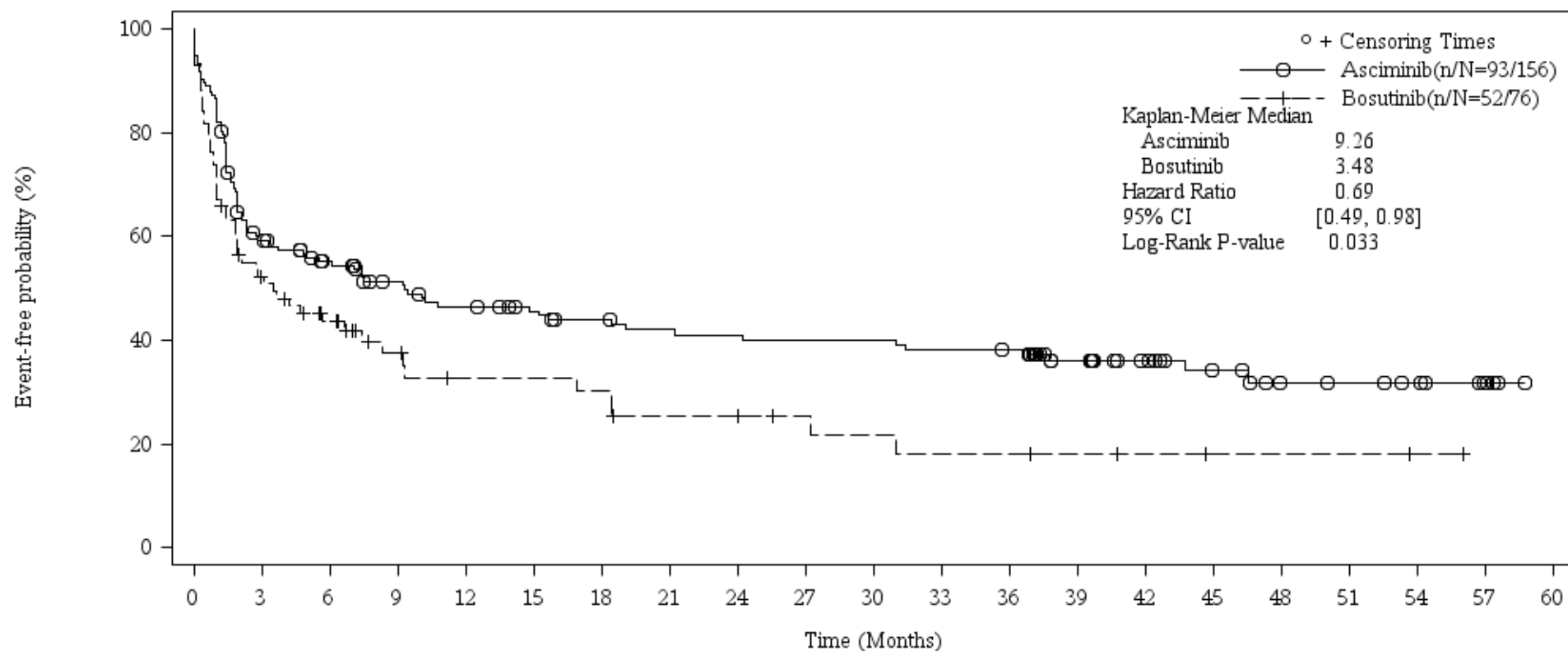
Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-2.1.1 (Page 1 of 1)

Grade ≥ 3 AE: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

Number of patients still at risk

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	89	75	64	57	52	48	45	44	43	43	41	40	29	22	16	11	10	8	4	0
Bosutinib	76	37	27	17	13	13	12	9	9	7	6	5	5	4	3	2	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation. Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 4-2.1.2 Grade ≥ 3 AE: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	93 (59.6)	52 (68.4)			
censored					
Discontinued from study treatment	63 (40.4)	15 (19.7)			
Treatment switched	0	9 (11.8)			
Percentiles (months) (95% CI)					
25th	1.41 [1.18, 1.87]	0.82 [0.36, 1.41]	0.71	[0.50, 1.00]	0.045
median	9.26 [3.25, 21.19]	3.48 [1.84, 8.31]			
75th	NE [46.55, NE]	27.24 [9.23, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Table 4-2.1.2 Grade ≥3 AE: time to first event - stratified per CRF
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	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.59 [0.51, 0.67]	0.52 [0.40, 0.63]			
Month 6	0.55 [0.47, 0.63]	0.44 [0.32, 0.54]			
Month 9	0.51 [0.43, 0.59]	0.37 [0.26, 0.49]			
Month 12	0.46 [0.38, 0.54]	0.33 [0.21, 0.45]			
Month 15	0.46 [0.37, 0.54]	0.33 [0.21, 0.45]			
Month 18	0.44 [0.36, 0.52]	0.30 [0.19, 0.42]			
Month 21	0.42 [0.34, 0.50]	0.25 [0.14, 0.38]			
Month 24	0.41 [0.33, 0.49]	0.25 [0.14, 0.38]			
Month 27	0.40 [0.32, 0.48]	0.25 [0.14, 0.38]			
Month 30	0.40 [0.32, 0.48]	0.22 [0.11, 0.35]			
Month 33	0.38 [0.30, 0.46]	0.18 [0.08, 0.31]			
Month 36	0.38 [0.30, 0.46]	0.18 [0.08, 0.31]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-2.1.2 Grade ≥3 AE: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 39	0.36 [0.28, 0.44]	0.18 [0.08, 0.31]			
Month 42	0.36 [0.28, 0.44]	0.18 [0.08, 0.31]			
Month 45	0.34 [0.26, 0.43]	0.18 [0.08, 0.31]			
Month 48	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 51	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 54	0.32 [0.23, 0.41]	0.18 [0.08, 0.31]			
Month 57	0.32 [0.23, 0.41]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Blood and lymphatic system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	14 (18.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	43 (56.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.77, NE]	NE [4.63, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.31	[0.71, 2.43]	0.398
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.77 [0.69, 0.83]	0.89 [0.79, 0.94]			
Month 6	0.77 [0.69, 0.83]	0.83 [0.71, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 12	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 15	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 18	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 21	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 24	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 27	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 30	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 33	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 36	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 39	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 42	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 45	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 48	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 51	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 54	0.77 [0.69, 0.83]	0.78 [0.65, 0.86]			
Month 57	0.77 [0.69, 0.83]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Gastrointestinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	12 (15.8)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	144 (92.3)	42 (55.3)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.09, 0.55]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.88 [0.78, 0.94]			
Month 6	0.99 [0.95, 1.00]	0.83 [0.72, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.93, 0.99]		0.83 [0.72, 0.90]			
Month 12	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 15	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 18	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 21	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 24	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 27	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 30	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 33	0.95 [0.89, 0.98]		0.83 [0.72, 0.90]			
Month 36	0.95 [0.89, 0.98]		0.83 [0.72, 0.90]			
Month 39	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 42	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 45	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 48	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 51	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 54	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 57	0.90 [0.79, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
General disorders and administration site conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	2 (2.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	144 (92.3)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [50.17, NE]	NE [27.24, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.11	[0.23, 5.29]	0.899
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.99 [0.90, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.99 [0.94, 1.00]	0.99 [0.90, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.90, 1.00]			
Month 12	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 15	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 18	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 21	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 24	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 27	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 30	0.94 [0.88, 0.97]	0.92 [0.62, 0.98]			
Month 33	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 36	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 39	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 42	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 45	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 48	0.90 [0.80, 0.96]	0.92 [0.62, 0.98]			
Month 51	0.86 [0.70, 0.94]	0.92 [0.62, 0.98]			
Month 54	0.86 [0.70, 0.94]	0.92 [0.62, 0.98]			
Month 57	0.86 [0.70, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Investigations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	28 (17.9)	24 (31.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	125 (80.1)	36 (47.4)			
Treatment switched	0	15 (19.7)			
Percentiles (months) (95% CI)					
25th	NE [10.18, NE]	3.75 [1.87, 9.23]			
median	NE [NE, NE]	NE [NE, NE]	0.45	[0.26, 0.79]	0.004
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.78 [0.67, 0.86]			
Month 6	0.87 [0.80, 0.91]	0.70 [0.58, 0.80]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.85 [0.78, 0.90]		0.67 [0.54, 0.77]			
Month 12	0.82 [0.74, 0.88]		0.64 [0.50, 0.74]			
Month 15	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 18	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 21	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 24	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 27	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 30	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 33	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 36	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 39	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 42	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 45	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 48	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 51	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 54	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 57	0.79 [0.70, 0.85]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Metabolism and nutrition disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	141 (90.4)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [18.43, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.15	[0.36, 3.61]	0.816
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.95 [0.89, 0.97]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 12	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 15	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 18	0.93 [0.87, 0.96]	0.95 [0.86, 0.98]			
Month 21	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 24	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 27	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 30	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 33	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 36	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 39	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 42	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 45	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 48	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 51	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 54	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 57	0.92 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	5 (6.6)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	150 (96.2)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.95, NE]			
median	NE [NE, NE]	NE [32.62, NE]	0.04	[0.00, 0.34]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 9	1.00 [1.00, 1.00]		0.96 [0.84, 0.99]			
Month 12	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 15	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 18	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 21	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 24	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 27	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.77 [0.49, 0.91]			
Month 36	1.00 [1.00, 1.00]		0.77 [0.49, 0.91]			
Month 39	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 42	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 45	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 48	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 51	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 54	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 57	0.99 [0.90, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.06	[0.01, 0.45]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.89 [0.80, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.89 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 12	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 15	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 18	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 21	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 24	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 27	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 30	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 33	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 36	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 39	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 42	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 45	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 48	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 51	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 54	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 57	0.99 [0.94, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
(Page 15 of 16)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vascular disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [48.33, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.78	[0.51, 6.18]	0.361
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.1 Grade ≥3 AE by SOC: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.89, 0.97]	0.97 [0.89, 0.99]			
Month 12	0.94 [0.88, 0.97]	0.94 [0.79, 0.98]			
Month 15	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 18	0.92 [0.85, 0.95]	0.94 [0.79, 0.98]			
Month 21	0.89 [0.82, 0.94]	0.94 [0.79, 0.98]			
Month 24	0.89 [0.82, 0.94]	0.94 [0.79, 0.98]			
Month 27	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 30	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 33	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 36	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 39	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 42	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 45	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 48	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 51	0.83 [0.70, 0.91]	0.94 [0.79, 0.98]			
Month 54	0.83 [0.70, 0.91]	0.94 [0.79, 0.98]			
Month 57	0.83 [0.70, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

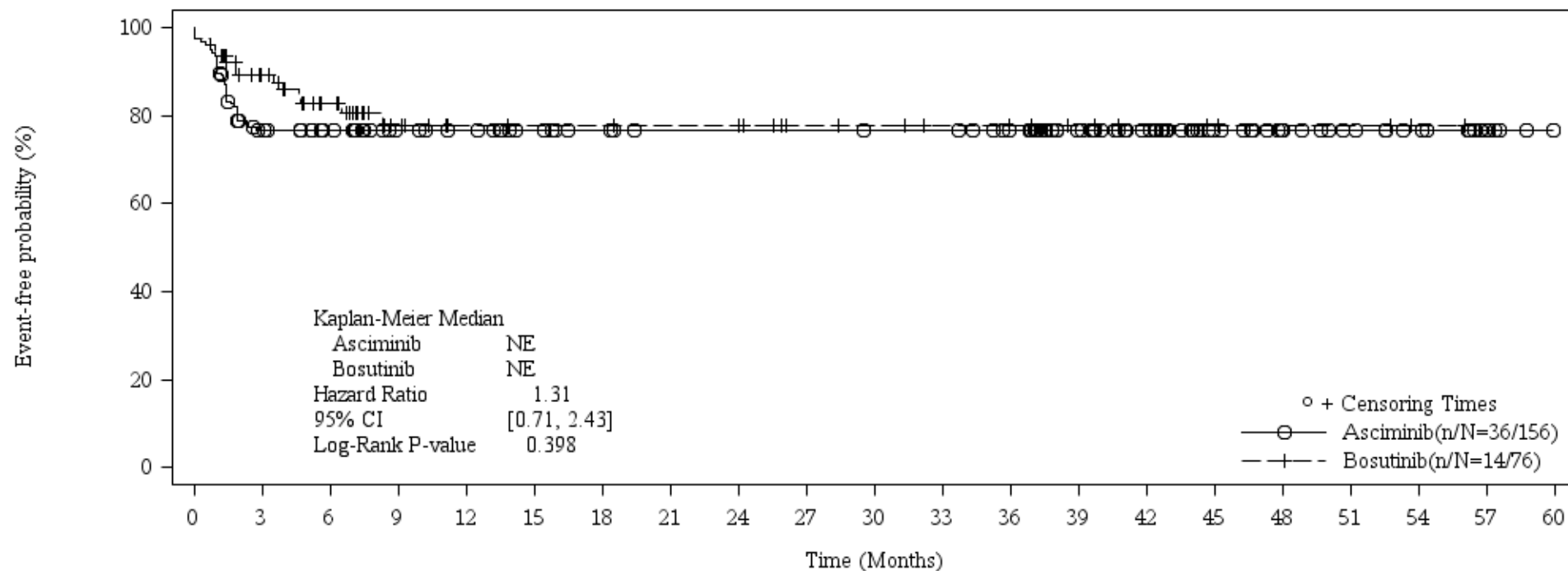
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Figure 4-2.2.1 (Page 1 of 8)
Grade >=3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Blood and lymphatic system disorders



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	113	103	93	90	84	80	77	77	77	76	76	71	57	43	29	21	17	13	5	0
Bosutinib	76	57	42	26	20	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

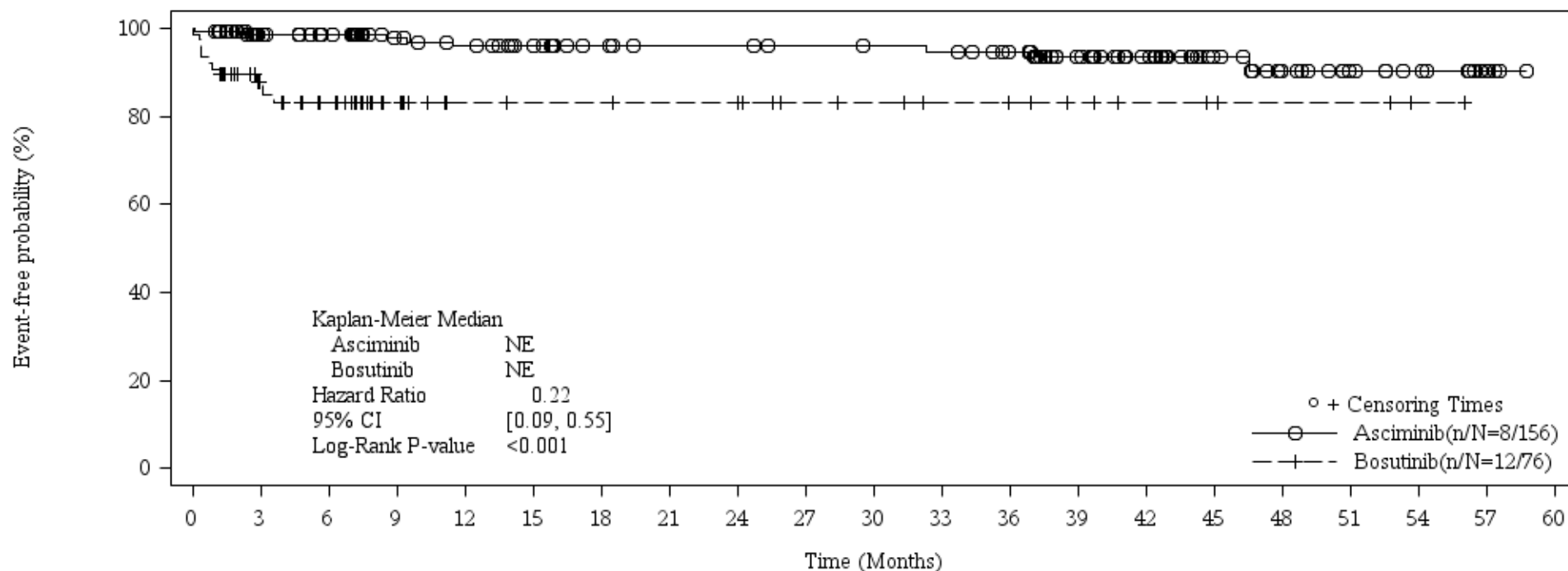
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 2 of 8)
Grade ≥3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Gastrointestinal disorders



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	128	107	102	95	89	86	86	84	83	82	77	61	47	32	23	16	12	4	0
Bosutinib	76	55	43	27	19	18	18	17	17	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

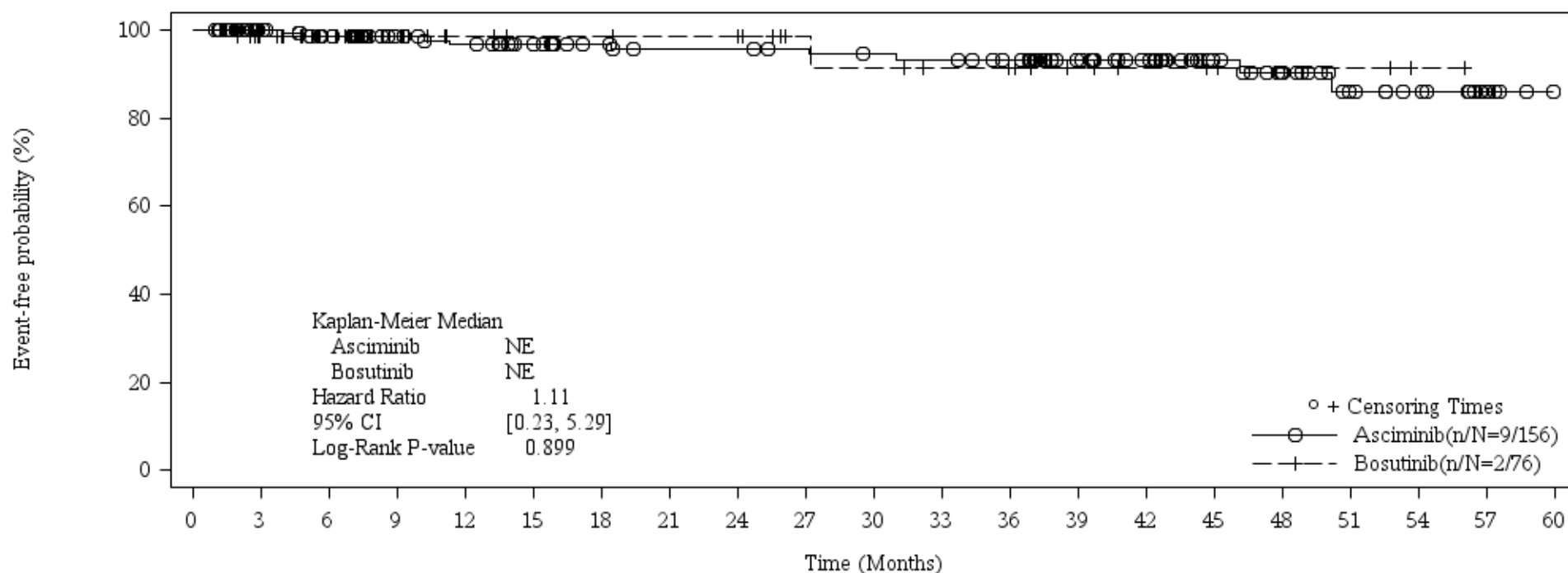
- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 3 of 8)

Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

SOC: General disorders and administration site conditions



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	128	108	103	95	89	85	85	83	81	80	76	60	48	34	25	17	13	5	0
Bosutinib	76	61	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

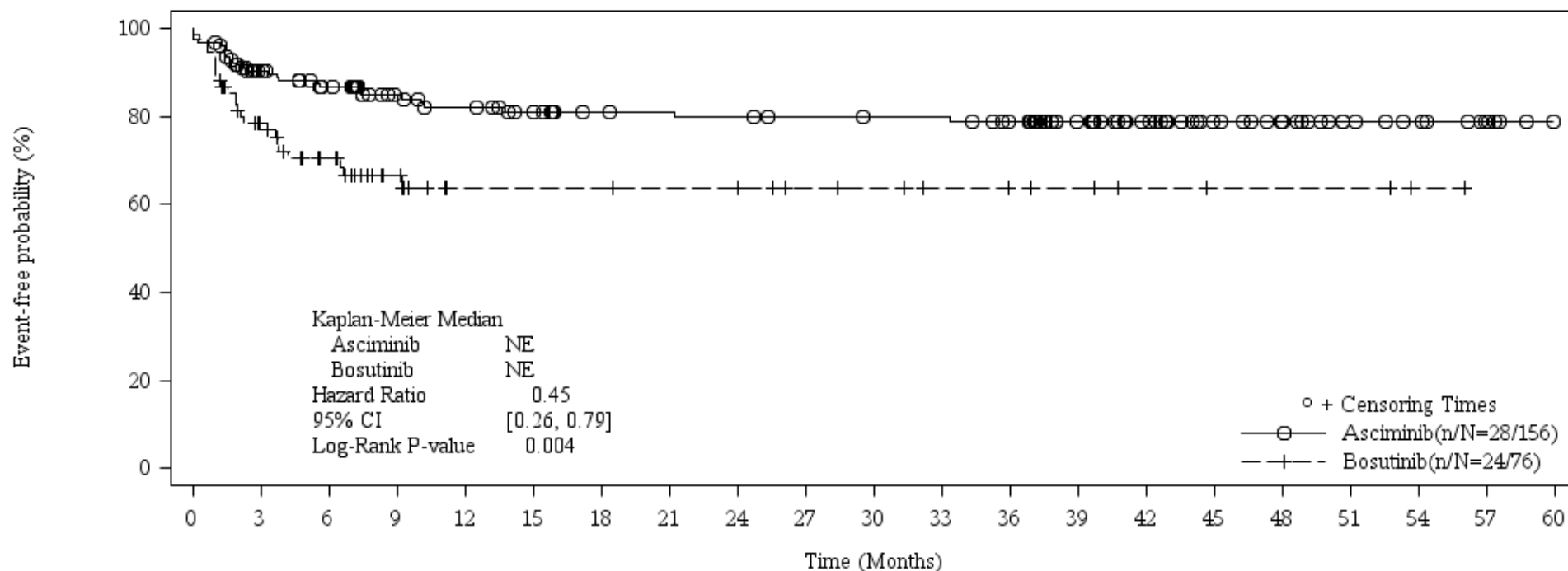
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 4 of 8)
Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Investigations



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	128	114	92	86	79	74	73	72	70	69	69	64	50	37	26	20	13	10	5	0
Bosutinib	76	51	38	24	15	15	15	14	14	11	10	8	7	6	4	3	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

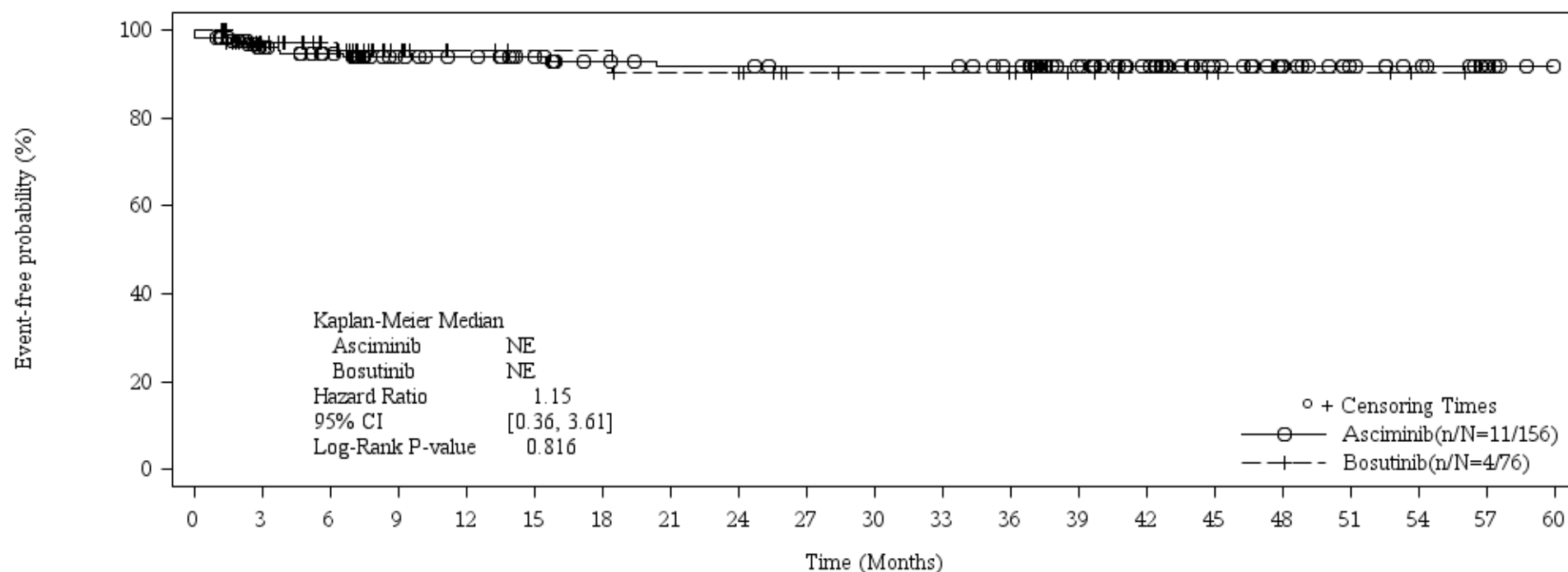
- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 5 of 8)

Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

SOC: Metabolism and nutrition disorders



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	135	122	101	97	90	84	81	81	79	79	79	75	59	45	32	23	16	12	5	0
Bosutinib	76	60	48	29	22	20	20	18	18	13	12	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

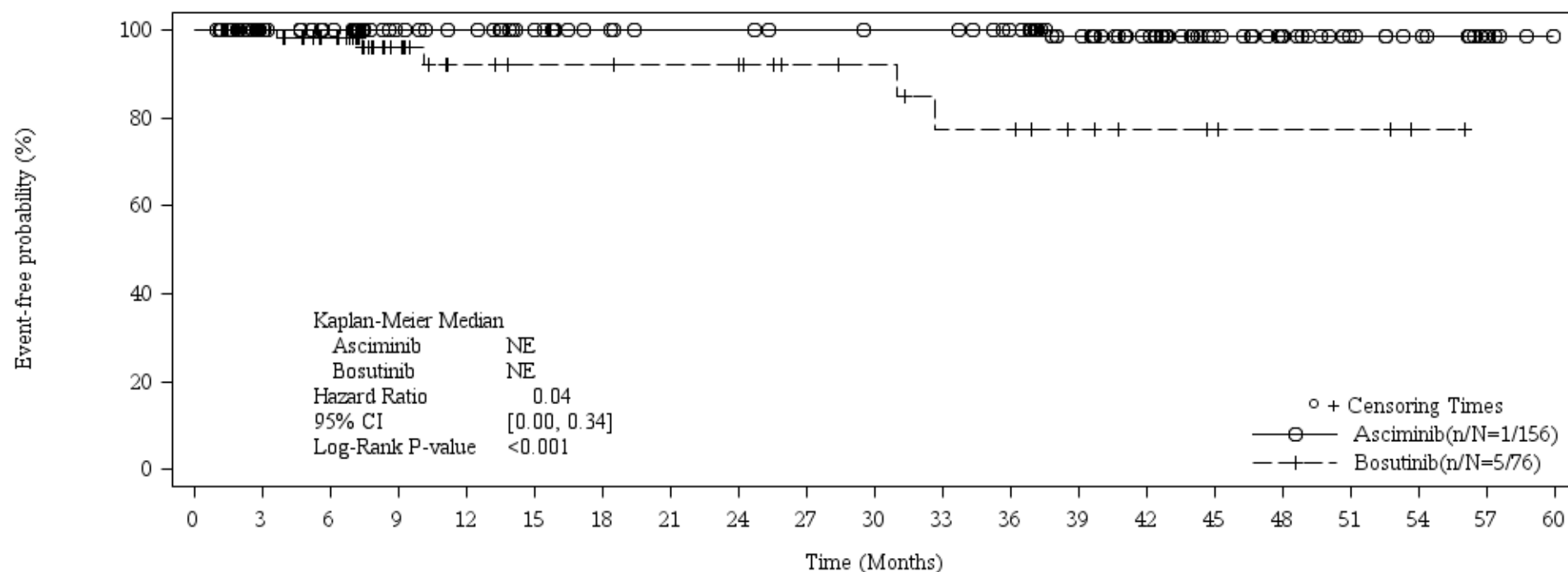
- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 6 of 8)

Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

SOC: Respiratory/ thoracic and mediastinal disorders



Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	50	29	21	19	19	18	18	14	13	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

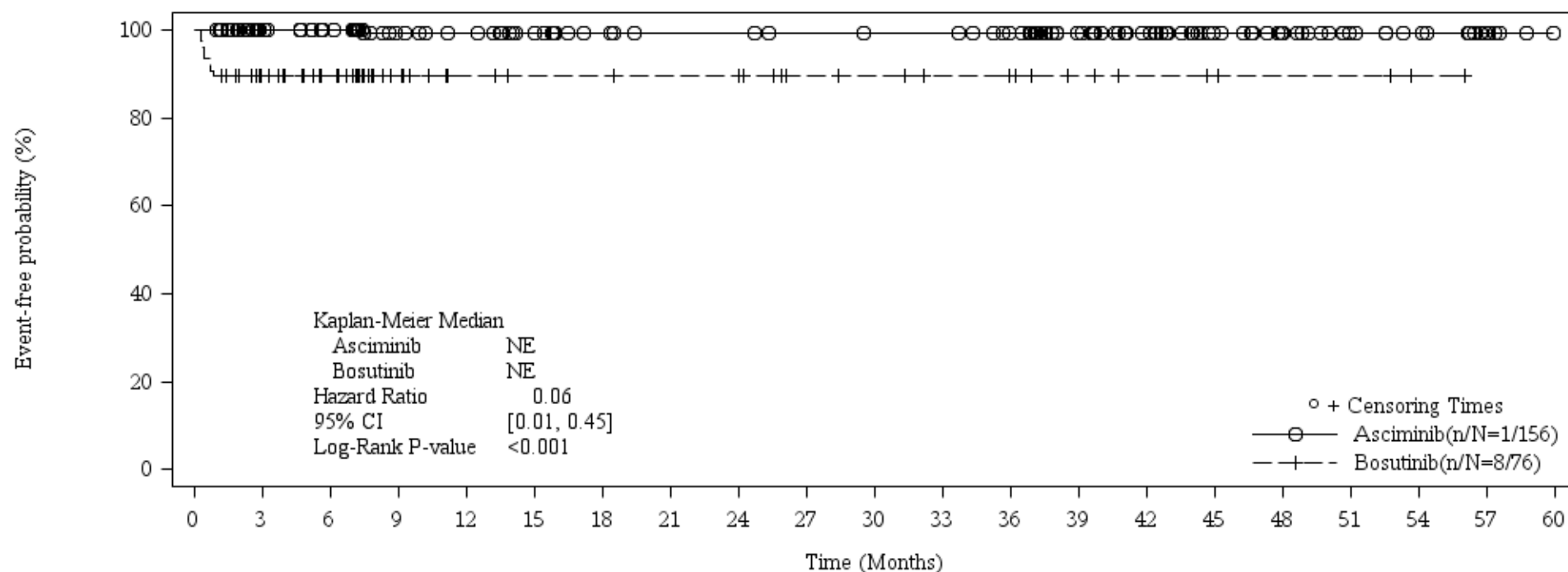
- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 7 of 8)

Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

SOC: Skin and subcutaneous tissue disorders



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	87	85	84	84	79	62	48	34	25	17	13	5	0
Bosutinib	76	58	46	29	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

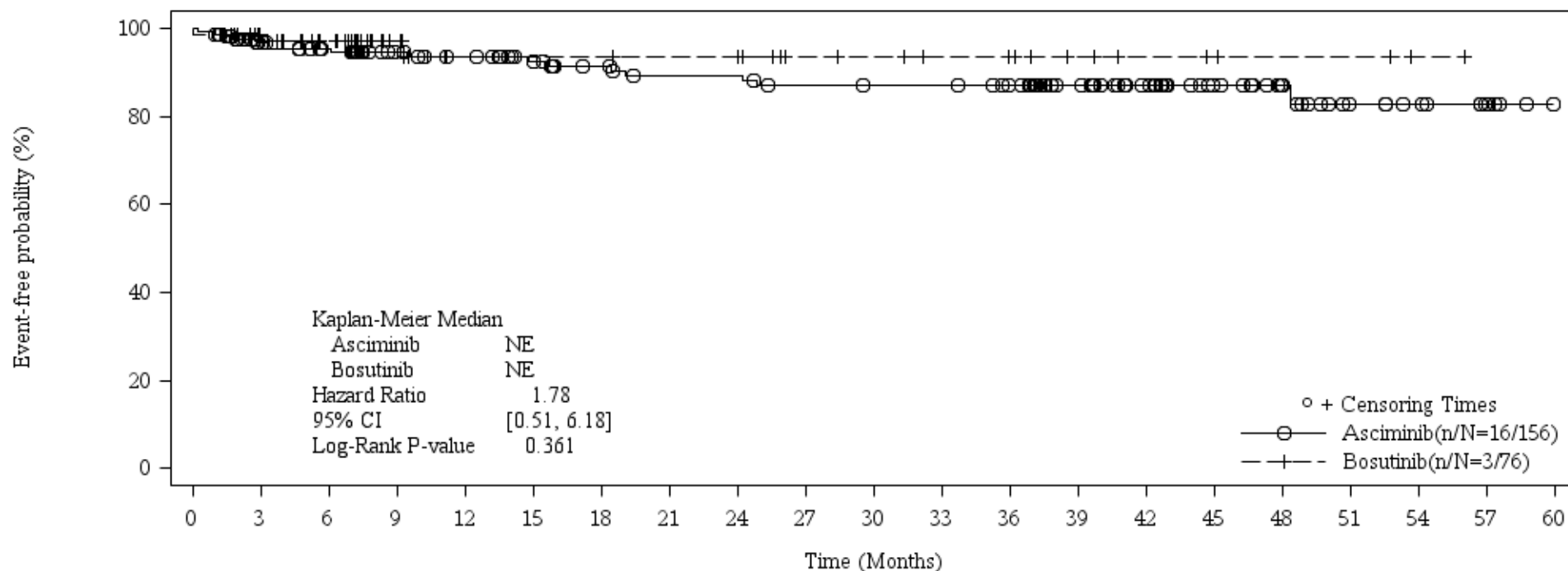
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.2.1 (Page 8 of 8)
Grade ≥3 AE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Vascular disorders



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	137	124	104	99	90	84	79	79	75	74	74	70	56	42	30	21	13	10	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 1 of 16)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Blood and lymphatic system disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	14 (18.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	43 (56.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.77, NE]	NE [4.63, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.37	[0.74, 2.55]	0.315
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.77 [0.69, 0.83]	0.89 [0.79, 0.94]			
Month 6	0.77 [0.69, 0.83]	0.83 [0.71, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and
in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 2 of 16)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 12	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 15	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 18	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 21	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 24	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 27	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 30	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 33	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 36	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 39	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 42	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 45	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 48	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 51	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 54	0.77 [0.69, 0.83]		0.78 [0.65, 0.86]			
Month 57	0.77 [0.69, 0.83]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 3 of 16)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Gastrointestinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	12 (15.8)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	144 (92.3)	42 (55.3)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.09, 0.55]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.88 [0.78, 0.94]			
Month 6	0.99 [0.95, 1.00]	0.83 [0.72, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 4 of 16)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.93, 0.99]		0.83 [0.72, 0.90]			
Month 12	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 15	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 18	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 21	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 24	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 27	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 30	0.96 [0.90, 0.98]		0.83 [0.72, 0.90]			
Month 33	0.95 [0.89, 0.98]		0.83 [0.72, 0.90]			
Month 36	0.95 [0.89, 0.98]		0.83 [0.72, 0.90]			
Month 39	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 42	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 45	0.93 [0.86, 0.97]		0.83 [0.72, 0.90]			
Month 48	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 51	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 54	0.90 [0.79, 0.96]		0.83 [0.72, 0.90]			
Month 57	0.90 [0.79, 0.96]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
General disorders and administration site conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	2 (2.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	144 (92.3)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [50.17, NE]	NE [27.24, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.11	[0.23, 5.34]	0.892
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.99 [0.90, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 6 of 16)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 6	0.99 [0.94, 1.00]	0.99 [0.90, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.90, 1.00]			
Month 12	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 15	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 18	0.97 [0.91, 0.99]	0.99 [0.90, 1.00]			
Month 21	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 24	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 27	0.96 [0.90, 0.98]	0.99 [0.90, 1.00]			
Month 30	0.94 [0.88, 0.97]	0.92 [0.62, 0.98]			
Month 33	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 36	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 39	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 42	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 45	0.93 [0.86, 0.97]	0.92 [0.62, 0.98]			
Month 48	0.90 [0.80, 0.96]	0.92 [0.62, 0.98]			
Month 51	0.86 [0.70, 0.94]	0.92 [0.62, 0.98]			
Month 54	0.86 [0.70, 0.94]	0.92 [0.62, 0.98]			
Month 57	0.86 [0.70, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Investigations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	28 (17.9)	24 (31.6)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	125 (80.1)	36 (47.4)			
Treatment switched	0	15 (19.7)			
Percentiles (months) (95% CI)					
25th	NE [10.18, NE]	3.75 [1.87, 9.23]			
median	NE [NE, NE]	NE [NE, NE]	0.45	[0.26, 0.79]	0.004
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.78 [0.67, 0.86]			
Month 6	0.87 [0.80, 0.91]	0.70 [0.58, 0.80]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 8 of 16)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.85 [0.78, 0.90]		0.67 [0.54, 0.77]			
Month 12	0.82 [0.74, 0.88]		0.64 [0.50, 0.74]			
Month 15	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 18	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 21	0.81 [0.73, 0.87]		0.64 [0.50, 0.74]			
Month 24	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 27	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 30	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 33	0.80 [0.72, 0.86]		0.64 [0.50, 0.74]			
Month 36	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 39	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 42	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 45	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 48	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 51	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 54	0.79 [0.70, 0.85]		0.64 [0.50, 0.74]			
Month 57	0.79 [0.70, 0.85]	NE	[NE, NE]			
Month 60	NE [NE, NE]	NE	[NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Metabolism and nutrition disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	11 (7.1)	4 (5.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	141 (90.4)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [18.43, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.12	[0.35, 3.53]	0.847
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.95 [0.89, 0.97]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 12	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 15	0.94 [0.88, 0.97]	0.95 [0.86, 0.98]			
Month 18	0.93 [0.87, 0.96]	0.95 [0.86, 0.98]			
Month 21	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 24	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 27	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 30	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 33	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 36	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 39	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 42	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 45	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 48	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 51	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 54	0.92 [0.85, 0.95]	0.90 [0.73, 0.97]			
Month 57	0.92 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
(Page 11 of 16)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	5 (6.6)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	150 (96.2)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.95, NE]			
median	NE [NE, NE]	NE [32.62, NE]	0.04	[0.00, 0.37]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 9	1.00 [1.00, 1.00]		0.96 [0.84, 0.99]			
Month 12	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 15	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 18	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 21	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 24	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 27	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.92 [0.76, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.77 [0.49, 0.91]			
Month 36	1.00 [1.00, 1.00]		0.77 [0.49, 0.91]			
Month 39	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 42	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 45	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 48	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 51	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 54	0.99 [0.90, 1.00]		0.77 [0.49, 0.91]			
Month 57	0.99 [0.90, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.05	[0.01, 0.43]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.89 [0.80, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.89 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 12	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 15	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 18	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 21	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 24	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 27	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 30	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 33	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 36	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 39	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 42	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 45	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 48	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 51	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 54	0.99 [0.94, 1.00]		0.89 [0.80, 0.95]			
Month 57	0.99 [0.94, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥ 3 AE by SOC: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Vascular disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [48.33, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.77	[0.51, 6.15]	0.366
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.2.2 Grade ≥3 AE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.89, 0.97]	0.97 [0.89, 0.99]			
Month 12	0.94 [0.88, 0.97]	0.94 [0.79, 0.98]			
Month 15	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 18	0.92 [0.85, 0.95]	0.94 [0.79, 0.98]			
Month 21	0.89 [0.82, 0.94]	0.94 [0.79, 0.98]			
Month 24	0.89 [0.82, 0.94]	0.94 [0.79, 0.98]			
Month 27	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 30	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 33	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 36	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 39	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 42	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 45	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 48	0.87 [0.79, 0.92]	0.94 [0.79, 0.98]			
Month 51	0.83 [0.70, 0.91]	0.94 [0.79, 0.98]			
Month 54	0.83 [0.70, 0.91]	0.94 [0.79, 0.98]			
Month 57	0.83 [0.70, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Alanine aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [4.17, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.04	[0.01, 0.31]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.88 [0.78, 0.93]			
Month 6	0.99 [0.95, 1.00]	0.84 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 12	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 15	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 18	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 21	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 24	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 27	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 30	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 33	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 36	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 39	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 42	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 45	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 48	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 51	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 54	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Aspartate aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.23	[0.05, 0.95]	0.027
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.96 [0.87, 0.99]			
Month 6	0.99 [0.95, 1.00]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 12	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 15	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 18	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 21	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 24	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 27	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 30	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 33	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 36	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 39	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 42	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 45	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 48	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 51	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 54	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 57	0.97 [0.92, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Diarrhoea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.91 [0.81, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.89 [0.79, 0.94]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 12	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 15	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 18	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 21	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 24	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 27	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 30	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 33	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 36	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 39	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 42	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 45	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 48	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 51	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 54	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
 (Page 7 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypertension					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [48.33, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.37	[0.38, 4.96]	0.625
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t42_3_1.sas@@/main/3 22NOV23:11:03

Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
 (Page 8 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			
Month 12	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 15	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 18	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 21	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 24	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 27	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 30	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 33	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 36	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 39	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 42	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 45	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 48	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 51	0.87 [0.75, 0.94]	0.94 [0.79, 0.98]			
Month 54	0.87 [0.75, 0.94]	0.94 [0.79, 0.98]			
Month 57	0.87 [0.75, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t42_3_1.sas@@/main/3 22NOV23:11:03

Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
 (Page 9 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Lipase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [15.64, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.61	[0.17, 2.16]	0.435
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.95 [0.86, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t42_3_1.sas@@/main/3 22NOV23:11:03

Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.92, 0.99]		0.95 [0.86, 0.99]			
Month 12	0.95 [0.90, 0.98]		0.95 [0.86, 0.99]			
Month 15	0.95 [0.90, 0.98]		0.95 [0.86, 0.99]			
Month 18	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 21	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 24	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 27	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 30	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 33	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 36	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 39	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 42	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 45	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 48	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 51	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 54	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 57	0.95 [0.90, 0.98]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Neutropenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	24 (15.4)	9 (11.8)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	127 (81.4)	45 (59.2)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.31	[0.61, 2.82]	0.492
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.93 [0.84, 0.97]			
Month 6	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			
Month 12	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			
Month 15	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 18	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 21	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 24	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 27	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 30	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 33	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 36	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 39	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 42	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 45	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 48	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 51	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 54	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 57	0.84 [0.77, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Final

Table 4-2.3.1 Grade ≥3 AE by PT: time to first event - stratified per IRT
Safety Set
(Page 13 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Thrombocytopenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	28 (17.9)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	123 (78.8)	48 (63.2)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [4.01, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.79	[1.08, 7.23]	0.027
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.84 [0.77, 0.89]	0.95 [0.86, 0.98]			
Month 6	0.82 [0.75, 0.87]	0.95 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t42_3_1.sas@@/main/3 22NOV23:11:03

Final

Table 4-2.3.1 Grade ≥ 3 AE by PT: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 12	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 15	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 18	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 21	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 24	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 27	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 30	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 33	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 36	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 39	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 42	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 45	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 48	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 51	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 54	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 57	0.82 [0.75, 0.87]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

MedDRA version 26.0

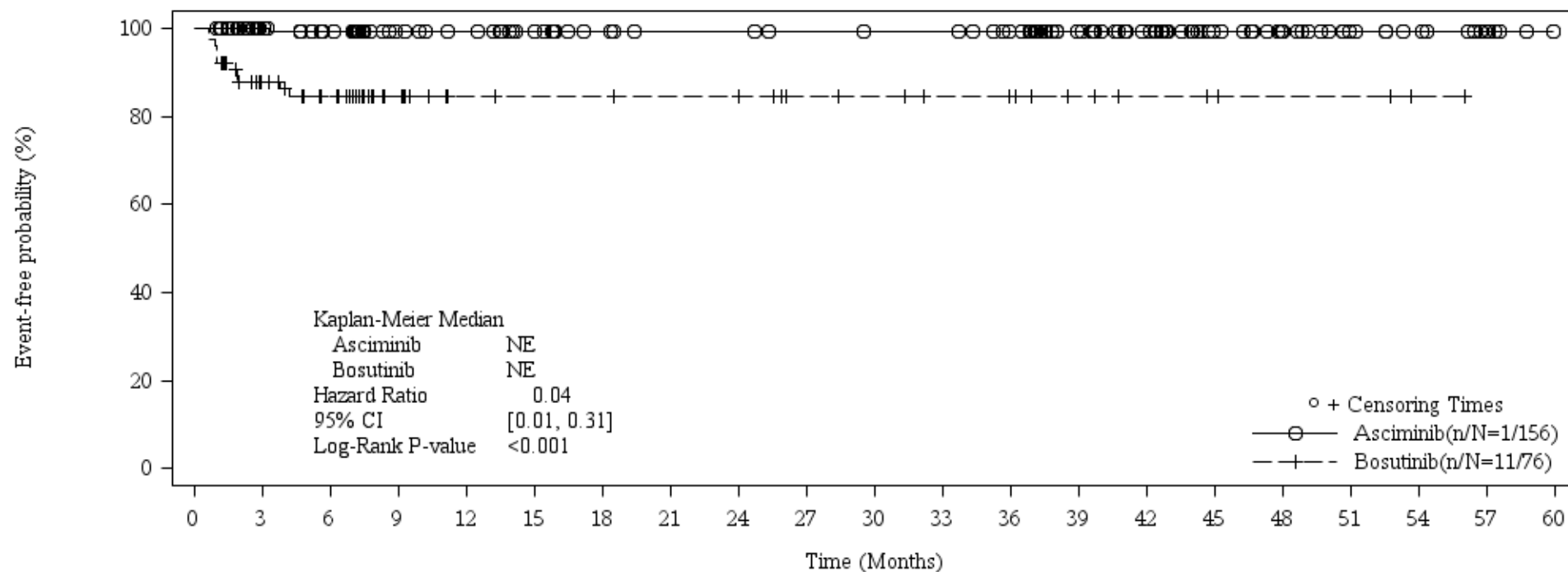
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Figure 4-2.3.1 (Page 1 of 7)
Grade ≥3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Alanine aminotransferase increased



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	108	104	96	90	87	87	85	84	84	79	62	48	33	24	16	12	5	0
Bosutinib	76	55	44	28	20	19	19	18	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

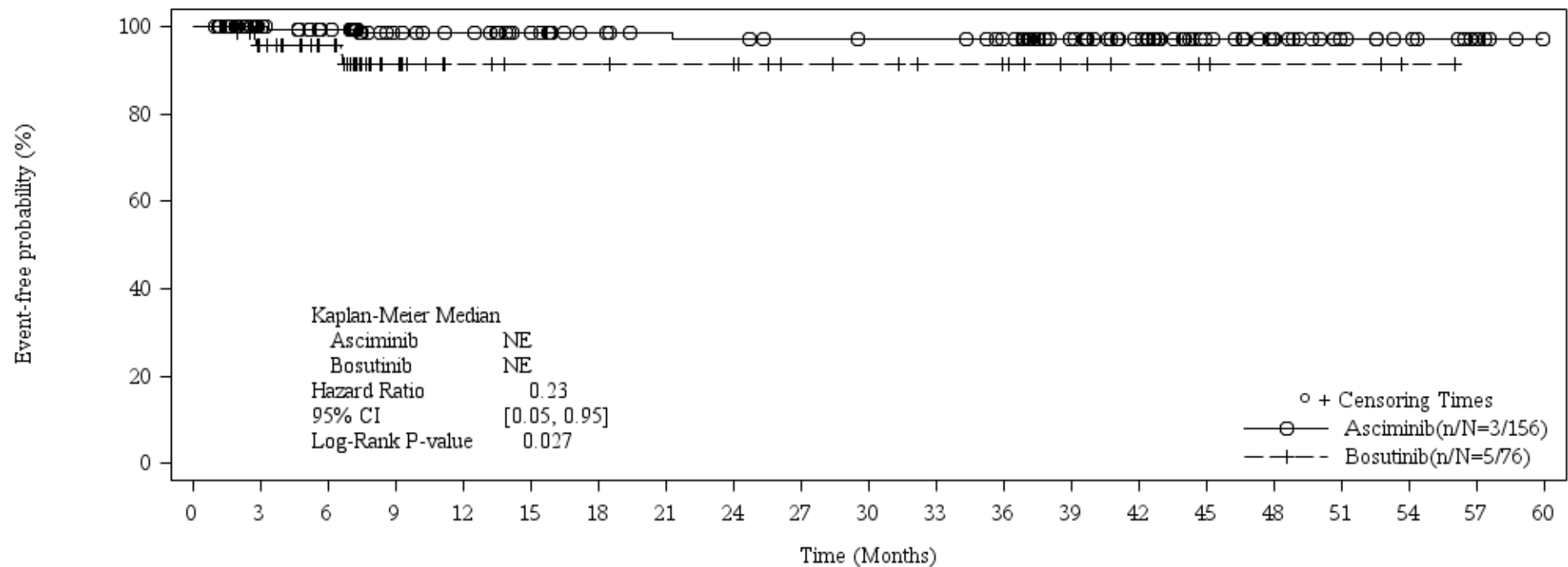
- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 2 of 7)

Grade ≥ 3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

PT: Aspartate aminotransferase increased



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	107	103	95	89	86	85	83	82	82	78	61	47	32	24	16	12	5	0
Bosutinib	76	60	49	29	21	19	19	18	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

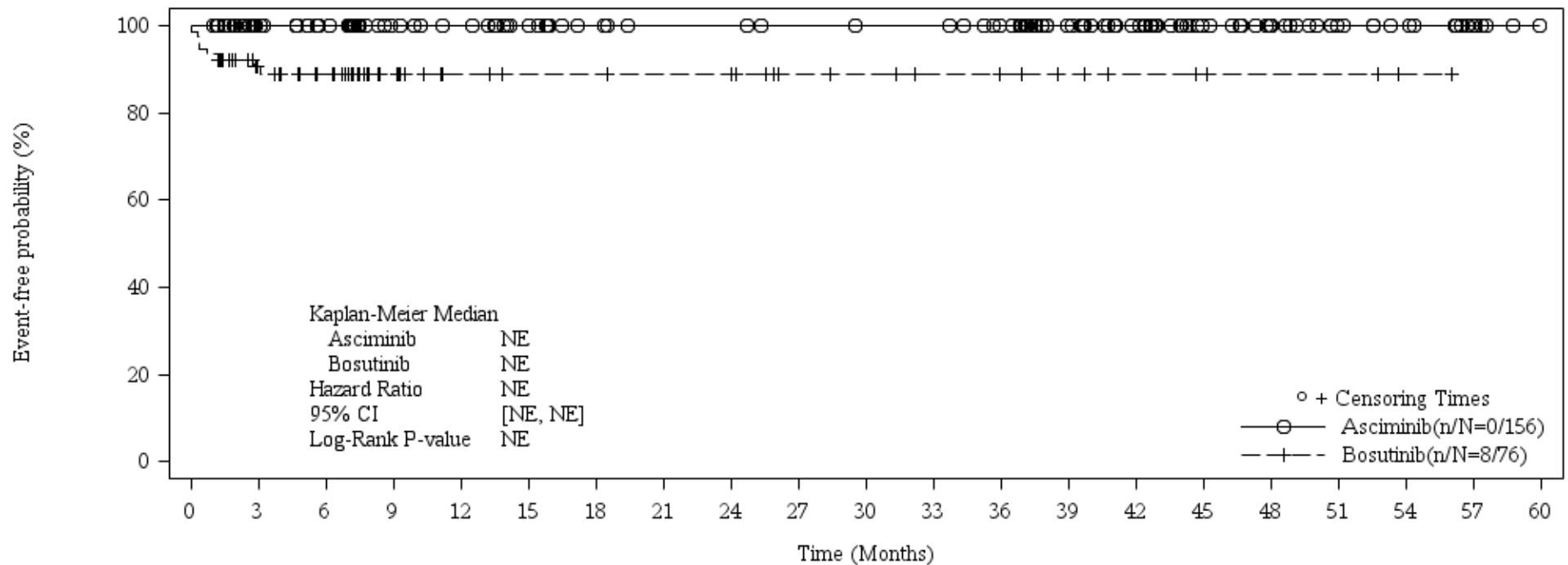
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 3 of 7)
Grade ≥3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Diarrhoea



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	57	46	29	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

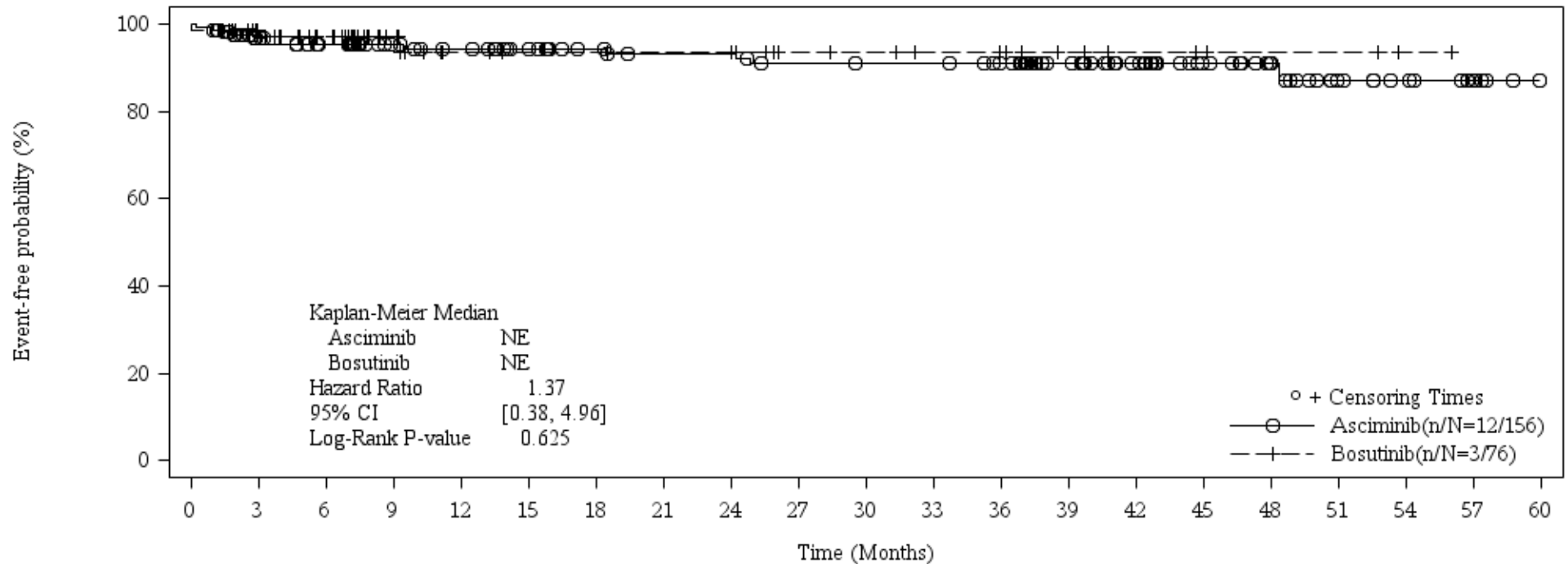
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 4 of 7)
Grade ≥3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Hypertension



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	137	124	105	100	92	86	82	82	78	77	77	73	59	45	33	24	15	11	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

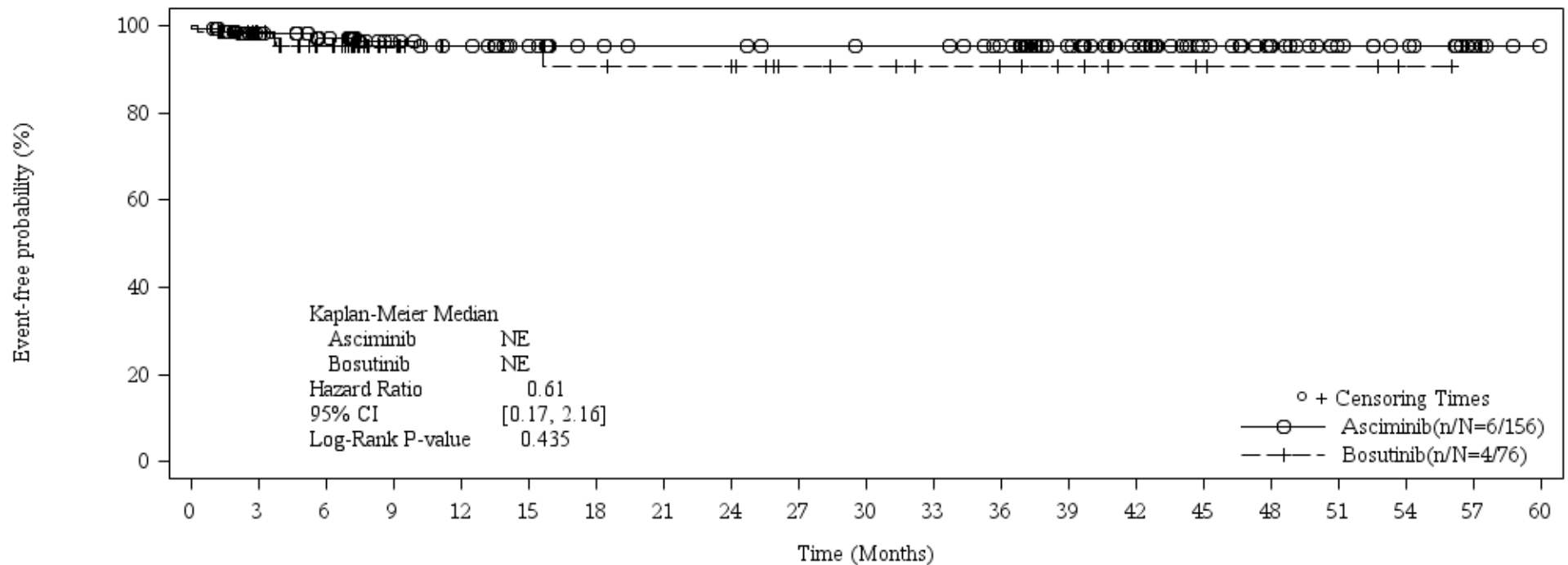
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 5 of 7)
Grade ≥ 3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Lipase increased



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	127	105	100	92	87	85	85	83	82	82	77	61	47	34	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

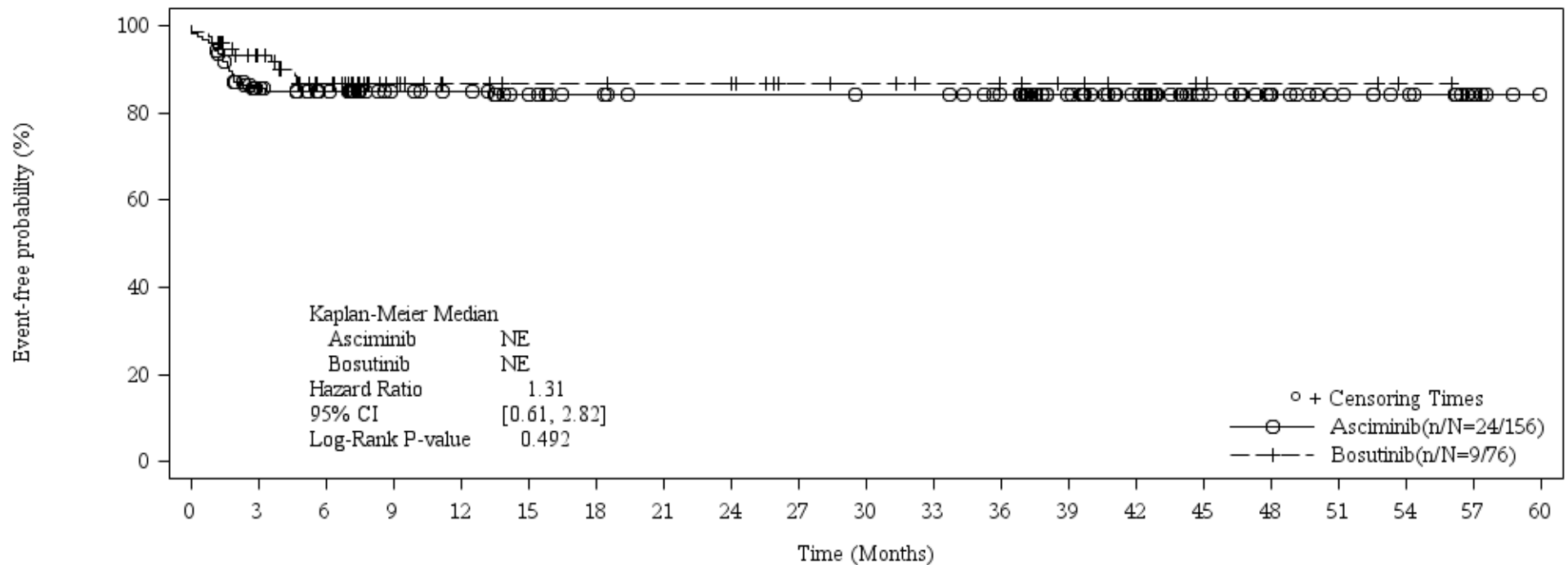
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 6 of 7)
Grade ≥3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Neutropenia



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	123	111	98	95	87	83	80	80	80	79	79	74	60	46	31	23	17	13	5	0
Bosutinib	76	60	44	28	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

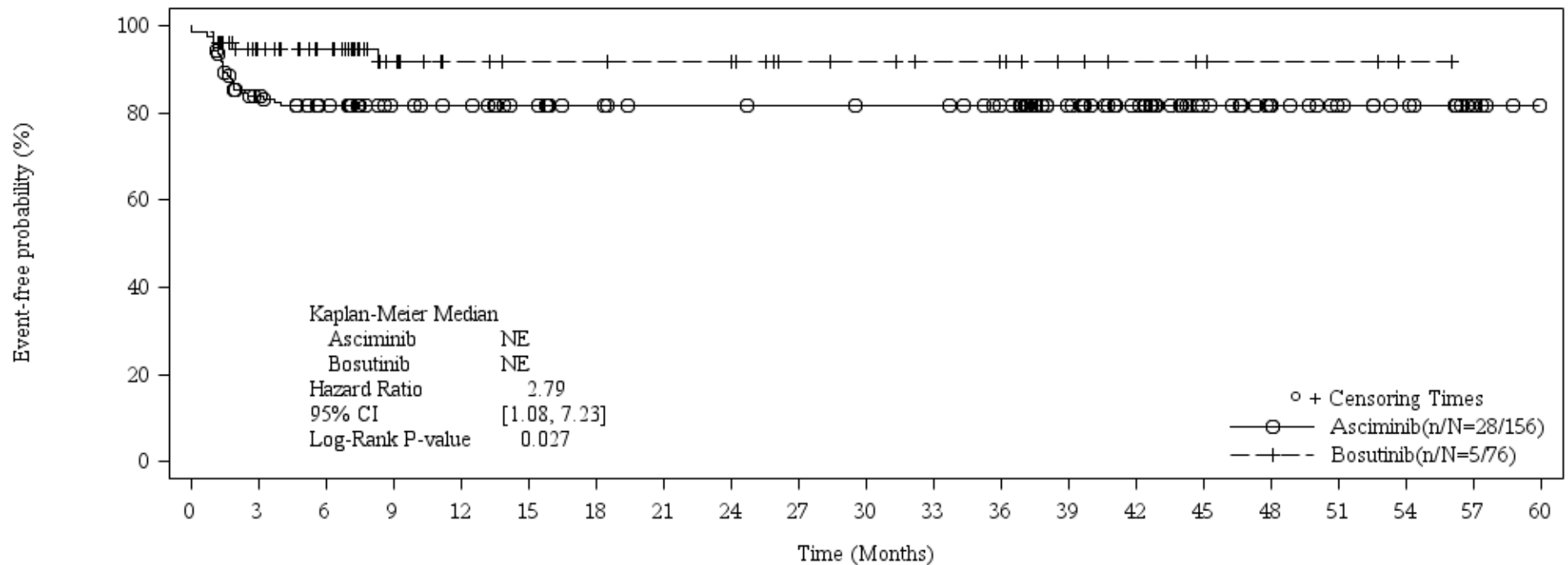
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-2.3.1 (Page 7 of 7)
Grade ≥3 AE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

PT: Thrombocytopenia



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	123	110	98	95	89	84	81	81	80	79	79	74	59	45	31	22	17	13	5	0
Bosutinib	76	59	48	29	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
Safety Set
(Page 1 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Alanine aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [4.17, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.04	[0.01, 0.31]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.88 [0.78, 0.93]			
Month 6	0.99 [0.95, 1.00]	0.84 [0.74, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 14)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 12	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 15	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 18	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 21	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 24	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 27	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 30	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 33	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 36	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 39	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 42	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 45	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 48	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 51	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 54	0.99 [0.95, 1.00]		0.84 [0.74, 0.91]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
Safety Set
(Page 3 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Aspartate aminotransferase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	5 (6.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	46 (60.5)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.22	[0.05, 0.95]	0.026
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.96 [0.87, 0.99]			
Month 6	0.99 [0.95, 1.00]	0.96 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
 (Page 4 of 14)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 12	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 15	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 18	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 21	0.98 [0.94, 1.00]		0.91 [0.80, 0.96]			
Month 24	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 27	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 30	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 33	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 36	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 39	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 42	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 45	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 48	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 51	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 54	0.97 [0.92, 0.99]		0.91 [0.80, 0.96]			
Month 57	0.97 [0.92, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Diarrhoea					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.91 [0.81, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.89 [0.79, 0.94]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
 (Page 6 of 14)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 12	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 15	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 18	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 21	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 24	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 27	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 30	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 33	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 36	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 39	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 42	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 45	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 48	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 51	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 54	1.00 [1.00, 1.00]		0.89 [0.79, 0.94]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
Safety Set
(Page 7 of 14)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypertension					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [48.33, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.38	[0.38, 4.98]	0.624
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.95 [0.90, 0.98]	0.97 [0.89, 0.99]			
Month 12	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 15	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 18	0.94 [0.89, 0.97]	0.94 [0.79, 0.98]			
Month 21	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 24	0.93 [0.87, 0.96]	0.94 [0.79, 0.98]			
Month 27	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 30	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 33	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 36	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 39	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 42	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 45	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 48	0.91 [0.84, 0.95]	0.94 [0.79, 0.98]			
Month 51	0.87 [0.75, 0.94]	0.94 [0.79, 0.98]			
Month 54	0.87 [0.75, 0.94]	0.94 [0.79, 0.98]			
Month 57	0.87 [0.75, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Lipase increased					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [15.64, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.59	[0.16, 2.10]	0.407
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.95 [0.86, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.96 [0.92, 0.99]		0.95 [0.86, 0.99]			
Month 12	0.95 [0.90, 0.98]		0.95 [0.86, 0.99]			
Month 15	0.95 [0.90, 0.98]		0.95 [0.86, 0.99]			
Month 18	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 21	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 24	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 27	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 30	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 33	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 36	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 39	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 42	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 45	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 48	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 51	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 54	0.95 [0.90, 0.98]		0.91 [0.73, 0.97]			
Month 57	0.95 [0.90, 0.98]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Neutropenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	24 (15.4)	9 (11.8)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	127 (81.4)	45 (59.2)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.38	[0.64, 2.96]	0.415
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.93 [0.84, 0.97]			
Month 6	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			
Month 12	0.85 [0.78, 0.90]	0.87 [0.76, 0.93]			
Month 15	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 18	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 21	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 24	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 27	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 30	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 33	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 36	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 39	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 42	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 45	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 48	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 51	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 54	0.84 [0.77, 0.89]	0.87 [0.76, 0.93]			
Month 57	0.84 [0.77, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥ 3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Thrombocytopenia					
N*	156	76			
Number of patients, n (%)					
with events					
AE	28 (17.9)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	123 (78.8)	48 (63.2)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [4.01, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.95	[1.14, 7.65]	0.019
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.84 [0.77, 0.89]	0.95 [0.86, 0.98]			
Month 6	0.82 [0.75, 0.87]	0.95 [0.86, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-2.3.2 Grade ≥3 AE by PT: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 12	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 15	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 18	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 21	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 24	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 27	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 30	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 33	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 36	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 39	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 42	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 45	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 48	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 51	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 54	0.82 [0.75, 0.87]	0.92 [0.80, 0.97]			
Month 57	0.82 [0.75, 0.87]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.1.1 SAE: time to first event - stratified per IRT
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	34 (21.8)	20 (26.3)			
censored					
Discontinued from study treatment	122 (78.2)	36 (47.4)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	30.98 [21.19, 50.10]	16.89 [3.48, 27.24]			
median	NE [50.10, NE]	NE [25.10, NE]	0.53	[0.30, 0.94]	0.027
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Table 4-3.1.1 SAE: time to first event - stratified per IRT
Safety Set
(Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.88 [0.78, 0.94]			
Month 6	0.91 [0.86, 0.95]	0.80 [0.69, 0.88]			
Month 9	0.89 [0.82, 0.93]	0.80 [0.69, 0.88]			
Month 12	0.85 [0.78, 0.90]	0.77 [0.64, 0.86]			
Month 15	0.85 [0.78, 0.90]	0.77 [0.64, 0.86]			
Month 18	0.84 [0.77, 0.90]	0.73 [0.57, 0.83]			
Month 21	0.83 [0.75, 0.89]	0.69 [0.52, 0.81]			
Month 24	0.80 [0.71, 0.86]	0.69 [0.52, 0.81]			
Month 27	0.79 [0.70, 0.85]	0.64 [0.45, 0.78]			
Month 30	0.77 [0.68, 0.83]	0.58 [0.38, 0.74]			
Month 33	0.74 [0.65, 0.82]	0.52 [0.31, 0.70]			
Month 36	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-3.1.1 SAE: time to first event - stratified per IRT
Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 39	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			
Month 42	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			
Month 45	0.71 [0.60, 0.79]	0.52 [0.31, 0.70]			
Month 48	0.71 [0.60, 0.79]	0.52 [0.31, 0.70]			
Month 51	0.61 [0.44, 0.74]	0.52 [0.31, 0.70]			
Month 54	0.61 [0.44, 0.74]	0.52 [0.31, 0.70]			
Month 57	0.61 [0.44, 0.74]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

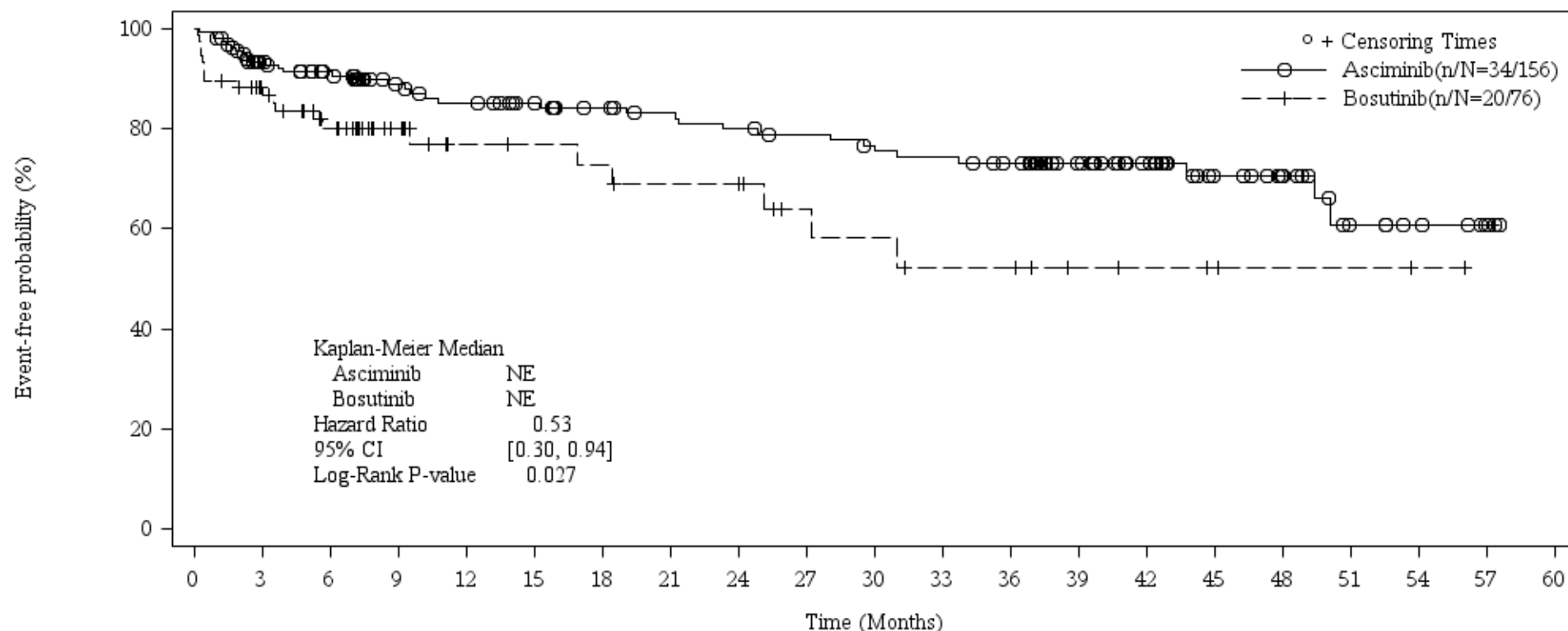
Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-3.1.1 (Page 1 of 1)
SAE: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set



Number of patients still at risk

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	133	119	99	93	86	81	77	74	71	68	66	62	48	36	24	18	10	7	3	0
Bosutinib	76	59	45	29	20	19	18	16	16	11	10	8	8	5	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-3.1.2 SAE: time to first event - stratified per CRF
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	34 (21.8)	20 (26.3)			
censored					
Discontinued from study treatment	122 (78.2)	36 (47.4)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	30.98 [21.19, 50.10]	16.89 [3.48, 27.24]			
median	NE [50.10, NE]	NE [25.10, NE]	0.56	[0.32, 0.98]	0.039
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Table 4-3.1.2 SAE: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.88 [0.78, 0.94]			
Month 6	0.91 [0.86, 0.95]	0.80 [0.69, 0.88]			
Month 9	0.89 [0.82, 0.93]	0.80 [0.69, 0.88]			
Month 12	0.85 [0.78, 0.90]	0.77 [0.64, 0.86]			
Month 15	0.85 [0.78, 0.90]	0.77 [0.64, 0.86]			
Month 18	0.84 [0.77, 0.90]	0.73 [0.57, 0.83]			
Month 21	0.83 [0.75, 0.89]	0.69 [0.52, 0.81]			
Month 24	0.80 [0.71, 0.86]	0.69 [0.52, 0.81]			
Month 27	0.79 [0.70, 0.85]	0.64 [0.45, 0.78]			
Month 30	0.77 [0.68, 0.83]	0.58 [0.38, 0.74]			
Month 33	0.74 [0.65, 0.82]	0.52 [0.31, 0.70]			
Month 36	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-3.1.2 SAE: time to first event - stratified per CRF
Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 39	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			
Month 42	0.73 [0.64, 0.81]	0.52 [0.31, 0.70]			
Month 45	0.71 [0.60, 0.79]	0.52 [0.31, 0.70]			
Month 48	0.71 [0.60, 0.79]	0.52 [0.31, 0.70]			
Month 51	0.61 [0.44, 0.74]	0.52 [0.31, 0.70]			
Month 54	0.61 [0.44, 0.74]	0.52 [0.31, 0.70]			
Month 57	0.61 [0.44, 0.74]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
 Safety Set
 (Page 1 of 6)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Infections and infestations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	2 (2.6)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	143 (91.7)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [16.89, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.33	[0.28, 6.36]	0.719
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.97 [0.93, 0.99]		0.98 [0.89, 1.00]			
Month 12	0.96 [0.91, 0.98]		0.98 [0.89, 1.00]			
Month 15	0.96 [0.91, 0.98]		0.98 [0.89, 1.00]			
Month 18	0.96 [0.91, 0.98]		0.93 [0.72, 0.99]			
Month 21	0.94 [0.87, 0.97]		0.93 [0.72, 0.99]			
Month 24	0.94 [0.87, 0.97]		0.93 [0.72, 0.99]			
Month 27	0.94 [0.87, 0.97]		0.93 [0.72, 0.99]			
Month 30	0.94 [0.87, 0.97]		0.93 [0.72, 0.99]			
Month 33	0.93 [0.86, 0.96]		0.93 [0.72, 0.99]			
Month 36	0.93 [0.86, 0.96]		0.93 [0.72, 0.99]			
Month 39	0.93 [0.86, 0.96]		0.93 [0.72, 0.99]			
Month 42	0.93 [0.86, 0.96]		0.93 [0.72, 0.99]			
Month 45	0.90 [0.81, 0.95]		0.93 [0.72, 0.99]			
Month 48	0.90 [0.81, 0.95]		0.93 [0.72, 0.99]			
Month 51	0.90 [0.81, 0.95]		0.93 [0.72, 0.99]			
Month 54	0.90 [0.81, 0.95]		0.93 [0.72, 0.99]			
Month 57	0.90 [0.81, 0.95]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
Safety Set
(Page 3 of 6)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [25.10, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 9	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]		0.93 [0.68, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.93 [0.68, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 36	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 39	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 42	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 45	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 48	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 51	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 54	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 6	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.1 SAE by SOC: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 12	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 15	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 18	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 21	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 24	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 27	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 36	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 39	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 42	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 45	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 48	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 51	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 54	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

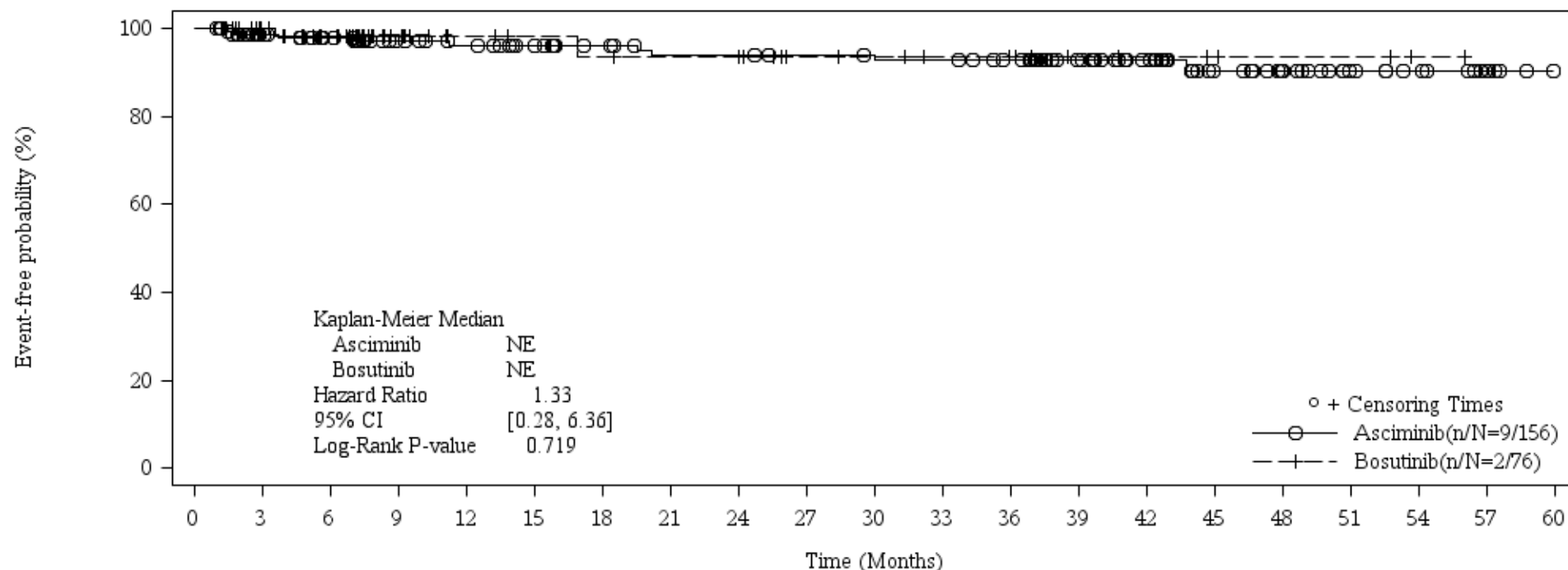
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Figure 4-3.2.1 (Page 1 of 3)
SAE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Infections and infestations



Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	127	105	100	93	88	83	83	81	80	79	75	60	46	32	24	16	12	5	0
Bosutinib	76	62	50	30	22	20	19	18	18	13	12	10	9	6	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

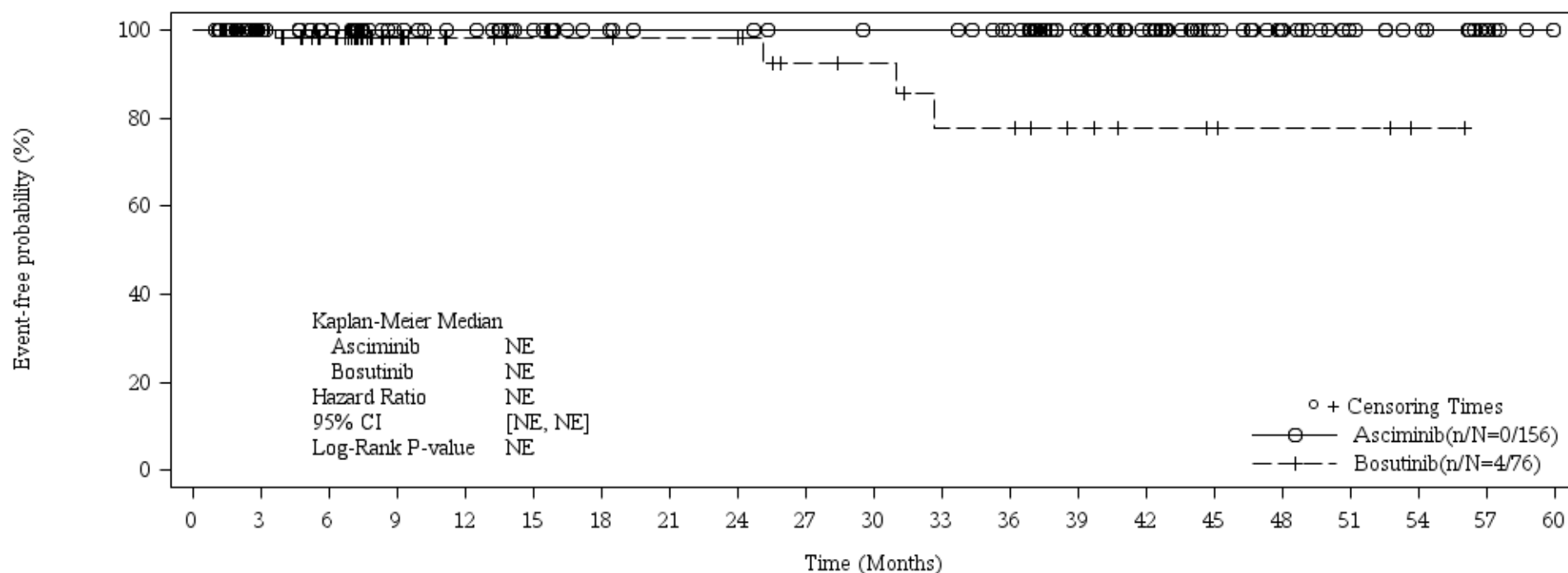
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-3.2.1 (Page 2 of 3)
SAE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Respiratory/ thoracic and mediastinal disorders



Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	10	10	7	5	4	3	3	1	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

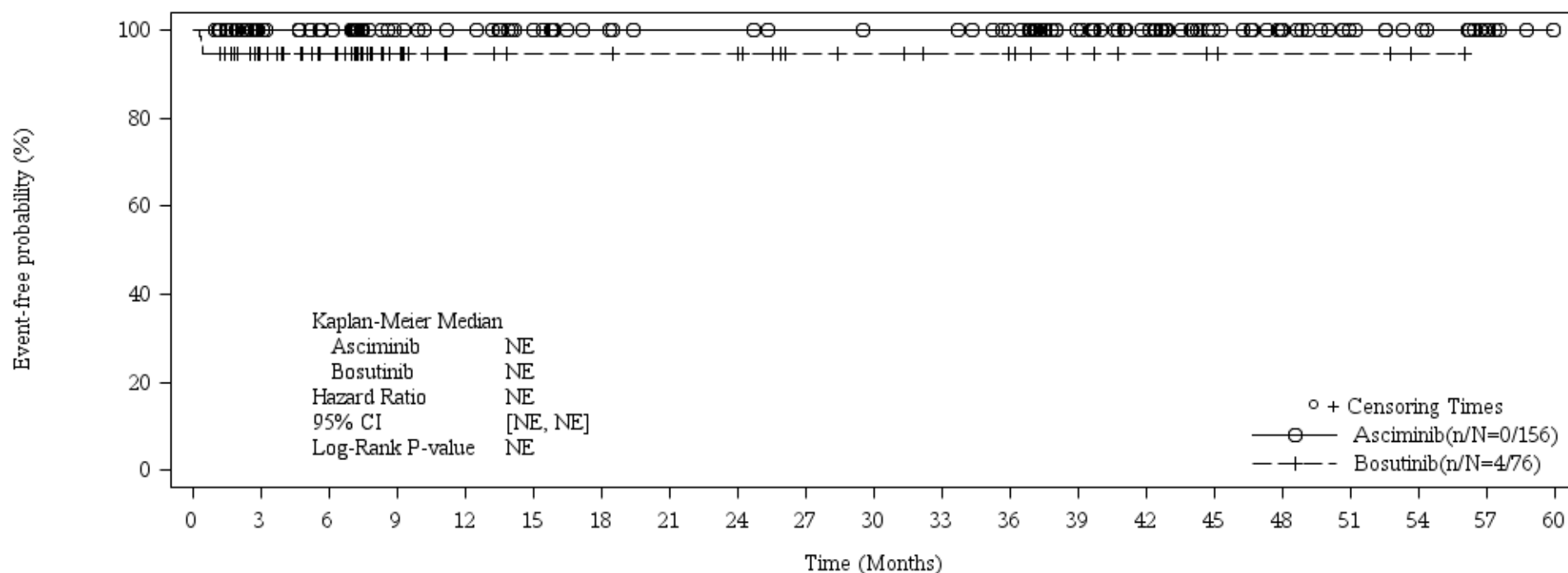
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Figure 4-3.2.1 (Page 3 of 3)
SAE by SOC: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

SOC: Skin and subcutaneous tissue disorders



Kaplan-Meier Median
 Asciminib NE
 Bosutinib NE
 Hazard Ratio NE
 95% CI [NE, NE]
 Log-Rank P-value NE

Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	61	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10

patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 1 of 6)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Infections and infestations					
N*	156	76			
Number of patients, n (%)					
with events					
AE	9 (5.8)	2 (2.6)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	143 (91.7)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [16.89, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.35	[0.28, 6.43]	0.703
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and
 in at least 1% of patients in one treatment arm

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Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 6)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.97 [0.93, 0.99]	0.98 [0.89, 1.00]			
Month 12	0.96 [0.91, 0.98]	0.98 [0.89, 1.00]			
Month 15	0.96 [0.91, 0.98]	0.98 [0.89, 1.00]			
Month 18	0.96 [0.91, 0.98]	0.93 [0.72, 0.99]			
Month 21	0.94 [0.87, 0.97]	0.93 [0.72, 0.99]			
Month 24	0.94 [0.87, 0.97]	0.93 [0.72, 0.99]			
Month 27	0.94 [0.87, 0.97]	0.93 [0.72, 0.99]			
Month 30	0.94 [0.87, 0.97]	0.93 [0.72, 0.99]			
Month 33	0.93 [0.86, 0.96]	0.93 [0.72, 0.99]			
Month 36	0.93 [0.86, 0.96]	0.93 [0.72, 0.99]			
Month 39	0.93 [0.86, 0.96]	0.93 [0.72, 0.99]			
Month 42	0.93 [0.86, 0.96]	0.93 [0.72, 0.99]			
Month 45	0.90 [0.81, 0.95]	0.93 [0.72, 0.99]			
Month 48	0.90 [0.81, 0.95]	0.93 [0.72, 0.99]			
Month 51	0.90 [0.81, 0.95]	0.93 [0.72, 0.99]			
Month 54	0.90 [0.81, 0.95]	0.93 [0.72, 0.99]			
Month 57	0.90 [0.81, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Respiratory, thoracic and mediastinal disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	0			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [25.10, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 4 of 6)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 6	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 9	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]		0.93 [0.68, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.93 [0.68, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 36	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 39	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 42	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 45	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 48	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 51	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 54	1.00 [1.00, 1.00]		0.78 [0.47, 0.92]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 5 of 6)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Skin and subcutaneous tissue disorders					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 6	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.2.2 SAE by SOC: time to first event - stratified per CRF
 Safety Set
 (Page 6 of 6)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 12	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 15	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 18	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 21	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 24	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 27	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 36	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 39	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 42	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 45	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 48	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 51	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 54	1.00 [1.00, 1.00]		0.95 [0.87, 0.98]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 4-3.3.1 SAE by PT: time to first event - stratified per IRT
Safety Set
(Page 1 of 1)

Treatment Groups		Comparison		
Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value

No data for this analysis

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

-NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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CABL001A2301 German Pricing and reimbursement (Cut-off date:22MAR2023)

**Figure 4-3.3.1 SAE by PT: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set
(Page 1 of 1)**

There are NO observations for this output

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

- NE: Not Estimable. MedDRA version 26.0

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Final

Table 4-3.3.2 SAE by PT: time to first event - stratified per CRF
Safety Set
(Page 1 of 1)

Treatment Groups		Comparison		
Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value

No data for this analysis

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

-NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

MedDRA version 26.0

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Final

Table 4-4.1.1 AE leading to discontinuation: time to first event - stratified per IRT
Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	13 (8.3)	21 (27.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	29 (38.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	9.69 [3.71, 30.95]	0.20	[0.10, 0.41]	<0.001
median	NE [NE, NE]	NE [25.10, NE]			
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable					

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Table 4-4.1.1 AE leading to discontinuation: time to first event - stratified per IRT
Safety Set
(Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
[95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.86 [0.76, 0.92]			
Month 6	0.94 [0.89, 0.97]	0.82 [0.71, 0.89]			
Month 9	0.94 [0.89, 0.97]	0.77 [0.65, 0.86]			
Month 12	0.93 [0.88, 0.96]	0.74 [0.61, 0.84]			
Month 15	0.93 [0.88, 0.96]	0.74 [0.61, 0.84]			
Month 18	0.92 [0.86, 0.96]	0.74 [0.61, 0.84]			
Month 21	0.92 [0.86, 0.96]	0.74 [0.61, 0.84]			
Month 24	0.92 [0.86, 0.96]	0.70 [0.55, 0.81]			
Month 27	0.92 [0.86, 0.96]	0.66 [0.49, 0.79]			
Month 30	0.92 [0.86, 0.96]	0.62 [0.43, 0.76]			
Month 33	0.92 [0.86, 0.96]	0.57 [0.38, 0.72]			
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable					

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Final

Table 4-4.1.1 AE leading to discontinuation: time to first event - stratified per IRT

Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 36	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 39	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 42	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 45	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 48	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 51	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 54	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 57	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

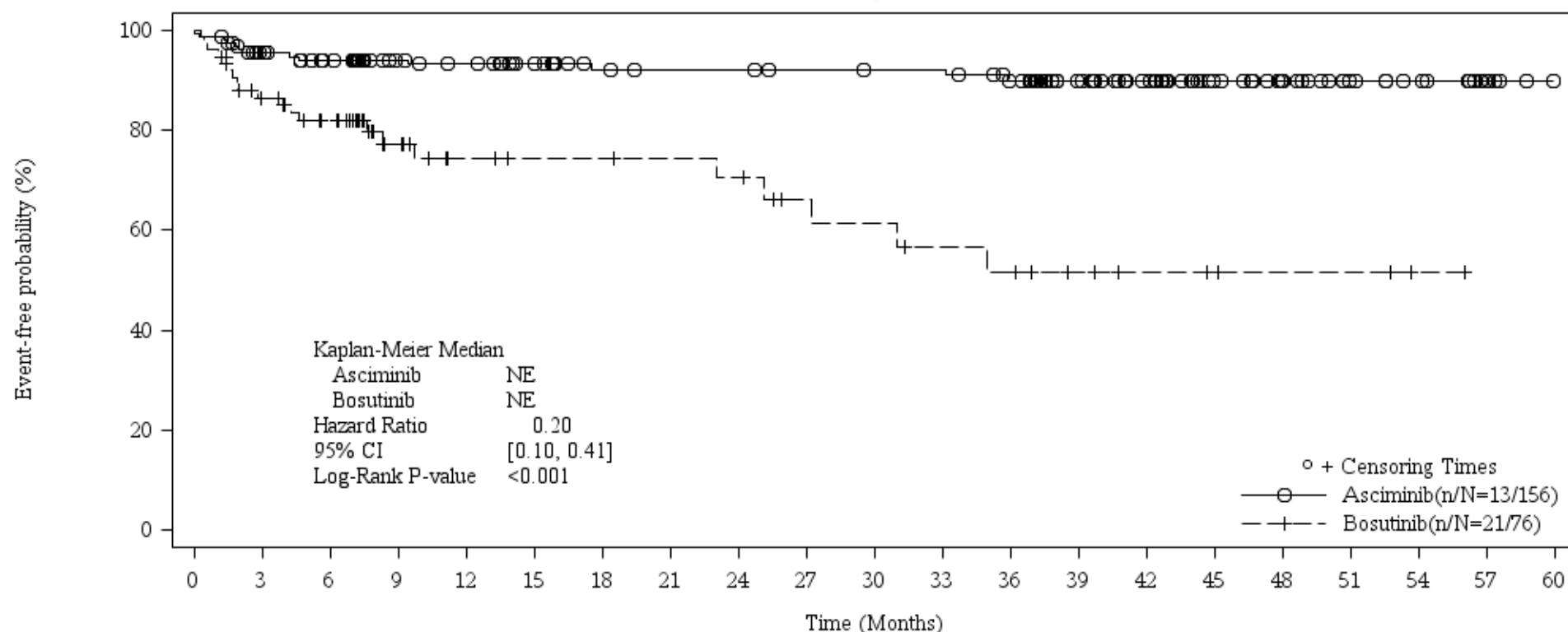
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable

Figure 4-4.1.1 (Page 1 of 1)

AE leading to discontinuation: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set



Number of patients still at risk

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	90	88	88	86	85	85	79	63	49	34	25	17	13	5	0
Bosutinib	76	60	50	29	22	20	20	19	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-4.1.2 AE leading to discontinuation: time to first event - stratified per CRF

Safety Set
(Page 1 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
N*	156	76			
Number of patients, n (%)					
with events					
AE	13 (8.3)	21 (27.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	29 (38.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	9.69 [3.71, 30.95]	0.20	[0.10, 0.41]	<0.001
median	NE [NE, NE]	NE [25.10, NE]			
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates					
Median (time to event) and its 95% CI are generated by KM estimation.					
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test					
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).					
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.					
- NE: Not Estimable.					

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Final

Table 4-4.1.2 AE leading to discontinuation: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
[95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.86 [0.76, 0.92]			
Month 6	0.94 [0.89, 0.97]	0.82 [0.71, 0.89]			
Month 9	0.94 [0.89, 0.97]	0.77 [0.65, 0.86]			
Month 12	0.93 [0.88, 0.96]	0.74 [0.61, 0.84]			
Month 15	0.93 [0.88, 0.96]	0.74 [0.61, 0.84]			
Month 18	0.92 [0.86, 0.96]	0.74 [0.61, 0.84]			
Month 21	0.92 [0.86, 0.96]	0.74 [0.61, 0.84]			
Month 24	0.92 [0.86, 0.96]	0.70 [0.55, 0.81]			
Month 27	0.92 [0.86, 0.96]	0.66 [0.49, 0.79]			
Month 30	0.92 [0.86, 0.96]	0.62 [0.43, 0.76]			
Month 33	0.92 [0.86, 0.96]	0.57 [0.38, 0.72]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-4.1.2 AE leading to discontinuation: time to first event - stratified per CRF

Safety Set
(Page 3 of 3)

	Treatment Groups		Comparison		
	Asciminib (N=156)	Bosutinib (N=76)	HR	[95% CI]	p-value
Month 36	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 39	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 42	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 45	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 48	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 51	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 54	0.90 [0.83, 0.94]	0.52 [0.32, 0.68]			
Month 57	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-4.2.1 AE leading to discontinuation by SOC: number and percentage of patients with event
Safety Set
(Page 1 of 1)

	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Primary system organ class			
Number of subjects with at least one event	13 (8.3)	23 (30.3)	36 (15.5)
Investigations	6 (3.8)	5 (6.6)	11 (4.7)
Blood and lymphatic system disorders	4 (2.6)	5 (6.6)	9 (3.9)
Nervous system disorders	2 (1.3)	0	2 (0.9)
Pregnancy, puerperium and perinatal conditions	1 (0.6)	0	1 (0.4)
Gastrointestinal disorders	0	3 (3.9)	3 (1.3)
General disorders and administration site conditions	0	1 (1.3)	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	3 (3.9)	3 (1.3)
Respiratory, thoracic and mediastinal disorders	0	4 (5.3)	4 (1.7)
Skin and subcutaneous tissue disorders	0	2 (2.6)	2 (0.9)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Table 4-4.2.2 AE leading to discontinuation by SOC: censored at switch timepoint

Safety Set
(Page 1 of 1)

	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Primary system organ class			
Number of subjects with at least one event	13 (8.3)	21 (27.6)	34 (14.7)
Investigations	6 (3.8)	5 (6.6)	11 (4.7)
Blood and lymphatic system disorders	4 (2.6)	4 (5.3)	8 (3.4)
Nervous system disorders	2 (1.3)	0	2 (0.9)
Pregnancy, puerperium and perinatal conditions	1 (0.6)	0	1 (0.4)
Gastrointestinal disorders	0	3 (3.9)	3 (1.3)
General disorders and administration site conditions	0	1 (1.3)	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (2.6)	2 (0.9)
Respiratory, thoracic and mediastinal disorders	0	4 (5.3)	4 (1.7)
Skin and subcutaneous tissue disorders	0	2 (2.6)	2 (0.9)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Final

Table 4-4.3.1 AE leading to discontinuation by PT: number and percentage of patients with event
 Safety Set
 (Page 1 of 2)

Preferred term	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Number of subjects with at least one event	13 (8.3)	23 (30.3)	36 (15.5)
Lipase increased	3 (1.9)	0	3 (1.3)
Thrombocytopenia	3 (1.9)	2 (2.6)	5 (2.2)
Neutropenia	2 (1.3)	3 (3.9)	5 (2.2)
Neutrophil count decreased	2 (1.3)	0	2 (0.9)
Platelet count decreased	2 (1.3)	0	2 (0.9)
Amylase increased	1 (0.6)	0	1 (0.4)
Cerebral disorder	1 (0.6)	0	1 (0.4)
Ejection fraction decreased	1 (0.6)	0	1 (0.4)
Ischaemic stroke	1 (0.6)	0	1 (0.4)
Pregnancy	1 (0.6)	0	1 (0.4)
Acute myeloid leukaemia	0	1 (1.3)	1 (0.4)
Alanine aminotransferase increased	0	4 (5.3)	4 (1.7)
Aspartate aminotransferase increased	0	2 (2.6)	2 (0.9)
Blood creatinine increased	0	1 (1.3)	1 (0.4)
Diarrhoea	0	3 (3.9)	3 (1.3)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Table 4-4.3.1 AE leading to discontinuation by PT: number and percentage of patients with event
 Safety Set
 (Page 2 of 2)

	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Preferred term			
Diffuse large B-cell lymphoma	0	1 (1.3)	1 (0.4)
Drug eruption	0	1 (1.3)	1 (0.4)
Hydrothorax	0	1 (1.3)	1 (0.4)
Pleural effusion	0	3 (3.9)	3 (1.3)
Pyrexia	0	1 (1.3)	1 (0.4)
Rash	0	1 (1.3)	1 (0.4)
Squamous cell carcinoma	0	1 (1.3)	1 (0.4)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Table 4-4.3.2 AE leading to discontinuation by PT: censored at switch timepoint
 Safety Set
 (Page 1 of 2)

Preferred term	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Number of subjects with at least one event	13 (8.3)	21 (27.6)	34 (14.7)
Lipase increased	3 (1.9)	0	3 (1.3)
Thrombocytopenia	3 (1.9)	1 (1.3)	4 (1.7)
Neutropenia	2 (1.3)	3 (3.9)	5 (2.2)
Neutrophil count decreased	2 (1.3)	0	2 (0.9)
Platelet count decreased	2 (1.3)	0	2 (0.9)
Amylase increased	1 (0.6)	0	1 (0.4)
Cerebral disorder	1 (0.6)	0	1 (0.4)
Ejection fraction decreased	1 (0.6)	0	1 (0.4)
Ischaemic stroke	1 (0.6)	0	1 (0.4)
Pregnancy	1 (0.6)	0	1 (0.4)
Alanine aminotransferase increased	0	4 (5.3)	4 (1.7)
Aspartate aminotransferase increased	0	2 (2.6)	2 (0.9)
Blood creatinine increased	0	1 (1.3)	1 (0.4)
Diarrhoea	0	3 (3.9)	3 (1.3)
Diffuse large B-cell lymphoma	0	1 (1.3)	1 (0.4)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Table 4-4.3.2
(Page 2 of 2)
AE leading to discontinuation by PT: censored at switch timepoint
Safety Set

Preferred term	Asciminib N=156 n (%)	Bosutinib N=76 n (%)	All subjects N=232 n (%)
Drug eruption	0	1 (1.3)	1 (0.4)
Hydrothorax	0	1 (1.3)	1 (0.4)
Pleural effusion	0	3 (3.9)	3 (1.3)
Pyrexia	0	1 (1.3)	1 (0.4)
Rash	0	1 (1.3)	1 (0.4)
Squamous cell carcinoma	0	1 (1.3)	1 (0.4)
Numbers (n) represent counts of subjects.			
MedDRA version 26.0			

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Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 1 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	1 (1.3)			
censored					
Death	1 (0.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.92	[0.36, 23.51]	0.292
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	1.00 [1.00, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.98 [0.87, 1.00]			
Month 9	0.96 [0.90, 0.98]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 2 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 15	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 18	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 21	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 24	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 27	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 30	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 33	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 36	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 45	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 48	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 51	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 54	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 57	0.94 [0.87, 0.97]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.28	[0.14, 11.94]	0.826
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	43 (56.6)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.08, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.76	[0.33, 1.80]	0.536
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 21	0.89 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 36	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 39	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 42	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 45	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 48	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 51	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 54	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 57	0.86 [0.78, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	52 (33.3)	60 (78.9)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	101 (64.7)	11 (14.5)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	10.09 [1.81, 13.83]	0.03 [0.03, 0.07]			
median	NE [NE, NE]	0.23 [0.07, 0.36]	0.18	[0.12, 0.27]	<0.001
75th	NE [NE, NE]	2.79 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.25 [0.16, 0.35]			
Month 6	0.78 [0.70, 0.84]	0.21 [0.13, 0.31]			
Month 9	0.75 [0.67, 0.81]	0.19 [0.11, 0.29]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.62, 0.78]	0.19 [0.11, 0.29]			
Month 15	0.67 [0.58, 0.74]	0.19 [0.11, 0.29]			
Month 18	0.66 [0.57, 0.73]	0.19 [0.11, 0.29]			
Month 21	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 24	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 27	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 30	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 33	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 36	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 39	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 42	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 45	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 48	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 51	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 54	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 57	0.60 [0.50, 0.68]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	20 (12.8)	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	131 (84.0)	46 (60.5)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.95	[0.41, 2.17]	0.899
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.93 [0.85, 0.97]			
Month 6	0.91 [0.85, 0.94]	0.90 [0.80, 0.95]			
Month 9	0.90 [0.84, 0.94]	0.90 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.89 [0.83, 0.93]	0.90 [0.80, 0.95]			
Month 15	0.87 [0.80, 0.92]	0.90 [0.80, 0.95]			
Month 18	0.86 [0.79, 0.91]	0.90 [0.80, 0.95]			
Month 21	0.86 [0.79, 0.91]	0.90 [0.80, 0.95]			
Month 24	0.86 [0.79, 0.91]	0.85 [0.68, 0.93]			
Month 27	0.86 [0.79, 0.91]	0.85 [0.68, 0.93]			
Month 30	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 33	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 36	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 39	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 42	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 45	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 48	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 51	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 54	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 57	0.85 [0.78, 0.90]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

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CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	19 (12.2)	25 (32.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	36 (47.4)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [38.70, NE]	3.71 [1.25, 6.60]			
median	NE [NE, NE]	NE [6.60, NE]	0.25	[0.13, 0.46]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.77 [0.66, 0.85]			
Month 6	0.94 [0.89, 0.97]	0.67 [0.54, 0.77]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.63 [0.50, 0.73]			
Month 12	0.91 [0.85, 0.95]	0.63 [0.50, 0.73]			
Month 15	0.91 [0.85, 0.95]	0.63 [0.50, 0.73]			
Month 18	0.90 [0.84, 0.94]	0.63 [0.50, 0.73]			
Month 21	0.89 [0.82, 0.93]	0.63 [0.50, 0.73]			
Month 24	0.88 [0.80, 0.93]	0.63 [0.50, 0.73]			
Month 27	0.88 [0.80, 0.93]	0.63 [0.50, 0.73]			
Month 30	0.87 [0.79, 0.92]	0.63 [0.50, 0.73]			
Month 33	0.86 [0.77, 0.91]	0.63 [0.50, 0.73]			
Month 36	0.84 [0.76, 0.90]	0.63 [0.50, 0.73]			
Month 39	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 42	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 45	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 48	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 51	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 54	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 57	0.83 [0.74, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	26 (34.2)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	31 (40.8)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [7.62, NE]	1.64 [0.53, 6.21]			
median	NE [NE, NE]	NE [NE, NE]	0.43	[0.26, 0.74]	0.002
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.74 [0.62, 0.82]			
Month 6	0.84 [0.76, 0.89]	0.67 [0.55, 0.77]			
Month 9	0.80 [0.72, 0.86]	0.63 [0.50, 0.73]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

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CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 15	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 18	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 21	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 24	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 27	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 30	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 33	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 36	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 39	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 42	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 45	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 48	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 51	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 54	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 57	0.75 [0.66, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

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CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	10 (6.4)	4 (5.3)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	144 (92.3)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.91	[0.28, 2.93]	0.878
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.92, 0.99]	0.95 [0.85, 0.98]			
Month 9	0.95 [0.90, 0.98]	0.93 [0.82, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 15	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 18	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 21	0.93 [0.87, 0.96]	0.93 [0.82, 0.97]			
Month 24	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 27	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 30	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 33	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 36	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 39	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 42	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 45	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 48	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 51	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 54	0.92 [0.85, 0.96]	NE [NE, NE]			
Month 57	0.92 [0.85, 0.96]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	7 (9.2)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	47 (61.8)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.05	[0.43, 2.56]	0.916
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.93 [0.84, 0.97]			
Month 6	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 9	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 15	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 18	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 21	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 24	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 27	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 30	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 33	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 36	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 39	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 42	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 45	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 48	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 51	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 54	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 57	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	16 (21.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	40 (52.6)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.05	[0.58, 1.89]	0.874
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.80 [0.69, 0.87]			
Month 6	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 9	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 15	0.77 [0.69, 0.83]	0.78 [0.67, 0.86]			
Month 18	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 21	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 24	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 27	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 30	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 33	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 36	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 39	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 42	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 45	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 48	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 51	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 54	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 57	0.76 [0.68, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	17 (22.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	40 (52.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.98	[0.55, 1.74]	0.945
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 6	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			
Month 9	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			
Month 15	0.77 [0.69, 0.83]	0.77 [0.65, 0.85]			
Month 18	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 21	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 24	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 27	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 30	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 33	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 36	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 39	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 42	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 45	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 48	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 51	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 54	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 57	0.76 [0.68, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	46 (29.5)	16 (21.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	105 (67.3)	43 (56.6)			
Treatment switched	0	16 (21.1)			
Percentiles (months) (95% CI)					
25th	1.87 [1.35, NE]	30.39 [2.23, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.41	[0.80, 2.49]	0.241
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.73 [0.65, 0.79]	0.82 [0.71, 0.89]			
Month 6	0.71 [0.63, 0.77]	0.81 [0.69, 0.88]			
Month 9	0.71 [0.63, 0.77]	0.81 [0.69, 0.88]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.63, 0.77]	0.77 [0.63, 0.86]			
Month 15	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 18	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 21	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 24	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 27	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 30	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 33	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 36	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 39	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 42	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 45	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 48	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 51	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 54	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 57	0.70 [0.62, 0.77]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	13 (8.3)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	138 (88.5)	46 (60.5)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.77	[0.31, 1.94]	0.577
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.93 [0.88, 0.96]	0.92 [0.82, 0.97]			
Month 9	0.92 [0.87, 0.96]	0.90 [0.79, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 28 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.92 [0.85, 0.95]	0.86 [0.70, 0.93]			
Month 15	0.92 [0.85, 0.95]	0.86 [0.70, 0.93]			
Month 18	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 21	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 24	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 27	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 30	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 33	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 36	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 39	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 42	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 45	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 48	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 51	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 54	0.91 [0.84, 0.94]	NE [NE, NE]			
Month 57	0.91 [0.84, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
(Page 29 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.43	[0.30, 19.90]	0.392
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 30 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 15	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 18	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 21	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 24	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 27	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 30	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 33	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 36	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 45	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 48	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 51	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 54	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 57	0.91 [0.82, 0.96]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
Safety Set
(Page 31 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.54	[0.18, 13.29]	0.693
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.1 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 32 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			
Month 15	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 18	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 21	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 24	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 27	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 30	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 33	0.96 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 36	0.95 [0.89, 0.98]	0.98 [0.88, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 45	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 48	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 51	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 54	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 57	0.94 [0.87, 0.97]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

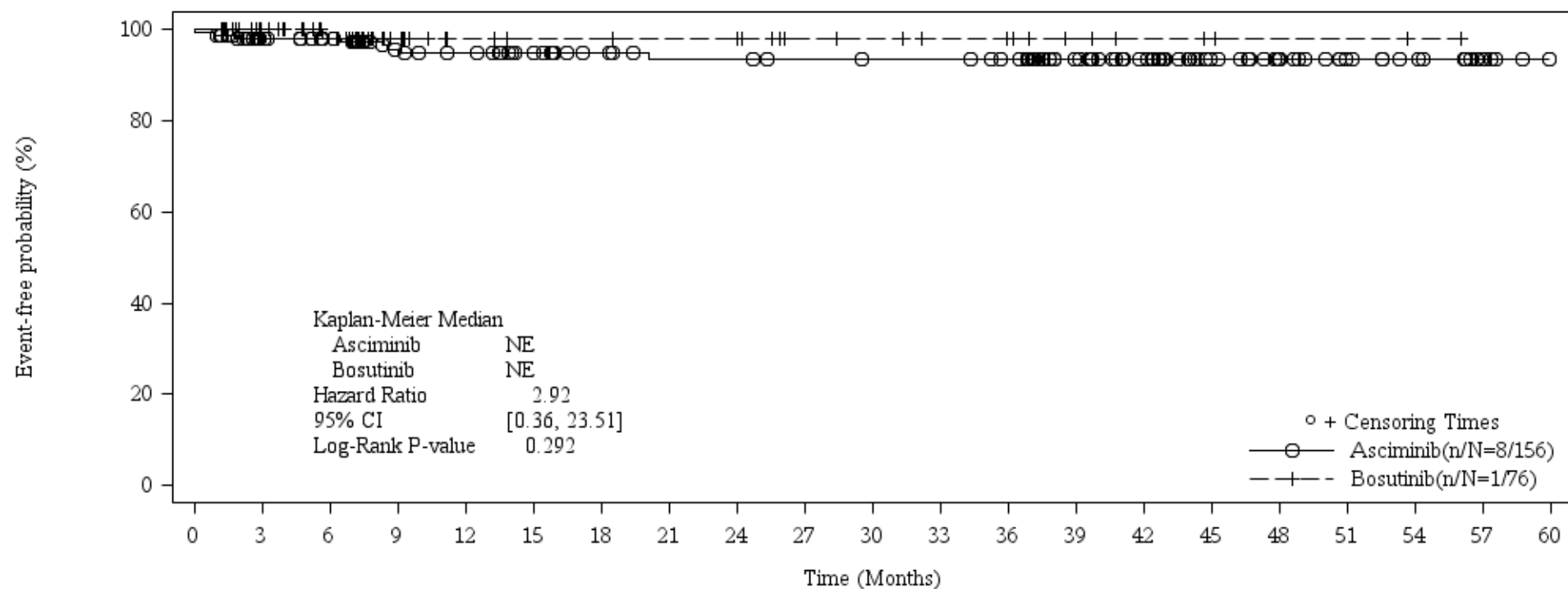
N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.1.1 AESI: Kaplan Meier plot of time to first event - stratified per IRT

Figure 4-5.1.1 (Page 1 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Arterial-occlusive events (AOEs)



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	129	107	103	95	89	85	85	83	82	82	79	62	48	33	24	17	13	5	0
Bosutinib	76	62	49	29	21	19	19	18	18	13	12	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

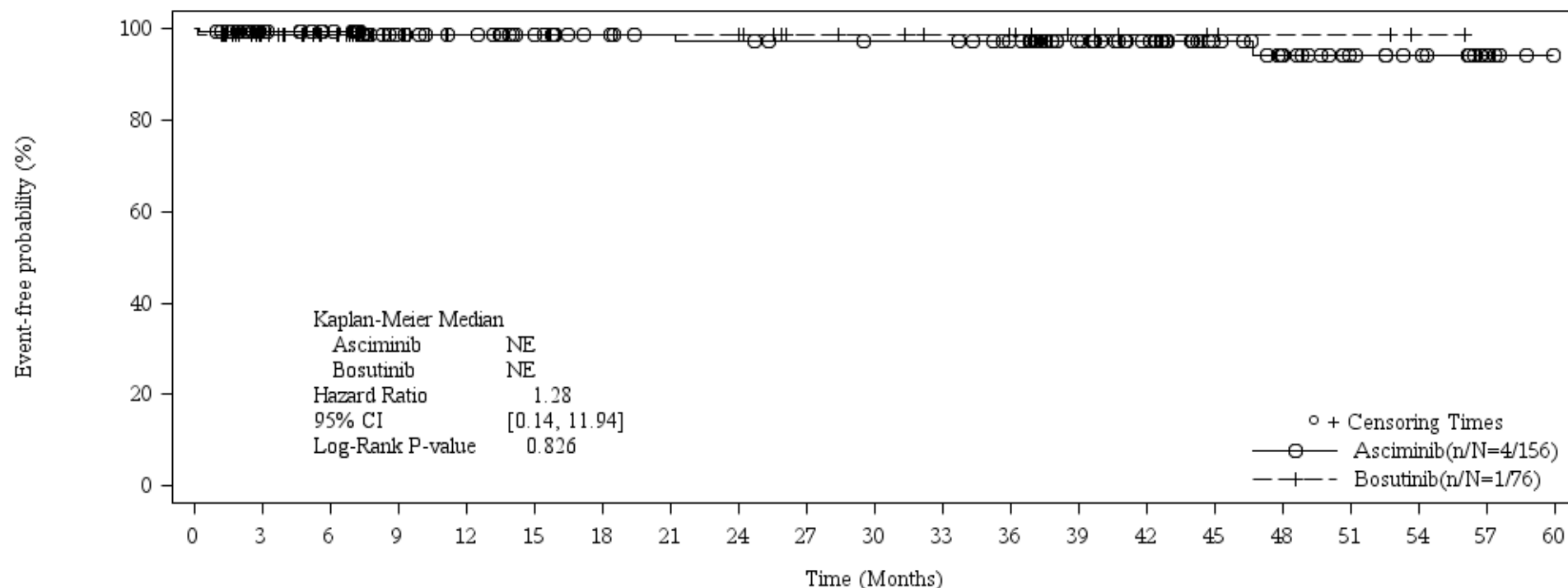
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.1.1 (Page 2 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Cardiac failure (clinical events)

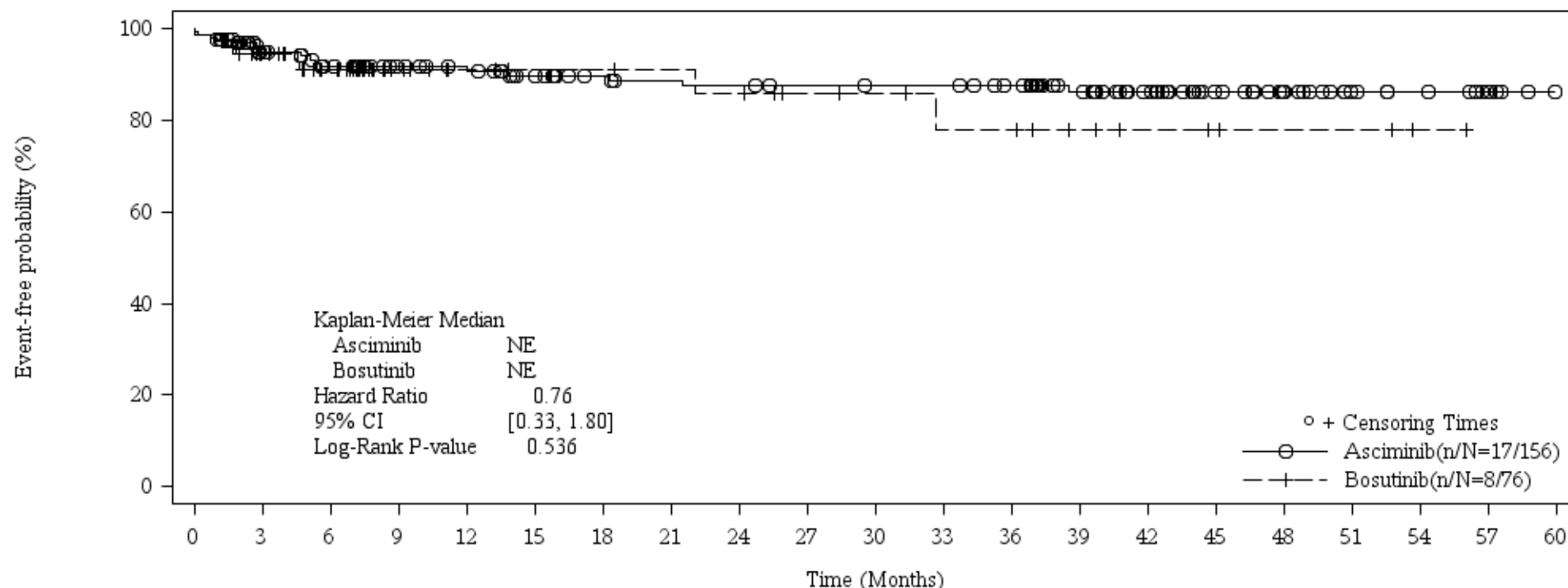


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	86	84	83	83	78	61	48	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 3 of 16)
 AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set

AESI: Edema and fluid retention

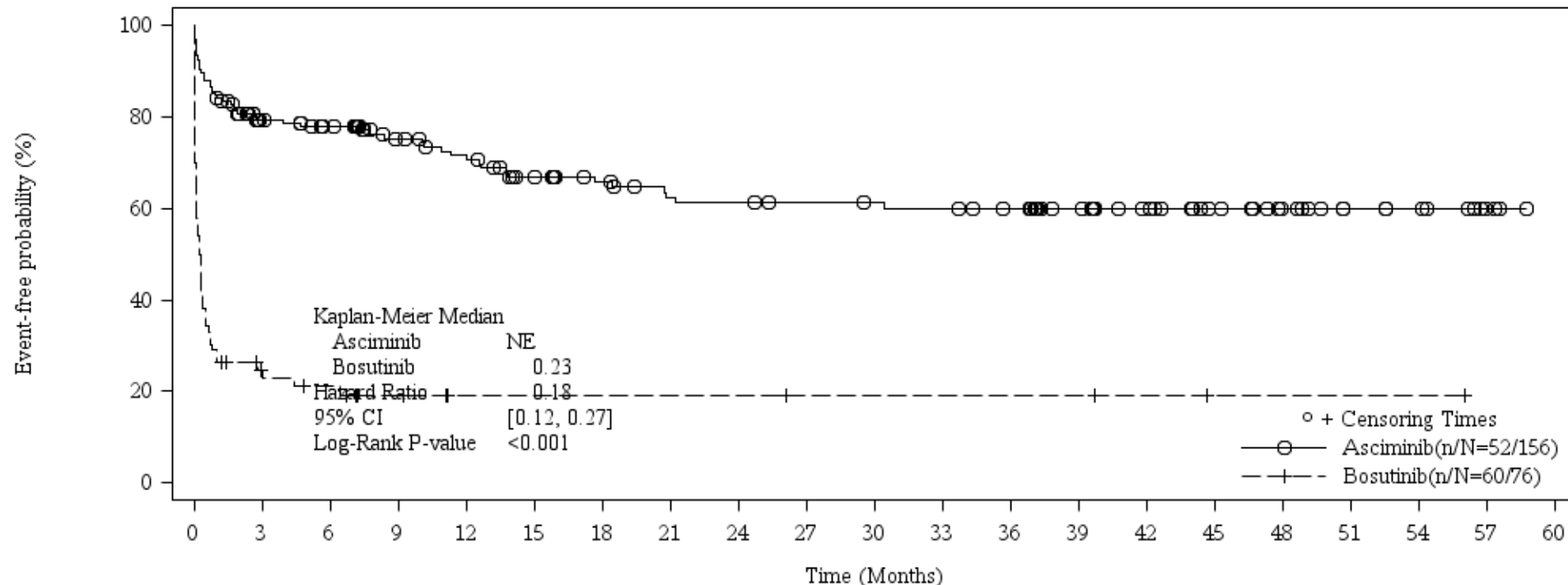


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	133	119	101	96	87	81	78	77	75	74	74	70	56	42	30	21	13	10	5	0
Bosutinib	76	58	44	25	20	18	18	17	16	13	12	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 4 of 16)
 AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set

AESI: GI toxicity

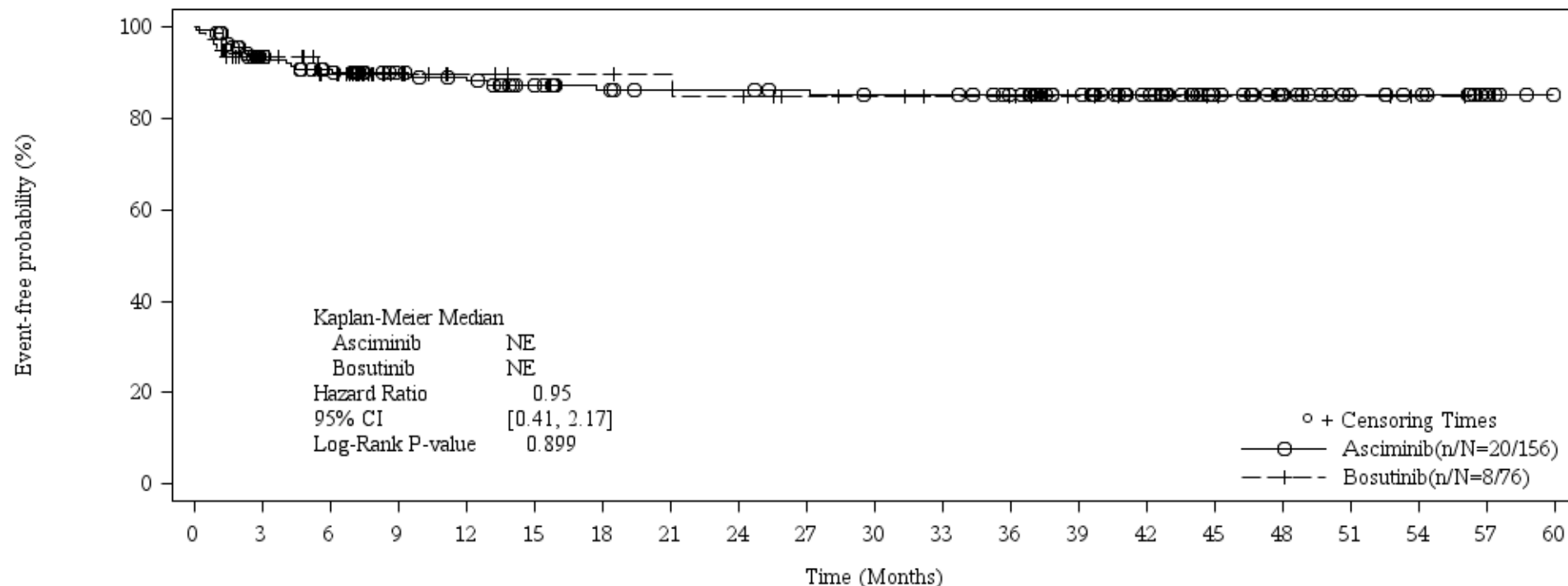


Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	111	101	84	76	65	60	54	53	51	50	49	46	38	30	23	17	11	9	3
Bosutinib	76	14	11	7	4	4	4	4	4	3	3	3	3	3	2	1	1	1	1	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 5 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hemorrhage

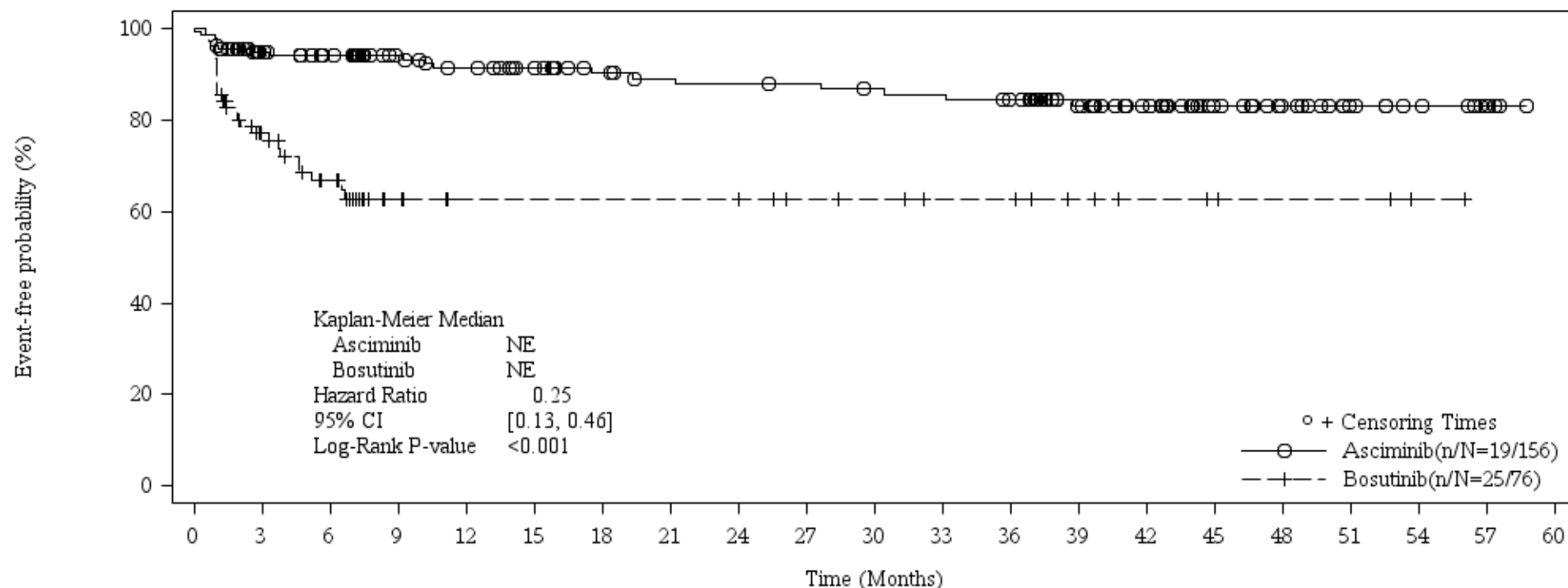


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	133	121	103	99	89	84	81	81	79	77	77	72	59	47	33	24	16	13	5	0
Bosutinib	76	58	47	27	21	19	19	18	17	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 6 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hepatotoxicity (including laboratory terms)

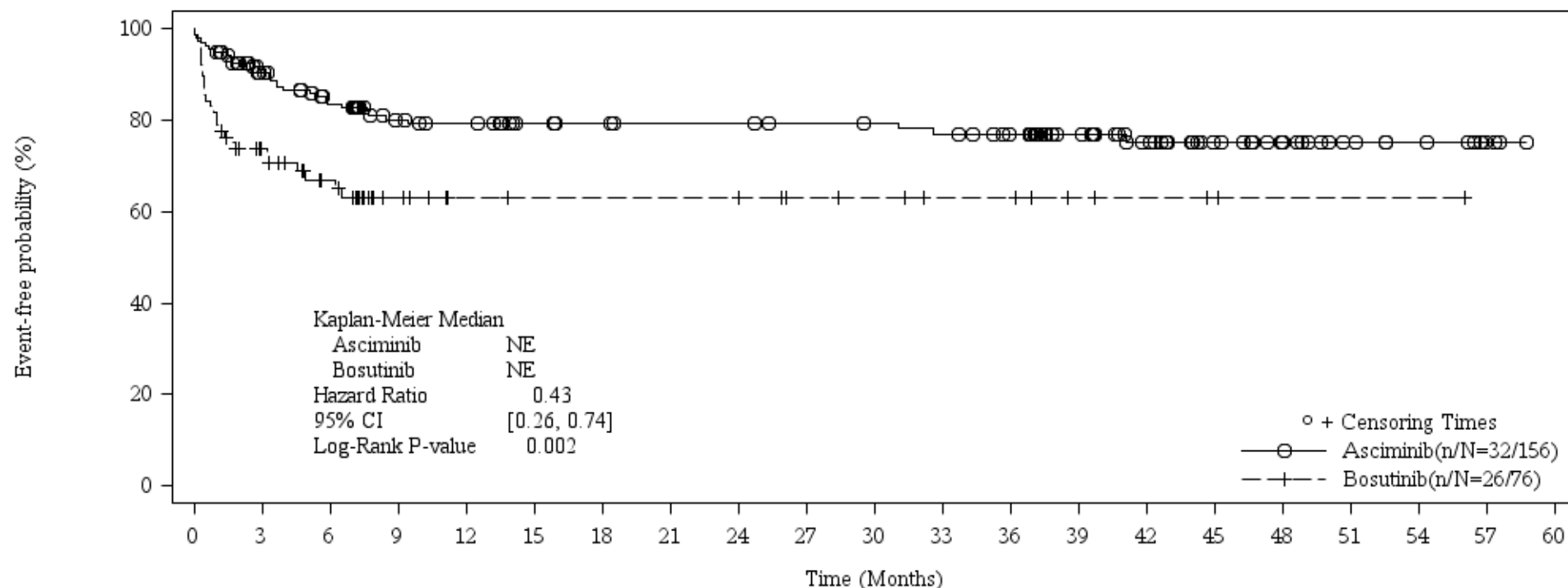


Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	134	122	103	96	89	82	78	77	76	74	73	70	54	41	28	21	13	9	4
Bosutinib	76	48	35	20	16	16	16	16	16	13	12	10	10	7	5	4	3	3	1	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 7 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hypersensitivity

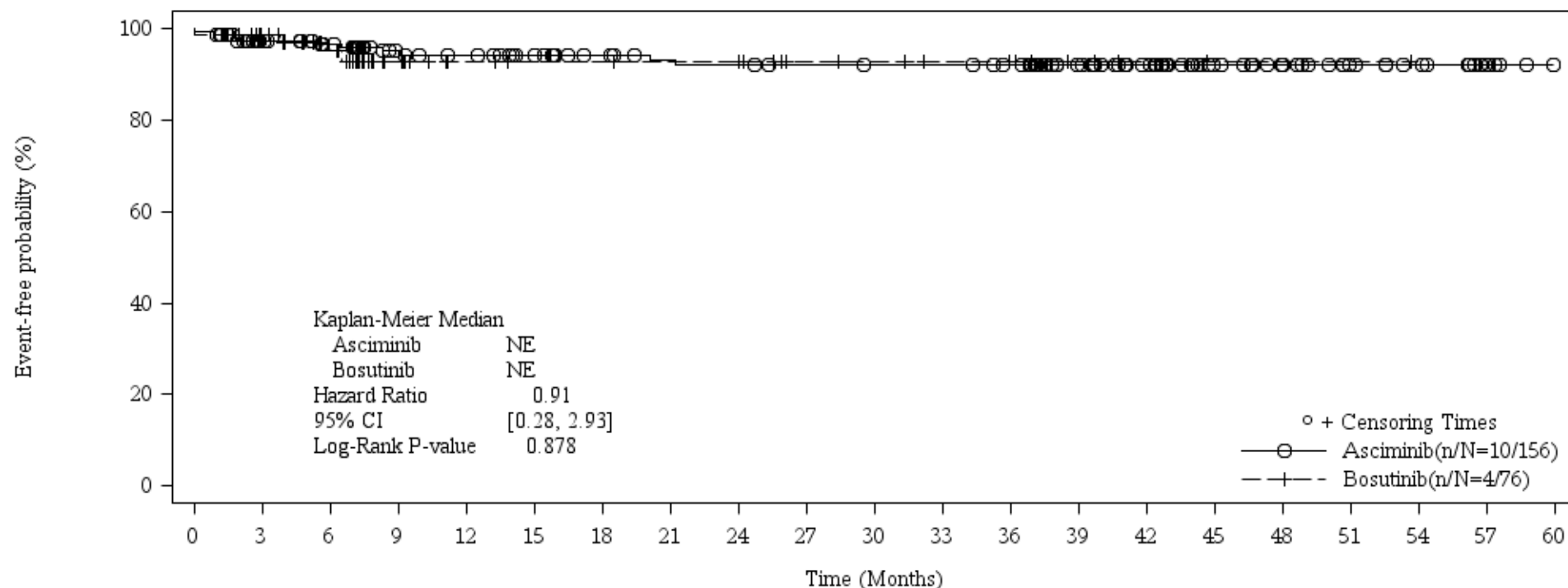


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	127	108	89	85	78	76	74	74	72	71	69	64	50	37	26	18	12	9	3	0
Bosutinib	76	47	34	20	14	13	13	13	13	10	9	7	7	4	3	2	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 8 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Ischemic heart and CNS conditions

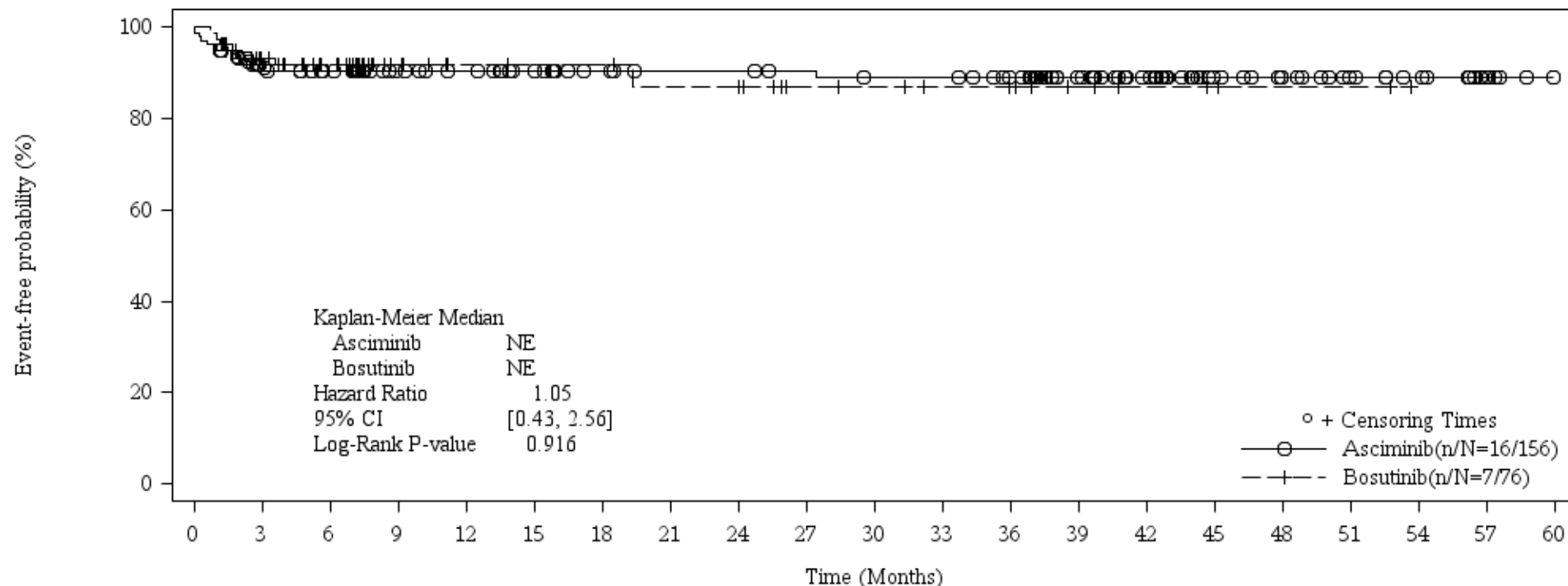


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	138	127	105	101	94	88	84	83	81	80	80	77	60	46	31	24	17	13	5	0
Bosutinib	76	61	47	27	19	17	17	16	16	11	10	8	7	4	2	1	1	1	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 9 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Erythropenia)

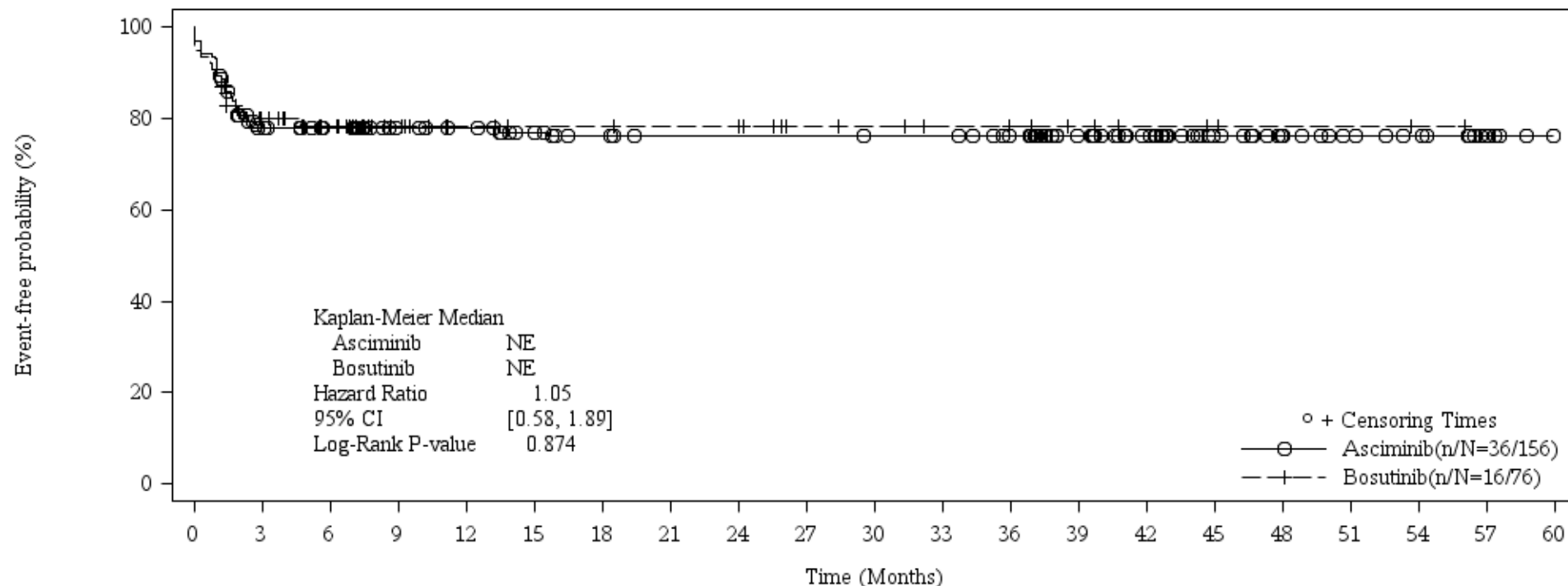


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	132	121	101	97	90	84	81	81	79	77	77	72	57	43	29	23	17	13	5	0
Bosutinib	76	57	44	27	21	20	20	18	18	13	12	10	9	6	4	3	2	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 10 of 16)
**AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set**

AESI: Myelosuppression (Neutropenia)

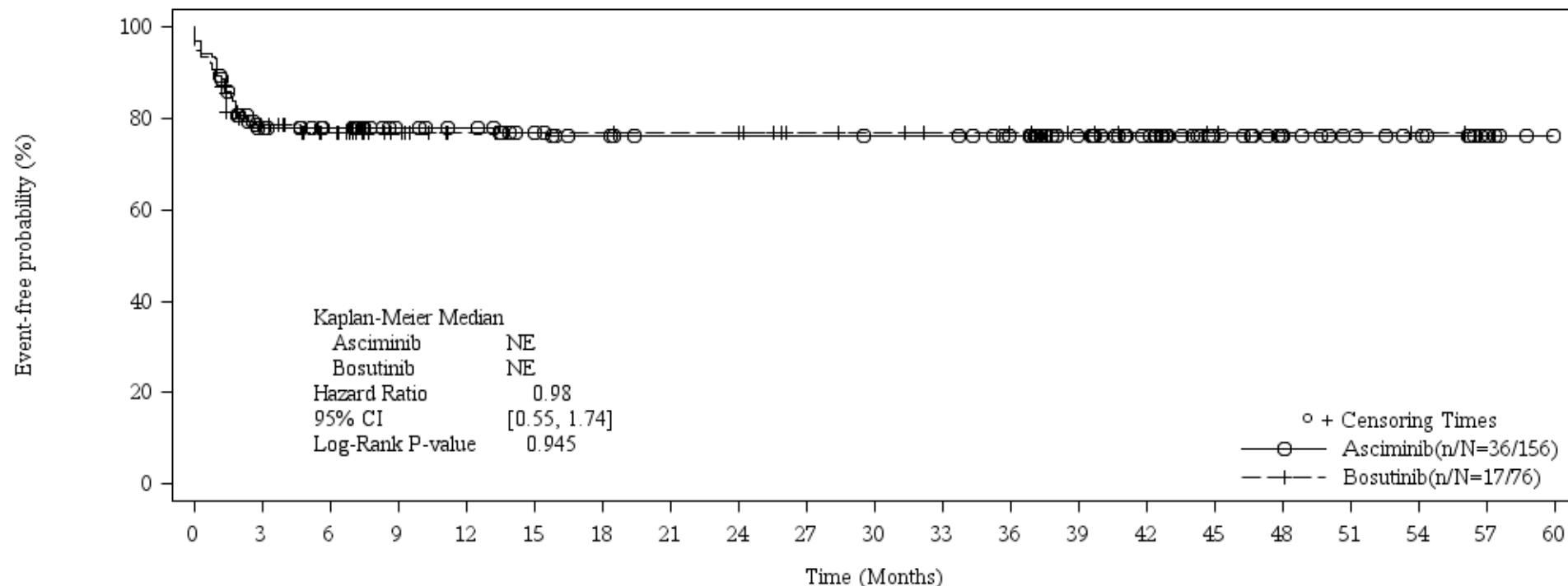


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	112	103	91	88	80	75	72	72	72	71	71	66	53	41	27	19	15	12	5	0
Bosutinib	76	52	41	27	20	18	18	17	17	12	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 11 of 16)
 AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set

AESI: Myelosuppression (Leucopenia)

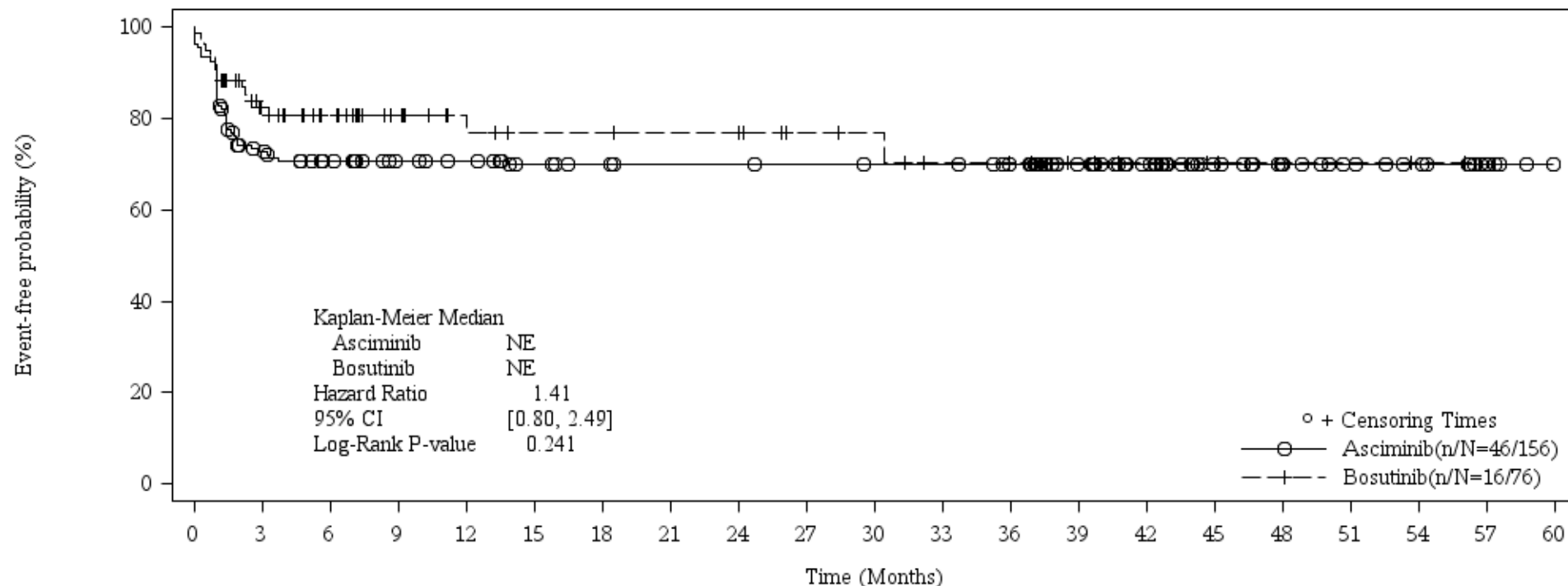


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	112	103	91	88	80	75	72	72	72	71	71	66	53	41	27	19	15	12	5	0
Bosutinib	76	51	40	27	20	18	18	17	17	12	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 12 of 16)
**AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set**

AESI: Myelosuppression (Thrombocytopenia)

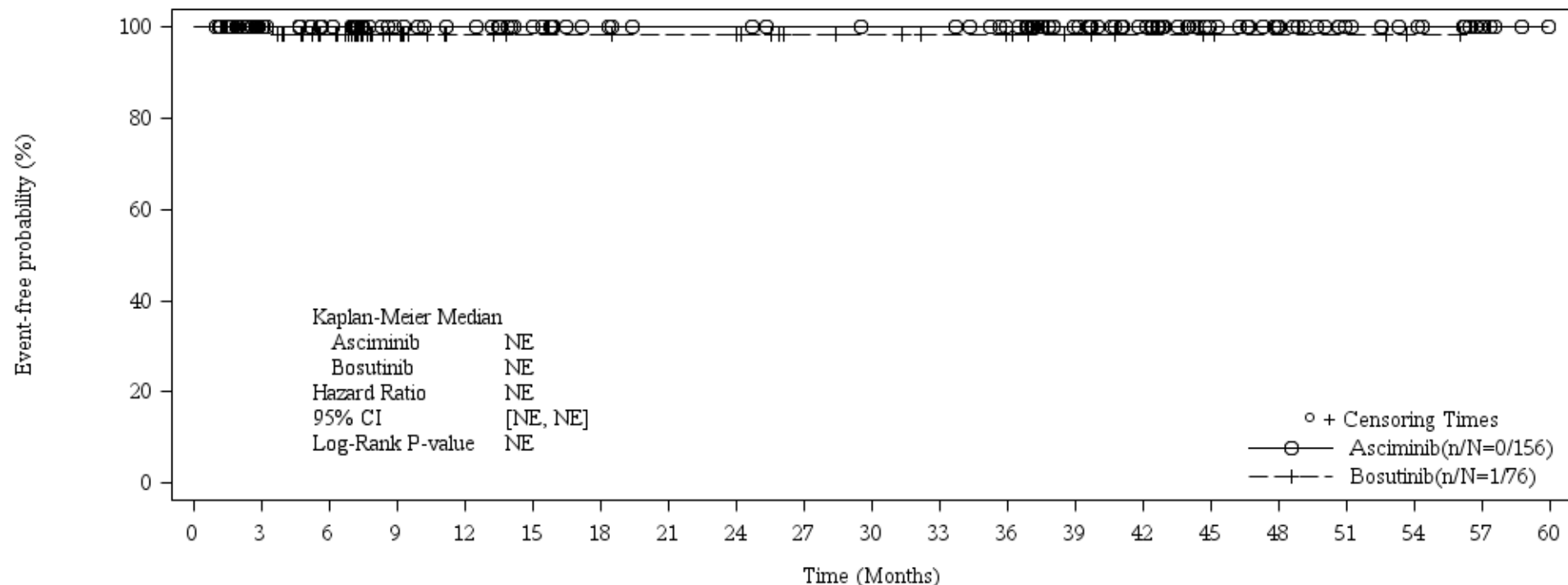


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	107	96	87	84	77	74	72	72	71	70	70	66	53	40	27	19	15	12	5	0
Bosutinib	76	51	39	28	20	18	18	17	17	13	12	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 13 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (cytopenias affecting more than one lineage)



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

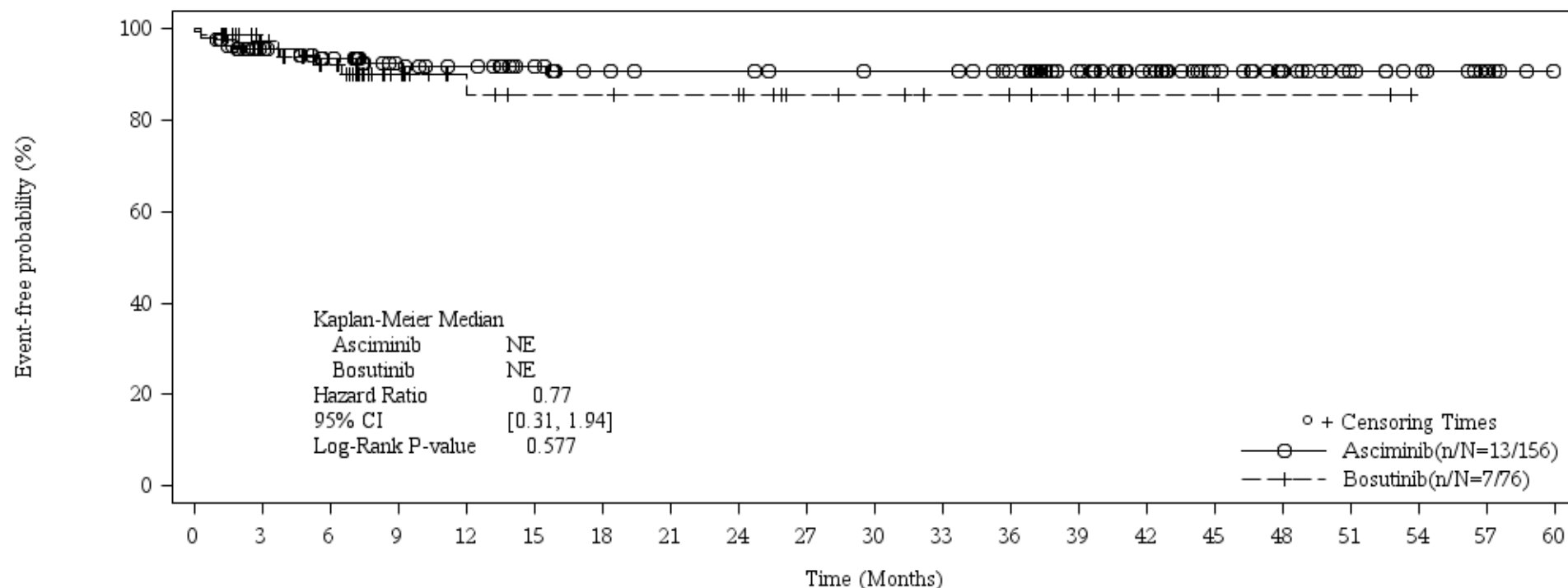
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.1.1 (Page 14 of 16)
**AESI: Kaplan Meier plot of time to first event - stratified per IRT
 Safety Set**

AESI: Pancreatic toxicity

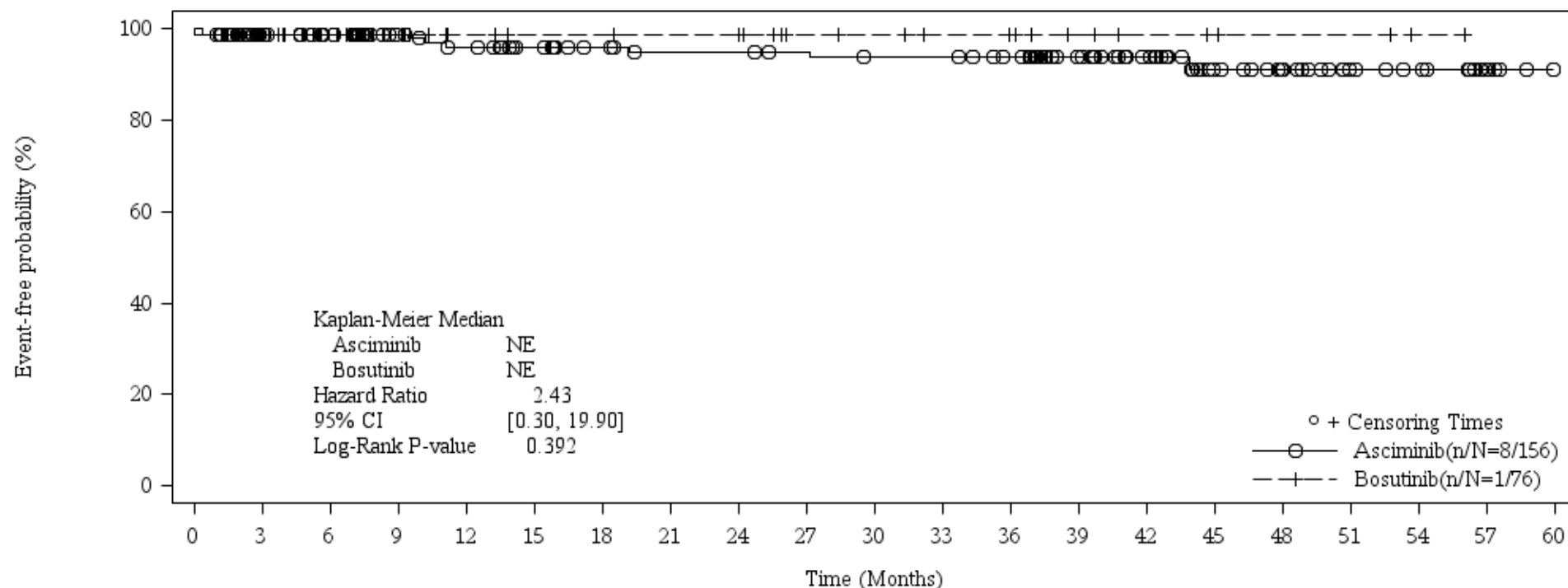


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	135	121	103	98	90	84	82	82	80	79	79	74	58	45	32	23	16	12	5	0
Bosutinib	76	61	47	28	19	17	17	16	16	11	10	8	7	5	3	3	2	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 15 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: QTc prolongation

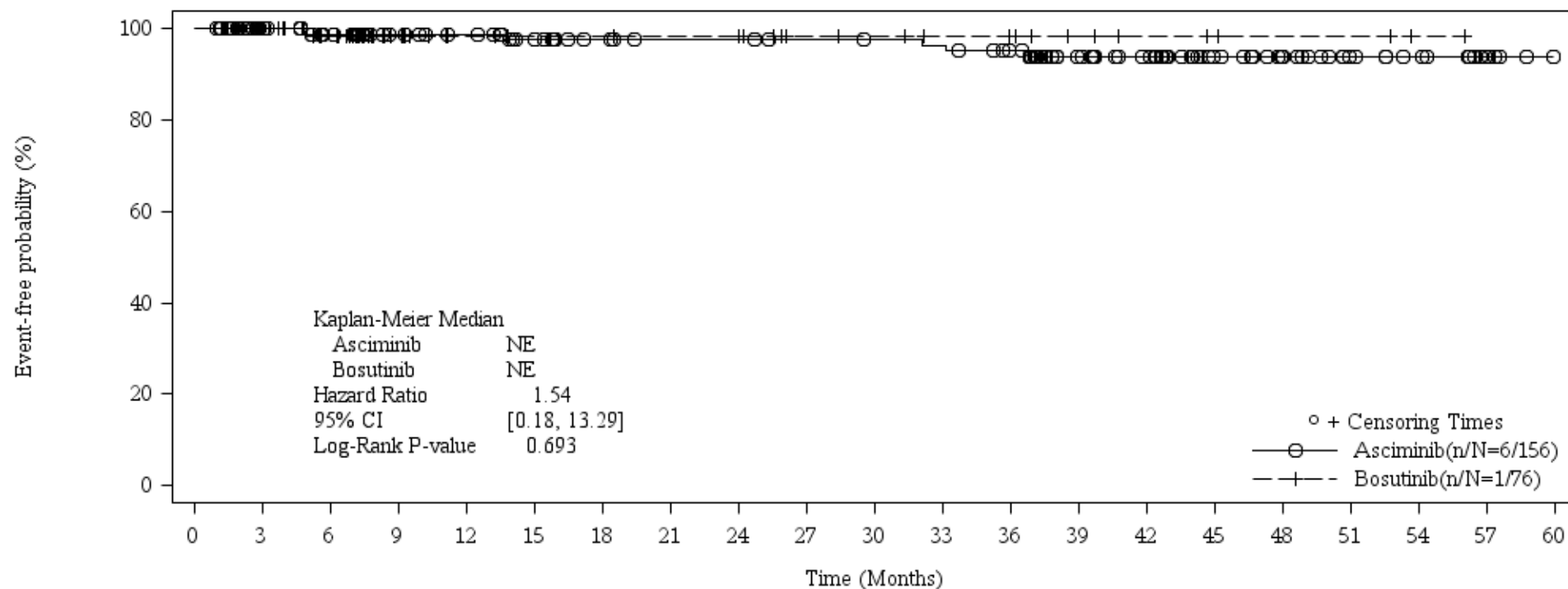


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	128	107	101	94	88	84	84	82	80	80	76	60	46	31	24	16	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.1.1 (Page 16 of 16)
AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Reproductive toxicity



Number of patients still at risk		Time (Months)																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	128	108	104	95	89	86	86	84	83	82	77	59	48	33	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
(Page 1 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	1 (1.3)			
censored					
Death	1 (0.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	3.03	[0.38, 24.43]	0.274
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	1.00 [1.00, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.98 [0.87, 1.00]			
Month 9	0.96 [0.90, 0.98]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 15	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 18	0.95 [0.89, 0.97]	0.98 [0.87, 1.00]			
Month 21	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 24	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 27	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 30	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 33	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 36	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 45	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 48	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 51	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 54	0.94 [0.87, 0.97]	0.98 [0.87, 1.00]			
Month 57	0.94 [0.87, 0.97]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
(Page 3 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.24	[0.13, 11.81]	0.849
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 5 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	43 (56.6)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.08, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.78	[0.33, 1.83]	0.564
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 21	0.89 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 36	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 39	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 42	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 45	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 48	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 51	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 54	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 57	0.86 [0.78, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	52 (33.3)	60 (78.9)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	101 (64.7)	11 (14.5)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	10.09 [1.81, 13.83]	0.03 [0.03, 0.07]			
median	NE [NE, NE]	0.23 [0.07, 0.36]	0.18	[0.12, 0.26]	<0.001
75th	NE [NE, NE]	2.79 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.25 [0.16, 0.35]			
Month 6	0.78 [0.70, 0.84]	0.21 [0.13, 0.31]			
Month 9	0.75 [0.67, 0.81]	0.19 [0.11, 0.29]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.62, 0.78]	0.19 [0.11, 0.29]			
Month 15	0.67 [0.58, 0.74]	0.19 [0.11, 0.29]			
Month 18	0.66 [0.57, 0.73]	0.19 [0.11, 0.29]			
Month 21	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 24	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 27	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 30	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 33	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 36	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 39	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 42	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 45	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 48	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 51	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 54	0.60 [0.50, 0.68]	0.19 [0.11, 0.29]			
Month 57	0.60 [0.50, 0.68]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
(Page 9 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	20 (12.8)	8 (10.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	131 (84.0)	46 (60.5)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.00	[0.44, 2.29]	0.996
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.93 [0.85, 0.97]			
Month 6	0.91 [0.85, 0.94]	0.90 [0.80, 0.95]			
Month 9	0.90 [0.84, 0.94]	0.90 [0.80, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.89 [0.83, 0.93]	0.90 [0.80, 0.95]			
Month 15	0.87 [0.80, 0.92]	0.90 [0.80, 0.95]			
Month 18	0.86 [0.79, 0.91]	0.90 [0.80, 0.95]			
Month 21	0.86 [0.79, 0.91]	0.90 [0.80, 0.95]			
Month 24	0.86 [0.79, 0.91]	0.85 [0.68, 0.93]			
Month 27	0.86 [0.79, 0.91]	0.85 [0.68, 0.93]			
Month 30	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 33	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 36	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 39	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 42	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 45	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 48	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 51	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 54	0.85 [0.78, 0.90]	0.85 [0.68, 0.93]			
Month 57	0.85 [0.78, 0.90]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	19 (12.2)	25 (32.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	36 (47.4)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [38.70, NE]	3.71 [1.25, 6.60]			
median	NE [NE, NE]	NE [6.60, NE]	0.25	[0.14, 0.46]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.77 [0.66, 0.85]			
Month 6	0.94 [0.89, 0.97]	0.67 [0.54, 0.77]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.63 [0.50, 0.73]			
Month 12	0.91 [0.85, 0.95]	0.63 [0.50, 0.73]			
Month 15	0.91 [0.85, 0.95]	0.63 [0.50, 0.73]			
Month 18	0.90 [0.84, 0.94]	0.63 [0.50, 0.73]			
Month 21	0.89 [0.82, 0.93]	0.63 [0.50, 0.73]			
Month 24	0.88 [0.80, 0.93]	0.63 [0.50, 0.73]			
Month 27	0.88 [0.80, 0.93]	0.63 [0.50, 0.73]			
Month 30	0.87 [0.79, 0.92]	0.63 [0.50, 0.73]			
Month 33	0.86 [0.77, 0.91]	0.63 [0.50, 0.73]			
Month 36	0.84 [0.76, 0.90]	0.63 [0.50, 0.73]			
Month 39	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 42	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 45	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 48	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 51	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 54	0.83 [0.74, 0.89]	0.63 [0.50, 0.73]			
Month 57	0.83 [0.74, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	26 (34.2)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	31 (40.8)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [7.62, NE]	1.64 [0.53, 6.21]			
median	NE [NE, NE]	NE [NE, NE]	0.44	[0.26, 0.75]	0.002
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.74 [0.62, 0.82]			
Month 6	0.84 [0.76, 0.89]	0.67 [0.55, 0.77]			
Month 9	0.80 [0.72, 0.86]	0.63 [0.50, 0.73]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 15	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 18	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 21	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 24	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 27	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 30	0.79 [0.71, 0.85]	0.63 [0.50, 0.73]			
Month 33	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 36	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 39	0.77 [0.69, 0.83]	0.63 [0.50, 0.73]			
Month 42	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 45	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 48	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 51	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 54	0.75 [0.66, 0.82]	0.63 [0.50, 0.73]			
Month 57	0.75 [0.66, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	10 (6.4)	4 (5.3)			
censored					
Death	2 (1.3)	1 (1.3)			
Discontinued from study treatment	144 (92.3)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.92	[0.29, 2.97]	0.889
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.97 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.92, 0.99]	0.95 [0.85, 0.98]			
Month 9	0.95 [0.90, 0.98]	0.93 [0.82, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 15	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 18	0.94 [0.88, 0.97]	0.93 [0.82, 0.97]			
Month 21	0.93 [0.87, 0.96]	0.93 [0.82, 0.97]			
Month 24	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 27	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 30	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 33	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 36	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 39	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 42	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 45	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 48	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 51	0.92 [0.85, 0.96]	0.93 [0.82, 0.97]			
Month 54	0.92 [0.85, 0.96]	NE [NE, NE]			
Month 57	0.92 [0.85, 0.96]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	16 (10.3)	7 (9.2)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	136 (87.2)	47 (61.8)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.04	[0.43, 2.55]	0.927
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.92 [0.86, 0.95]	0.93 [0.84, 0.97]			
Month 6	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 9	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 15	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 18	0.90 [0.84, 0.94]	0.92 [0.82, 0.96]			
Month 21	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 24	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 27	0.90 [0.84, 0.94]	0.87 [0.71, 0.94]			
Month 30	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 33	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 36	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 39	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 42	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 45	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 48	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 51	0.89 [0.83, 0.93]	0.87 [0.71, 0.94]			
Month 54	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 57	0.89 [0.83, 0.93]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	16 (21.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	40 (52.6)			
Treatment switched	0	19 (25.0)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.08	[0.60, 1.96]	0.784
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.80 [0.69, 0.87]			
Month 6	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 9	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 15	0.77 [0.69, 0.83]	0.78 [0.67, 0.86]			
Month 18	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 21	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 24	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 27	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 30	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 33	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 36	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 39	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 42	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 45	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 48	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 51	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 54	0.76 [0.68, 0.82]	0.78 [0.67, 0.86]			
Month 57	0.76 [0.68, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	36 (23.1)	17 (22.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	115 (73.7)	40 (52.6)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.01	[0.57, 1.81]	0.959
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.78 [0.70, 0.84]	0.78 [0.67, 0.86]			
Month 6	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			
Month 9	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.78 [0.70, 0.84]	0.77 [0.65, 0.85]			
Month 15	0.77 [0.69, 0.83]	0.77 [0.65, 0.85]			
Month 18	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 21	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 24	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 27	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 30	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 33	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 36	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 39	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 42	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 45	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 48	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 51	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 54	0.76 [0.68, 0.82]	0.77 [0.65, 0.85]			
Month 57	0.76 [0.68, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	46 (29.5)	16 (21.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	105 (67.3)	43 (56.6)			
Treatment switched	0	16 (21.1)			
Percentiles (months) (95% CI)					
25th	1.87 [1.35, NE]	30.39 [2.23, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.48	[0.84, 2.62]	0.179
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.73 [0.65, 0.79]	0.82 [0.71, 0.89]			
Month 6	0.71 [0.63, 0.77]	0.81 [0.69, 0.88]			
Month 9	0.71 [0.63, 0.77]	0.81 [0.69, 0.88]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.63, 0.77]	0.77 [0.63, 0.86]			
Month 15	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 18	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 21	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 24	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 27	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 30	0.70 [0.62, 0.77]	0.77 [0.63, 0.86]			
Month 33	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 36	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 39	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 42	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 45	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 48	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 51	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 54	0.70 [0.62, 0.77]	0.70 [0.51, 0.83]			
Month 57	0.70 [0.62, 0.77]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
(Page 25 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	13 (8.3)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	138 (88.5)	46 (60.5)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.76	[0.30, 1.91]	0.557
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.91, 0.98]	0.97 [0.89, 0.99]			
Month 6	0.93 [0.88, 0.96]	0.92 [0.82, 0.97]			
Month 9	0.92 [0.87, 0.96]	0.90 [0.79, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.92 [0.85, 0.95]	0.86 [0.70, 0.93]			
Month 15	0.92 [0.85, 0.95]	0.86 [0.70, 0.93]			
Month 18	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 21	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 24	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 27	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 30	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 33	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 36	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 39	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 42	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 45	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 48	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 51	0.91 [0.84, 0.94]	0.86 [0.70, 0.93]			
Month 54	0.91 [0.84, 0.94]	NE [NE, NE]			
Month 57	0.91 [0.84, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	8 (5.1)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.44	[0.30, 20.01]	0.391
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 15	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 18	0.96 [0.90, 0.98]	0.99 [0.91, 1.00]			
Month 21	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 24	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 27	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 30	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 33	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 36	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.99 [0.91, 1.00]			
Month 45	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 48	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 51	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 54	0.91 [0.82, 0.96]	0.99 [0.91, 1.00]			
Month 57	0.91 [0.82, 0.96]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.52	[0.18, 13.07]	0.703
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.2 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 32 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.98 [0.88, 1.00]			
Month 15	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 18	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 21	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 24	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 27	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 30	0.98 [0.92, 0.99]	0.98 [0.88, 1.00]			
Month 33	0.96 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 36	0.95 [0.89, 0.98]	0.98 [0.88, 1.00]			
Month 39	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 42	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 45	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 48	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 51	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 54	0.94 [0.87, 0.97]	0.98 [0.88, 1.00]			
Month 57	0.94 [0.87, 0.97]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.1.3 Overview of AESI: Switched patients who do not have this event prior to switch
Switch Analysis Set
(Page 1 of 1)

	Bosutinib	
	N=25	
Safety topic	All grades n (%)	Grade >=3 n (%)
Number of subjects with at least one event	6 (24.0)	2 (8.0)
Hypersensitivity	3 (12.0)	0
Edema and fluid retention	2 (8.0)	0
Arterial-occlusive events (AOEs)	1 (4.0)	1 (4.0)
Myelosuppression*	1 (4.0)	1 (4.0)

Numbers (n) represent counts of subjects.
A subject with multiple severity grades for an AE is only counted under the maximum grade.
Patients included in this table are randomized to Bosutinib and switched to Asciminib.
*Myelosuppression includes Erythropenia, Leucopenia, Thrombocytopenia, cytopenias affecting more than one lineage.
MedDRA version 26.0, CTCAE version 4.03, Case Retrieval Strategy version released 2023-05-25.

/haq_eu_4/pgm/saf/germ_t45_1_3.sas@@/main/2-22NOV2023:11:09

Final

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
(Page 1 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	0			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.97 [0.92, 0.99]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
(Page 2 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.91, 0.98]	1.00 [1.00, 1.00]			
Month 15	0.96 [0.91, 0.98]	1.00 [1.00, 1.00]			
Month 18	0.96 [0.91, 0.98]	1.00 [1.00, 1.00]			
Month 21	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 24	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 27	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 30	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 33	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 36	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 39	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 42	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 45	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 48	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 51	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 54	0.95 [0.89, 0.98]	1.00 [1.00, 1.00]			
Month 57	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
(Page 3 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	43 (56.6)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.08, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.76	[0.33, 1.80]	0.536
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 21	0.89 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 36	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 39	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 42	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 45	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 48	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 51	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 54	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 57	0.86 [0.78, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	51 (32.7)	60 (78.9)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	102 (65.4)	11 (14.5)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	10.09 [1.81, 13.83]	0.03 [0.03, 0.07]			
median	NE [NE, NE]	0.23 [0.07, 0.46]	0.18	[0.12, 0.26]	<0.001
75th	NE [NE, NE]	2.79 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.25 [0.16, 0.35]			
Month 6	0.78 [0.70, 0.84]	0.21 [0.13, 0.31]			
Month 9	0.75 [0.67, 0.81]	0.19 [0.11, 0.29]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.62, 0.78]	0.19 [0.11, 0.29]			
Month 15	0.67 [0.58, 0.74]	0.19 [0.11, 0.29]			
Month 18	0.66 [0.57, 0.73]	0.19 [0.11, 0.29]			
Month 21	0.63 [0.54, 0.71]	0.19 [0.11, 0.29]			
Month 24	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 27	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 30	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 33	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 36	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 39	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 42	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 45	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 48	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 51	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 54	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 57	0.61 [0.52, 0.69]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	134 (85.9)	47 (61.8)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.94	[0.39, 2.29]	0.891
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.89 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.88 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 21	0.88 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.82, 0.93]	0.86 [0.70, 0.94]			
Month 27	0.88 [0.82, 0.93]	0.86 [0.70, 0.94]			
Month 30	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 33	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 36	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 39	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 42	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 45	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 48	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 51	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 54	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 57	0.87 [0.80, 0.92]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	19 (12.2)	22 (28.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	39 (51.3)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [38.70, NE]	4.60 [1.87, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.29	[0.15, 0.54]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.79 [0.68, 0.87]			
Month 6	0.94 [0.89, 0.97]	0.69 [0.56, 0.79]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.67 [0.54, 0.77]			
Month 12	0.91 [0.85, 0.95]	0.67 [0.54, 0.77]			
Month 15	0.91 [0.85, 0.95]	0.67 [0.54, 0.77]			
Month 18	0.90 [0.84, 0.94]	0.67 [0.54, 0.77]			
Month 21	0.89 [0.82, 0.93]	0.67 [0.54, 0.77]			
Month 24	0.88 [0.80, 0.93]	0.67 [0.54, 0.77]			
Month 27	0.88 [0.80, 0.93]	0.67 [0.54, 0.77]			
Month 30	0.87 [0.79, 0.92]	0.67 [0.54, 0.77]			
Month 33	0.86 [0.77, 0.91]	0.67 [0.54, 0.77]			
Month 36	0.84 [0.76, 0.90]	0.67 [0.54, 0.77]			
Month 39	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 42	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 45	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 48	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 51	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 54	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 57	0.83 [0.74, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	23 (30.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	34 (44.7)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [7.62, NE]	3.29 [0.95, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.50	[0.29, 0.87]	0.012
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.77 [0.66, 0.85]			
Month 6	0.84 [0.76, 0.89]	0.71 [0.58, 0.80]			
Month 9	0.80 [0.72, 0.86]	0.67 [0.54, 0.77]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 15	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 18	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 21	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 24	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 27	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 30	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 33	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 36	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 39	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 42	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 45	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 48	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 51	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 54	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 57	0.75 [0.66, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	3 (3.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.73	[0.18, 2.95]	0.657
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.97 [0.88, 0.99]			
Month 9	0.97 [0.92, 0.99]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 15	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 18	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 21	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 24	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 27	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 30	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 33	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 36	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 39	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 42	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 45	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 48	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 51	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 54	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 57	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	6 (7.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	47 (61.8)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.14	[0.44, 2.95]	0.787
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.95 [0.86, 0.98]			
Month 6	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 9	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 15	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 18	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 21	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 24	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 27	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 30	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 33	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 36	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 39	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 42	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 45	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 48	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 51	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 54	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 57	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	26 (16.7)	13 (17.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	125 (80.1)	41 (53.9)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [15.57, NE]	NE [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.90	[0.46, 1.76]	0.763
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.84 [0.73, 0.91]			
Month 6	0.84 [0.77, 0.89]	0.82 [0.71, 0.89]			
Month 9	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			
Month 15	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			
Month 18	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 21	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 24	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 27	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 30	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 33	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 36	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 39	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 42	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 45	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 48	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 51	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 54	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 57	0.82 [0.75, 0.88]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	27 (17.3)	14 (18.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	124 (79.5)	41 (53.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [15.57, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.86	[0.45, 1.65]	0.659
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.83 [0.72, 0.89]			
Month 6	0.83 [0.76, 0.89]	0.81 [0.70, 0.88]			
Month 9	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			
Month 15	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			
Month 18	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 21	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 24	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 27	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 30	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 33	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 36	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 39	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 42	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 45	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 48	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 51	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 54	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 57	0.82 [0.74, 0.87]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	37 (23.7)	15 (19.7)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	114 (73.1)	43 (56.6)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	NE [2.60, NE]	30.39 [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.15	[0.63, 2.10]	0.649
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.72, 0.85]	0.83 [0.73, 0.90]			
Month 6	0.76 [0.68, 0.82]	0.82 [0.71, 0.89]			
Month 9	0.76 [0.68, 0.82]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.76 [0.68, 0.82]	0.78 [0.64, 0.87]			
Month 15	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 18	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 21	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 24	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 27	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 30	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 33	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 36	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 39	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 42	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 45	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 48	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 51	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 54	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 57	0.75 [0.67, 0.81]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	47 (61.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.97	[0.34, 2.76]	0.947
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.98 [0.90, 1.00]			
Month 6	0.94 [0.89, 0.97]	0.95 [0.85, 0.98]			
Month 9	0.94 [0.89, 0.97]	0.93 [0.82, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.92 [0.86, 0.96]	0.88 [0.71, 0.95]			
Month 15	0.92 [0.86, 0.96]	0.88 [0.71, 0.95]			
Month 18	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 21	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 24	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 27	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 30	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 33	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 36	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 39	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 42	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 45	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 48	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 51	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 54	0.91 [0.85, 0.95]	NE [NE, NE]			
Month 57	0.91 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.72	[0.20, 15.21]	0.620
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 21	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 33	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 36	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 39	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 42	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 45	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 48	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.77	[0.08, 7.92]	0.828
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.1 Grade 1/2 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 15	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 18	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 21	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 24	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 27	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 30	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 33	0.98 [0.92, 1.00]	0.98 [0.88, 1.00]			
Month 36	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 39	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 42	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 45	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 48	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 51	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 54	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 57	0.97 [0.90, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

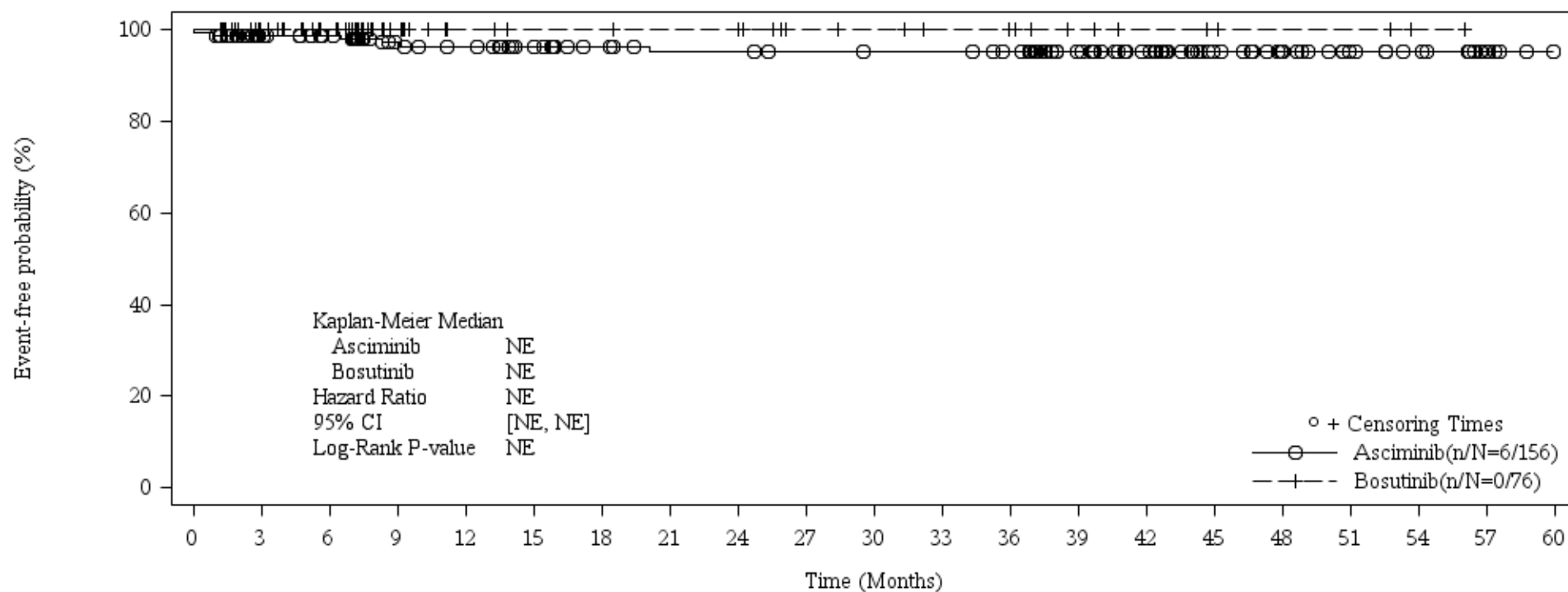
Figure 4-5.2.1 Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT

Figure 4-5.2.1 (Page 1 of 14)

Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

AESI: Arterial-occlusive events (AOEs)



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	129	107	103	95	89	85	85	83	82	82	79	62	48	33	24	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

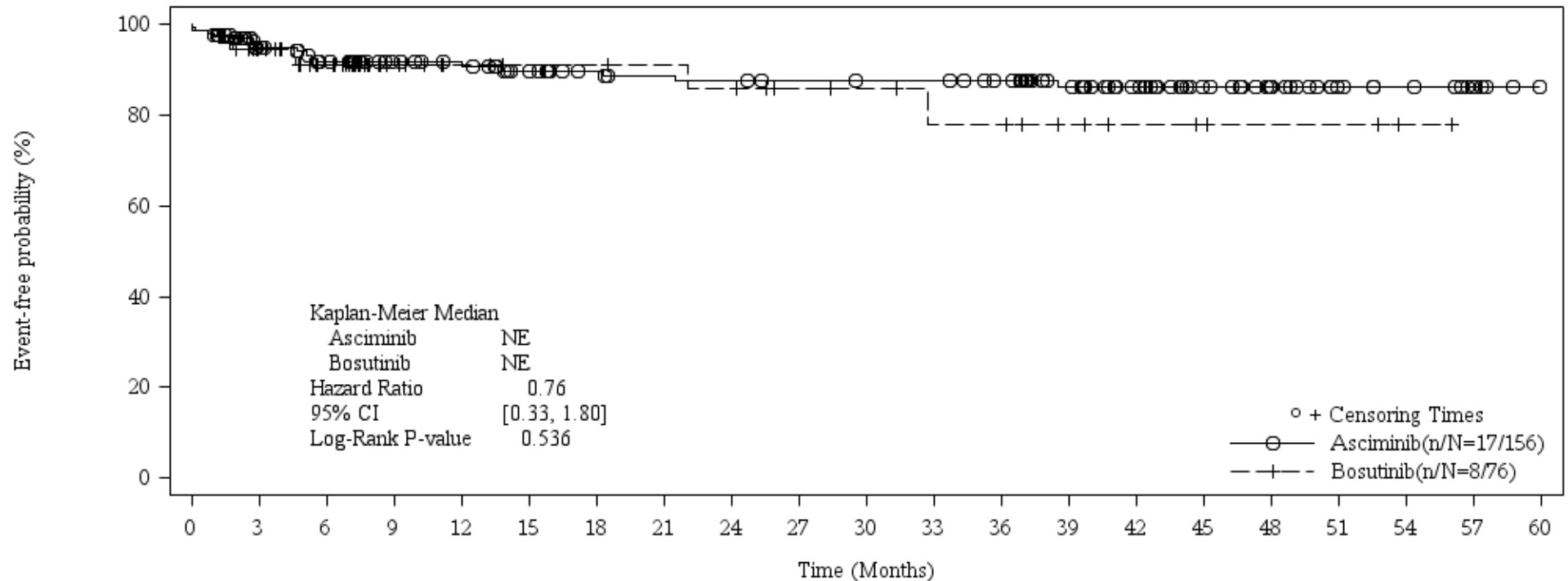
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.2.1 (Page 2 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Edema and fluid retention

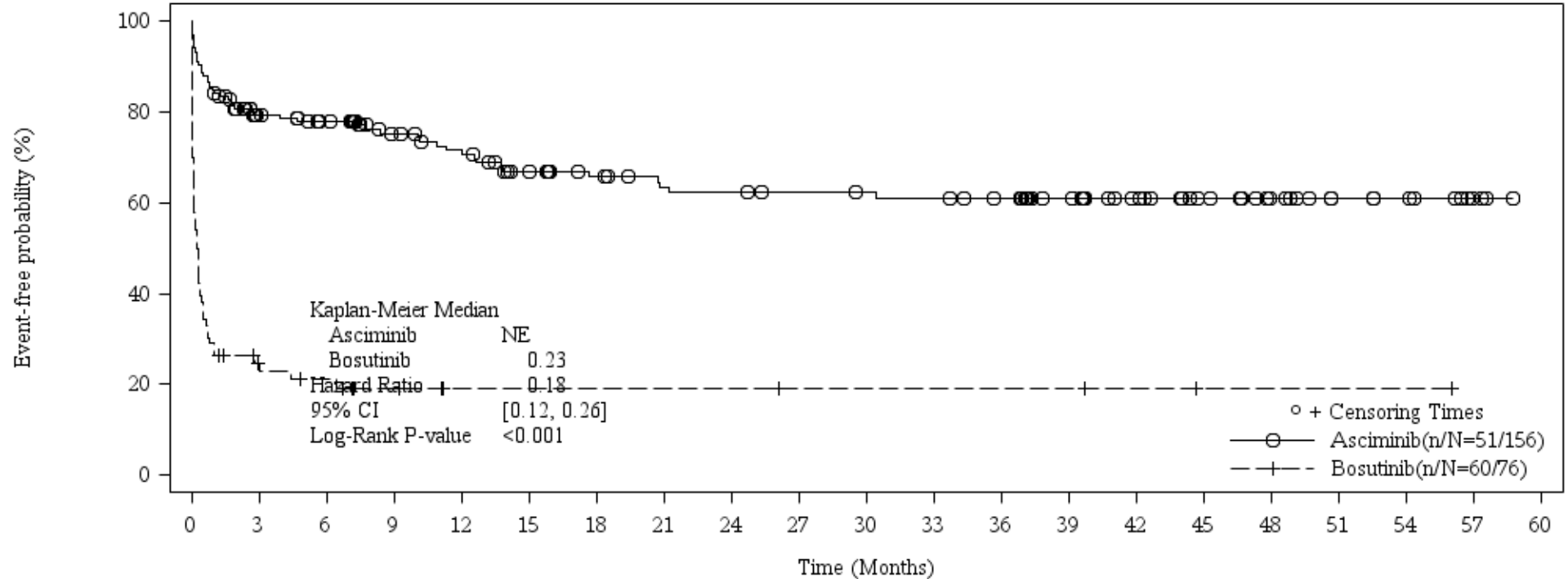


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	133	119	101	96	87	81	78	77	75	74	74	70	56	42	30	21	13	10	5	0
Bosutinib	76	58	44	25	20	18	18	17	16	13	12	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 3 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: GI toxicity

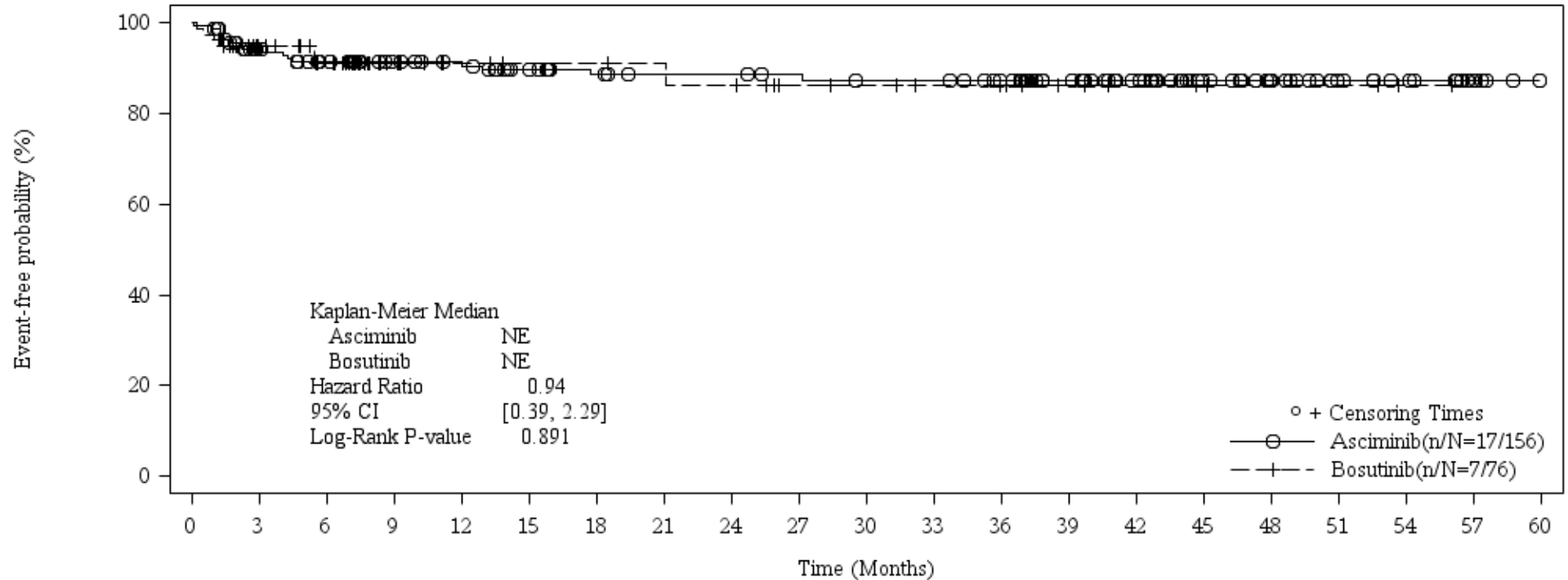


Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	111	101	84	76	65	60	55	54	52	51	50	47	39	30	23	17	11	9	3
Bosutinib	76	14	11	7	4	4	4	4	4	3	3	3	3	3	2	1	1	1	1	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 4 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hemorrhage

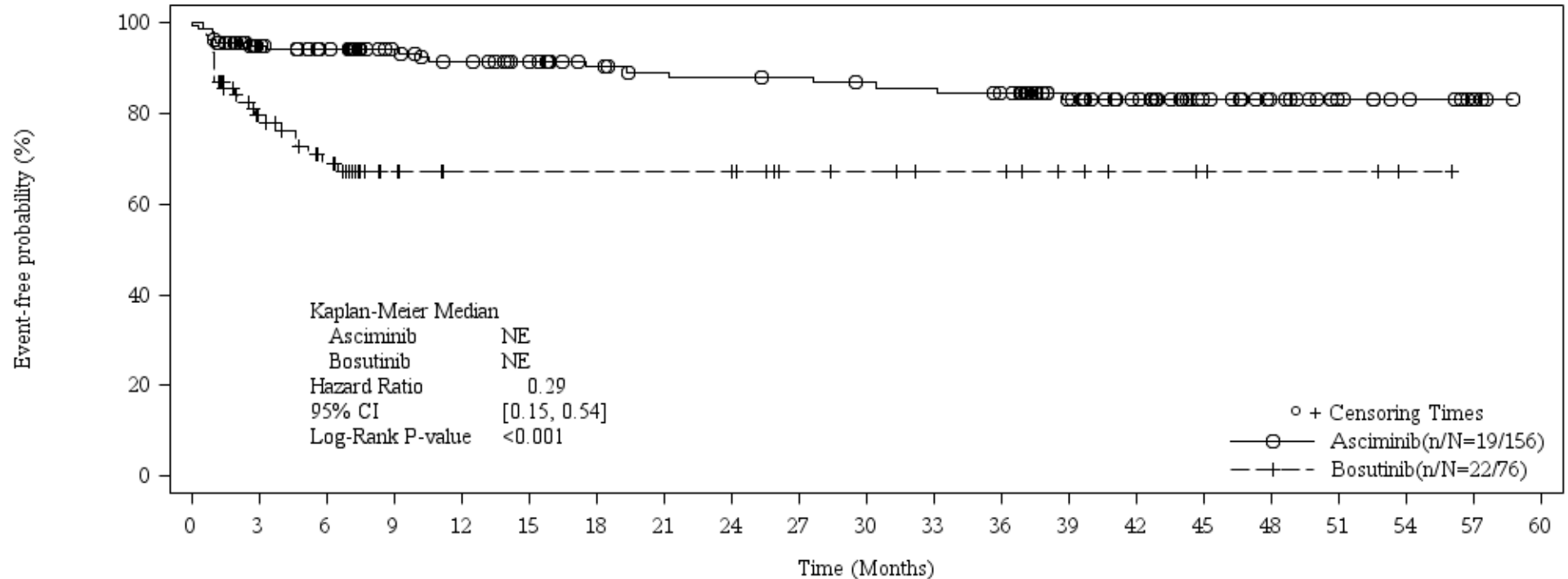


Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	134	122	105	101	91	86	83	83	81	79	79	74	60	48	34	25	17	13	5
Bosutinib	76	59	48	28	22	20	20	19	18	14	13	11	10	7	5	4	3	3	1	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 5 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hepatotoxicity (including laboratory terms)

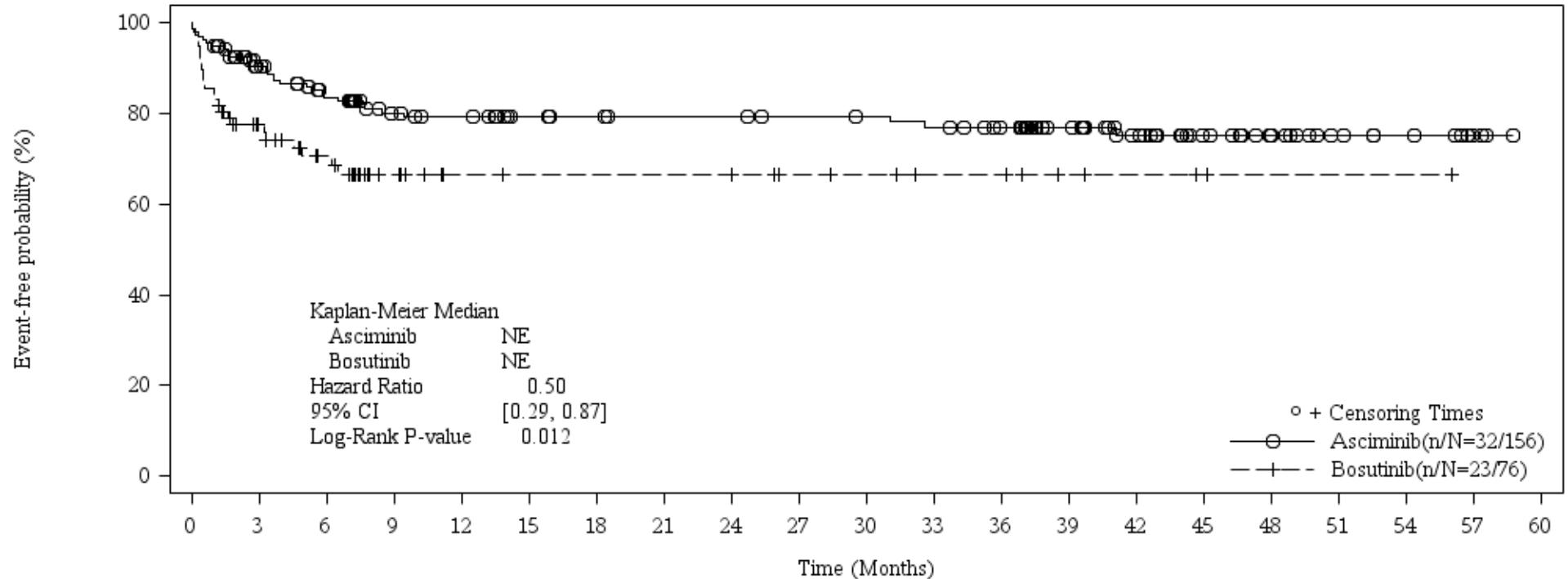


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	134	122	103	96	89	82	78	77	76	74	73	70	54	41	28	21	13	9	4	0
Bosutinib	76	49	36	22	18	18	18	18	18	13	12	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 6 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hypersensitivity

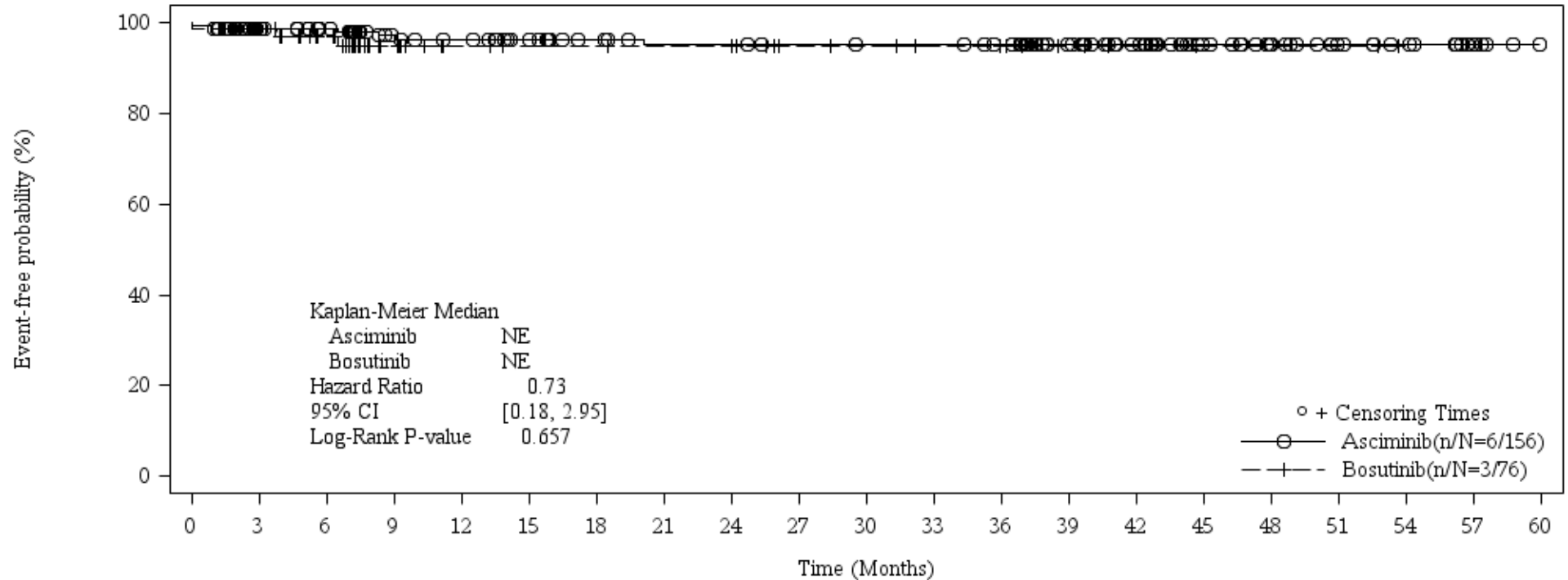


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	127	108	89	85	78	76	74	74	72	71	69	64	50	37	26	18	12	9	3	0
Bosutinib	76	48	35	21	14	13	13	13	13	10	9	7	7	4	3	2	1	1	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 7 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Ischemic heart and CNS conditions

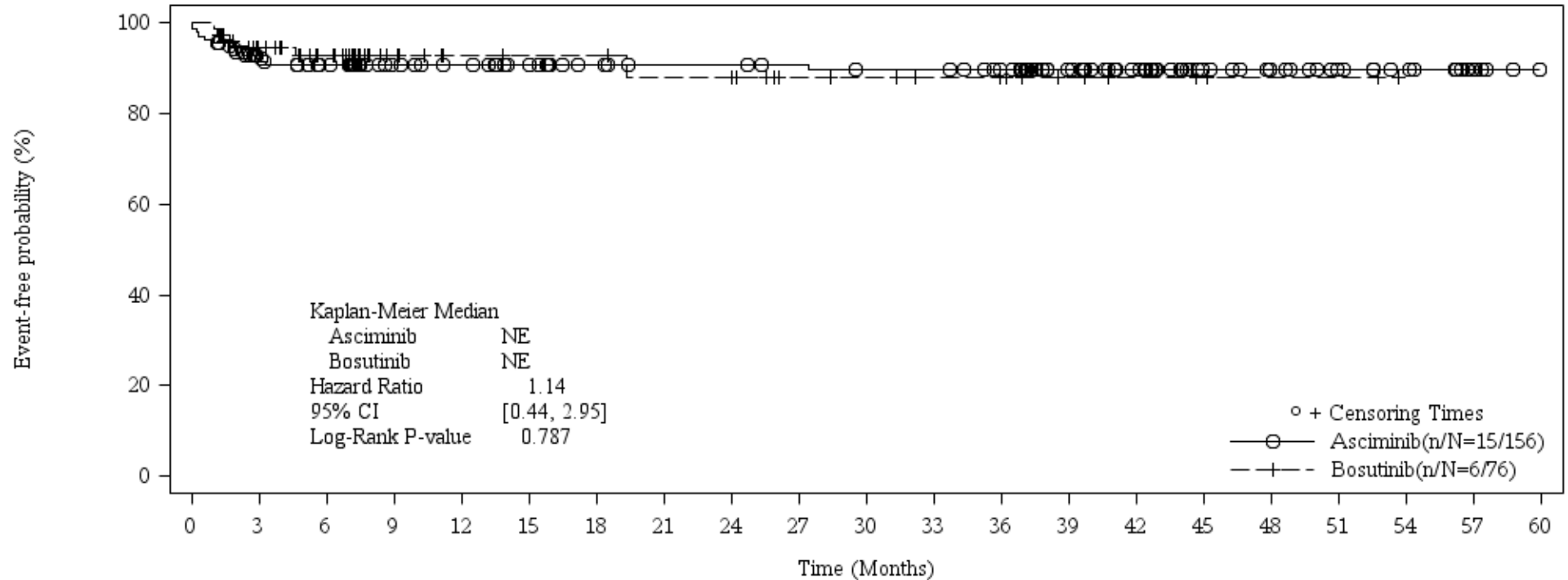


Number of patients still at risk																				
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	60
Asciminib	156	139	129	107	103	95	89	85	85	83	82	82	79	62	48	33	24	17	13	5
Bosutinib	76	61	48	28	20	18	18	17	17	12	11	9	8	5	3	2	2	2	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 8 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Erythropenia)

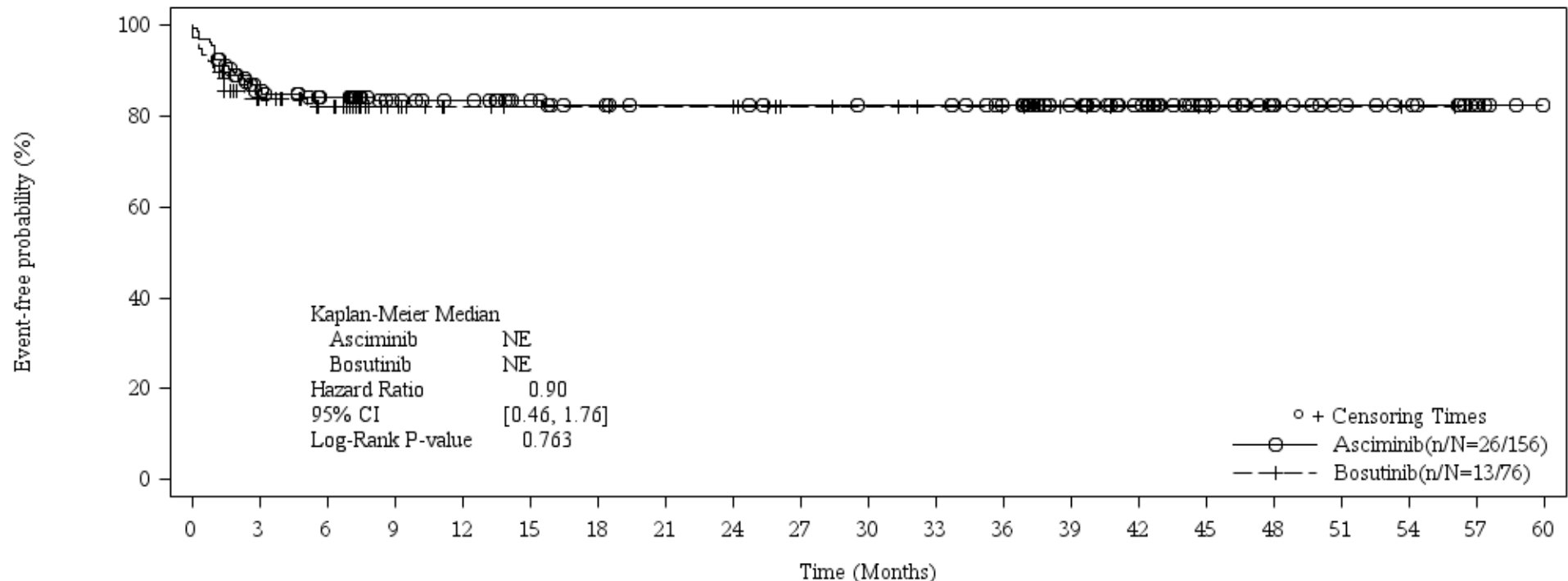


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	133	121	101	97	90	84	81	81	79	77	77	72	57	43	29	23	17	13	5	0
Bosutinib	76	58	45	27	21	20	20	18	18	13	12	10	9	6	4	3	2	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 9 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Neutropenia)

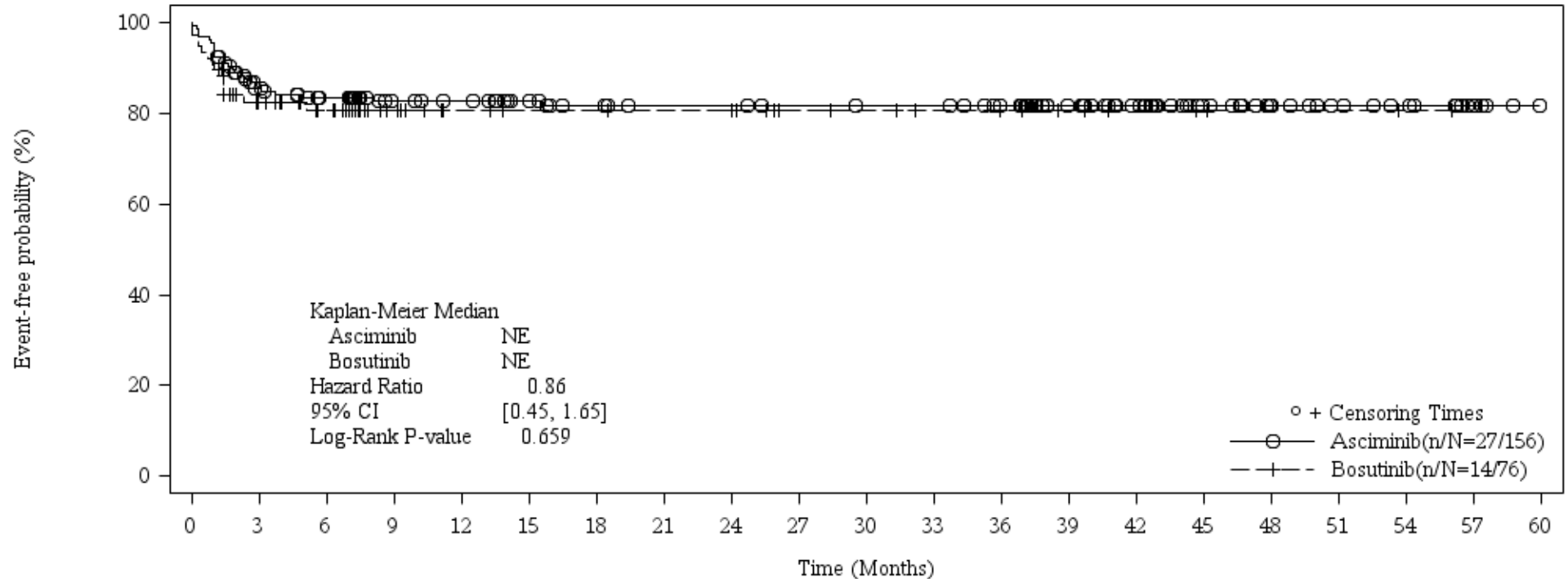


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	122	111	94	90	82	77	74	74	72	71	71	66	53	41	27	19	15	12	5	0
Bosutinib	76	54	43	27	20	18	18	17	17	12	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 10 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Leucopenia)

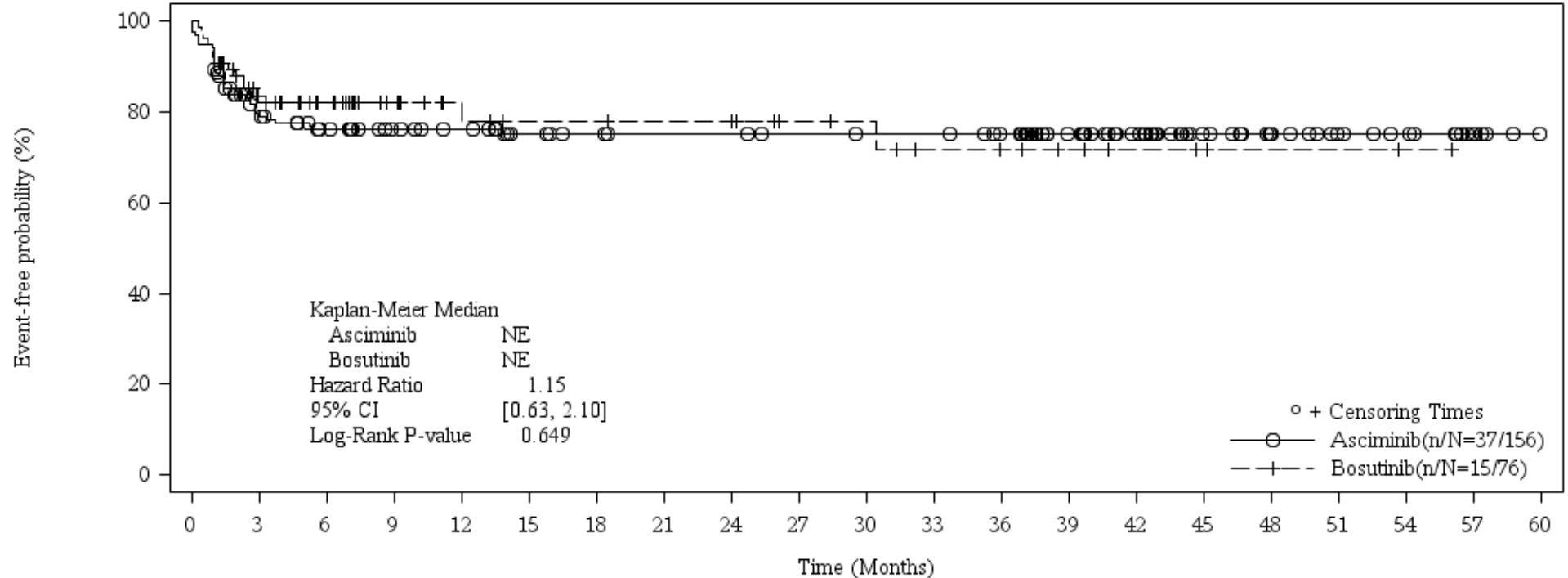


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	122	110	93	90	82	77	74	74	72	71	71	66	53	41	27	19	15	12	5	0
Bosutinib	76	53	42	27	20	18	18	17	17	12	11	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 11 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Thrombocytopenia)

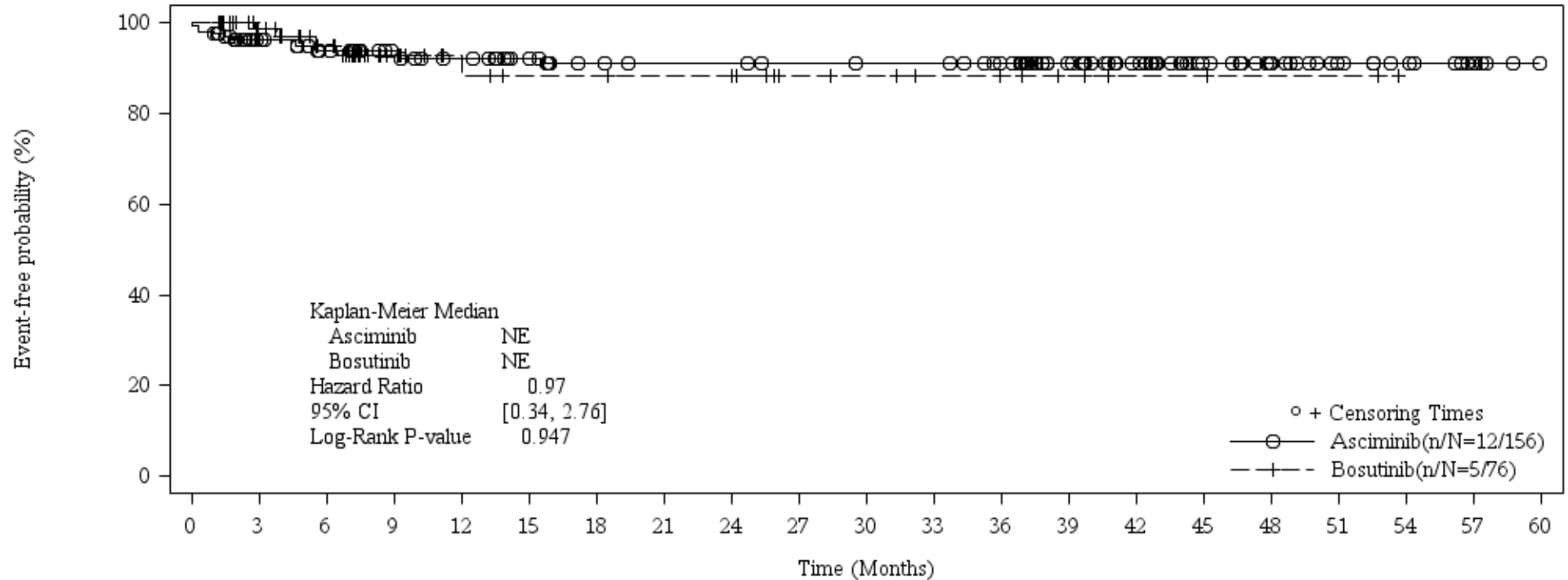


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	114	100	91	87	79	76	74	74	72	71	71	67	54	41	28	20	15	12	5	0
Bosutinib	76	52	40	28	20	18	18	17	17	13	12	9	8	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 12 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Pancreatic toxicity

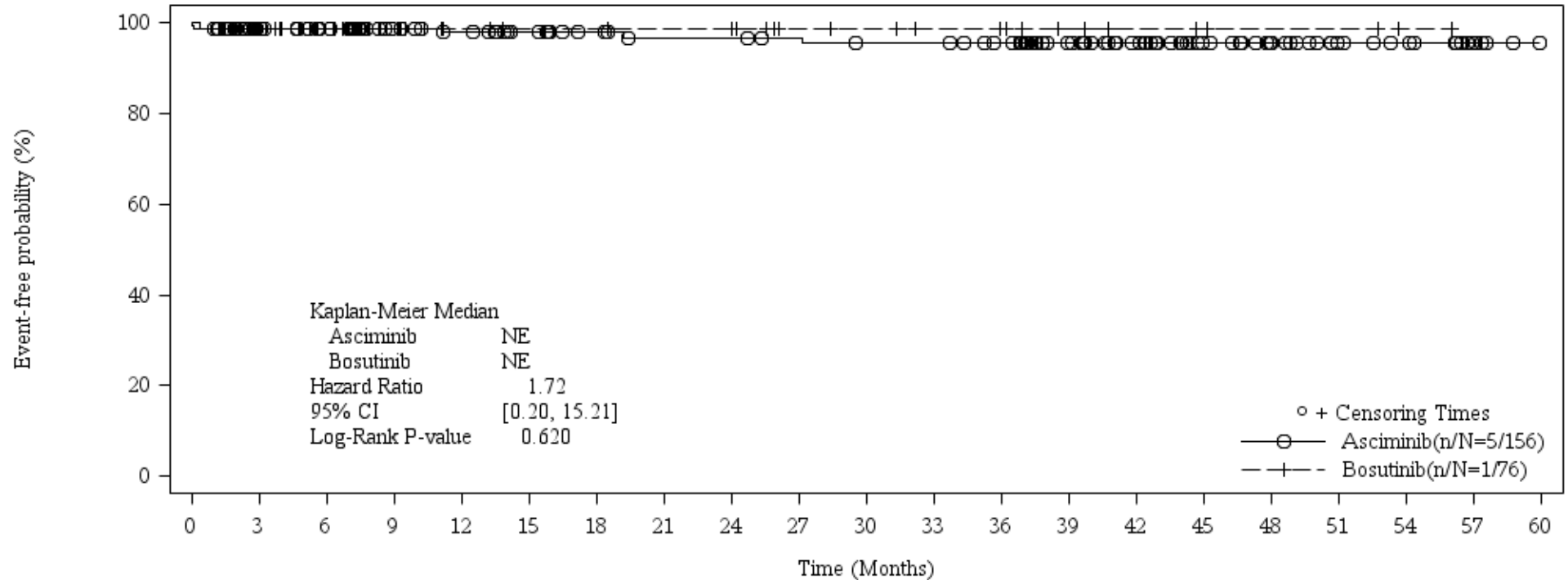


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	136	122	105	99	91	85	83	83	81	80	80	75	59	46	32	23	16	12	5	0
Bosutinib	76	61	47	28	19	17	17	16	16	11	10	8	7	5	3	3	2	2	0	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.2.1 (Page 13 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: QTc prolongation

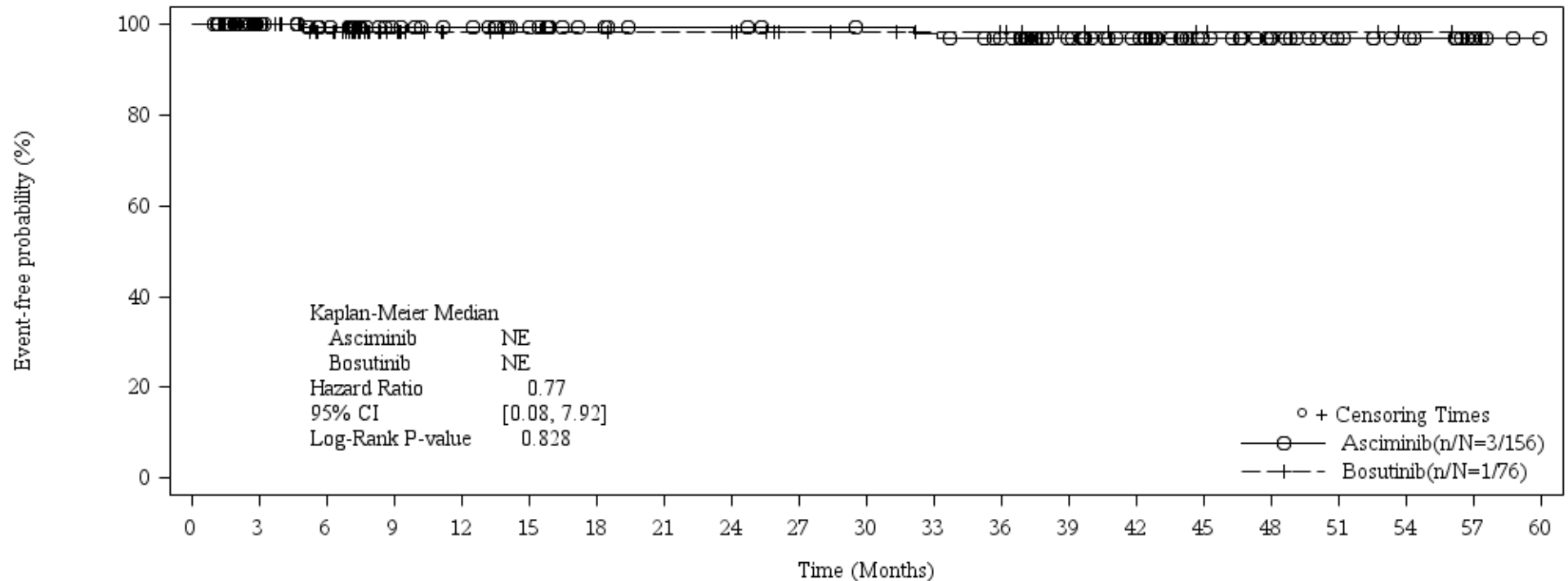


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	128	107	102	95	89	85	85	83	81	81	77	61	47	33	24	16	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

Figure 4-5.2.1 (Page 14 of 14)
Grade 1/2 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Reproductive toxicity



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	108	104	96	90	87	87	85	84	83	78	61	48	33	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
(Page 1 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	0			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.97 [0.92, 0.99]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 28)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.91, 0.98]		1.00 [1.00, 1.00]			
Month 15	0.96 [0.91, 0.98]		1.00 [1.00, 1.00]			
Month 18	0.96 [0.91, 0.98]		1.00 [1.00, 1.00]			
Month 21	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 24	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 27	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 30	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 33	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 36	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 39	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 42	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 45	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 48	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 51	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 54	0.95 [0.89, 0.98]		1.00 [1.00, 1.00]			
Month 57	0.95 [0.89, 0.98]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
(Page 3 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	8 (10.5)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	135 (86.5)	43 (56.6)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [22.08, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.78	[0.33, 1.83]	0.564
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.92 [0.86, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 4 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.90 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 21	0.89 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 27	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 30	0.88 [0.80, 0.92]	0.86 [0.68, 0.94]			
Month 33	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 36	0.88 [0.80, 0.92]	0.78 [0.53, 0.91]			
Month 39	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 42	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 45	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 48	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 51	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 54	0.86 [0.78, 0.91]	0.78 [0.53, 0.91]			
Month 57	0.86 [0.78, 0.91]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	51 (32.7)	60 (78.9)			
censored					
Death	3 (1.9)	0			
Discontinued from study treatment	102 (65.4)	11 (14.5)			
Treatment switched	0	5 (6.6)			
Percentiles (months) (95% CI)					
25th	10.09 [1.81, 13.83]	0.03 [0.03, 0.07]			
median	NE [NE, NE]	0.23 [0.07, 0.46]	0.17	[0.12, 0.26]	<0.001
75th	NE [NE, NE]	2.79 [0.49, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.79 [0.72, 0.85]	0.25 [0.16, 0.35]			
Month 6	0.78 [0.70, 0.84]	0.21 [0.13, 0.31]			
Month 9	0.75 [0.67, 0.81]	0.19 [0.11, 0.29]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.71 [0.62, 0.78]	0.19 [0.11, 0.29]			
Month 15	0.67 [0.58, 0.74]	0.19 [0.11, 0.29]			
Month 18	0.66 [0.57, 0.73]	0.19 [0.11, 0.29]			
Month 21	0.63 [0.54, 0.71]	0.19 [0.11, 0.29]			
Month 24	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 27	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 30	0.62 [0.53, 0.70]	0.19 [0.11, 0.29]			
Month 33	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 36	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 39	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 42	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 45	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 48	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 51	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 54	0.61 [0.52, 0.69]	0.19 [0.11, 0.29]			
Month 57	0.61 [0.52, 0.69]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	17 (10.9)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	134 (85.9)	47 (61.8)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [21.06, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.99	[0.41, 2.41]	0.985
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.94 [0.89, 0.97]	0.95 [0.86, 0.98]			
Month 6	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 9	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.95]	0.91 [0.81, 0.96]			
Month 15	0.89 [0.83, 0.94]	0.91 [0.81, 0.96]			
Month 18	0.88 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 21	0.88 [0.82, 0.93]	0.91 [0.81, 0.96]			
Month 24	0.88 [0.82, 0.93]	0.86 [0.70, 0.94]			
Month 27	0.88 [0.82, 0.93]	0.86 [0.70, 0.94]			
Month 30	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 33	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 36	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 39	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 42	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 45	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 48	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 51	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 54	0.87 [0.80, 0.92]	0.86 [0.70, 0.94]			
Month 57	0.87 [0.80, 0.92]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	19 (12.2)	22 (28.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	133 (85.3)	39 (51.3)			
Treatment switched	0	14 (18.4)			
Percentiles (months) (95% CI)					
25th	NE [38.70, NE]	4.60 [1.87, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.29	[0.16, 0.55]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.95 [0.90, 0.97]	0.79 [0.68, 0.87]			
Month 6	0.94 [0.89, 0.97]	0.69 [0.56, 0.79]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.94 [0.89, 0.97]	0.67 [0.54, 0.77]			
Month 12	0.91 [0.85, 0.95]	0.67 [0.54, 0.77]			
Month 15	0.91 [0.85, 0.95]	0.67 [0.54, 0.77]			
Month 18	0.90 [0.84, 0.94]	0.67 [0.54, 0.77]			
Month 21	0.89 [0.82, 0.93]	0.67 [0.54, 0.77]			
Month 24	0.88 [0.80, 0.93]	0.67 [0.54, 0.77]			
Month 27	0.88 [0.80, 0.93]	0.67 [0.54, 0.77]			
Month 30	0.87 [0.79, 0.92]	0.67 [0.54, 0.77]			
Month 33	0.86 [0.77, 0.91]	0.67 [0.54, 0.77]			
Month 36	0.84 [0.76, 0.90]	0.67 [0.54, 0.77]			
Month 39	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 42	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 45	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 48	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 51	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 54	0.83 [0.74, 0.89]	0.67 [0.54, 0.77]			
Month 57	0.83 [0.74, 0.89]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	32 (20.5)	23 (30.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	120 (76.9)	34 (44.7)			
Treatment switched	0	18 (23.7)			
Percentiles (months) (95% CI)					
25th	NE [7.62, NE]	3.29 [0.95, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.51	[0.30, 0.88]	0.014
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.90 [0.84, 0.94]	0.77 [0.66, 0.85]			
Month 6	0.84 [0.76, 0.89]	0.71 [0.58, 0.80]			
Month 9	0.80 [0.72, 0.86]	0.67 [0.54, 0.77]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 15	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 18	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 21	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 24	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 27	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 30	0.79 [0.71, 0.85]	0.67 [0.54, 0.77]			
Month 33	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 36	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 39	0.77 [0.69, 0.83]	0.67 [0.54, 0.77]			
Month 42	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 45	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 48	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 51	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 54	0.75 [0.66, 0.82]	0.67 [0.54, 0.77]			
Month 57	0.75 [0.66, 0.82]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	3 (3.9)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.73	[0.18, 2.95]	0.654
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.97 [0.88, 0.99]			
Month 9	0.97 [0.92, 0.99]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 15	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 18	0.96 [0.91, 0.98]	0.95 [0.85, 0.98]			
Month 21	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 24	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 27	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 30	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 33	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 36	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 39	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 42	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 45	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 48	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 51	0.95 [0.89, 0.98]	0.95 [0.85, 0.98]			
Month 54	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 57	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	15 (9.6)	6 (7.9)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	137 (87.8)	47 (61.8)			
Treatment switched	0	22 (28.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [19.35, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.13	[0.43, 2.92]	0.807
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.93 [0.88, 0.96]	0.95 [0.86, 0.98]			
Month 6	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 9	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 15	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 18	0.91 [0.85, 0.94]	0.93 [0.83, 0.97]			
Month 21	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 24	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 27	0.91 [0.85, 0.94]	0.88 [0.71, 0.95]			
Month 30	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 33	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 36	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 39	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 42	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 45	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 48	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 51	0.90 [0.83, 0.94]	0.88 [0.71, 0.95]			
Month 54	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 57	0.90 [0.83, 0.94]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	26 (16.7)	13 (17.1)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	125 (80.1)	41 (53.9)			
Treatment switched	0	21 (27.6)			
Percentiles (months) (95% CI)					
25th	NE [15.57, NE]	NE [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.92	[0.47, 1.78]	0.795
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.84 [0.73, 0.91]			
Month 6	0.84 [0.77, 0.89]	0.82 [0.71, 0.89]			
Month 9	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			
Month 15	0.83 [0.76, 0.88]	0.82 [0.71, 0.89]			
Month 18	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 21	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 24	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 27	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 30	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 33	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 36	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 39	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 42	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 45	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 48	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 51	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 54	0.82 [0.75, 0.88]	0.82 [0.71, 0.89]			
Month 57	0.82 [0.75, 0.88]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	27 (17.3)	14 (18.4)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	124 (79.5)	41 (53.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [15.57, NE]	NE [1.41, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.88	[0.46, 1.68]	0.698
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.86 [0.79, 0.90]	0.83 [0.72, 0.89]			
Month 6	0.83 [0.76, 0.89]	0.81 [0.70, 0.88]			
Month 9	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			
Month 15	0.83 [0.75, 0.88]	0.81 [0.70, 0.88]			
Month 18	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 21	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 24	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 27	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 30	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 33	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 36	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 39	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 42	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 45	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 48	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 51	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 54	0.82 [0.74, 0.87]	0.81 [0.70, 0.88]			
Month 57	0.82 [0.74, 0.87]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	37 (23.7)	15 (19.7)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	114 (73.1)	43 (56.6)			
Treatment switched	0	17 (22.4)			
Percentiles (months) (95% CI)					
25th	NE [2.60, NE]	30.39 [2.33, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.19	[0.65, 2.18]	0.572
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.72, 0.85]	0.83 [0.73, 0.90]			
Month 6	0.76 [0.68, 0.82]	0.82 [0.71, 0.89]			
Month 9	0.76 [0.68, 0.82]	0.82 [0.71, 0.89]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.76 [0.68, 0.82]	0.78 [0.64, 0.87]			
Month 15	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 18	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 21	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 24	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 27	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 30	0.75 [0.67, 0.81]	0.78 [0.64, 0.87]			
Month 33	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 36	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 39	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 42	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 45	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 48	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 51	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 54	0.75 [0.67, 0.81]	0.71 [0.52, 0.84]			
Month 57	0.75 [0.67, 0.81]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	12 (7.7)	5 (6.6)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	139 (89.1)	47 (61.8)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [11.99, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.95	[0.33, 2.71]	0.922
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.96 [0.92, 0.98]	0.98 [0.90, 1.00]			
Month 6	0.94 [0.89, 0.97]	0.95 [0.85, 0.98]			
Month 9	0.94 [0.89, 0.97]	0.93 [0.82, 0.97]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.92 [0.86, 0.96]	0.88 [0.71, 0.95]			
Month 15	0.92 [0.86, 0.96]	0.88 [0.71, 0.95]			
Month 18	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 21	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 24	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 27	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 30	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 33	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 36	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 39	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 42	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 45	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 48	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 51	0.91 [0.85, 0.95]	0.88 [0.71, 0.95]			
Month 54	0.91 [0.85, 0.95]	NE [NE, NE]			
Month 57	0.91 [0.85, 0.95]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.72	[0.19, 15.26]	0.624
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 21	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.91, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 33	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 36	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 39	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 42	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 45	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 48	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.95 [0.89, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.95 [0.89, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.77	[0.08, 7.85]	0.828
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.2.2 Grade 1/2 AESI: time to first event - stratified per CRF
Safety Set
(Page 28 of 28)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 15	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 18	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 21	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 24	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 27	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 30	0.99 [0.95, 1.00]	0.98 [0.88, 1.00]			
Month 33	0.98 [0.92, 1.00]	0.98 [0.88, 1.00]			
Month 36	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 39	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 42	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 45	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 48	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 51	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 54	0.97 [0.90, 0.99]	0.98 [0.88, 1.00]			
Month 57	0.97 [0.90, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.99	[0.10, 9.73]	0.995
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.98 [0.94, 1.00]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.98 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.16	[0.12, 11.30]	0.898
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 51	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.95, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	0.98 [0.84, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 15	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 18	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 21	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 24	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 27	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 30	1.00 [1.00, 1.00]		0.94 [0.76, 0.98]			
Month 33	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 36	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 39	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 42	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 45	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 48	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 51	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 54	1.00 [1.00, 1.00]		0.79 [0.49, 0.92]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	9 (11.8)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	147 (94.2)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.20	[0.06, 0.61]	0.002
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.91 [0.81, 0.95]			
Month 6	0.99 [0.96, 1.00]	0.87 [0.77, 0.93]			
Month 9	0.99 [0.96, 1.00]	0.87 [0.77, 0.93]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade >= 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 15	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 18	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 21	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 24	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 27	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 30	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 33	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 36	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 39	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 42	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 45	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 48	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 51	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 54	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 57	0.93 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.12	[0.11, 11.03]	0.923
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 21	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 24	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 51	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.98 [0.93, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	13 (17.1)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	42 (55.3)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.75, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.09	[0.03, 0.32]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.87 [0.76, 0.93]			
Month 6	0.99 [0.95, 1.00]	0.83 [0.72, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 12	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 15	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 18	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 21	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 24	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 27	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 30	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 33	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 36	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 39	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 42	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 45	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 48	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 51	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 54	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.06	[0.01, 0.53]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.91 [0.82, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.91 [0.82, 0.95]			
Month 9	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade >= 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 15	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 18	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 21	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 24	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 27	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 30	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 33	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 36	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 39	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 42	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 45	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 48	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 51	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 54	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 57	0.99 [0.94, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	2 (2.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.90	[0.17, 4.72]	0.904
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.97 [0.87, 0.99]			
Month 9	0.98 [0.94, 0.99]	0.97 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 15	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 18	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 21	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 24	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 27	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 30	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 33	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 36	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 39	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 42	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 45	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 48	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 51	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 54	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 57	0.96 [0.90, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.30	[0.05, 1.79]	0.161
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Month 9	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade >= 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 15	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 18	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 21	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 24	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 27	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 30	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 33	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 36	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 39	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 42	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 45	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 48	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 51	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 54	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 57	0.99 [0.95, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	29 (18.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [2.76, NE]	NE [4.70, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.29	[0.64, 2.58]	0.476
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.87]	0.89 [0.79, 0.94]			
Month 6	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 9	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 15	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 18	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 21	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 24	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 27	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 30	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 33	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 36	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 39	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 42	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 45	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 48	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 51	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 54	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 57	0.81 [0.74, 0.86]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	29 (18.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [2.76, NE]	NE [4.70, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.29	[0.64, 2.58]	0.476
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.87]	0.89 [0.79, 0.94]			
Month 6	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 9	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 15	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 18	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 21	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 24	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 27	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 30	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 33	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 36	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 39	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 42	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 45	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 48	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 51	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 54	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 57	0.81 [0.74, 0.86]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	35 (22.4)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	116 (74.4)	48 (63.2)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.58	[1.14, 5.80]	0.018
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.73, 0.85]	0.92 [0.82, 0.96]			
Month 6	0.77 [0.70, 0.83]	0.92 [0.82, 0.96]			
Month 9	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade >= 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 15	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 18	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 21	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 24	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 27	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 30	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 33	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 36	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 39	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 42	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 45	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 48	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 51	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 54	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 57	0.77 [0.70, 0.83]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]		0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [15.64, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.61	[0.17, 2.16]	0.435
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.95 [0.86, 0.99]			
Month 9	0.96 [0.92, 0.99]	0.95 [0.86, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 28 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.95 [0.90, 0.98]	0.95 [0.86, 0.99]			
Month 15	0.95 [0.90, 0.98]	0.95 [0.86, 0.99]			
Month 18	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 21	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 24	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 27	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 30	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 33	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 36	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 39	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 42	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 45	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 48	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 51	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 54	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 57	0.95 [0.90, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	0			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade >= 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 15	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 18	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 21	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 24	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 27	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 30	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 33	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 36	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 39	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 48	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 51	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 54	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 57	0.94 [0.84, 0.98]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade ≥ 3 AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.1 Grade $\geq$ 3 AESI: time to first event - stratified per IRT
 Safety Set
 (Page 32 of 32)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 48	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 51	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 54	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 57	0.97 [0.91, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

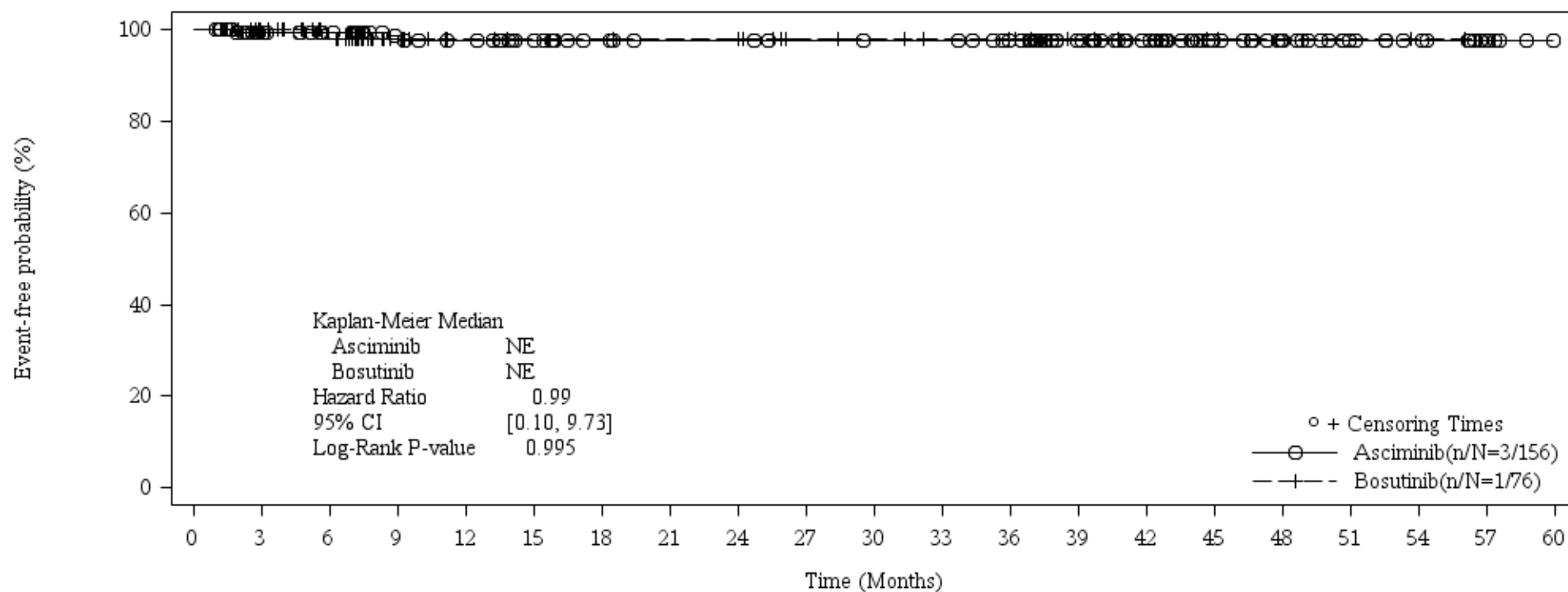
- NE: Not Estimable.

Figure 4-5.3.1 Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT

Figure 4-5.3.1 (Page 1 of 16)

Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Arterial-occlusive events (AOEs)



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	29	21	19	19	18	18	13	12	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

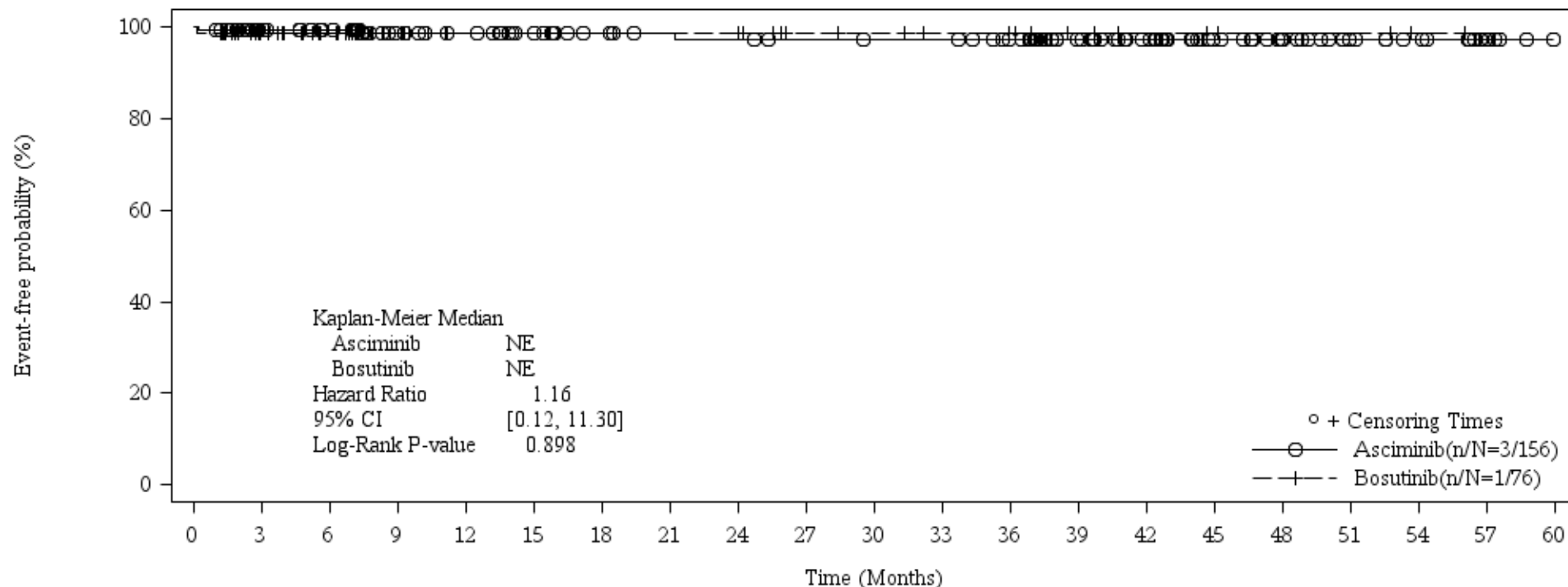
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.3.1 (Page 2 of 16)
Grade ≥3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Cardiac failure (clinical events)

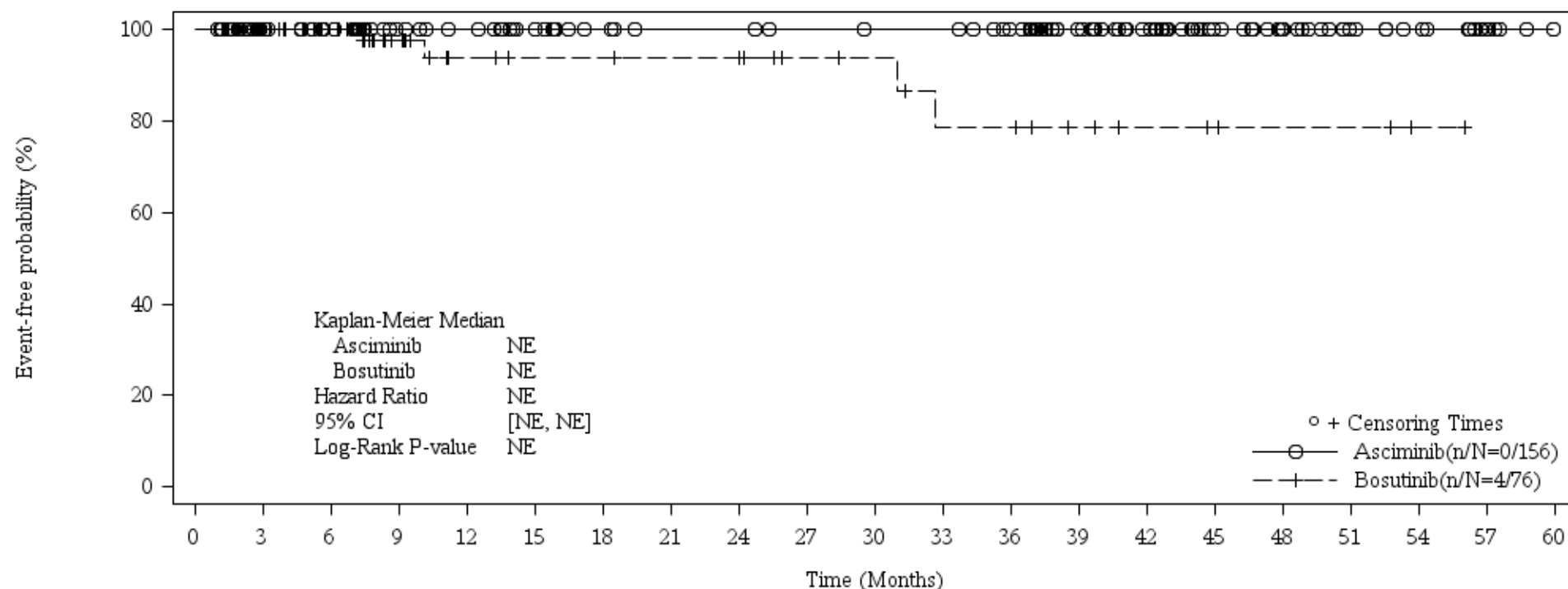


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	86	84	83	83	78	61	48	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

Figure 4-5.3.1 (Page 3 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Edema and fluid retention

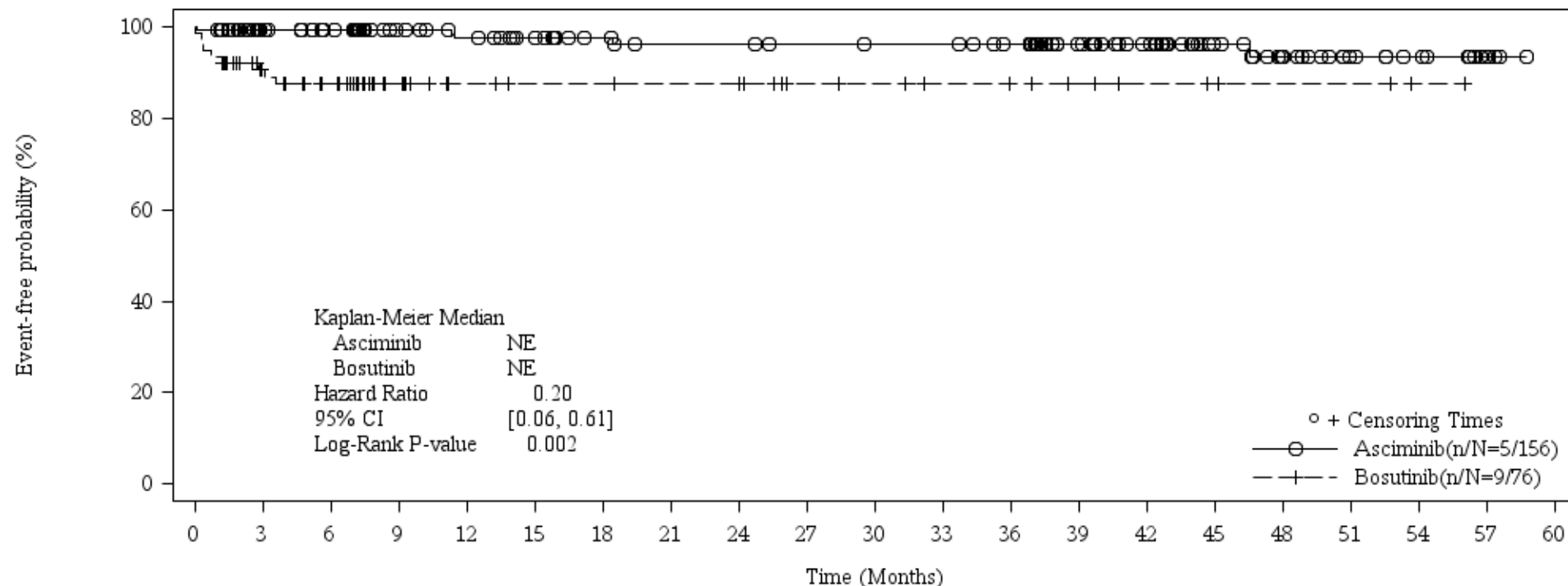


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	50	29	21	19	19	18	18	14	13	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

Figure 4-5.3.1 (Page 4 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: GI toxicity

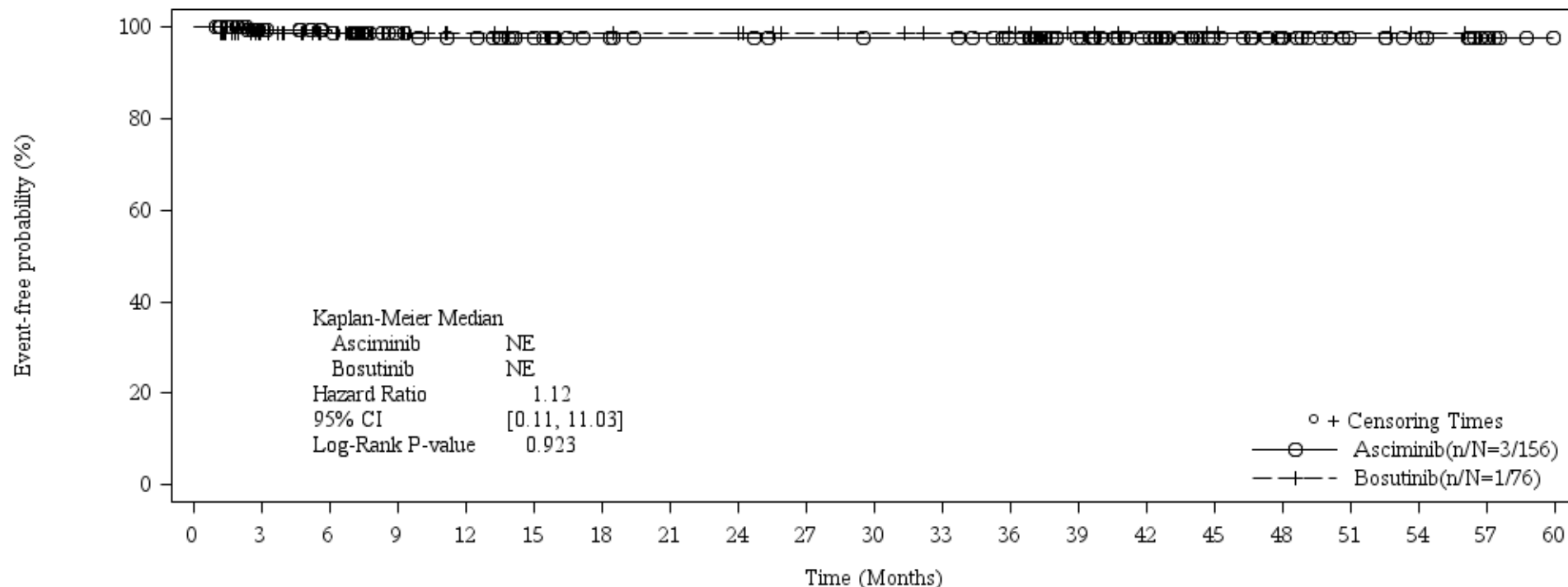


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	108	102	95	89	85	85	83	82	82	78	62	49	34	24	16	12	4	0
Bosutinib	76	57	46	29	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 5 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hemorrhage

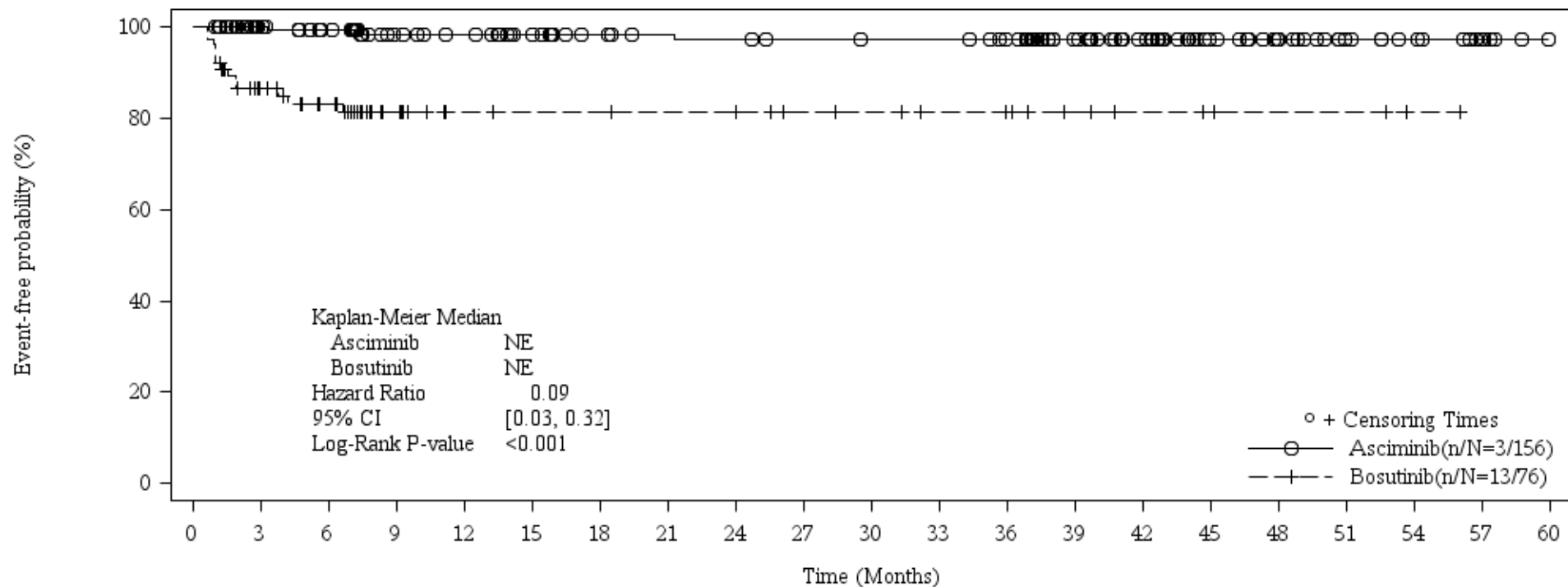


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	107	103	95	89	86	86	84	83	83	78	62	48	33	24	16	13	5	0
Bosutinib	76	61	49	29	21	19	19	18	18	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 6 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hepatotoxicity (including laboratory terms)

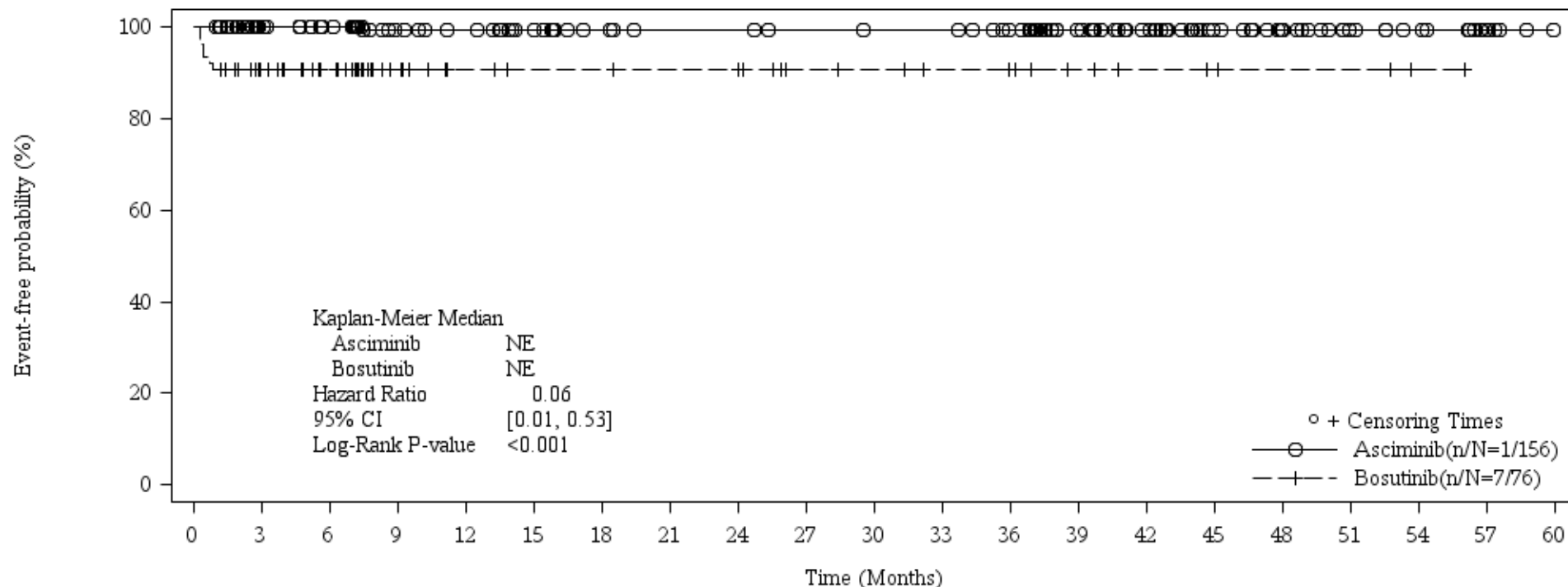


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	107	103	95	89	86	85	83	82	82	78	61	47	32	24	16	12	5	0
Bosutinib	76	55	44	27	19	18	18	17	17	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 7 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hypersensitivity

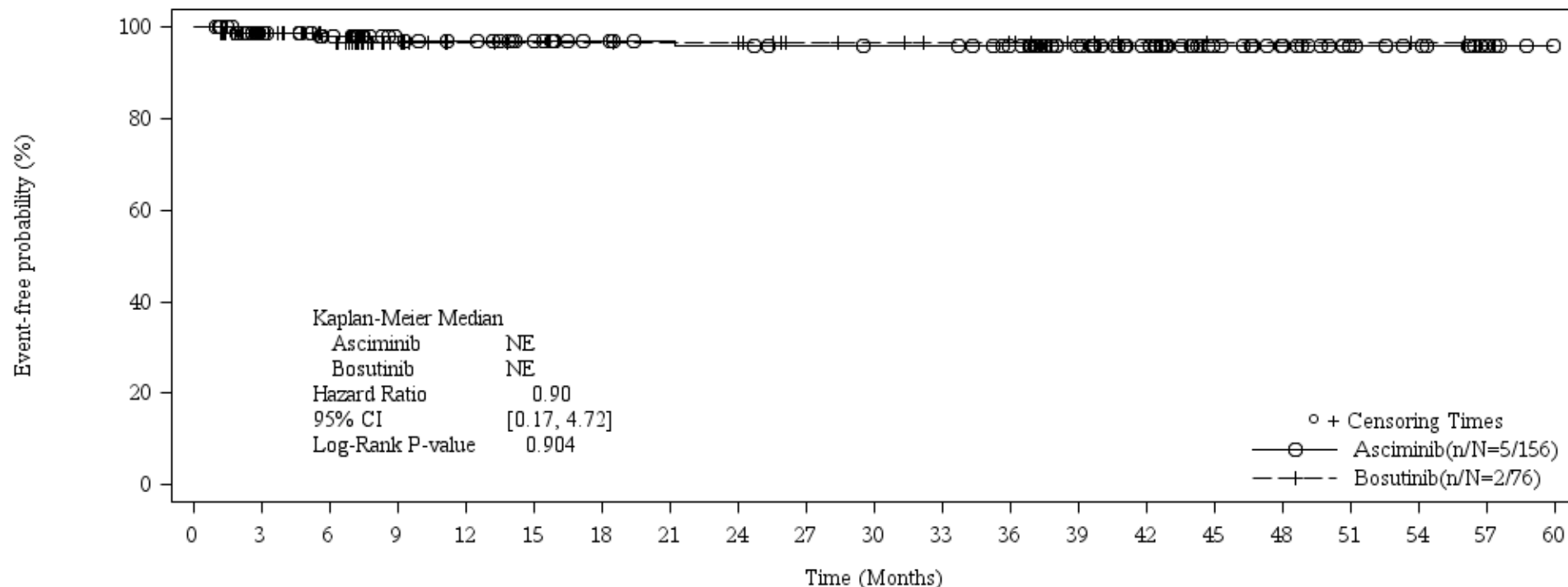


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	87	85	84	84	79	62	48	34	25	17	13	5	0
Bosutinib	76	59	47	29	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 8 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Ischemic heart and CNS conditions

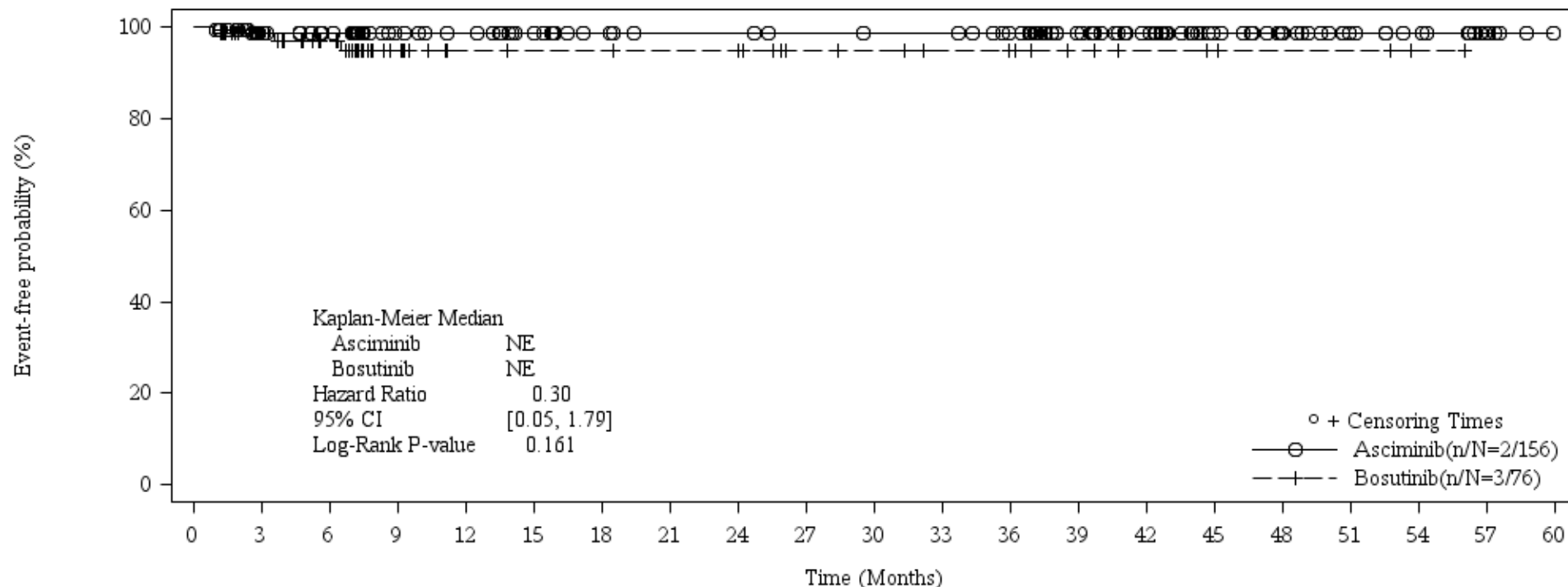


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	128	107	103	96	90	87	86	84	83	83	78	61	47	32	25	17	13	5	0
Bosutinib	76	61	48	28	20	18	18	17	17	12	11	9	8	5	3	2	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 9 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Erythropenia)

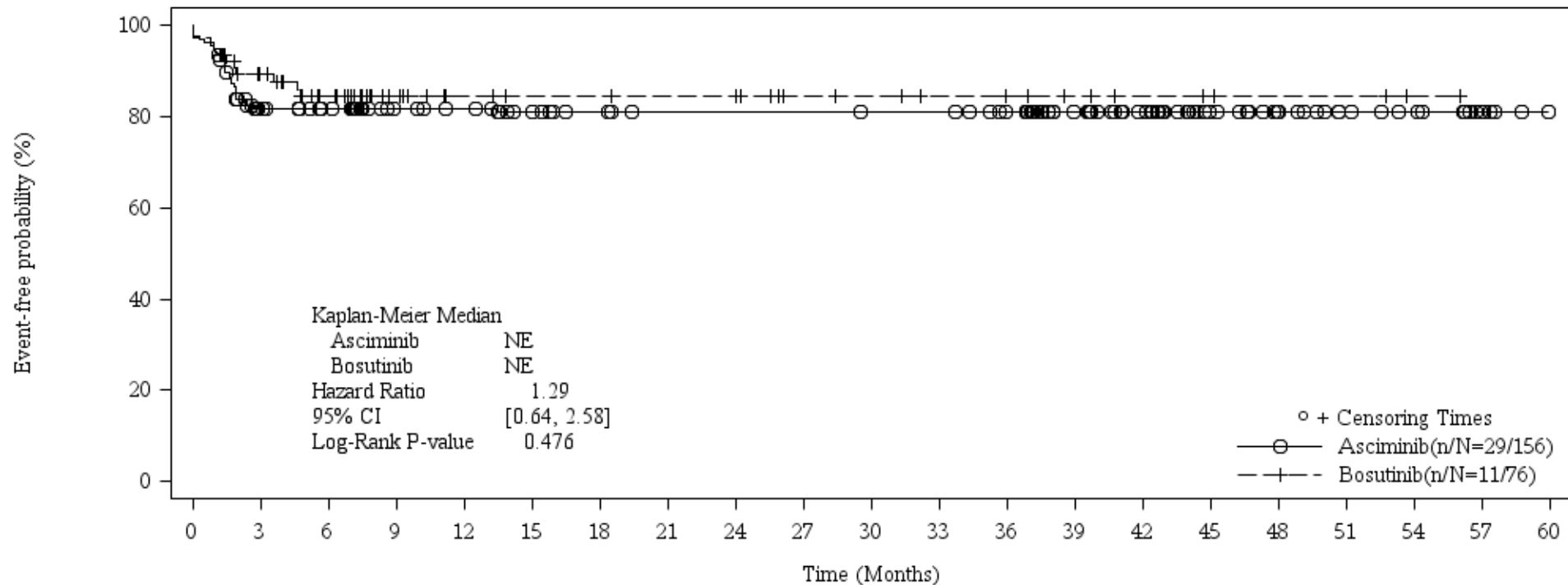


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	108	104	96	90	87	87	85	84	84	79	63	49	34	25	17	13	5	0
Bosutinib	76	61	48	29	21	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 10 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Neutropenia)



		Number of patients still at risk																			
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	117	108	95	92	84	80	77	77	77	76	76	71	57	44	29	21	15	12	5	0
Bosutinib	76	58	43	28	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

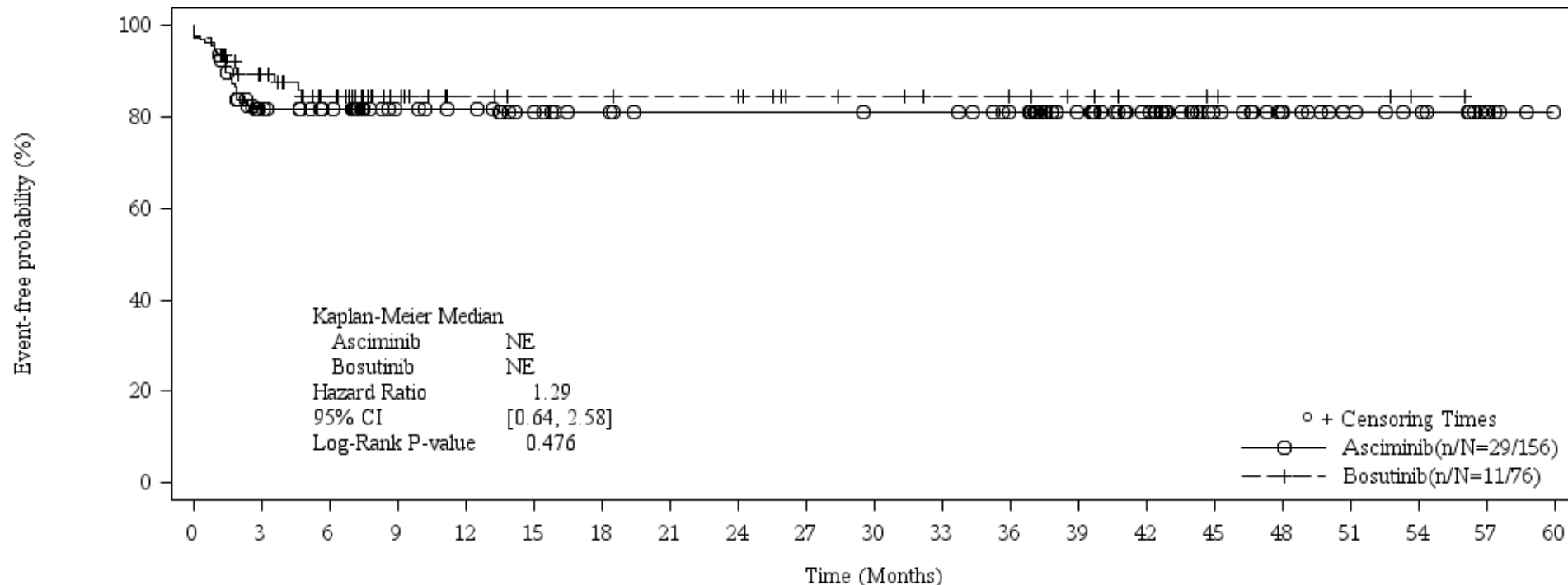
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.3.1 (Page 11 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Leucopenia)

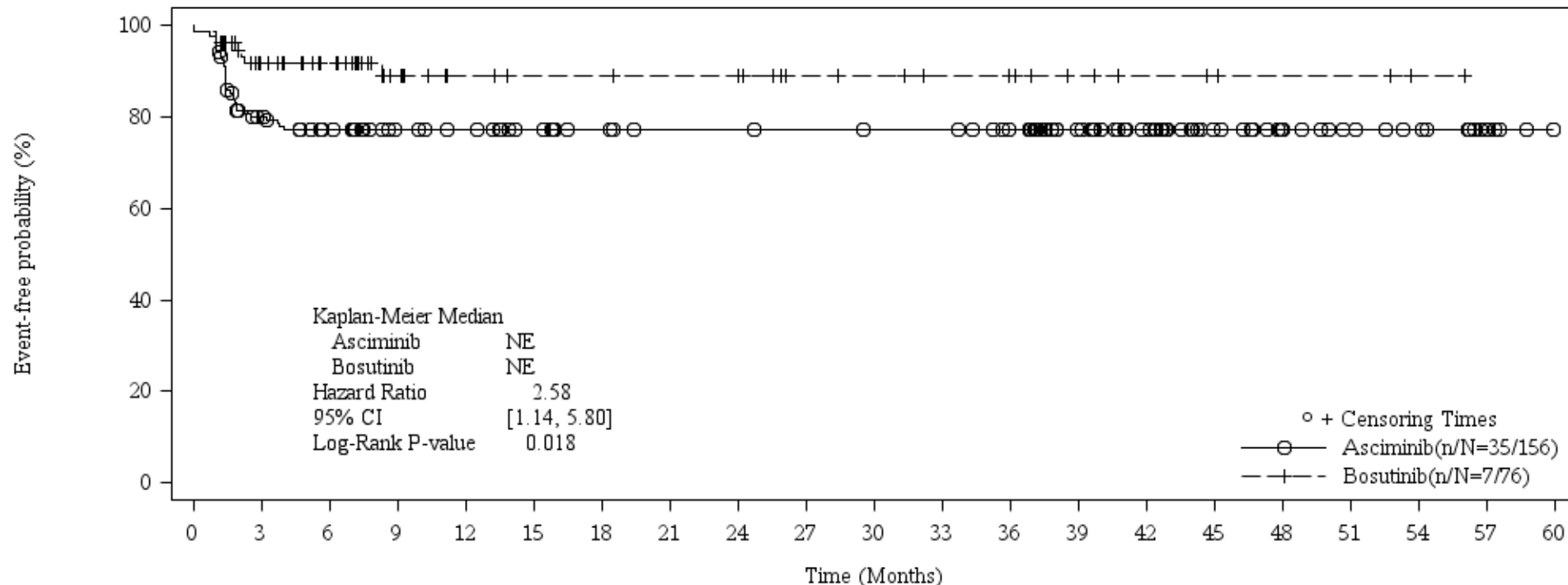


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	117	108	95	92	84	80	77	77	77	76	76	71	57	44	29	21	15	12	5	0
Bosutinib	76	58	43	28	21	19	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 12 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Thrombocytopenia)

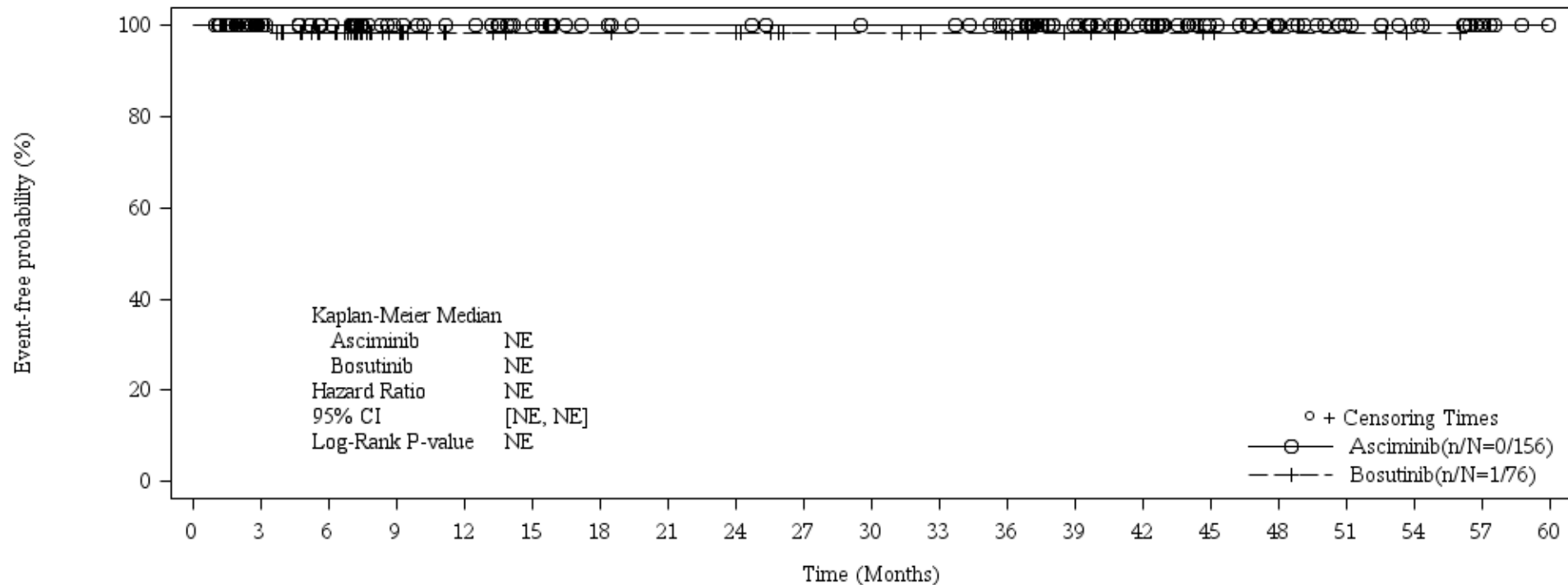


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	117	105	93	90	84	79	76	76	75	74	74	69	55	41	28	19	15	12	5	0
Bosutinib	76	57	46	29	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 13 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (cytopenias affecting more than one lineage)

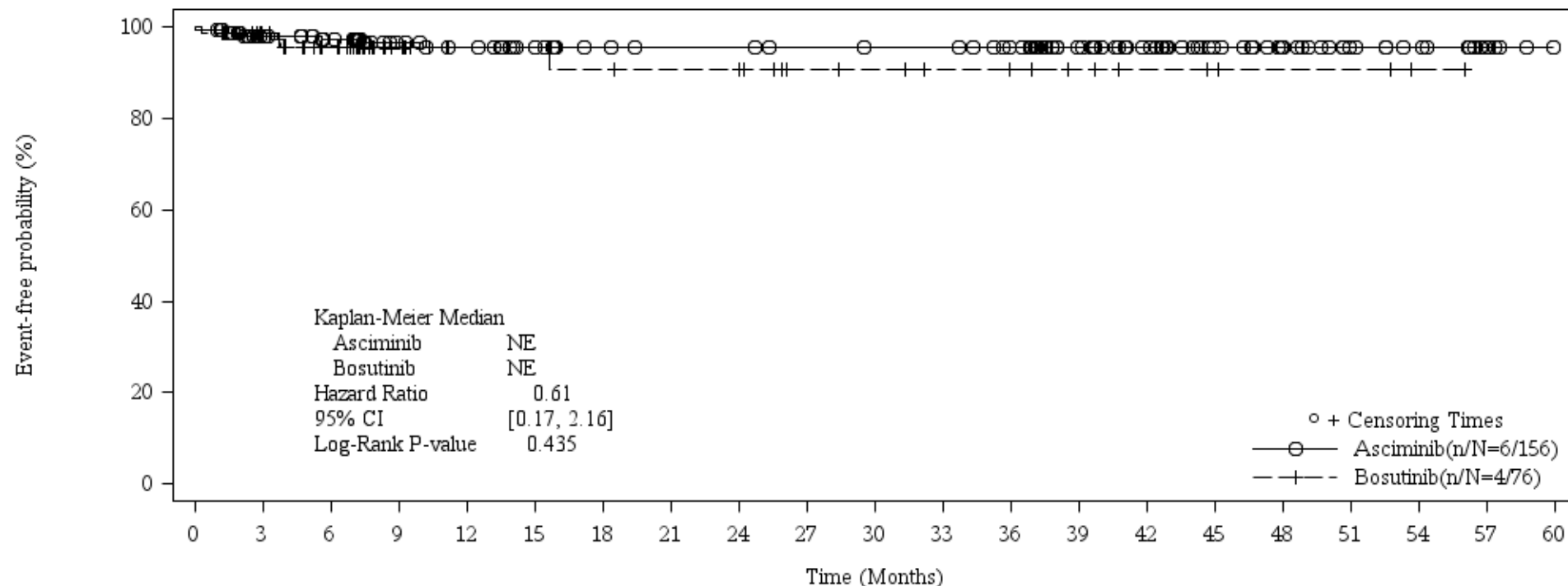


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 14 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Pancreatic toxicity

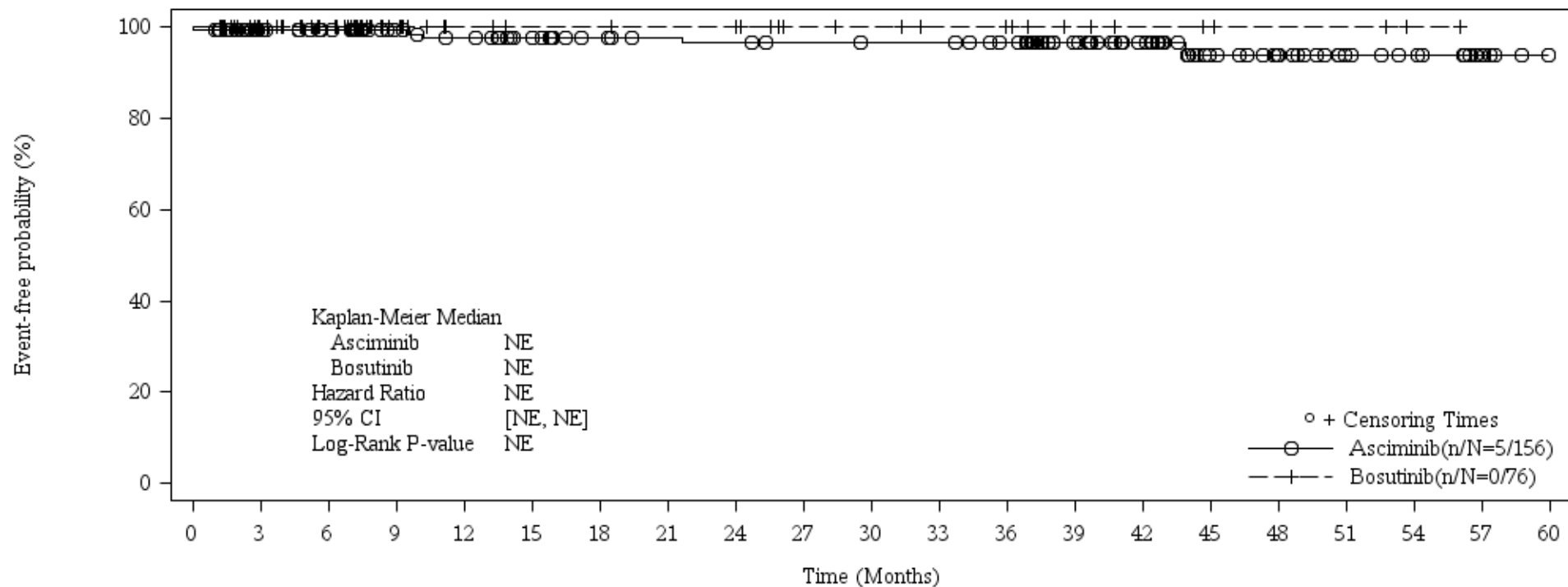


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	127	105	100	92	87	85	85	83	82	82	77	61	47	34	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	19	18	18	13	12	10	9	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.3.1 (Page 15 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: QTc prolongation

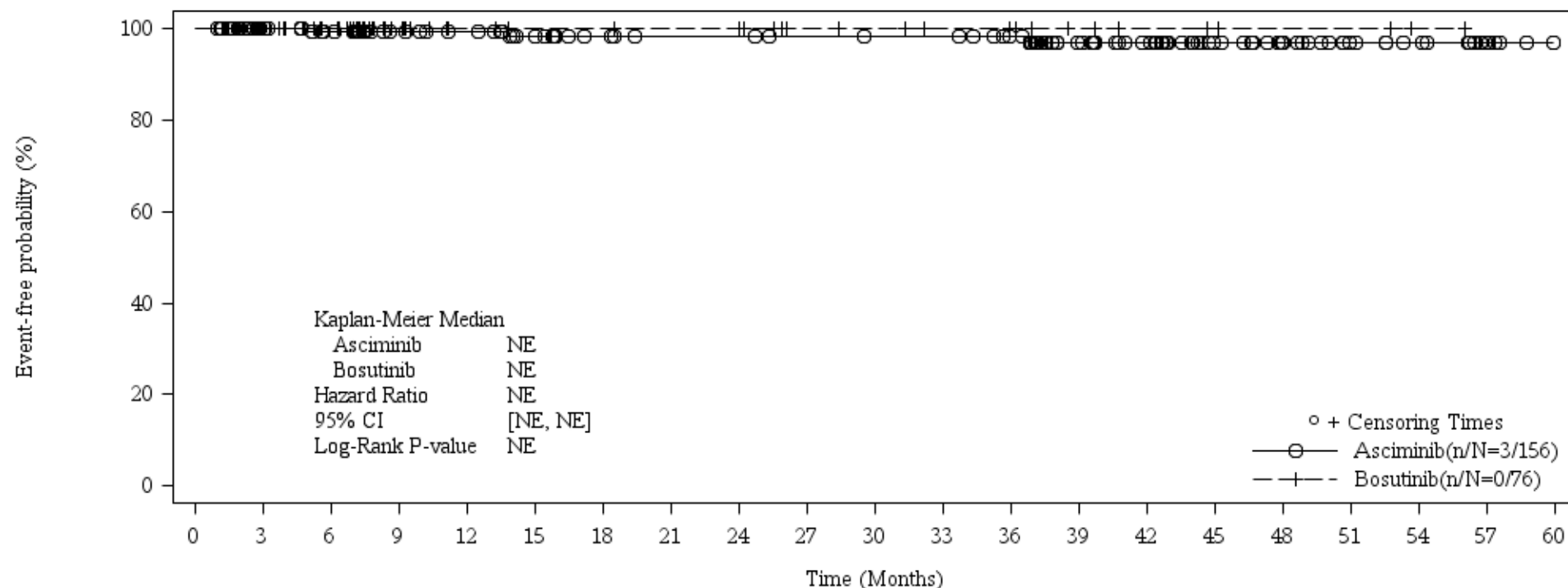


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	108	103	95	89	86	85	83	82	82	78	61	47	31	24	16	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

Figure 4-5.3.1 (Page 16 of 16)
Grade ≥ 3 AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Reproductive toxicity



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	109	105	96	90	87	87	85	84	84	79	61	49	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 1 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.05	[0.11, 10.25]	0.968
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.98 [0.94, 1.00]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 2 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.98 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.98 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
(Page 3 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.16	[0.12, 11.43]	0.896
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 51	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
 (Page 5 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	46 (60.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [30.95, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	0.98 [0.84, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 15	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 18	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 21	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 24	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 27	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 30	1.00 [1.00, 1.00]	0.94 [0.76, 0.98]			
Month 33	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 36	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 39	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 42	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 45	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 48	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 51	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 54	1.00 [1.00, 1.00]	0.79 [0.49, 0.92]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
(Page 7 of 32)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	9 (11.8)			
censored					
Death	4 (2.6)	0			
Discontinued from study treatment	147 (94.2)	44 (57.9)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.20	[0.07, 0.61]	0.002
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.91 [0.81, 0.95]			
Month 6	0.99 [0.96, 1.00]	0.87 [0.77, 0.93]			
Month 9	0.99 [0.96, 1.00]	0.87 [0.77, 0.93]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 15	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 18	0.97 [0.92, 0.99]	0.87 [0.77, 0.93]			
Month 21	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 24	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 27	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 30	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 33	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 36	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 39	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 42	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 45	0.96 [0.90, 0.99]	0.87 [0.77, 0.93]			
Month 48	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 51	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 54	0.93 [0.82, 0.98]	0.87 [0.77, 0.93]			
Month 57	0.93 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.21	[0.12, 11.81]	0.873
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 21	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 24	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 51	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.98 [0.93, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.98 [0.93, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hepatotoxicity (including laboratory terms)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	13 (17.1)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	42 (55.3)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [3.75, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.09	[0.03, 0.32]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.87 [0.76, 0.93]			
Month 6	0.99 [0.95, 1.00]	0.83 [0.72, 0.90]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 12	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 15	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 18	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 21	0.98 [0.94, 1.00]	0.81 [0.70, 0.89]			
Month 24	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 27	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 30	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 33	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 36	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 39	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 42	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 45	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 48	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 51	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 54	0.97 [0.92, 0.99]	0.81 [0.70, 0.89]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	44 (57.9)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.06	[0.01, 0.50]	<0.001
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.91 [0.82, 0.95]			
Month 6	1.00 [1.00, 1.00]	0.91 [0.82, 0.95]			
Month 9	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 15	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 18	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 21	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 24	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 27	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 30	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 33	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 36	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 39	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 42	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 45	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 48	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 51	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 54	0.99 [0.94, 1.00]	0.91 [0.82, 0.95]			
Month 57	0.99 [0.94, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	2 (2.6)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	147 (94.2)	48 (63.2)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.93	[0.18, 4.89]	0.934
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.98 [0.94, 0.99]	0.97 [0.87, 0.99]			
Month 9	0.98 [0.94, 0.99]	0.97 [0.87, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 15	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 18	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 21	0.97 [0.92, 0.99]	0.97 [0.87, 0.99]			
Month 24	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 27	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 30	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 33	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 36	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 39	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 42	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 45	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 48	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 51	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 54	0.96 [0.90, 0.98]	0.97 [0.87, 0.99]			
Month 57	0.96 [0.90, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Erythropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.31	[0.05, 1.84]	0.171
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.97 [0.89, 0.99]			
Month 9	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 15	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 18	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 21	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 24	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 27	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 30	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 33	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 36	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 39	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 42	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 45	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 48	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 51	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 54	0.99 [0.95, 1.00]	0.95 [0.85, 0.98]			
Month 57	0.99 [0.95, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Neutropenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	29 (18.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [2.76, NE]	NE [4.70, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.35	[0.67, 2.70]	0.399
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.87]	0.89 [0.79, 0.94]			
Month 6	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 9	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 15	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 18	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 21	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 24	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 27	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 30	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 33	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 36	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 39	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 42	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 45	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 48	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 51	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 54	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 57	0.81 [0.74, 0.86]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	29 (18.6)	11 (14.5)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	122 (78.2)	44 (57.9)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [2.76, NE]	NE [4.70, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.35	[0.67, 2.70]	0.399
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.82 [0.75, 0.87]	0.89 [0.79, 0.94]			
Month 6	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 9	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.82 [0.75, 0.87]	0.84 [0.73, 0.91]			
Month 15	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 18	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 21	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 24	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 27	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 30	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 33	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 36	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 39	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 42	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 45	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 48	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 51	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 54	0.81 [0.74, 0.86]	0.84 [0.73, 0.91]			
Month 57	0.81 [0.74, 0.86]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	35 (22.4)	7 (9.2)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	116 (74.4)	48 (63.2)			
Treatment switched	0	20 (26.3)			
Percentiles (months) (95% CI)					
25th	NE [1.87, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	2.75	[1.22, 6.19]	0.011
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.80 [0.73, 0.85]	0.92 [0.82, 0.96]			
Month 6	0.77 [0.70, 0.83]	0.92 [0.82, 0.96]			
Month 9	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 15	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 18	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 21	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 24	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 27	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 30	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 33	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 36	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 39	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 42	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 45	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 48	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 51	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 54	0.77 [0.70, 0.83]	0.89 [0.77, 0.95]			
Month 57	0.77 [0.70, 0.83]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Pancreatic toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	6 (3.8)	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	145 (92.9)	48 (63.2)			
Treatment switched	0	23 (30.3)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [15.64, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.59	[0.16, 2.10]	0.407
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.98 [0.94, 0.99]	0.99 [0.91, 1.00]			
Month 6	0.97 [0.93, 0.99]	0.95 [0.86, 0.99]			
Month 9	0.96 [0.92, 0.99]	0.95 [0.86, 0.99]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.95 [0.90, 0.98]	0.95 [0.86, 0.99]			
Month 15	0.95 [0.90, 0.98]	0.95 [0.86, 0.99]			
Month 18	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 21	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 24	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 27	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 30	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 33	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 36	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 39	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 42	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 45	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 48	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 51	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 54	0.95 [0.90, 0.98]	0.91 [0.73, 0.97]			
Month 57	0.95 [0.90, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	5 (3.2)	0			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.96, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 15	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 18	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 21	0.97 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 24	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 27	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 30	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 33	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 36	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 39	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.96 [0.90, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 48	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 51	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 54	0.94 [0.84, 0.98]		1.00 [1.00, 1.00]			
Month 57	0.94 [0.84, 0.98]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Reproductive toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.3.2 Grade ≥ 3 AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 48	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 51	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 54	0.97 [0.91, 0.99]		1.00 [1.00, 1.00]			
Month 57	0.97 [0.91, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.46	[0.16, 13.24]	0.737
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
(Page 3 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.28	[0.14, 11.94]	0.826
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [25.10, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 15	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 18	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 21	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 24	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.94 [0.65, 0.99]			
Month 30	1.00 [1.00, 1.00]	0.94 [0.65, 0.99]			
Month 33	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 36	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 39	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 42	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 45	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 48	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 51	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 54	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	0.94	[0.09, 9.48]	0.958
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 27	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 30	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 33	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 36	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 39	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 42	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 45	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 48	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.76, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.76, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.76, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.98 [0.93, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 6	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 9	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 15	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 18	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 21	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 24	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 27	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 30	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 33	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 36	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 39	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 42	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 45	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 48	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 51	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 54	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.15	[0.12, 11.33]	0.902
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.98 [0.93, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
 Safety Set
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	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
(Page 18 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
(Page 19 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
 Safety Set
 (Page 20 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
(Page 21 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.1 Serious AESI: time to first event - stratified per IRT
Safety Set
(Page 22 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 39	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 48	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 51	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 54	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 57	0.98 [0.92, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

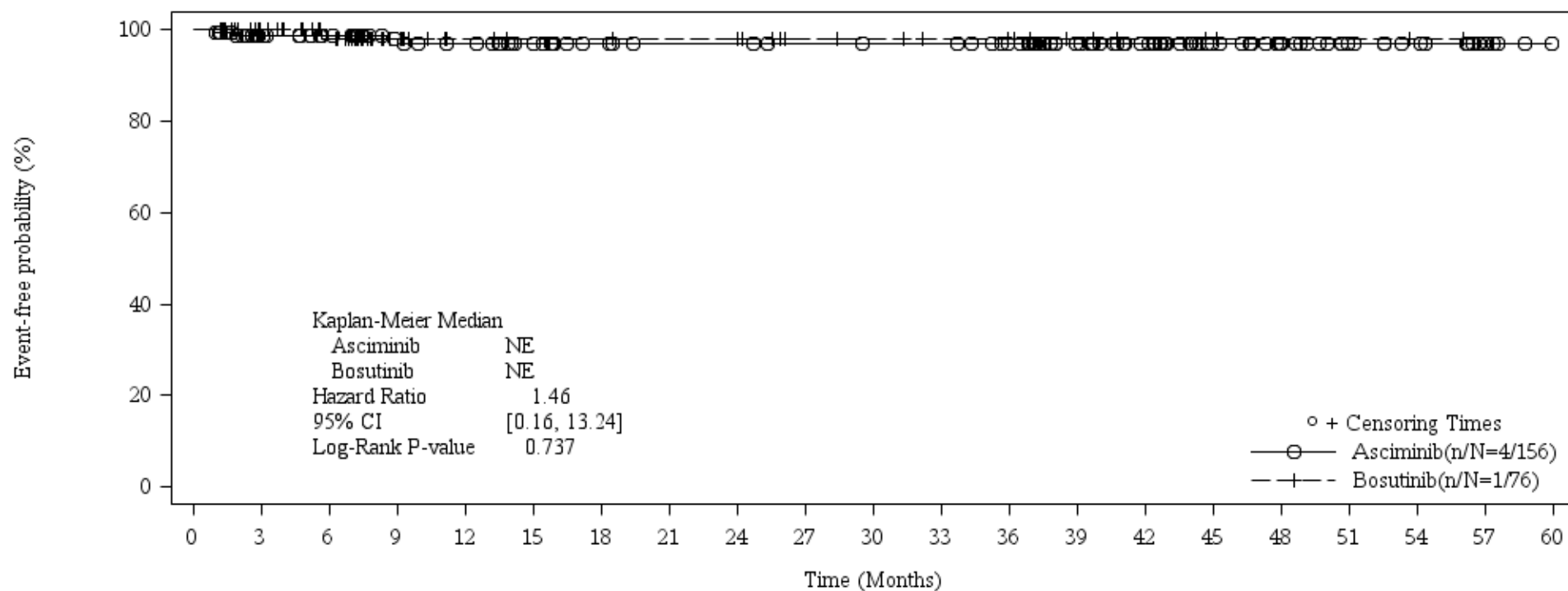
Figure 4-5.4.1 Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT

Figure 4-5.4.1 (Page 1 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT

Safety Set

AESI: Arterial-occlusive events (AOEs)



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	29	21	19	19	18	18	13	12	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

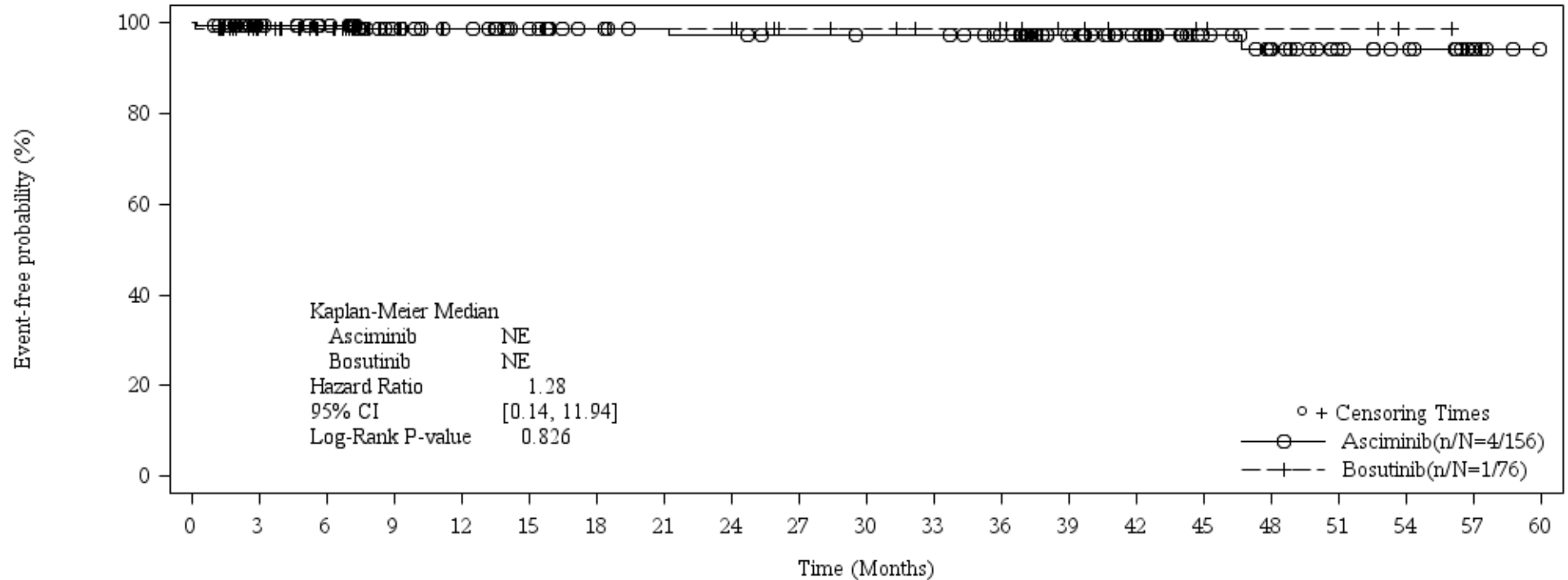
N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.4.1 (Page 2 of 11)

**Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set**

AESI: Cardiac failure (clinical events)

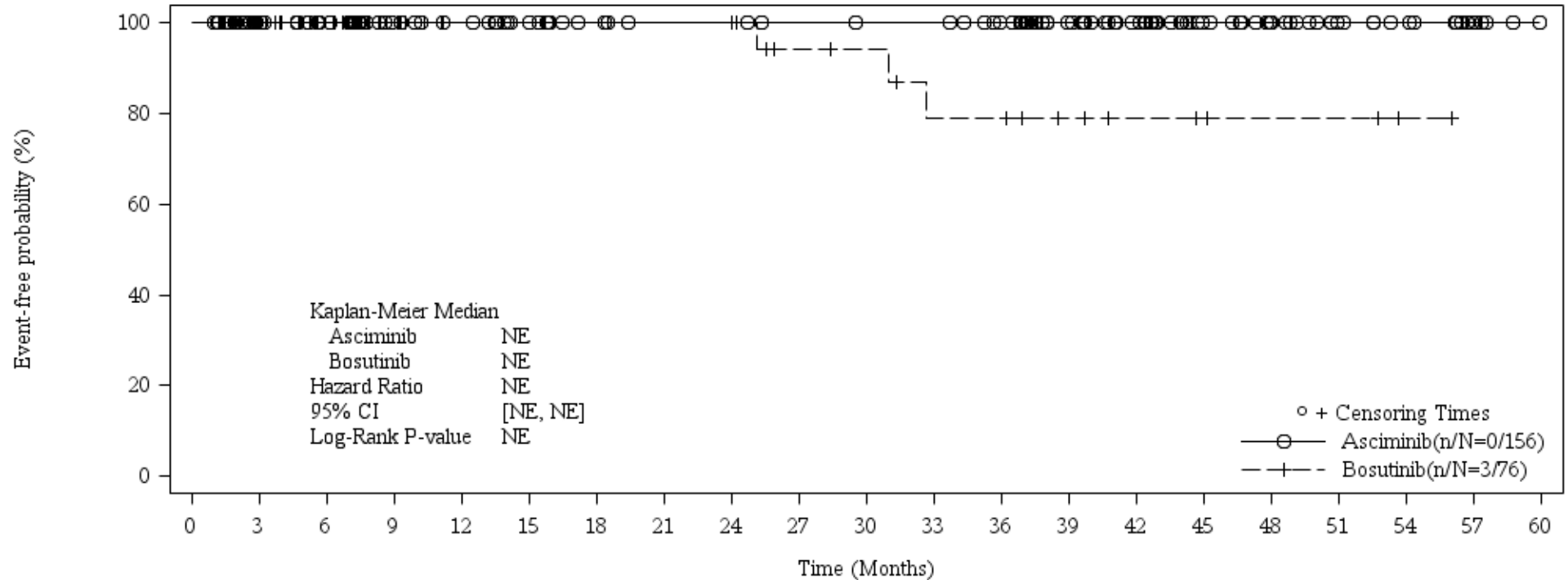


Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	86	84	83	83	78	61	48	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.4.1 (Page 3 of 11)
Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Edema and fluid retention

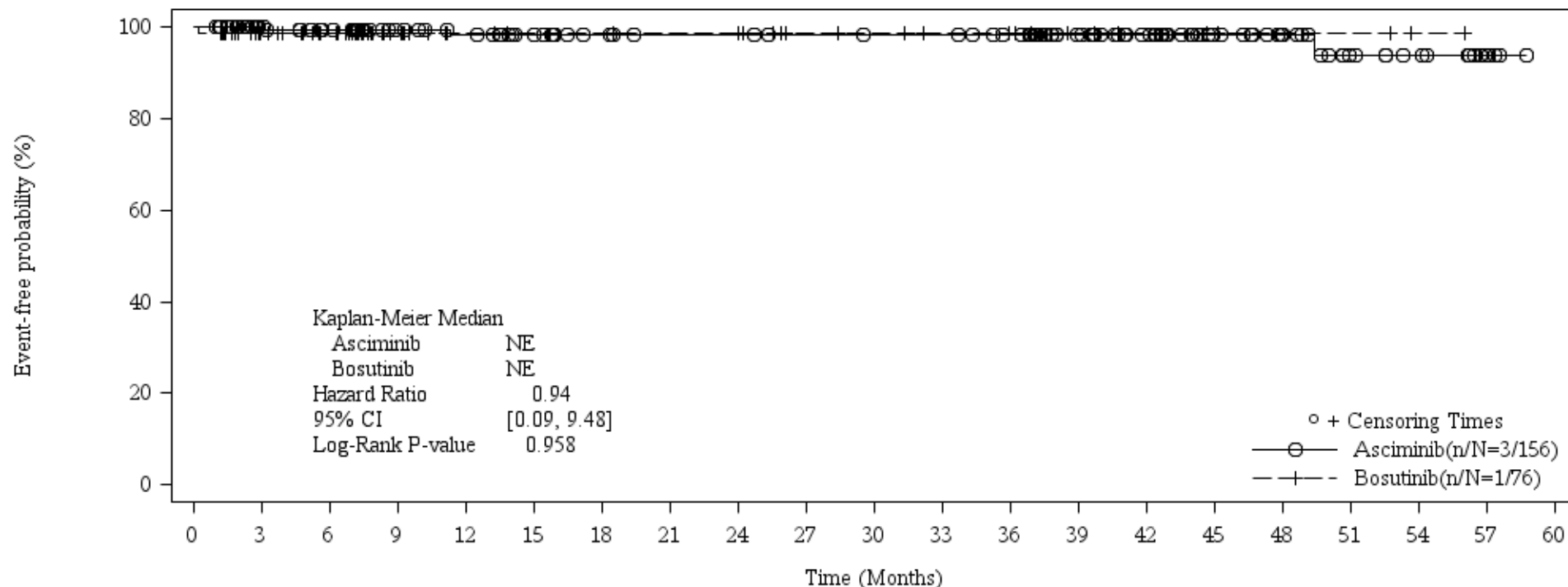


Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	10	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.4.1 (Page 4 of 11)
Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: GI toxicity



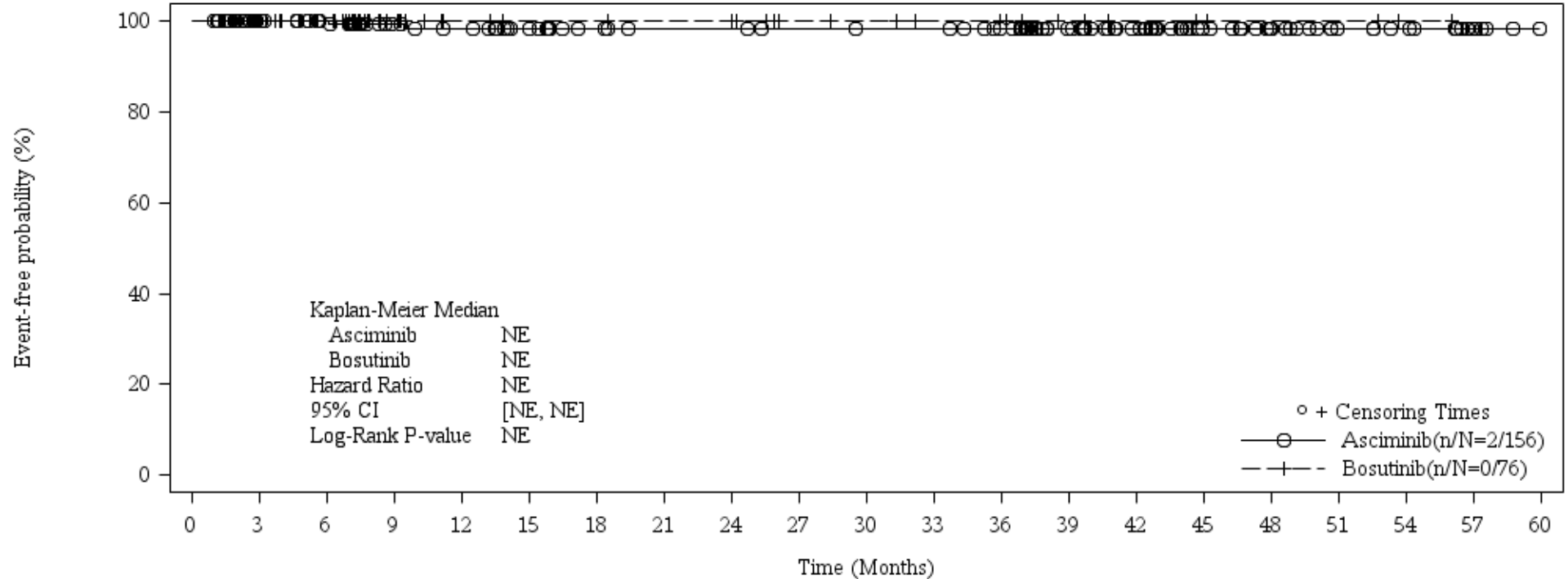
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	129	109	104	96	90	87	87	85	84	84	80	63	49	34	25	16	12	4	0
Bosutinib	76	61	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.4.1 (Page 5 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Hemorrhage



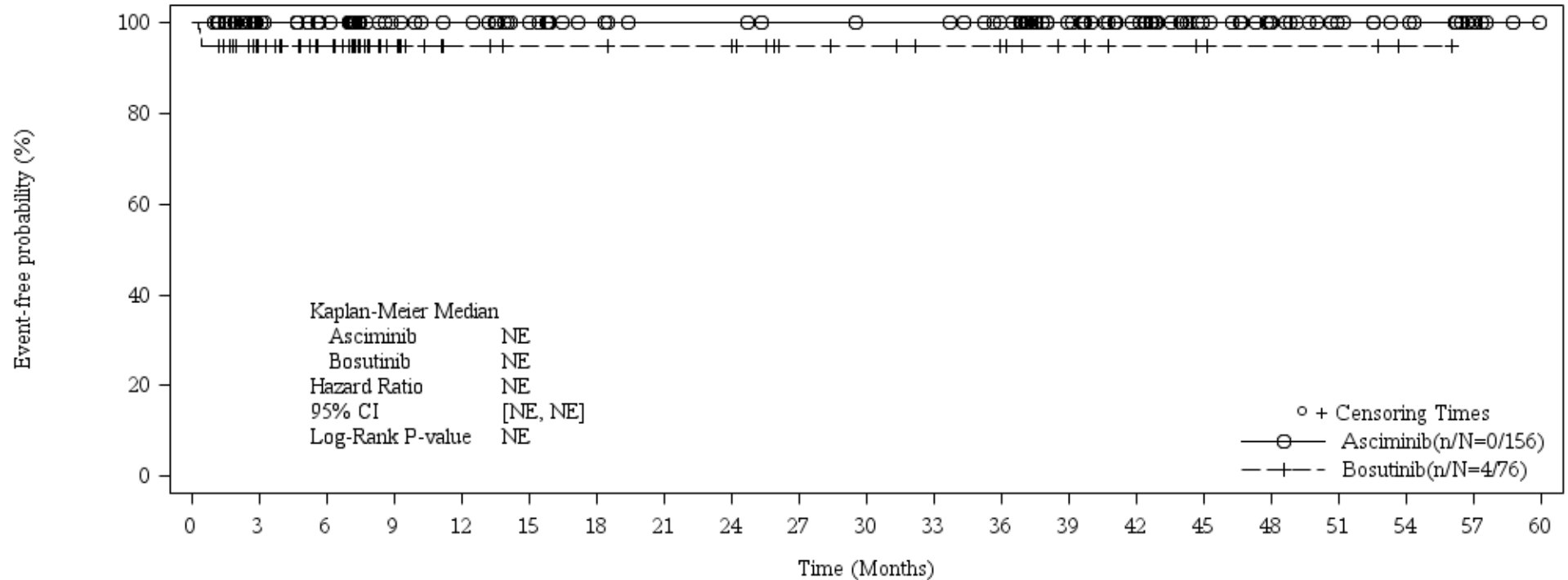
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	108	104	96	90	87	87	85	84	84	79	62	48	33	24	16	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.4.1 (Page 6 of 11)

**Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set**

AESI: Hypersensitivity



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	61	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

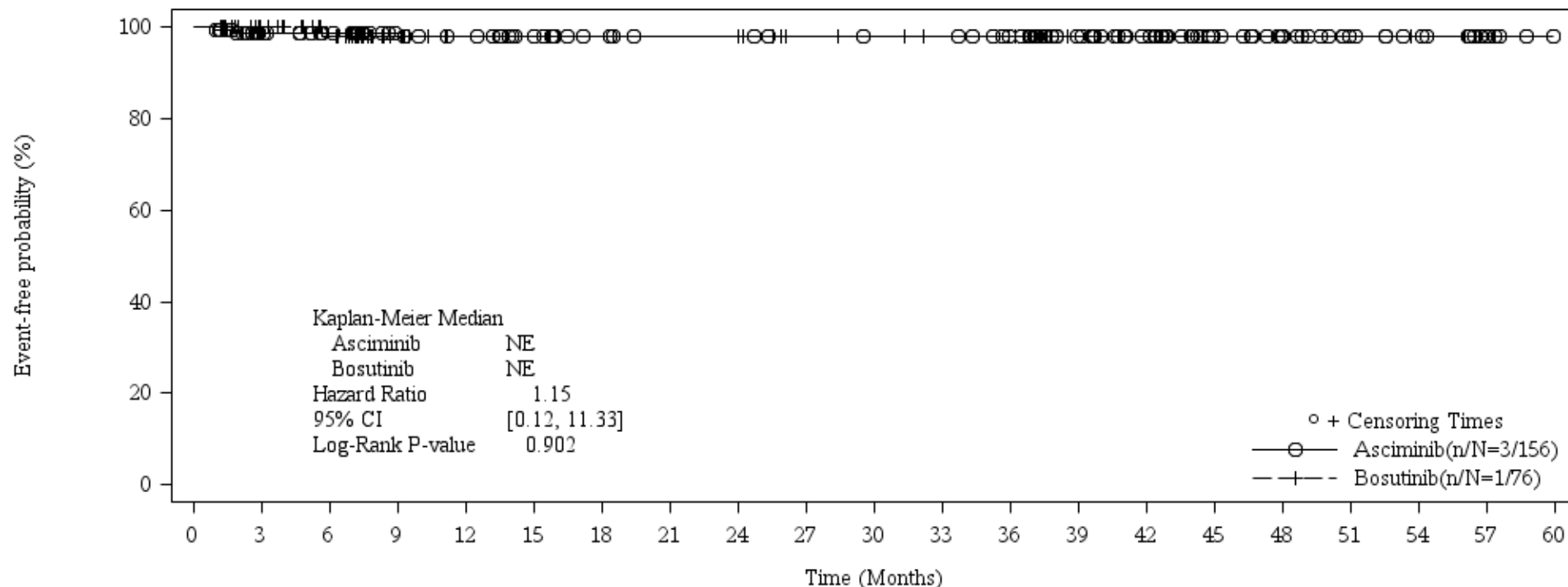
N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.4.1 (Page 7 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Ischemic heart and CNS conditions



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	29	21	19	19	18	18	13	12	10	9	6	4	3	2	2	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

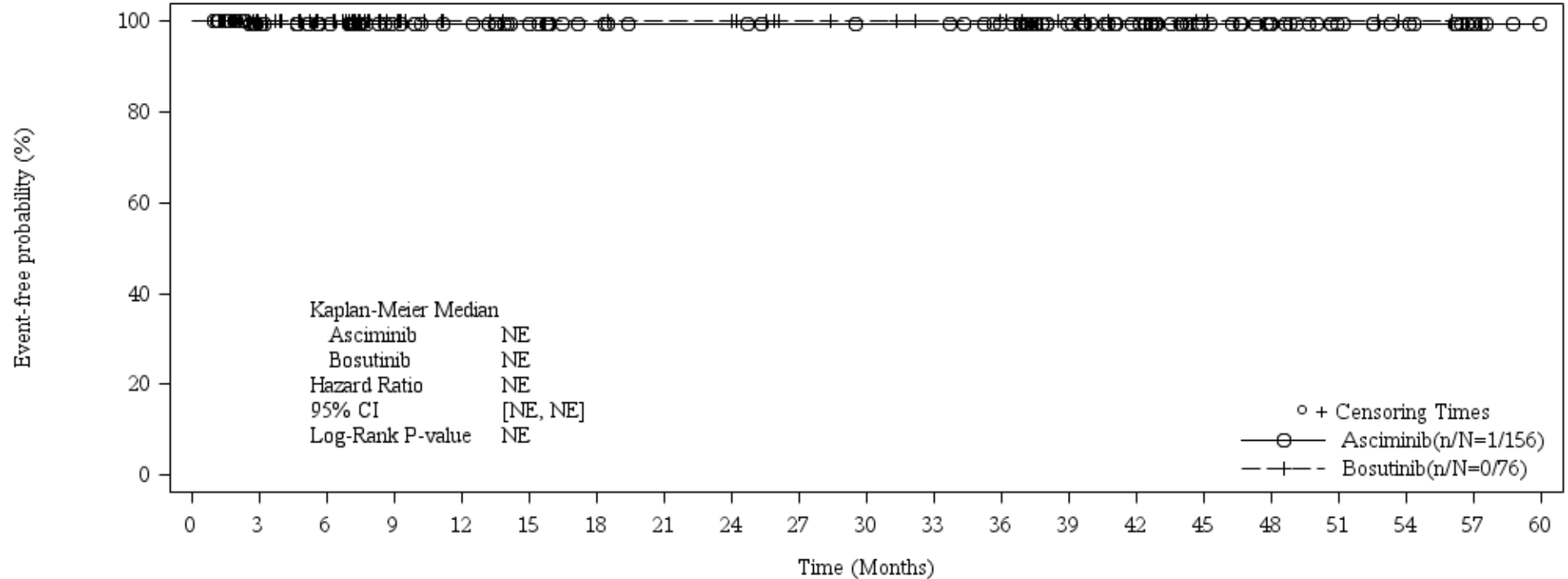
N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.4.1 (Page 8 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Leucopenia)



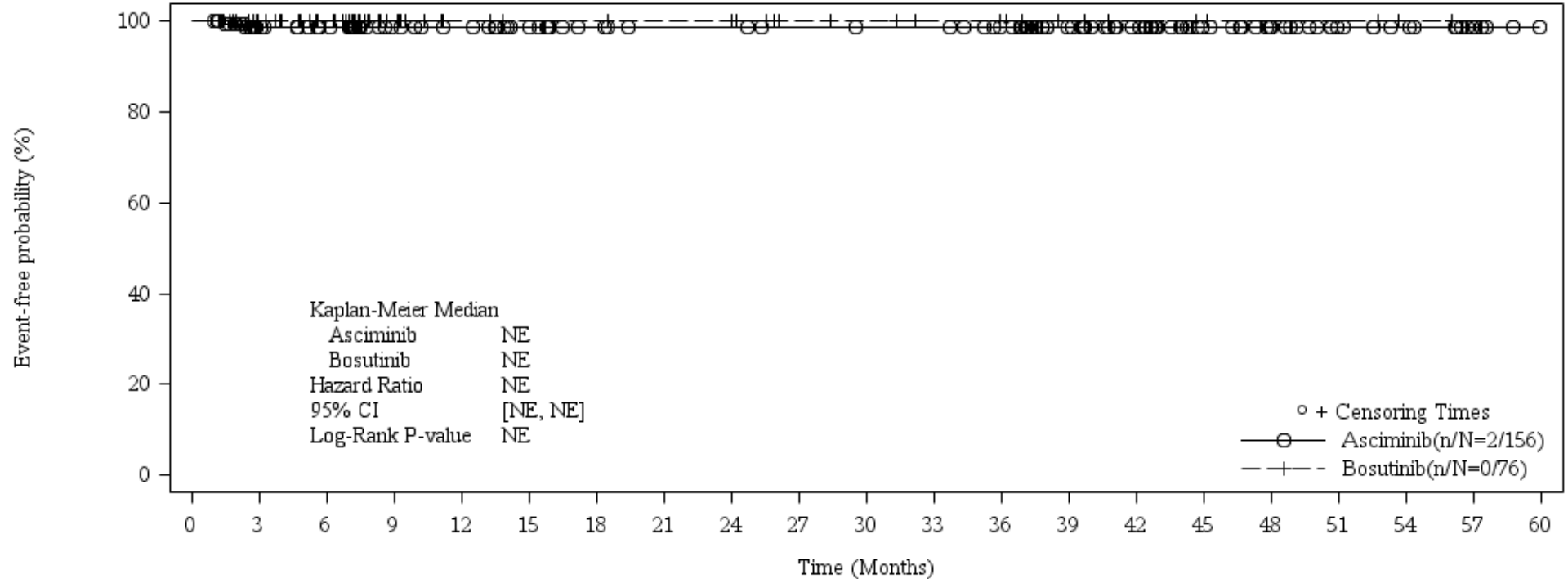
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	140	129	108	104	96	90	87	87	85	84	84	79	63	49	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Figure 4-5.4.1 (Page 9 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (Thrombocytopenia)



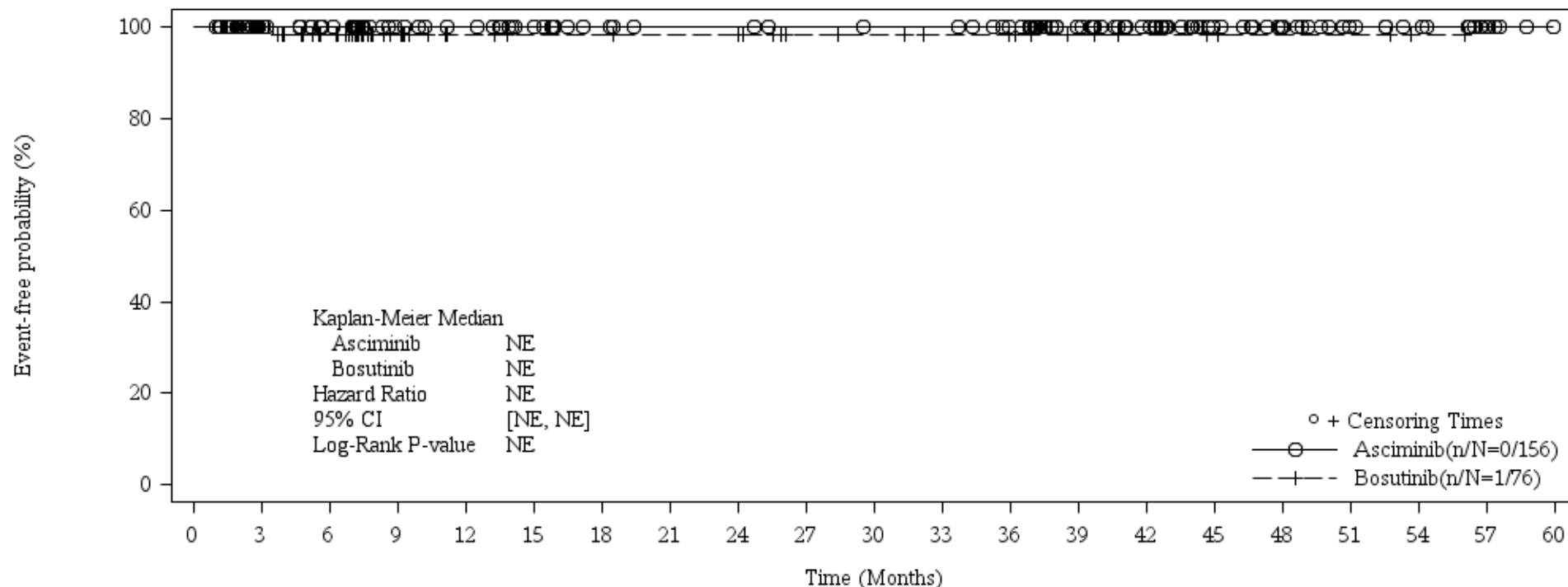
Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	139	128	107	103	95	89	86	86	84	83	83	78	62	48	33	24	16	12	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

Figure 4-5.4.1 (Page 10 of 11)

Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: Myelosuppression (cytopenias affecting more than one lineage)



Number of patients still at risk																					
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	88	86	85	85	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	49	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

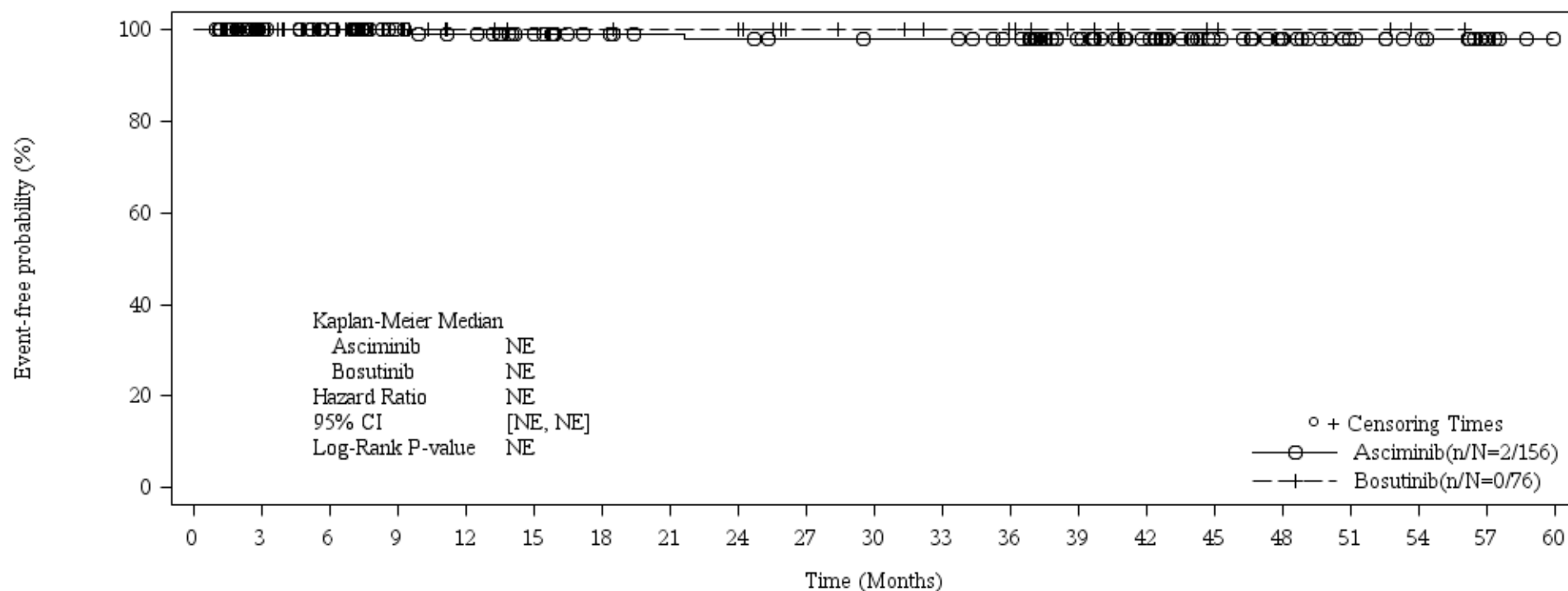
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.4.1 (Page 11 of 11)
Serious AESI: Kaplan Meier plot of time to first event - stratified per IRT
Safety Set

AESI: QTc prolongation



Time (Months)	Number of patients still at risk																				
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Asciminib	156	141	130	109	105	97	91	88	87	85	84	84	80	63	49	34	25	17	13	5	0
Bosutinib	76	62	50	30	22	20	20	19	19	14	13	11	10	7	5	4	3	3	1	0	0

Median (time to event) and its 95% CI are generated by KM estimation.
 Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
 (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
 CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
 N*: Number of patients included in the analysis.
 - NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 1 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Arterial-occlusive events (AOEs)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	3 (1.9)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.54	[0.17, 13.97]	0.699
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.97 [0.92, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.97 [0.92, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

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Final

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 3 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Cardiac failure (clinical events)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	4 (2.6)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	148 (94.9)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.24	[0.13, 11.81]	0.849
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.96, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 4 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.99 [0.94, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 27	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 30	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 33	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 36	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 39	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 42	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 45	0.97 [0.92, 0.99]	0.99 [0.91, 1.00]			
Month 48	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.82, 0.98]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.82, 0.98]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t45_4_2.sas@@/main/3 22JAN24:12:36

Final

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 5 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Edema and fluid retention					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	3 (3.9)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [25.10, NE]			
median	NE [NE, NE]	NE [32.62, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 6 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 15	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 18	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 21	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 24	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.94 [0.65, 0.99]			
Month 30	1.00 [1.00, 1.00]	0.94 [0.65, 0.99]			
Month 33	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 36	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 39	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 42	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 45	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 48	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 51	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 54	1.00 [1.00, 1.00]	0.79 [0.47, 0.93]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 7 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
GI toxicity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.03	[0.10, 10.23]	0.983
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.99 [0.91, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.99 [0.91, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 8 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 15	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 18	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 21	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 24	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 27	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 30	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 33	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 36	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 39	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 42	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 45	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 48	0.98 [0.93, 1.00]	0.99 [0.91, 1.00]			
Month 51	0.94 [0.76, 0.99]	0.99 [0.91, 1.00]			
Month 54	0.94 [0.76, 0.99]	0.99 [0.91, 1.00]			
Month 57	0.94 [0.76, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 9 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hemorrhage					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 10 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.98 [0.93, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.98 [0.93, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 11 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Hypersensitivity					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	4 (5.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	47 (61.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 6	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 9	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
 (Page 12 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 15	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 18	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 21	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 24	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 27	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 30	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 33	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 36	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 39	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 42	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 45	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 48	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 51	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 54	1.00 [1.00, 1.00]	0.95 [0.87, 0.98]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 13 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Ischemic heart and CNS conditions					
N*	156	76			
Number of patients, n (%)					
with events					
AE	3 (1.9)	1 (1.3)			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	49 (64.5)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	1.24	[0.13, 12.09]	0.854
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			
Month 9	0.99 [0.95, 1.00]	0.98 [0.87, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
 Safety Set
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	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 15	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 18	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 21	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 24	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 27	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 30	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 33	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 36	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 39	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 42	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 45	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 48	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 51	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 54	0.98 [0.93, 0.99]	0.98 [0.87, 1.00]			
Month 57	0.98 [0.93, 0.99]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 15 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Leucopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	1 (0.6)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 16 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 17 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (Thrombocytopenia)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	149 (95.5)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 6	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			
Month 9	0.99 [0.95, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 18 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 27	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 30	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 33	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 36	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 39	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 42	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 45	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 48	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 51	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 54	0.99 [0.95, 1.00]		1.00 [1.00, 1.00]			
Month 57	0.99 [0.95, 1.00]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 19 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Myelosuppression (cytopenias affecting more than one lineage)					
N*	156	76			
Number of patients, n (%)					
with events					
AE	0	1 (1.3)			
censored					
Death	5 (3.2)	1 (1.3)			
Discontinued from study treatment	151 (96.8)	50 (65.8)			
Treatment switched	0	24 (31.6)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 20 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
Month 9	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 12	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 15	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 18	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 21	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 24	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 27	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 30	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 33	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 36	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 39	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 42	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 45	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 48	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 51	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 54	1.00 [1.00, 1.00]	0.98 [0.89, 1.00]			
Month 57	1.00 [1.00, 1.00]	NE [NE, NE]			
Month 60	NE [NE, NE]	NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 21 of 22)

	Treatment Groups		Comparison		
	Asciminib N=156	Bosutinib N=76	HR	[95% CI]	p-value
QTc prolongation					
N*	156	76			
Number of patients, n (%)					
with events					
AE	2 (1.3)	0			
censored					
Death	4 (2.6)	1 (1.3)			
Discontinued from study treatment	150 (96.2)	50 (65.8)			
Treatment switched	0	25 (32.9)			
Percentiles (months) (95% CI)					
25th	NE [NE, NE]	NE [NE, NE]			
median	NE [NE, NE]	NE [NE, NE]	NE	[NE, NE]	NE
75th	NE [NE, NE]	NE [NE, NE]			
Kaplan Meier event probability					
estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 6	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 9	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.4.2 Serious AESI: time to first event - stratified per CRF
Safety Set
(Page 22 of 22)

	Treatment Groups			Comparison		
	Asciminib N=156		Bosutinib N=76	HR	[95% CI]	p-value
Month 12	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 15	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 18	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 21	0.99 [0.94, 1.00]		1.00 [1.00, 1.00]			
Month 24	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 27	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 30	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 33	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 36	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 39	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 42	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 45	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 48	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 51	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 54	0.98 [0.92, 0.99]		1.00 [1.00, 1.00]			
Month 57	0.98 [0.92, 0.99]		NE [NE, NE]			
Month 60	NE [NE, NE]		NE [NE, NE]			

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per CRF).

A subject with multiple severity grades for an AESI is only counted under the maximum grade.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.5.1 AESI Myelosuppression (Thrombocytopenia): time to resolution of grade ≥ 3 AESI myelosuppression (thrombocytopenia)
subset of Safety set: patients with at least one event
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib N=35	Bosutinib N=7	HR	[95% CI]	p-value
Time to Resolution of Myelosuppression (Thrombocytopenia)					
N*	35	7			
Number of patients, n (%) with resolution					
AE	31 (88.6)	7 (100.0)			
Discontinued from study treatment	4 (11.4)	0			
Total number of episodes	51	13			
Total resolved among all episodes	22	11			
Percentiles (months) (95% CI)					
25th	0.56 [0.46, 0.72]	0.23 [0.13, 1.61]	0.97	[0.42, 2.26]	0.941
median	1.05 [0.69, 3.06]	1.61 [0.13, 4.60]			
75th	3.94 [1.18, 6.01]	4.60 [0.23, NE]			
Kaplan Meier Resolution probability estimates [95% CI]					
Month 0	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]			
Month 3	0.36 [0.21, 0.52]	0.43 [0.10, 0.73]			
Month 6	0.13 [0.04, 0.27]	0.14 [0.01, 0.46]			
Month 9	0.05 [0.00, 0.19]	0.00 [NE, NE]			

Median (time to Resolution) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable.

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Final

Table 4-5.5.1 AESI Myelosuppression (Thrombocytopenia): time to resolution of grade ≥ 3 AESI myelosuppression (thrombocytopenia)
subset of Safety set: patients with at least one event
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib N=35	Bosutinib N=7	HR	[95% CI]	p-value
Month 12	0.05 [0.00, 0.19]	0.00 [NE, NE]			
Month 15	0.05 [0.00, 0.19]	0.00 [NE, NE]			
Month 18	0.05 [0.00, 0.19]	0.00 [NE, NE]			
Month 21	0.05 [0.00, 0.19]	0.00 [NE, NE]			
Month 24	0.05 [0.00, 0.19]	0.00 [NE, NE]			
Month 27	NE [NE, NE]	0.00 [NE, NE]			

Median (time to Resolution) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

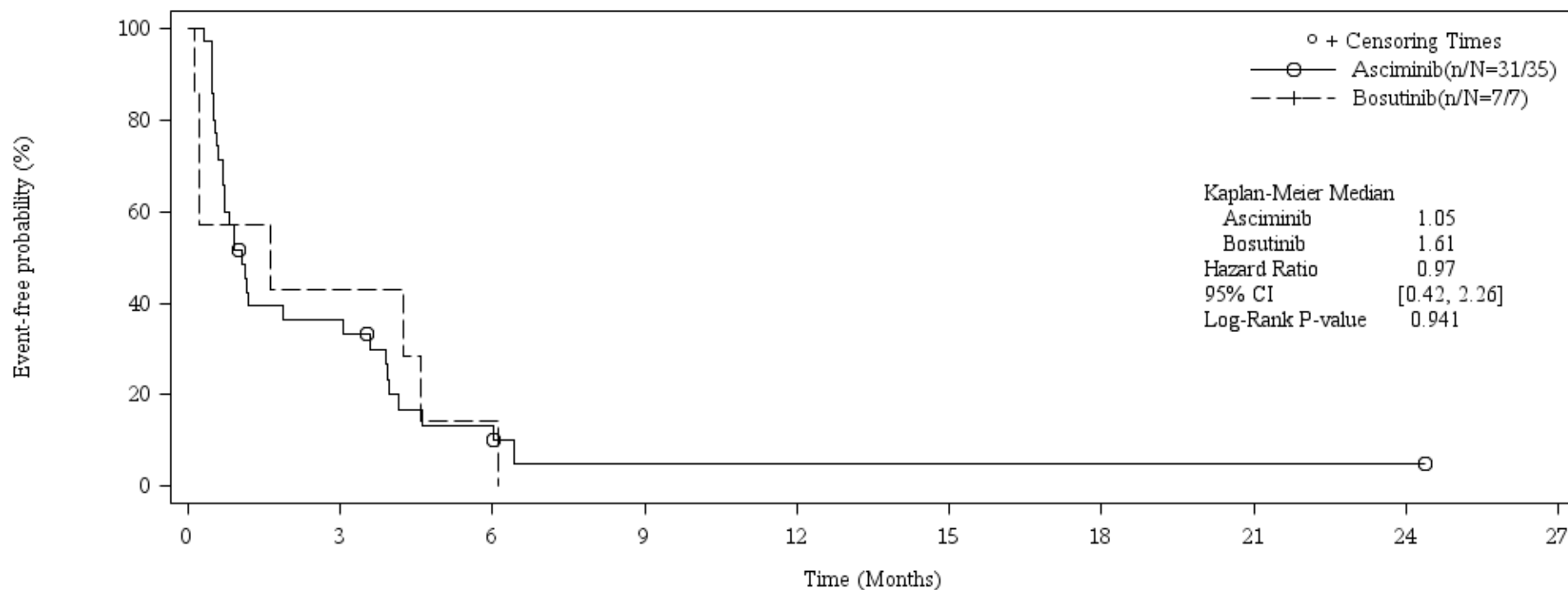
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Figure 4-5.5 (Page 1 of 1)

AESI Myelosuppression (Thrombocytopenia): KM plot for time to resolution of grade ≥ 3 AESI
subset of Safety set: patients with at least one event

AESI: Time to Resolution of Myelosuppression (Thrombocytopenia)

Number of patients still at risk		Time (Months)									
Time (Months)	0	3	6	9	12	15	18	21	24	27	
Asciminib	35	12	4	1	1	1	1	1	1	0	
Bosutinib	7	3	1	0	0	0	0	0	0	0	

Median (time to Resolution) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis.

- NE: Not Estimable.

Table 4-5.5.2 AESI Myelosuppression (Thrombocytopenia): time to resolution of grade ≥ 3 AESI myelosuppression (thrombocytopenia)
descriptive summary
subset of Safety set: patients with at least one event
(Page 1 of 1)

	Asciminib N=35	Bosutinib N=7	All subjects N=42
Time to Resolution (months)			
n	31	7	38
Mean (SD)	1.8 (1.81)	2.4 (2.49)	1.9 (1.93)
Median	0.9	1.6	0.9
Min-Max	0-6	0-6	0-6

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Table 4-5.5.3 AESI Myelosuppression (Thrombocytopenia): number and percentage of patients with grade ≥ 3 AESI myelosuppression to dose reduction/drug interruption or treatment discontinuation
subset of Safety set: patients with at least one event
(Page 1 of 1)

	Asciminib N=35	Bosutinib N=7
Event leads to dose reduction / drug interruption	31 (88.6)	6 (85.7)
Event leads to treatment discontinuation	5 (14.3)	2 (28.6)

N: Subset population of grade ≥ 3 myelosuppression (thrombocytopenia).

n: represent counts of subjects of individual category.

Same Subject have multiple values (Drug interruption/Drug Withdrawn) then count the subject in both categories.

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Table 4-5.5.4 AESI Myelosuppression (Thrombocytopenia): number and percentage of episodes of grade ≥ 3 event
subset of Safety set: patients with at least one event
(Page 1 of 1)

	Asciminib N=35	Bosutinib N=7
Number of episodes, n (%)		
1	23 (65.7)	4 (57.1)
2	9 (25.7)	1 (14.3)
≥ 3	3 (8.6)	2 (28.6)

**Table 4-5.5.5 AESI Myelosuppression (Thrombocytopenia): duration of days of grade ≥ 3 event
subset of Safety set: patients with at least one event
(Page 1 of 1)**

	Asciminib N=35	Bosutinib N=7	All subjects N=42
Duration			
N Patients	35	7	42
Mean (SD)	56.6 (122.68)	33.1 (36.48)	52.7 (112.93)
Median	30.0	7.0	29.0
Min-Max	10-742	4-95	4-742

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**Table 4-5.5.6 AESI Myelosuppression (Thrombocytopenia): duration of days of grade ≥ 3 event
subset of Safety set: patients with at least one event
(Page 1 of 1)**

	Asciminib N=35	Bosutinib N=7	All subjects N=42
Duration of episodes			
N Episodes	51	13	64
Mean (SD)	38.8 (101.92)	17.8 (14.02)	34.6 (91.40)
Median	22.0	18.0	21.0
Min-Max	8-742	3-49	3-742
Statistic should refer to individual episodes, regardless of the fact that a patient had more than one record.			

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Table 4-5.5.7 AESI Myelosuppression (Thrombocytopenia): Grade >=3 events by time interval
 Safety Set
 (Page 1 of 2)

AESI	N=156			
	0-<6M n/N* (%)	6M-<12M n/N* (%)	12M-<18M n/N* (%)	>=18M n/N* (%)
Grade >=3 AESI Myelosuppression (Thrombocytopenia)	35/156 (22.4)	8/128 (6.3)	1/104 (1.0)	1/ 89 (1.1)

Table displays number of subjects with new, recurring or ongoing event/sample size.

Sample size N* is the number of subjects at the beginning of the interval

A subject with multiple occurrences of an AE with the same preferred term within the same time interval under one treatment is counted only once in that time interval for that treatment.

MedDRA version 26.0, CTCAE version 4.03.

Table 4-5.5.7 AESI Myelosuppression (Thrombocytopenia): Grade ≥ 3 events by time interval
 Safety Set
 (Page 2 of 2)

AESI	N=76			
	0-<6M n/N* (%)	6M-<12M n/N* (%)	12M-<18M n/N* (%)	≥ 18 M n/N* (%)
Grade ≥ 3 AESI Myelosuppression (Thrombocytopenia)	6/ 76 (7.9)	3/ 49 (6.1)	0/ 22 (0.0)	0/ 20 (0.0)

Table displays number of subjects with new, recurring or ongoing event/sample size.

Sample size N* is the number of subjects at the beginning of the interval

A subject with multiple occurrences of an AE with the same preferred term within the same time interval under one treatment is counted only once in that time interval for that treatment.

MedDRA version 26.0, CTCAE version 4.03.

Table 4-5.5.8 AESI Hemorrhage: number and percentage of patients with AESI Hemorrhage in which the event outcome was recovered/resolved or leads to treatment discontinuation
subset of Safety set: patients with at least one event
(Page 1 of 1)

	Asciminib N=20	Bosutinib N=8
Event outcome was recovered/resolved	19 (95.0)	8 (100)
Event leads to treatment discontinuation	0	0

N: Subset population of Hemorrhage.

n: represent counts of subjects of individual category.

Table 5-1.2.1.1 Overall survival: Interaction tests
Full Analysis Set
(Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.698
Treatment Vs Sex (Male and Female)	0.682
Treatment Vs Race (Asian,Caucasian and Others)	0.896
Treatment Vs Age (18 - <65 years and >=65 years)	0.766
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.992
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.962
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.263
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	1.000
Treatment Vs Geographic region (Europe and Others)	0.821
[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization. Subgroup Missing will not be analyzed for any of the attributes.	

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Table 5-1.2.1.1.1: Overall survival: Interaction tests
Full Analysis Set

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.973
Treatment Vs Sex (Male and Female)	0.711
Treatment Vs Race (Asian, Caucasian and Others)	0.991
Treatment Vs Age (18 - <65 years and ≥65 years)	0.844
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.991
Treatment Vs Number of prior TKI therapies (2,3 and ≥4)	0.575
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥5)	0.629
Treatment Vs With or without Week 1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.644
Treatment Vs BCR-ABL ratio at baseline (≥ 1% and < 1%)	1.000
Treatment Vs Geographic region (Europe and Others)	0.909

Data cut-off: 04DEC2024

[1] Stratified Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup Missing will not be analyzed for any of the attributes.

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Table 5-1.2.2.1 Progression Free Survival: Interaction tests
Full Analysis Set
(Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.199
Treatment Vs Sex (Male and Female)	0.911
Treatment Vs Race (Asian,Caucasian and Others)	0.935
Treatment Vs Age (18 - <65 years and >=65 years)	0.478
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.991
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.836
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.464
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.706
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.631
[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization. Subgroup Missing will not be analyzed for any of the attributes.	

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**Table 5-1.2.2.1.1: Progression free survival: Interaction tests
Full Analysis Set**

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.125
Treatment Vs Sex (Male and Female)	0.746
Treatment Vs Race (Asian, Caucasian and Others)	0.729
Treatment Vs Age (18 - <65 years and >=65 years)	0.483
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.991
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.665
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.875
Treatment Vs With or without Week 1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.657
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.993
Treatment Vs Geographic region (Europe and Others)	0.326

Data cut-off: 04DEC2024

[1] Stratified Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup Missing will not be analyzed for any of the attributes.

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Table 5-1.3.1 MMR: Rate at week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 1 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Week 24	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.302
Treatment Vs Sex (Male and Female)	0.101
Treatment Vs Race (Asian,Caucasian and Others)	0.889
Treatment Vs Age (18 - <65 years and >=65 years)	0.913
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.091
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.997
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.962
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.653
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.271
Treatment Vs Geographic region (Europe and Others)	0.212
Week 48	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.227
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.1 MMR: Rate at week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 2 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Sex (Male and Female)	0.042
Treatment Vs Race (Asian,Caucasian and Others)	0.791
Treatment Vs Age (18 - <65 years and >=65 years)	0.284
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.097
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.278
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.208
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.614
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.435
Treatment Vs Geographic region (Europe and Others)	0.681
Week 96	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.128
Treatment Vs Sex (Male and Female)	0.014
Treatment Vs Race (Asian,Caucasian and Others)	0.876
Treatment Vs Age (18 - <65 years and >=65 years)	0.096
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.1 MMR: Rate at week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 3 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.146
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.458
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.412
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.684
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.684
Treatment Vs Geographic region (Europe and Others)	0.740
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.2 MMR: Rate by week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 1 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Week 24	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.294
Treatment Vs Sex (Male and Female)	0.143
Treatment Vs Race (Asian,Caucasian and Others)	0.775
Treatment Vs Age (18 - <65 years and >=65 years)	0.575
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.044
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.966
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.982
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.668
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.276
Treatment Vs Geographic region (Europe and Others)	0.330
Week 48	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.367
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.2 MMR: Rate by week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 2 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Sex (Male and Female)	0.012
Treatment Vs Race (Asian,Caucasian and Others)	0.549
Treatment Vs Age (18 - <65 years and >=65 years)	0.313
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.024
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.953
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.926
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.267
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.155
Treatment Vs Geographic region (Europe and Others)	0.622
Week 96	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.107
Treatment Vs Sex (Male and Female)	0.002
Treatment Vs Race (Asian,Caucasian and Others)	0.952
Treatment Vs Age (18 - <65 years and >=65 years)	0.152
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.2 MMR: Rate by week 24, 48 and 96 - Interaction tests
Full Analysis Set
(Page 3 of 3)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.058
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.895
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.892
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.366
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.458
Treatment Vs Geographic region (Europe and Others)	0.950
[1] Logistic regression model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. MMR: Major molecular response, Subgroup Missing will not be analyzed for any of the attributes. - NE: Not Estimable.	

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Table 5-1.3.3 MMR: Time to event - subdistribution hazard model - Interaction tests
Full Analysis Set
(Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.217
Treatment Vs Sex (Male and Female)	0.001
Treatment Vs Race (Asian,Caucasian and Others)	0.834
Treatment Vs Age (18 - <65 years and >=65 years)	0.182
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.012
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	<0.001
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	<0.001
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.380
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.188
Treatment Vs Geographic region (Europe and Others)	0.786
[1] Sub-distribution hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. Subgroup Missing will not be analyzed for any of the attributes. MMR: Major molecular response	

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Table 5-1.3.4 MMR: Duration of event - Interaction tests
MMR Responder Set
(Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
None of the attribute have at least 10 events occurred in one of the subgroups	
[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. Subgroup Missing will not be analyzed for any of the attributes. MMR: Major molecular response	

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Table 5-1.4.1.1 Any AE: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.665
Treatment Vs Sex (Male and Female)	0.346
Treatment Vs Race (Asian,Caucasian and Others)	0.518
Treatment Vs Age (18 - <65 years and >=65 years)	0.776
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.203
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.981
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.778
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.780
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.950
Treatment Vs Geographic region (Europe and Others)	0.776

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.1.2 Any AE by SOC: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 1 of 2)

	Treatment-by-Subgroup Interaction p-value[1]
Gastrointestinal disorders	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.268
Treatment Vs Sex (Male and Female)	0.236
Treatment Vs Race (Asian,Caucasian and Others)	0.691
Treatment Vs Age (18 - <65 years and >=65 years)	0.775
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.870
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.492
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.381
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.828
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.451
Treatment Vs Geographic region (Europe and Others)	0.426

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) SOC terms from related total population output are included.
 MedDRA version 26.0

Table 5-1.4.1.2 Any AE by SOC: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 2 of 2)

	Treatment-by-Subgroup Interaction p-value[1]
Investigations	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.073
Treatment Vs Sex (Male and Female)	0.309
Treatment Vs Race (Asian,Caucasian and Others)	0.128
Treatment Vs Age (18 - <65 years and >=65 years)	0.978
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.718
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.450
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.163
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.296
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.116
Treatment Vs Geographic region (Europe and Others)	0.923

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) SOC terms from related total population output are included.
 MedDRA version 26.0

Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 1 of 8)

	Treatment-by-Subgroup Interaction p-value[1]
Abdominal pain	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.920
Treatment Vs Sex (Male and Female)	0.863
Treatment Vs Race (Asian,Caucasian and Others)	0.893
Treatment Vs Age (18 - <65 years and >=65 years)	0.905
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.204
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.890
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.406
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.992
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.989
Treatment Vs Geographic region (Europe and Others)	0.028

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
 MedDRA version 26.0

Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 2 of 8)

	Treatment-by-Subgroup Interaction p-value[1]
Alanine aminotransferase increased	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.445
Treatment Vs Sex (Male and Female)	0.240
Treatment Vs Race (Asian,Caucasian and Others)	0.845
Treatment Vs Age (18 - <65 years and >=65 years)	0.493
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.346
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.350
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.120
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.943
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.736
Treatment Vs Geographic region (Europe and Others)	0.990

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Arthralgia	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.992
Treatment Vs Sex (Male and Female)	0.981
Treatment Vs Race (Asian,Caucasian and Others)	0.162
Treatment Vs Age (18 - <65 years and >=65 years)	0.989
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.991
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.660
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	1.000
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.992
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.597

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Aspartate aminotransferase increased	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.173
Treatment Vs Sex (Male and Female)	0.155
Treatment Vs Race (Asian,Caucasian and Others)	0.839
Treatment Vs Age (18 - <65 years and >=65 years)	0.350
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.413
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.667
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.299
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.826
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.989
Treatment Vs Geographic region (Europe and Others)	0.680

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Diarrhoea	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.162
Treatment Vs Sex (Male and Female)	0.968
Treatment Vs Race (Asian,Caucasian and Others)	0.749
Treatment Vs Age (18 - <65 years and >=65 years)	0.763
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.899
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.475
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.539
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.925
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.213
Treatment Vs Geographic region (Europe and Others)	0.205

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Nausea	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.454
Treatment Vs Sex (Male and Female)	0.976
Treatment Vs Race (Asian,Caucasian and Others)	0.865
Treatment Vs Age (18 - <65 years and >=65 years)	0.524
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.160
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.209
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.555
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.990
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.139
Treatment Vs Geographic region (Europe and Others)	0.032

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Rash	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.064
Treatment Vs Sex (Male and Female)	0.371
Treatment Vs Race (Asian,Caucasian and Others)	1.000
Treatment Vs Age (18 - <65 years and >=65 years)	0.481
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.359
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.416
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.467
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.400
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.986
Treatment Vs Geographic region (Europe and Others)	0.157

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.1.3 Any AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Vomiting	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.279
Treatment Vs Sex (Male and Female)	0.535
Treatment Vs Race (Asian,Caucasian and Others)	0.635
Treatment Vs Age (18 - <65 years and >=65 years)	0.450
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.678
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.377
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.811
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.988
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.869
Treatment Vs Geographic region (Europe and Others)	0.187

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant (p<0.05) PT terms from related total population output are included.
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Table 5-1.4.2.1 Grade ≥3 AE: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.217
Treatment Vs Sex (Male and Female)	0.326
Treatment Vs Race (Asian,Caucasian and Others)	0.477
Treatment Vs Age (18 - <65 years and ≥65 years)	0.771
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.935
Treatment Vs Number of prior TKI therapies (2,3 and ≥4)	0.843
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥5)	0.774
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.608
Treatment Vs BCR-ABL ratio at baseline (≥ 1% and < 1%)	0.130
Treatment Vs Geographic region (Europe and Others)	0.938

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.2.2 Grade ≥ 3 AE by SOC: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Gastrointestinal disorders	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.398
Treatment Vs Sex (Male and Female)	0.430
Treatment Vs Race (Asian,Caucasian and Others)	0.991
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.943
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.498
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.769
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.651
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.993
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000
Treatment Vs Geographic region (Europe and Others)	0.336

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant ($p < 0.05$) SOC terms from related total population output are included.
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Table 5-1.4.2.2 Grade ≥ 3 AE by SOC: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Investigations	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.109
Treatment Vs Sex (Male and Female)	0.366
Treatment Vs Race (Asian,Caucasian and Others)	0.321
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.775
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.462
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.412
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.329
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.797
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	0.192
Treatment Vs Geographic region (Europe and Others)	0.276

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant ($p < 0.05$) SOC terms from related total population output are included.
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Table 5-1.4.2.3 Grade ≥ 3 AE by PT: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Alanine aminotransferase increased	
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.995
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
Subgroup "Missing" will not be analyzed for any of the attributes.
Only statistically significant ($p < 0.05$) PT terms from related total population output are included.
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Table 5-1.4.2.3 Grade ≥ 3 AE by PT: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Thrombocytopenia	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.991
Treatment Vs Sex (Male and Female)	0.601
Treatment Vs Race (Asian,Caucasian and Others)	0.971
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.991
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.569
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.387
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.554
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.990
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000
Treatment Vs Geographic region (Europe and Others)	0.136

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 - events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
 Subgroup "Missing" will not be analyzed for any of the attributes.
 Only statistically significant ($p < 0.05$) PT terms from related total population output are included.
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Table 5-1.4.3.1 SAE: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.636
Treatment Vs Sex (Male and Female)	0.354
Treatment Vs Race (Asian,Caucasian and Others)	0.468
Treatment Vs Age (18 - <65 years and >=65 years)	0.279
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.596
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.288
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.125
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.287
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.308
Treatment Vs Geographic region (Europe and Others)	0.745

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.3.2 SAE by SOC: time to first event - interaction of treatment by subgroup
Safety Set
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Treatment-by-Subgroup
Interaction p-value[1]

None of the attribute have at least 10 events occurred in one of the subgroups

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
Subgroup "Missing" will not be analyzed for any of the attributes.
Only statistically significant ($p < 0.05$) SOC terms from related total population output are included.
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Table 5-1.4.3.3 SAE by PT: time to first event - interaction of treatment by subgroup
Safety Set
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No data selected based on the below condition
Events occurring in at least 5% of patients in one study arm or occurring in at least 10 patients
and in at least 1% of patients in one study arm

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm
Subgroup "Missing" will not be analyzed for any of the attributes.
Only statistically significant ($p < 0.05$) PT terms from related total population output are included.
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Table 5-1.4.4.1 AE leading to discontinuation: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.317
Treatment Vs Sex (Male and Female)	0.108
Treatment Vs Race (Asian,Caucasian and Others)	0.953
Treatment Vs Age (18 - <65 years and >=65 years)	0.955
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.292
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.100
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.230
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	1.000
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.539
Treatment Vs Geographic region (Europe and Others)	0.190

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Final

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Edema and fluid retention	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.298
Treatment Vs Sex (Male and Female)	0.157
Treatment Vs Race (Asian,Caucasian and Others)	0.820
Treatment Vs Age (18 - <65 years and >=65 years)	0.284
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.194
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.239
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.548
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.926
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.053
Treatment Vs Geographic region (Europe and Others)	0.044

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
GI toxicity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.245
Treatment Vs Sex (Male and Female)	0.380
Treatment Vs Race (Asian,Caucasian and Others)	0.680
Treatment Vs Age (18 - <65 years and >=65 years)	0.806
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.774
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.738
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.561
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.612
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.555
Treatment Vs Geographic region (Europe and Others)	0.012

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Hemorrhage	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.302
Treatment Vs Sex (Male and Female)	0.172
Treatment Vs Race (Asian,Caucasian and Others)	0.825
Treatment Vs Age (18 - <65 years and >=65 years)	0.834
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.716
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.972
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.596
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	1.000
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.990
Treatment Vs Geographic region (Europe and Others)	0.985

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Hepatotoxicity (including laboratory terms)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.255
Treatment Vs Sex (Male and Female)	0.040
Treatment Vs Race (Asian,Caucasian and Others)	0.295
Treatment Vs Age (18 - <65 years and >=65 years)	0.210
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.541
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.873
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.240
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.960
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.517
Treatment Vs Geographic region (Europe and Others)	0.313

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Hypersensitivity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.085
Treatment Vs Sex (Male and Female)	0.208
Treatment Vs Race (Asian,Caucasian and Others)	0.039
Treatment Vs Age (18 - <65 years and >=65 years)	0.803
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.401
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.893
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.876
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.419
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.312
Treatment Vs Geographic region (Europe and Others)	0.340

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Ischemic heart and CNS conditions	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.959
Treatment Vs Sex (Male and Female)	0.737
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.136
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Erythropenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.138
Treatment Vs Sex (Male and Female)	0.933
Treatment Vs Race (Asian,Caucasian and Others)	0.442
Treatment Vs Age (18 - <65 years and >=65 years)	0.988
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.317
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.511
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.914
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.496
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.571

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Neutropenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.403
Treatment Vs Sex (Male and Female)	0.519
Treatment Vs Race (Asian,Caucasian and Others)	0.979
Treatment Vs Age (18 - <65 years and >=65 years)	0.960
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.439
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.767
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.833
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.926
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.987
Treatment Vs Geographic region (Europe and Others)	0.920

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Leucopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.460
Treatment Vs Sex (Male and Female)	0.407
Treatment Vs Race (Asian,Caucasian and Others)	0.998
Treatment Vs Age (18 - <65 years and >=65 years)	0.875
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.361
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.882
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.876
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.971
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.986
Treatment Vs Geographic region (Europe and Others)	0.909

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Thrombocytopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.530
Treatment Vs Sex (Male and Female)	0.892
Treatment Vs Race (Asian,Caucasian and Others)	0.170
Treatment Vs Age (18 - <65 years and >=65 years)	0.759
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.125
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.669
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.273
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.205
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.986
Treatment Vs Geographic region (Europe and Others)	0.034

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.1 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 11 of 11)

	Treatment-by-Subgroup Interaction p-value[1]
Pancreatic toxicity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.992
Treatment Vs Sex (Male and Female)	0.366
Treatment Vs Race (Asian,Caucasian and Others)	0.844
Treatment Vs Age (18 - <65 years and >=65 years)	0.988
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.991
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.869
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.849
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.590
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.374

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 1 of 10)

	Treatment-by-Subgroup Interaction p-value[1]
Edema and fluid retention	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.298
Treatment Vs Sex (Male and Female)	0.157
Treatment Vs Race (Asian,Caucasian and Others)	0.820
Treatment Vs Age (18 - <65 years and >=65 years)	0.284
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.194
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.239
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.548
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.926
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.053
Treatment Vs Geographic region (Europe and Others)	0.044

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
GI toxicity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.285
Treatment Vs Sex (Male and Female)	0.465
Treatment Vs Race (Asian,Caucasian and Others)	0.714
Treatment Vs Age (18 - <65 years and >=65 years)	0.838
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.668
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.687
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.496
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.634
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.585
Treatment Vs Geographic region (Europe and Others)	0.016

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 3 of 10)

	Treatment-by-Subgroup Interaction p-value[1]
Hemorrhage	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.375
Treatment Vs Sex (Male and Female)	0.209
Treatment Vs Race (Asian,Caucasian and Others)	0.545
Treatment Vs Age (18 - <65 years and >=65 years)	0.462
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.657
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.793
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.793
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	1.000
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.802

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Hepatotoxicity (including laboratory terms)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.236
Treatment Vs Sex (Male and Female)	0.024
Treatment Vs Race (Asian,Caucasian and Others)	0.425
Treatment Vs Age (18 - <65 years and >=65 years)	0.224
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.399
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.950
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.401
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.817
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.761
Treatment Vs Geographic region (Europe and Others)	0.349

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Hypersensitivity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.089
Treatment Vs Sex (Male and Female)	0.189
Treatment Vs Race (Asian,Caucasian and Others)	0.049
Treatment Vs Age (18 - <65 years and >=65 years)	0.642
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.395
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.819
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.790
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.528
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.859
Treatment Vs Geographic region (Europe and Others)	0.394

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Erythropenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.112
Treatment Vs Sex (Male and Female)	0.981
Treatment Vs Race (Asian,Caucasian and Others)	0.216
Treatment Vs Age (18 - <65 years and >=65 years)	0.989
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.353
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.229
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.442
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.884

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Neutropenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.518
Treatment Vs Sex (Male and Female)	0.366
Treatment Vs Race (Asian,Caucasian and Others)	0.922
Treatment Vs Age (18 - <65 years and >=65 years)	0.870
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.243
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.997
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.805
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.958
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.988
Treatment Vs Geographic region (Europe and Others)	0.940

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Leucopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.560
Treatment Vs Sex (Male and Female)	0.237
Treatment Vs Race (Asian,Caucasian and Others)	0.895
Treatment Vs Age (18 - <65 years and >=65 years)	0.828
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.219
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.998
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.591
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.932
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.988
Treatment Vs Geographic region (Europe and Others)	0.857

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Thrombocytopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.703
Treatment Vs Sex (Male and Female)	0.871
Treatment Vs Race (Asian,Caucasian and Others)	0.507
Treatment Vs Age (18 - <65 years and >=65 years)	0.782
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.114
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.508
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.168
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.270
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.987
Treatment Vs Geographic region (Europe and Others)	0.115

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.2 Grade 1/2 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Pancreatic toxicity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.992
Treatment Vs Sex (Male and Female)	0.244
Treatment Vs Race (Asian,Caucasian and Others)	1.000
Treatment Vs Age (18 - <65 years and >=65 years)	0.989
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.992
Treatment Vs Number of prior TKI therapies (2,3 and >=4)	0.950
Treatment Vs Line of therapy of randomized treatment (3,4 and >=5)	0.983
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.546
Treatment Vs BCR-ABL ratio at baseline (>= 1% and < 1%)	0.991
Treatment Vs Geographic region (Europe and Others)	0.867

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
GI toxicity	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.990
Treatment Vs Race (Asian,Caucasian and Others)	0.964
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.551
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.992
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
Safety Set
(Page 2 of 6)

	Treatment-by-Subgroup Interaction p-value[1]
Hepatotoxicity (including laboratory terms)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.792
Treatment Vs Race (Asian,Caucasian and Others)	0.911
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.999
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.990
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.885
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.736
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.992
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	0.993

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 3 of 6)

	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Neutropenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.265
Treatment Vs Sex (Male and Female)	0.409
Treatment Vs Race (Asian,Caucasian and Others)	0.885
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.862
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.114
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.682
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.619
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.989
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000
Treatment Vs Geographic region (Europe and Others)	0.448

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 4 of 6)

	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Leucopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.265
Treatment Vs Sex (Male and Female)	0.409
Treatment Vs Race (Asian,Caucasian and Others)	0.885
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.862
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.114
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.682
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.619
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.989
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000
Treatment Vs Geographic region (Europe and Others)	0.448

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
 Safety Set
 (Page 5 of 6)

	Treatment-by-Subgroup Interaction p-value[1]
Myelosuppression (Thrombocytopenia)	
Treatment Vs Stratification factor by IRT (Major Cytogenetic Response and No Major Cytogenetic Response)	0.385
Treatment Vs Sex (Male and Female)	0.321
Treatment Vs Race (Asian,Caucasian and Others)	0.278
Treatment Vs Age (18 - <65 years and ≥ 65 years)	0.742
Treatment Vs Reason for discontinuation of the last prior TKI (Failure and Intolerance)	0.569
Treatment Vs Number of prior TKI therapies (2,3 and ≥ 4)	0.318
Treatment Vs Line of therapy of randomized treatment (3,4 and ≥ 5)	0.429
Treatment Vs With or without Week1 Day 1 BCR-ABL1 mutation (Wild type and Mutant)	0.988
Treatment Vs BCR-ABL ratio at baseline ($\geq 1\%$ and $< 1\%$)	1.000
Treatment Vs Geographic region (Europe and Others)	0.076

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
 Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.5.3 Grade ≥ 3 AESI: time to first event - interaction of treatment by subgroup
Safety Set
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	Treatment-by-Subgroup Interaction p-value[1]
Pancreatic toxicity	
Treatment Vs Age (18 - <65 years and ≥ 65 years)	1.000

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Table 5-1.4.5.4 Serious AESI: time to first event - interaction of treatment by subgroup
Safety Set
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Treatment-by-Subgroup
Interaction p-value[1]

None of the attribute have at least 10 events occurred in one of the subgroups

[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model.
Subgroup "Missing" will not be analyzed for any of the attributes.

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Final

Table 5-1.5.1 Progression to BC: Time to event - Interaction tests
Full Analysis Set
(Page 1 of 1)

	Treatment-by-Subgroup Interaction p-value[1]
None of the attribute have at least 10 events occurred in one of the subgroups	
[1] Cox proportional hazard model with treatment, subgroup factor and treatment-by-subgroup interaction in the model. Subgroup Missing will not be analyzed for any of the attributes. BC: Blast Crisis	

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Table 5-2.1.1 Overall Survival: Subgroups
Full Analysis Set
(Page 1 of 3)

	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Stratification factor						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	1/ 22 (4.5)	NE [3.69, NE]	0.79[0.07, 8.72]	0.848
No Major Cytogenetic Response	12/111 (10.8)	NE [NE, NE]	4/ 54 (7.4)	NE [NE, NE]	1.37[0.44, 4.24]	0.587
Age category						
18 - 65 years	8/128 (6.3)	NE [NE, NE]	3/ 61 (4.9)	NE [NE, NE]	1.13[0.30, 4.25]	0.860
>=65 years	6/ 29 (20.7)	NE [4.25, NE]	2/ 15 (13.3)	NE [3.58, NE]	1.44[0.29, 7.20]	0.658
Sex						
Female	6/ 75 (8.0)	NE [NE, NE]	3/ 45 (6.7)	NE [NE, NE]	0.97[0.24, 3.92]	0.972
Male	8/ 82 (9.8)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	1.48[0.31, 6.96]	0.619
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	1/ 11 (9.1)	NE [3.58, NE]	0.34[0.03, 4.64]	0.405
Caucasian	10/119 (8.4)	NE [NE, NE]	4/ 57 (7.0)	NE [NE, NE]	1.08[0.34, 3.44]	0.899

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Table 5-2.1.1 Overall Survival: Subgroups
Full Analysis Set
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	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Others	2/ 16 (12.5)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	10/ 95 (10.5)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	1.03[0.35, 3.02]	0.953
Intolerance	3/ 59 (5.1)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
Number of prior TKI therapies						
2	7/ 89 (7.9)	NE [NE, NE]	1/ 33 (3.0)	NE [NE, NE]	2.02[0.25, 16.43]	0.503
3	7/ 54 (13.0)	NE [NE, NE]	3/ 33 (9.1)	NE [NE, NE]	1.52[0.39, 5.90]	0.540
>=4	0/ 14	NE [NE, NE]	1/ 10 (10.0)	NE [2.91, NE]	NE [NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	11/125 (8.8)	NE [NE, NE]	3/ 63 (4.8)	NE [NE, NE]	1.66[0.46, 5.96]	0.431

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Table 5-2.1.1 Overall Survival: Subgroups
Full Analysis Set
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	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Mutant	2/ 17 (11.8)	NE [NE, NE]	2/ 8 (25.0)	NE [0.31, NE]	0.46 [0.06, 3.28]	0.426
BCR-ABL ratio at baseline						
>= 1%	14/142 (9.9)	NE [NE, NE]	5/ 72 (6.9)	NE [NE, NE]	1.29 [0.47, 3.59]	0.620
< 1%	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	6/ 90 (6.7)	NE [NE, NE]	2/ 45 (4.4)	NE [NE, NE]	1.28 [0.26, 6.33]	0.765
Others	8/ 67 (11.9)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	1.20 [0.31, 4.55]	0.793

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT). Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t52_1_1.sas@@/main/9 11JUN24:15:06

Final

Table 5-2.1.1.1: Overall survival: Subgroups
Full Analysis Set

	Treatment Groups				Comparison		
	Asciminib N=157		Bosutinib N=76				
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
Stratification factor: Cytogenetic response status at screening (IRT)							
Major Cytogenetic Response	2/46 (4.3)	NE [NE, NE]	1/22 (4.5)	NE [NE, NE]	0.82	[0.07, 9.07]	0.873
No Major Cytogenetic Response	14/111 (12.6)	NE [NE, NE]	8/54 (14.8)	NE [6.31, NE]	0.78	[0.33, 1.86]	0.578
Age category n(%)							
18 - 65 years	9/128 (7.0)	NE [NE, NE]	5/61 (8.2)	NE [NE, NE]	0.78	[0.26, 2.32]	0.649
>=65 years	7/29 (24.1)	NE [5.60, NE]	4/15 (26.7)	6.31 [3.58, NE]	0.91	[0.26, 3.23]	0.887
Sex							

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

PROGRAM: P:\NOV0070-ASCIMINIB\07_STAT\MAIN02\TEST\PGMS\TFT_5_2_1_1_1_OS_SUBGRP.SAS, 23JAN2025 15:22

Table 5-2.1.1.1: Overall survival: Subgroups
Full Analysis Set

	Treatment Groups						
	Asciminib N=157		Bosutinib N=76		Comparison		
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
Female	8/75 (10.7)	NE [NE, NE]	6/45 (13.3)	NE [6.09, NE]	0.69	[0.24, 1.99]	0.493
Male	8/82 (9.8)	NE [NE, NE]	3/31 (9.7)	NE [NE, NE]	0.96	[0.25, 3.61]	0.950
Race							
Asian	3/22 (13.6)	NE [5.60, NE]	2/11 (18.2)	6.31 [3.58, NE]	0.38	[0.06, 2.60]	0.311
Caucasian	11/119 (9.2)	NE [NE, NE]	7/57 (12.3)	NE [6.09, NE]	0.69	[0.27, 1.78]	0.442
Others	2/16 (12.5)	NE [NE, NE]	0/8	NE [NE, NE]	2.20	[0.05, 90.67]	0.349
Reason for discontinuation of the last prior TKI							
Failure	11/95 (11.6)	NE [NE, NE]	9/54 (16.7)	NE [6.31, NE]	0.64	[0.26, 1.54]	0.314

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

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Table 5-2.1.1.1: Overall survival: Subgroups
Full Analysis Set

	Treatment Groups							
	Asciminib N=157		Bosutinib N=76			Comparison		
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value	
Intolerance	4/59 (6.8)	NE [NE, NE]	0/22	NE [NE, NE]	2.73	[0.10, 71.76]	0.271	
Number of prior TKI therapies								
2	9/89 (10.1)	NE [NE, NE]	4/33 (12.1)	NE [6.31, NE]	0.61	[0.19, 2.00]	0.411	
3	7/54 (13.0)	NE [NE, NE]	3/33 (9.1)	NE [NE, NE]	1.50	[0.39, 5.79]	0.557	
>=4	0/14	NE [NE, NE]	2/10 (20.0)	6.09 [2.91, NE]	0.12	[0.00, 4.87]	0.066	
Line of therapy of randomized treatment								
3	9/82 (11.0)	NE [NE, NE]	2/30 (6.7)	NE [NE, NE]	1.24	[0.27, 5.76]	0.781	
4	5/44 (11.4)	NE [NE, NE]	4/29 (13.8)	NE [6.31, NE]	0.89	[0.24, 3.36]	0.868	

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

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Table 5-2.1.1.1: Overall survival: Subgroups
Full Analysis Set

	Treatment Groups							
	Asciminib N=157		Bosutinib N=76		Comparison			
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value	
>=5	2/31 (6.5)	NE [NE, NE]	3/17 (17.6)	NE [6.09, NE]	0.48	[0.08, 2.90]	0.416	
With or without Week1 Day 1 BCR-ABL mutation								
Mutant	2/17 (11.8)	NE [NE, NE]	2/8 (25.0)	NE [0.31, NE]	0.45	[0.06, 3.19]	0.410	
Wild type	13/125 (10.4)	NE [NE, NE]	7/63 (11.1)	NE [6.31, NE]	0.82	[0.33, 2.05]	0.669	
BCR-ABL ratio at baseline								
< 1%	0/15	NE [NE, NE]	0/4	NE [NE, NE]	NE	[NE, NE]	NE	
>= 1%	16/142 (11.3)	NE [NE, NE]	9/72 (12.5)	NE [6.31, NE]	0.82	[0.36, 1.86]	0.637	
Geographic region								

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

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**Table 5-2.1.1.1: Overall survival: Subgroups
Full Analysis Set**

	Treatment Groups							
	Asciminib N=157		Bosutinib N=76		Comparison			
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value	
Europe	6/90 (6.7)	NE [NE, NE]	3/45 (6.7)	NE [NE, NE]	0.87	[0.22, 3.48]	0.842	
Others	10/67 (14.9)	NE [NE, NE]	6/31 (19.4)	NE [6.09, NE]	0.78	[0.28, 2.18]	0.640	

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

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Figure 5-2.1.1 Overall Survival: Kaplan Meier plot - subgroups

Full Analysis Set

(Page 1 of 1)

No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_f52_1_1.sas@@/main/4 22NOV23:10:15

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Table 5-2.2.1 Progression Free Survival: Subgroups
Full Analysis Set
(Page 1 of 3)

	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Stratification factor						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.29[0.06, 1.47]	0.113
No Major Cytogenetic Response	15/111 (13.5)	NE [NE, NE]	6/ 54 (11.1)	NE [3.36, NE]	0.82[0.32, 2.14]	0.689
Age category						
18 - 65 years	12/128 (9.4)	NE [NE, NE]	7/ 61 (11.5)	NE [NE, NE]	0.56[0.22, 1.43]	0.219
>=65 years	6/ 29 (20.7)	NE [3.89, NE]	2/ 15 (13.3)	3.58 [3.36, NE]	1.02[0.20, 5.19]	0.981
Sex						
Female	9/ 75 (12.0)	NE [NE, NE]	5/ 45 (11.1)	NE [3.36, NE]	0.64[0.21, 1.94]	0.425
Male	9/ 82 (11.0)	NE [NE, NE]	4/ 31 (12.9)	NE [3.58, NE]	0.64[0.19, 2.13]	0.463
Race						
Asian	5/ 22 (22.7)	NE [2.81, NE]	2/ 11 (18.2)	3.58 [0.13, NE]	0.73[0.12, 4.26]	0.723
Caucasian	11/119 (9.2)	NE [NE, NE]	6/ 57 (10.5)	NE [3.36, NE]	0.52[0.19, 1.43]	0.197

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t52_2_1.sas@@/main/3 22NOV23:10:38

Final

Table 5-2.2.1 Progression Free Survival: Subgroups
Full Analysis Set
(Page 2 of 3)

	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Others	2/ 16 (12.5)	NE [NE, NE]	1/ 8 (12.5)	NE [0.90, NE]	0.55[0.05, 6.56]	0.632
Reason for discontinuation of the last prior TKI						
Failure	13/ 95 (13.7)	NE [NE, NE]	9/ 54 (16.7)	NE [3.36, NE]	0.55[0.23, 1.30]	0.168
Intolerance	4/ 59 (6.8)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
Number of prior TKI therapies						
2	9/ 89 (10.1)	NE [NE, NE]	3/ 33 (9.1)	3.58 [3.58, NE]	0.51[0.13, 2.02]	0.332
3	8/ 54 (14.8)	NE [4.07, NE]	5/ 33 (15.2)	NE [3.36, NE]	0.94[0.30, 2.91]	0.910
≥4	1/ 14 (7.1)	NE [NE, NE]	1/ 10 (10.0)	2.91 [NE, NE]	0.37[0.02, 7.48]	0.508
Line of therapy of randomized treatment						
3	9/ 82 (11.0)	NE [NE, NE]	3/ 30 (10.0)	3.58 [3.58, NE]	0.55[0.14, 2.12]	0.377
4	6/ 44 (13.6)	NE [4.07, NE]	3/ 29 (10.3)	NE [NE, NE]	1.02[0.25, 4.10]	0.981

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t52_2_1.sas@@/main/3 22NOV23:10:38

Final

Table 5-2.2.1 Progression Free Survival: Subgroups
Full Analysis Set
(Page 3 of 3)

	Treatment Groups				Comparison	
	Asciminib N=157		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	3/ 31 (9.7)	NE [NE, NE]	3/ 17 (17.6)	3.36 [0.90, NE]	0.39[0.07, 2.09]	0.260
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	14/125 (11.2)	NE [NE, NE]	5/ 63 (7.9)	NE [3.58, NE]	0.81[0.29, 2.31]	0.696
Mutant	2/ 17 (11.8)	NE [2.23, NE]	2/ 8 (25.0)	NE [0.26, NE]	0.50[0.07, 3.57]	0.477
BCR-ABL ratio at baseline						
>= 1%	17/142 (12.0)	NE [NE, NE]	9/ 72 (12.5)	NE [3.58, NE]	0.65[0.29, 1.46]	0.292
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	7/ 90 (7.8)	NE [NE, NE]	4/ 45 (8.9)	NE [3.36, NE]	0.45[0.13, 1.60]	0.208
Others	11/ 67 (16.4)	NE [NE, NE]	5/ 31 (16.1)	NE [2.91, NE]	0.85[0.29, 2.47]	0.767

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t52_2_1.sas@@/main/3 22NOV23:10:38

Final

**Table 5-2.2.1.1: Progression free survival: Subgroups
Full Analysis Set**

	Treatment Groups				Comparison		
	Asciminib N=157		Bosutinib N=76				
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
Stratification factor: Cytogenetic response status at screening (IRT)							
Major Cytogenetic Response	4/46 (8.7)	5.96 [NE, NE]	3/22 (13.6)	NE [NE, NE]	0.29	[0.06, 1.45]	0.109
No Major Cytogenetic Response	18/111 (16.2)	5.60 [4.24, NE]	10/54 (18.5)	5.03 [3.58, NE]	1.01	[0.43, 2.40]	0.975
Age category n(%)							
18 - 65 years	14/128 (10.9)	5.96 [NE, NE]	9/61 (14.8)	5.03 [5.03, NE]	0.64	[0.26, 1.62]	0.348
>=65 years	8/29 (27.6)	4.65 [3.89, NE]	4/15 (26.7)	3.67 [3.36, NE]	1.21	[0.31, 4.66]	0.784
Sex							

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

PROGRAM: P:\NOV0070-ASCIMINIB\07_STAT\MAIN02\TEST\PGMS\TF\T_5_2_2_1_1_PFS_SUBGRP.SAS, 23JAN2025 15:23

**Table 5-2.2.1.1: Progression free survival: Subgroups
Full Analysis Set**

	Treatment Groups						
	Asciminib N=157		Bosutinib N=76		Comparison		
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
Female	12/75 (16.0)	5.60 [5.60, NE]	8/45 (17.8)	6.05 [3.36, NE]	0.85	[0.31, 2.36]	0.756
Male	10/82 (12.2)	NE [4.65, NE]	5/31 (16.1)	5.03 [3.58, NE]	0.77	[0.24, 2.49]	0.657
Race							
Asian	6/22 (27.3)	5.60 [2.81, NE]	3/11 (27.3)	6.05 [0.13, NE]	1.14	[0.20, 6.32]	0.884
Caucasian	14/119 (11.8)	5.96 [4.65, NE]	9/57 (15.8)	5.03 [3.36, NE]	0.63	[0.25, 1.60]	0.329
Others	2/16 (12.5)	NE [NE, NE]	1/8 (12.5)	NE [0.90, NE]	0.55	[0.05, 6.56]	0.632
Reason for discontinuation of the last prior TKI							

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

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Table 5-2.2.1.1: Progression free survival: Subgroups
Full Analysis Set

	Treatment Groups						
	Asciminib N=157		Bosutinib N=76		Comparison		
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
Failure	16/95 (16.8)	5.96 [4.65, NE]	13/54 (24.1)	5.03 [3.36, NE]	0.70	[0.31, 1.58]	0.389
Intolerance	5/59 (8.5)	5.60 [NE, NE]	0/22	NE [NE, NE]	2.01	[0.08, 53.41]	0.345
Number of prior TKI therapies							
2	12/89 (13.5)	5.60 [5.60, NE]	6/33 (18.2)	5.03 [3.58, NE]	0.67	[0.22, 2.04]	0.476
3	8/54 (14.8)	NE [4.07, NE]	5/33 (15.2)	NE [3.36, NE]	0.94	[0.30, 2.91]	0.910
>=4	2/14 (14.3)	4.65 [NE, NE]	2/10 (20.0)	4.50 [2.91, NE]	1.31	[0.11, 15.50]	0.829
Line of therapy of randomized treatment							

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

PROGRAM: P:\NOV0070-ASCIMINIB\07_STAT\MAIN02\TEST\PGMS\TF\T_5_2_2_1_1_PFS_SUBGRP.SAS, 23JAN2025 15:23

Table 5-2.2.1.1: Progression free survival: Subgroups
Full Analysis Set

	Treatment Groups						
	Asciminib N=157		Bosutinib N=76				
	Comparison						
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
3	12/82 (14.6)	5.60 [5.60, NE]	4/30 (13.3)	5.03 [3.58, NE]	0.58	[0.17, 1.92]	0.364
4	6/44 (13.6)	NE [4.07, NE]	5/29 (17.2)	6.05 [3.67, NE]	0.83	[0.23, 2.95]	0.768
>=5	4/31 (12.9)	4.65 [4.65, NE]	4/17 (23.5)	3.36 [0.90, NE]	0.70	[0.15, 3.22]	0.643
With or without Week1 Day 1 BCR-ABL mutation							
Mutant	2/17 (11.8)	NE [2.23, NE]	2/8 (25.0)	NE [0.26, NE]	0.50	[0.07, 3.57]	0.477
Wild type	18/125 (14.4)	5.60 [4.65, NE]	9/63 (14.3)	5.03 [3.67, NE]	1.01	[0.40, 2.55]	0.980
BCR-ABL ratio at baseline							

(Continued)

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

PROGRAM: P:\NOV0070-ASCIMINIB\07_STAT\MAIN02\TEST\PGMS\TF\T_5_2_2_1_1_PFS_SUBGRP.SAS, 23JAN2025 15:23

Table 5-2.2.1.1: Progression free survival: Subgroups
Full Analysis Set

	Treatment Groups						
	Asciminib N=157		Bosutinib N=76		Comparison		
	n/N* (%)	Median (years) [95% CI]	n/N* (%)	Median (years) [95% CI]	HR	[95% CI]	p-value
< 1%	1/15 (6.7)	NE [NE, NE]	0/4	NE [NE, NE]	0.44	[0.01, 39.04]	0.695
>= 1%	21/142 (14.8)	5.60 [4.65, NE]	13/72 (18.1)	5.03 [3.58, NE]	0.80	[0.37, 1.70]	0.560
Geographic region							
Europe	8/90 (8.9)	NE [4.65, NE]	5/45 (11.1)	5.03 [3.36, NE]	0.60	[0.18, 2.03]	0.408
Others	14/67 (20.9)	5.60 [4.24, NE]	8/31 (25.8)	6.05 [3.58, NE]	1.07	[0.40, 2.88]	0.893

Data cut-off: 04DEC2024

Median (time to event) and its 95% CI are generated by KM estimation

Hazard Ratio (HR) estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test (both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Patients who are alive at the time of the analysis data cutoff date will be censored at the date of last contact before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

In case of extreme HR values due to zero/few events a Firth correction has been applied in the Cox model.

Subgroup Missing will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, - NE: Not Estimable.

PROGRAM: P:\NOV0070-ASCIMINIB\07_STAT\MAIN02\TEST\PGMS\TF\T_5_2_2_1_1_PFS_SUBGRP.SAS, 23JAN2025 15:23

Figure 5-2.2.1 Progression Free Survival: Kaplan Meier plot - subgroups

Full Analysis Set

(Page 1 of 1)

No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

For patients who have not experienced an event (disease progression to AP/BC or death from any cause), their PFS times will be censored at the date of last study assessment (PCR, cytogenetic, hematologic or extramedullary) before the cut-off date, regardless of subsequent intake of treatment(s) after randomization.

Subgroup "Missing" will not be analyzed for any of the attributes. CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis. - NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_f52_2_1.sas@@/main/3 22NOV23:10:16

Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 1 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Week 24						
Stratification factor by IRT						
Major Cytogenetic Response	21/ 46 (45.7)	4/ 22 (18.2)	OR	3.78 [	1.11, 12.92]	0.034
			RR	2.51 [	0.98, 6.43]	0.029
			RD	27.47 [	5.86, 49.08]	0.029
No Major Cytogenetic Response	19/111 (17.1)	6/ 54 (11.1)	OR	1.65 [	0.62, 4.41]	0.316
			RR	1.54 [	0.65, 3.63]	0.314
			RD	6.01 [	-4.92, 16.93]	0.314
Age category						
18 - 65 years	33/128 (25.8)	8/ 61 (13.1)	OR	2.38 [	1.00, 5.66]	0.049
			RR	1.95 [	0.96, 3.94]	0.046
			RD	12.46 [	1.23, 23.69]	0.046
>=65 years	7/ 29 (24.1)	2/ 15 (13.3)	OR	2.23 [	0.38, 13.06]	0.372
			RR	1.86 [	0.45, 7.65]	0.378
			RD	11.35 [	-11.21, 33.91]	0.378

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 2 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Sex						
Female	22/ 75 (29.3)	4/ 45 (8.9)	OR	4.48	[1.40, 14.38]	0.012
			RR	3.26	[1.22, 8.71]	0.008
			RD	20.18	[7.21, 33.15]	0.008
Male	18/ 82 (22.0)	6/ 31 (19.4)	OR	1.22	[0.42, 3.55]	0.719
			RR	1.16	[0.51, 2.62]	0.722
			RD	3.01	[-13.54, 19.55]	0.722
Race						
Asian	6/ 22 (27.3)	1/ 11 (9.1)	OR	2.83	[0.27, 29.06]	0.382
			RR	2.60	[0.23, 29.67]	0.383
			RD	12.99	[-12.74, 38.72]	0.383
Caucasian	30/119 (25.2)	8/ 57 (14.0)	OR	2.28	[0.94, 5.51]	0.067
			RR	1.87	[0.93, 3.75]	0.065
			RD	12.02	[0.41, 23.63]	0.065
Others	4/ 16 (25.0)	1/ 8 (12.5)	OR	2.77	[0.23, 33.55]	0.424
			RR	2.09	[0.28, 15.51]	0.440
			RD	14.09	[-19.41, 47.58]	0.440

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 3 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	20/ 95 (21.1)	3/ 54 (5.6)	OR	4.81 [1.34,	17.20]	0.016
			RR	3.79 [1.21,	11.90]	0.010
			RD	16.01 [5.50,	26.53]	0.010
Intolerance	20/ 59 (33.9)	7/ 22 (31.8)	OR	1.00 [0.32,	3.08]	0.995
			RR	1.00 [0.51,	1.95]	0.995
			RD	-0.07 [-21.59,	21.45]	0.995
Number of prior TKI therapies						
2	27/ 89 (30.3)	6/ 33 (18.2)	OR	2.10 [0.76,	5.79]	0.150
			RR	1.72 [0.79,	3.76]	0.149
			RD	13.07 [-3.24,	29.38]	0.149
3	12/ 54 (22.2)	4/ 33 (12.1)	OR	2.18 [0.60,	7.98]	0.238
			RR	1.79 [0.64,	4.97]	0.239
			RD	9.59 [-5.62,	24.80]	0.239
>=4	1/ 14 (7.1)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 4 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	24/ 82 (29.3)	6/ 30 (20.0)	OR	1.74 [	0.62, 4.89]	0.290
			RR	1.50 [	0.68, 3.28]	0.292
			RD	9.95 [	-7.47, 27.37]	0.292
4	11/ 44 (25.0)	4/ 29 (13.8)	OR	2.44 [	0.66, 9.00]	0.182
			RR	1.95 [	0.71, 5.41]	0.182
			RD	12.90 [	-4.84, 30.65]	0.182
>=5	5/ 31 (16.1)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	31/125 (24.8)	7/ 63 (11.1)	OR	2.95 [	1.18, 7.41]	0.021
			RR	2.29 [	1.09, 4.82]	0.018
			RD	14.21 [	3.73, 24.69]	0.018
Mutant	6/ 17 (35.3)	2/ 8 (25.0)	OR	1.64 [	0.25, 10.78]	0.608
			RR	1.41 [	0.36, 5.57]	0.624
			RD	10.31 [	-27.84, 48.45]	0.624

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 5 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	34/142 (23.9)	8/ 72 (11.1)	OR	2.71 [	1.16, 6.35]	0.022
			RR	2.19 [	1.07, 4.46]	0.019
			RD	13.20 [	3.08, 23.32]	0.019
< 1%	6/ 15 (40.0)	2/ 4 (50.0)	OR	0.63 [	0.07, 5.97]	0.683
			RR	0.77 [	0.23, 2.55]	0.691
			RD	-11.54 [	-67.22, 44.14]	0.691
Geographic region						
Europe	23/ 90 (25.6)	8/ 45 (17.8)	OR	1.75 [	0.69, 4.40]	0.237
			RR	1.52 [	0.75, 3.08]	0.238
			RD	9.03 [	-5.06, 23.12]	0.238
Others	17/ 67 (25.4)	2/ 31 (6.5)	OR	4.59 [	0.95, 22.10]	0.057
			RR	3.64 [	0.81, 16.40]	0.044
			RD	16.40 [	2.69, 30.11]	0.044

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 6 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Week 48						
Stratification factor by IRT						
Major Cytogenetic Response	21/ 46 (45.7)	3/ 22 (13.6)	OR	5.32 [	1.38, 20.49]	0.015
			RR	3.35 [	1.12, 10.04]	0.010
			RD	32.02 [	11.70, 52.33]	0.010
No Major Cytogenetic Response	25/111 (22.5)	7/ 54 (13.0)	OR	1.95 [	0.79, 4.85]	0.150
			RR	1.74 [	0.80, 3.76]	0.146
			RD	9.56 [	-2.30, 21.42]	0.146
Age category						
18 - 65 years	36/128 (28.1)	6/ 61 (9.8)	OR	3.73 [	1.45, 9.58]	0.006
			RR	2.84 [	1.27, 6.37]	0.004
			RD	18.11 [	7.37, 28.86]	0.004
>=65 years	10/ 29 (34.5)	4/ 15 (26.7)	OR	1.46 [	0.37, 5.80]	0.591
			RR	1.30 [	0.49, 3.45]	0.599
			RD	7.98 [	-20.37, 36.32]	0.599

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 7 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Sex						
Female	24/ 75 (32.0)	3/ 45 (6.7)	OR	6.81 [	1.89, 24.50]	0.003
			RR	4.73 [	1.54, 14.59]	0.001
			RD	25.14 [	12.51, 37.77]	0.001
Male	22/ 82 (26.8)	7/ 31 (22.6)	OR	1.29 [	0.48, 3.46]	0.617
			RR	1.20 [	0.56, 2.57]	0.620
			RD	4.54 [	-13.65, 22.74]	0.620
Race						
Asian	7/ 22 (31.8)	1/ 11 (9.1)	OR	3.96 [	0.40, 38.91]	0.238
			RR	3.40 [	0.35, 33.50]	0.228
			RD	19.48 [	-7.18, 46.14]	0.228
Caucasian	33/119 (27.7)	8/ 57 (14.0)	OR	2.52 [	1.06, 5.98]	0.037
			RR	2.03 [	1.01, 4.07]	0.034
			RD	14.35 [	2.35, 26.35]	0.034
Others	6/ 16 (37.5)	1/ 8 (12.5)	OR	4.59 [	0.43, 49.47]	0.209
			RR	3.02 [	0.44, 20.50]	0.208
			RD	25.99 [	-8.47, 60.46]	0.208

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 8 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	23/ 95 (24.2)	3/ 54 (5.6)	OR	5.64 [1.60,	19.91]	0.007
			RR	4.32 [1.39,	13.43]	0.004
			RD	19.03 [8.23,	29.83]	0.004
Intolerance	23/ 59 (39.0)	7/ 22 (31.8)	OR	1.31 [0.45,	3.81]	0.625
			RR	1.18 [0.59,	2.35]	0.629
			RD	5.71 [-17.09,	28.51]	0.629
Number of prior TKI therapies						
2	29/ 89 (32.6)	8/ 33 (24.2)	OR	1.57 [0.63,	3.94]	0.337
			RR	1.37 [0.70,	2.68]	0.339
			RD	9.00 [-8.52,	26.53]	0.339
3	16/ 54 (29.6)	2/ 33 (6.1)	OR	6.97 [1.44,	33.64]	0.016
			RR	4.87 [1.15,	20.72]	0.009
			RD	23.22 [8.16,	38.28]	0.009
>=4	1/ 14 (7.1)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 9 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	25/ 82 (30.5)	8/ 30 (26.7)	OR	1.24 [	0.48, 3.19]	0.654
			RR	1.16 [	0.59, 2.28]	0.657
			RD	4.34 [	-14.30, 22.98]	0.657
4	14/ 44 (31.8)	2/ 29 (6.9)	OR	6.63 [	1.36, 32.29]	0.019
			RR	4.50 [	1.15, 17.59]	0.011
			RD	25.50 [	8.33, 42.67]	0.011
>=5	7/ 31 (22.6)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	36/125 (28.8)	8/ 63 (12.7)	OR	2.91 [	1.25, 6.79]	0.014
			RR	2.30 [	1.14, 4.62]	0.012
			RD	16.42 [	5.04, 27.79]	0.012
Mutant	6/ 17 (35.3)	2/ 8 (25.0)	OR	1.64 [	0.25, 10.78]	0.608
			RR	1.41 [	0.36, 5.57]	0.624
			RD	10.31 [	-27.84, 48.45]	0.624

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 10 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	38/142 (26.8)	8/ 72 (11.1)	OR	3.00 [	1.31, 6.87]	0.010
			RR	2.42 [	1.19, 4.92]	0.008
			RD	15.84 [	5.43, 26.25]	0.008
< 1%	8/ 15 (53.3)	2/ 4 (50.0)	OR	1.17 [	0.12, 10.99]	0.893
			RR	1.08 [	0.36, 3.24]	0.896
			RD	3.85 [	-52.15, 59.84]	0.896
Geographic region						
Europe	28/ 90 (31.1)	7/ 45 (15.6)	OR	2.66 [	1.04, 6.79]	0.042
			RR	2.08 [	0.99, 4.36]	0.039
			RD	16.57 [	2.41, 30.73]	0.039
Others	18/ 67 (26.9)	3/ 31 (9.7)	OR	3.19 [	0.85, 11.98]	0.086
			RR	2.66 [	0.78, 9.05]	0.078
			RD	15.46 [	0.36, 30.55]	0.078

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

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Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison				
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value	
	n/N* (%)	n/N* (%)					
Week 96							
Stratification factor by IRT							
Major Cytogenetic Response	25/ 46 (54.3)	3/ 22 (13.6)	OR	7.54 [	1.96,	29.05]	0.003
			RR	3.99 [	1.35,	11.79]	0.002
			RD	40.71 [	20.39,	61.03]	0.002
No Major Cytogenetic Response	34/111 (30.6)	9/ 54 (16.7)	OR	2.21 [	0.97,	5.02]	0.059
			RR	1.84 [	0.95,	3.55]	0.056
			RD	13.96 [	0.84,	27.09]	0.056
Age category							
18 - 65 years	48/128 (37.5)	7/ 61 (11.5)	OR	4.78 [	1.99,	11.47]	<0.001
			RR	3.25 [	1.56,	6.78]	<0.001
			RD	25.87 [	14.27,	37.47]	<0.001
>=65 years	11/ 29 (37.9)	5/ 15 (33.3)	OR	1.24 [	0.33,	4.64]	0.747
			RR	1.15 [	0.49,	2.70]	0.753
			RD	4.91 [	-25.18,	34.99]	0.753

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

Final

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison				
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value	
	n/N* (%)	n/N* (%)					
Sex							
Female	30/ 75 (40.0)	3/ 45 (6.7)	OR	9.80	[2.74, 35.09]	<0.001	
			RR	5.92	[1.95, 18.00]	<0.001	
			RD	33.12	[20.06, 46.18]	<0.001	
Male	29/ 82 (35.4)	9/ 31 (29.0)	OR	1.36	[0.55, 3.36]	0.507	
			RR	1.23	[0.65, 2.33]	0.510	
			RD	6.57	[-13.29, 26.44]	0.510	
Race							
Asian	8/ 22 (36.4)	2/ 11 (18.2)	OR	2.53	[0.41, 15.48]	0.315	
			RR	2.10	[0.43, 10.27]	0.321	
			RD	17.86	[-13.31, 49.03]	0.321	
Caucasian	44/119 (37.0)	9/ 57 (15.8)	OR	3.41	[1.49, 7.76]	0.004	
			RR	2.39	[1.26, 4.53]	0.003	
			RD	21.93	[9.14, 34.71]	0.003	
Others	7/ 16 (43.8)	1/ 8 (12.5)	OR	5.76	[0.55, 60.20]	0.144	
			RR	3.48	[0.53, 23.01]	0.137	
			RD	31.94	[-2.64, 66.53]	0.137	

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

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Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	29/ 95 (30.5)	4/ 54 (7.4)	OR	5.61 [1.84,	17.07]	0.002
			RR	4.06 [1.53,	10.74]	0.001
			RD	23.39 [11.54,	35.24]	0.001
Intolerance	30/ 59 (50.8)	8/ 22 (36.4)	OR	1.76 [0.63,	4.94]	0.283
			RR	1.36 [0.74,	2.51]	0.286
			RD	13.13 [-10.67,	36.94]	0.286
Number of prior TKI therapies						
2	38/ 89 (42.7)	9/ 33 (27.3)	OR	2.07 [0.86,	5.01]	0.106
			RR	1.59 [0.87,	2.91]	0.106
			RD	16.11 [-2.25,	34.48]	0.106
3	19/ 54 (35.2)	3/ 33 (9.1)	OR	5.51 [1.47,	20.66]	0.011
			RR	3.88 [1.20,	12.50]	0.007
			RD	25.88 [9.36,	42.39]	0.007
>=4	2/ 14 (14.3)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

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Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	34/ 82 (41.5)	9/ 30 (30.0)	OR	1.70 [	0.69, 4.21]	0.248
			RR	1.40 [	0.77, 2.55]	0.250
			RD	11.99 [	-7.59, 31.57]	0.250
4	16/ 44 (36.4)	3/ 29 (10.3)	OR	4.97 [	1.29, 19.15]	0.020
			RR	3.38 [	1.12, 10.25]	0.015
			RD	26.09 [	7.45, 44.73]	0.015
>=5	9/ 31 (29.0)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	47/125 (37.6)	10/ 63 (15.9)	OR	3.34 [	1.53, 7.26]	0.002
			RR	2.39 [	1.30, 4.40]	0.002
			RD	22.05 [	9.63, 34.47]	0.002
Mutant	7/ 17 (41.2)	2/ 8 (25.0)	OR	2.10 [	0.32, 13.61]	0.437
			RR	1.64 [	0.43, 6.23]	0.454
			RD	16.16 [	-22.21, 54.52]	0.454

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

Table 5-2.3.1.1 MMR: Rate at week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 15 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	49/142 (34.5)	10/ 72 (13.9)	OR	3.34 [	1.57, 7.12]	0.002
			RR	2.49 [	1.34, 4.63]	0.001
			RD	20.80 [	9.44, 32.16]	0.001
< 1%	10/ 15 (66.7)	2/ 4 (50.0)	OR	1.60 [	0.17, 15.27]	0.683
			RR	1.23 [	0.42, 3.59]	0.691
			RD	11.54 [	-44.14, 67.22]	0.691
Geographic region						
Europe	35/ 90 (38.9)	8/ 45 (17.8)	OR	3.35 [	1.35, 8.30]	0.009
			RR	2.27 [	1.16, 4.45]	0.008
			RD	22.56 [	7.60, 37.52]	0.008
Others	24/ 67 (35.8)	4/ 31 (12.9)	OR	3.67 [	1.14, 11.77]	0.029
			RR	2.79 [	1.01, 7.71]	0.024
			RD	22.30 [	5.66, 38.94]	0.024

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_1.sas@@/main/11 03MAY24:09:26

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 1 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Week 24						
Stratification factor by IRT						
Major Cytogenetic Response	21/ 46 (45.7)	4/ 22 (18.2)	OR	3.78 [	1.11, 12.92]	0.034
			RR	2.51 [	0.98, 6.43]	0.029
			RD	27.47 [	5.86, 49.08]	0.029
No Major Cytogenetic Response	22/111 (19.8)	7/ 54 (13.0)	OR	1.66 [	0.66, 4.17]	0.281
			RR	1.53 [	0.70, 3.36]	0.279
			RD	6.86 [	-4.77, 18.49]	0.279
Age category						
18 - 65 years	35/128 (27.3)	8/ 61 (13.1)	OR	2.57 [	1.09, 6.07]	0.031
			RR	2.07 [	1.03, 4.17]	0.028
			RD	14.04 [	2.69, 25.38]	0.028
>=65 years	8/ 29 (27.6)	3/ 15 (20.0)	OR	1.57 [	0.34, 7.23]	0.560
			RR	1.40 [	0.44, 4.47]	0.569
			RD	7.98 [	-17.82, 33.77]	0.569

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 2 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Sex						
Female	24/ 75 (32.0)	5/ 45 (11.1)	OR	3.87	[1.33, 11.20]	0.013
			RR	2.85	[1.18, 6.90]	0.010
			RD	20.67	[6.83, 34.51]	0.010
Male	19/ 82 (23.2)	6/ 31 (19.4)	OR	1.31	[0.45, 3.76]	0.622
			RR	1.22	[0.54, 2.75]	0.625
			RD	4.20	[-12.43, 20.84]	0.625
Race						
Asian	7/ 22 (31.8)	1/ 11 (9.1)	OR	3.96	[0.40, 38.91]	0.238
			RR	3.40	[0.35, 33.50]	0.228
			RD	19.48	[-7.18, 46.14]	0.228
Caucasian	32/119 (26.9)	9/ 57 (15.8)	OR	2.12	[0.91, 4.91]	0.080
			RR	1.76	[0.91, 3.40]	0.078
			RD	11.86	[-0.30, 24.01]	0.078
Others	4/ 16 (25.0)	1/ 8 (12.5)	OR	2.77	[0.23, 33.55]	0.424
			RR	2.09	[0.28, 15.51]	0.440
			RD	14.09	[-19.41, 47.58]	0.440

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 3 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	22/ 95 (23.2)	3/ 54 (5.6)	OR	5.35 [1.51,	18.98]	0.009
			RR	4.14 [1.33,	12.92]	0.005
			RD	18.02 [7.31,	28.73]	0.005
Intolerance	21/ 59 (35.6)	8/ 22 (36.4)	OR	0.88 [0.30,	2.58]	0.813
			RR	0.93 [0.49,	1.74]	0.815
			RD	-2.68 [-25.26,	19.90]	0.815
Number of prior TKI therapies						
2	29/ 89 (32.6)	6/ 33 (18.2)	OR	2.31 [0.85,	6.31]	0.103
			RR	1.84 [0.84,	4.00]	0.100
			RD	15.20 [-1.21,	31.62]	0.100
3	13/ 54 (24.1)	5/ 33 (15.2)	OR	1.81 [0.55,	5.91]	0.326
			RR	1.56 [0.61,	3.96]	0.329
			RD	8.47 [-8.02,	24.96]	0.329
>=4	1/ 14 (7.1)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 4 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	26/ 82 (31.7)	6/ 30 (20.0)	OR	1.94 [	0.70, 5.38]	0.204
			RR	1.61 [	0.74, 3.52]	0.204
			RD	12.29 [	-5.25, 29.83]	0.204
4	11/ 44 (25.0)	5/ 29 (17.2)	OR	1.79 [	0.53, 6.04]	0.348
			RR	1.54 [	0.61, 3.88]	0.352
			RD	9.26 [	-9.66, 28.17]	0.352
>=5	6/ 31 (19.4)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	34/125 (27.2)	8/ 63 (12.7)	OR	2.79 [	1.17, 6.61]	0.020
			RR	2.19 [	1.09, 4.38]	0.018
			RD	14.96 [	3.87, 26.04]	0.018
Mutant	6/ 17 (35.3)	2/ 8 (25.0)	OR	1.64 [	0.25, 10.78]	0.608
			RR	1.41 [	0.36, 5.57]	0.624
			RD	10.31 [	-27.84, 48.45]	0.624

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 5 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	37/142 (26.1)	9/ 72 (12.5)	OR	2.60 [	1.16, 5.85]	0.020
			RR	2.11 [	1.08, 4.12]	0.018
			RD	13.88 [	3.31, 24.45]	0.018
< 1%	6/ 15 (40.0)	2/ 4 (50.0)	OR	0.63 [	0.07, 5.97]	0.683
			RR	0.77 [	0.23, 2.55]	0.691
			RD	-11.54 [	-67.22, 44.14]	0.691
Geographic region						
Europe	24/ 90 (26.7)	8/ 45 (17.8)	OR	1.84 [	0.73, 4.60]	0.193
			RR	1.58 [	0.78, 3.20]	0.193
			RD	10.08 [	-4.10, 24.26]	0.193
Others	19/ 67 (28.4)	3/ 31 (9.7)	OR	3.43 [	0.91, 12.93]	0.068
			RR	2.78 [	0.82, 9.47]	0.060
			RD	16.61 [	1.33, 31.89]	0.060

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 6 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Week 48						
Stratification factor by IRT						
Major Cytogenetic Response	23/ 46 (50.0)	5/ 22 (22.7)	OR	3.40 [	1.07, 10.76]	0.037
			RR	2.20 [	0.97, 5.01]	0.034
			RD	27.27 [	4.57, 49.98]	0.034
No Major Cytogenetic Response	32/111 (28.8)	10/ 54 (18.5)	OR	1.78 [	0.80, 3.97]	0.157
			RR	1.56 [	0.83, 2.93]	0.155
			RD	10.31 [	-3.04, 23.67]	0.155
Age category						
18 - 65 years	44/128 (34.4)	10/ 61 (16.4)	OR	2.75 [	1.25, 6.02]	0.012
			RR	2.08 [	1.13, 3.83]	0.010
			RD	17.80 [	5.54, 30.05]	0.010
>=65 years	11/ 29 (37.9)	5/ 15 (33.3)	OR	1.22 [	0.33, 4.53]	0.764
			RR	1.14 [	0.48, 2.67]	0.769
			RD	4.60 [	-25.20, 34.41]	0.769

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Sex						
Female	30/ 75 (40.0)	5/ 45 (11.1)	OR	5.45 [	1.91, 15.56]	0.002
			RR	3.58 [	1.50, 8.50]	<0.001
			RD	28.71 [	14.42, 43.00]	<0.001
Male	25/ 82 (30.5)	10/ 31 (32.3)	OR	0.93 [	0.38, 2.30]	0.879
			RR	0.95 [	0.52, 1.75]	0.880
			RD	-1.47 [	-20.80, 17.87]	0.880
Race						
Asian	9/ 22 (40.9)	1/ 11 (9.1)	OR	7.16 [	0.74, 69.46]	0.089
			RR	5.00 [	0.60, 41.82]	0.071
			RD	32.47 [	5.16, 59.77]	0.071
Caucasian	40/119 (33.6)	12/ 57 (21.1)	OR	2.03 [	0.95, 4.33]	0.068
			RR	1.64 [	0.94, 2.85]	0.067
			RD	13.32 [	-0.03, 26.66]	0.067
Others	6/ 16 (37.5)	2/ 8 (25.0)	OR	1.86 [	0.28, 12.54]	0.525
			RR	1.51 [	0.39, 5.86]	0.542
			RD	13.10 [	-27.52, 53.71]	0.542

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	27/ 95 (28.4)	4/ 54 (7.4)	OR	5.01 [1.64,	15.27]	0.005
			RR	3.76 [1.42,	10.01]	0.003
			RD	21.14 [9.48,	32.81]	0.003
Intolerance	28/ 59 (47.5)	11/ 22 (50.0)	OR	0.84 [0.30,	2.31]	0.733
			RR	0.92 [0.56,	1.49]	0.736
			RD	-4.13 [-27.95,	19.70]	0.736
Number of prior TKI therapies						
2	36/ 89 (40.4)	9/ 33 (27.3)	OR	1.85 [0.77,	4.45]	0.171
			RR	1.50 [0.81,	2.76]	0.171
			RD	13.57 [-4.76,	31.89]	0.171
3	18/ 54 (33.3)	6/ 33 (18.2)	OR	2.32 [0.78,	6.87]	0.128
			RR	1.81 [0.80,	4.11]	0.128
			RD	14.71 [-3.48,	32.90]	0.128
>=4	1/ 14 (7.1)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 9 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	32/ 82 (39.0)	9/ 30 (30.0)	OR	1.51 [	0.61, 3.73]	0.367
			RR	1.31 [	0.71, 2.41]	0.370
			RD	9.31 [	-10.22, 28.83]	0.370
4	15/ 44 (34.1)	6/ 29 (20.7)	OR	2.14 [	0.70, 6.54]	0.180
			RR	1.70 [	0.76, 3.82]	0.182
			RD	14.60 [	-6.03, 35.24]	0.182
>=5	8/ 31 (25.8)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	45/125 (36.0)	11/ 63 (17.5)	OR	2.77 [	1.30, 5.91]	0.008
			RR	2.09 [	1.17, 3.73]	0.007
			RD	18.87 [	6.44, 31.30]	0.007
Mutant	6/ 17 (35.3)	3/ 8 (37.5)	OR	0.91 [	0.16, 5.19]	0.914
			RR	0.94 [	0.31, 2.87]	0.918
			RD	-2.23 [	-43.43, 38.97]	0.918

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 10 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	47/142 (33.1)	12/ 72 (16.7)	OR	2.52 [	1.23, 5.16]	0.011
			RR	1.99 [	1.13, 3.52]	0.010
			RD	16.62 [	4.93, 28.30]	0.010
< 1%	8/ 15 (53.3)	3/ 4 (75.0)	OR	0.39 [	0.03, 4.80]	0.461
			RR	0.72 [	0.34, 1.53]	0.466
			RD	-21.15 [	-71.50, 29.20]	0.466
Geographic region						
Europe	32/ 90 (35.6)	10/ 45 (22.2)	OR	2.10 [	0.90, 4.90]	0.085
			RR	1.67 [	0.91, 3.06]	0.084
			RD	14.57 [	-0.78, 29.92]	0.084
Others	23/ 67 (34.3)	5/ 31 (16.1)	OR	2.59 [	0.87, 7.70]	0.087
			RR	2.09 [	0.83, 5.30]	0.083
			RD	17.02 [	-0.57, 34.62]	0.083

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Week 96						
Stratification factor by IRT						
Major Cytogenetic Response	28/ 46 (60.9)	5/ 22 (22.7)	OR	5.29 [	1.66, 16.87]	0.005
			RR	2.68 [	1.20, 5.99]	0.004
			RD	38.14 [	15.66, 60.63]	0.004
No Major Cytogenetic Response	39/111 (35.1)	13/ 54 (24.1)	OR	1.71 [	0.82, 3.56]	0.154
			RR	1.46 [	0.85, 2.50]	0.153
			RD	11.06 [	-3.39, 25.51]	0.153
Age category						
18 - 65 years	55/128 (43.0)	12/ 61 (19.7)	OR	3.18 [	1.52, 6.64]	0.002
			RR	2.17 [	1.26, 3.74]	0.002
			RD	23.11 [	10.02, 36.20]	0.002
>=65 years	12/ 29 (41.4)	6/ 15 (40.0)	OR	1.07 [	0.30, 3.80]	0.922
			RR	1.04 [	0.48, 2.22]	0.924
			RD	1.53 [	-29.61, 32.68]	0.924

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
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	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Sex						
Female	35/ 75 (46.7)	5/ 45 (11.1)	OR	7.54 [	2.61, 21.84]	<0.001
			RR	4.17 [	1.77, 9.79]	<0.001
			RD	35.28 [	20.90, 49.67]	<0.001
Male	32/ 82 (39.0)	13/ 31 (41.9)	OR	0.89 [	0.38, 2.08]	0.793
			RR	0.94 [	0.57, 1.55]	0.795
			RD	-2.69 [	-23.42, 18.04]	0.795
Race						
Asian	9/ 22 (40.9)	2/ 11 (18.2)	OR	3.37 [	0.55, 20.66]	0.189
			RR	2.50 [	0.55, 11.34]	0.190
			RD	24.35 [	-6.67, 55.37]	0.190
Caucasian	51/119 (42.9)	14/ 57 (24.6)	OR	2.53 [	1.22, 5.24]	0.013
			RR	1.79 [	1.09, 2.92]	0.012
			RD	19.22 [	5.12, 33.33]	0.012
Others	7/ 16 (43.8)	2/ 8 (25.0)	OR	2.37 [	0.36, 15.66]	0.371
			RR	1.74 [	0.47, 6.48]	0.388
			RD	19.05 [	-21.47, 59.57]	0.388

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 13 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Reason for discontinuation of the last prior TKI						
Failure	33/ 95 (34.7)	6/ 54 (11.1)	OR	4.31 [1.67,	11.16]	0.003
			RR	3.08 [1.40,	6.78]	0.002
			RD	23.82 [10.77,	36.87]	0.002
Intolerance	34/ 59 (57.6)	12/ 22 (54.5)	OR	1.07 [0.38,	2.96]	0.902
			RR	1.03 [0.66,	1.59]	0.904
			RD	1.47 [-22.45,	25.39]	0.904
Number of prior TKI therapies						
2	43/ 89 (48.3)	11/ 33 (33.3)	OR	1.91 [0.83,	4.43]	0.130
			RR	1.46 [0.86,	2.47]	0.130
			RD	15.45 [-3.87,	34.76]	0.130
3	22/ 54 (40.7)	7/ 33 (21.2)	OR	2.61 [0.94,	7.23]	0.064
			RR	1.90 [0.91,	4.00]	0.063
			RD	19.16 [-0.15,	38.47]	0.063
>=4	2/ 14 (14.3)	0/ 10	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_1_2.sas@@/main/11 03MAY24:09:27

Final

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 14 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
Line of therapy of randomized treatment						
3	39/ 82 (47.6)	11/ 30 (36.7)	OR	1.59 [	0.67, 3.78]	0.291
			RR	1.31 [	0.77, 2.20]	0.294
			RD	11.22 [	-9.30, 31.74]	0.294
4	18/ 44 (40.9)	7/ 29 (24.1)	OR	2.32 [	0.80, 6.69]	0.120
			RR	1.73 [	0.84, 3.57]	0.121
			RD	17.83 [	-3.94, 39.61]	0.121
>=5	10/ 31 (32.3)	0/ 17	OR	NE	[NE, NE]	NE
			RR	NE	[NE, NE]	NE
			RD	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	55/125 (44.0)	14/ 63 (22.2)	OR	2.90 [	1.43, 5.87]	0.003
			RR	2.00 [	1.21, 3.29]	0.003
			RD	22.17 [	8.80, 35.55]	0.003
Mutant	7/ 17 (41.2)	3/ 8 (37.5)	OR	1.16 [	0.21, 6.56]	0.863
			RR	1.10 [	0.38, 3.18]	0.869
			RD	3.62 [	-37.70, 44.94]	0.869

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

Table 5-2.3.1.2 MMR: Rate by week 24, 48 and 96 - Subgroups
Full Analysis Set
(Page 15 of 15)

	Treatment Groups		Comparison			
	Asciminib N=157	Bosutinib N=76	Parameter	Estimate	[95% CI]	p-value
	n/N* (%)	n/N* (%)				
BCR-ABL ratio at baseline						
>= 1%	56/142 (39.4)	15/ 72 (20.8)	OR	2.52 [	1.30, 4.90]	0.006
			RR	1.90 [	1.16, 3.12]	0.006
			RD	18.80 [	6.24, 31.35]	0.006
< 1%	11/ 15 (73.3)	3/ 4 (75.0)	OR	0.75 [	0.06, 9.62]	0.825
			RR	0.92 [	0.47, 1.81]	0.830
			RD	-5.77 [	-55.07, 43.53]	0.830
Geographic region						
Europe	39/ 90 (43.3)	11/ 45 (24.4)	OR	2.71 [	1.18, 6.24]	0.019
			RR	1.85 [	1.06, 3.23]	0.018
			RD	20.56 [	4.76, 36.36]	0.018
Others	28/ 67 (41.8)	7/ 31 (22.6)	OR	2.40 [	0.90, 6.37]	0.079
			RR	1.85 [	0.87, 3.96]	0.077
			RD	18.59 [	-0.70, 37.88]	0.077

The risk ratio, then respective 95% CIs and p-values were estimated using the Cochran-Mantel-Haenszel method, adjusted for stratification factor baseline MCyR response per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, RR: Risk Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis, MMR: Major molecular response, NE: Not Estimable.

No analysis displayed when each subgroup has less than 10 events.

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Final

Table 5-2.3.2 MMR: Time to event - subdistribution hazard model - Subgroups
Full Analysis Set
(Page 1 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR*	[95% CI]	p-value
	n/N* (%)	n/N* (%)			
Stratification factor by IRT					
Major Cytogenetic Response	31/ 46 (67.4)	6/ 22 (27.3)	3.42	[1.42, 8.24]	0.006
No Major Cytogenetic Response	43/111 (38.7)	13/ 54 (24.1)	1.75	[0.94, 3.25]	0.075
Age category					
18 - 65 years	60/128 (46.9)	13/ 61 (21.3)	2.70	[1.47, 4.95]	0.001
>=65 years	14/ 29 (48.3)	6/ 15 (40.0)	1.27	[0.50, 3.22]	0.612
Sex					
Female	40/ 75 (53.3)	5/ 45 (11.1)	6.22	[2.36, 16.37]	<0.001
Male	34/ 82 (41.5)	14/ 31 (45.2)	0.97	[0.52, 1.80]	0.930
Race					
Asian	10/ 22 (45.5)	2/ 11 (18.2)	3.16	[0.76, 13.15]	0.115
Caucasian	56/119 (47.1)	15/ 57 (26.3)	2.25	[1.25, 4.06]	0.007
Others	8/ 16 (50.0)	2/ 8 (25.0)	2.13	[0.45, 10.09]	0.339
Reason for discontinuation of the last prior TKI					
Failure	37/ 95 (38.9)	6/ 54 (11.1)	4.31	[1.77, 10.47]	0.001
Intolerance	37/ 59 (62.7)	13/ 22 (59.1)	1.06	[0.57, 1.98]	0.847

MMR: Major molecular response

*HR and two-sided p-value estimated by sub-distribution hazard model

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

Table 5-2.3.2 MMR: Time to event - subdistribution hazard model - Subgroups
Full Analysis Set
(Page 2 of 2)

	Treatment Groups		Comparison		
	Asciminib N=157	Bosutinib N=76	HR*	[95% CI]	p-value
	n/N* (%)	n/N* (%)			
Number of prior TKI therapies					
2	47/ 89 (52.8)	12/ 33 (36.4)	1.83	[0.98, 3.40]	0.057
3	23/ 54 (42.6)	7/ 33 (21.2)	2.18	[0.91, 5.24]	0.082
>=4	4/ 14 (28.6)	0/ 10	NE	[NE, NE]	NE
Line of therapy of randomized treatment					
3	43/ 82 (52.4)	12/ 30 (40.0)	1.59	[0.85, 2.96]	0.146
4	19/ 44 (43.2)	7/ 29 (24.1)	1.98	[0.81, 4.83]	0.135
>=5	12/ 31 (38.7)	0/ 17	NE	[NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation					
Wild type	61/125 (48.8)	15/ 63 (23.8)	2.54	[1.44, 4.48]	0.001
Mutant	7/ 17 (41.2)	3/ 8 (37.5)	1.17	[0.35, 3.94]	0.801
BCR-ABL ratio at baseline					
>= 1%	63/142 (44.4)	16/ 72 (22.2)	2.43	[1.38, 4.26]	0.002
< 1%	11/ 15 (73.3)	3/ 4 (75.0)	0.79	[0.23, 2.79]	0.720
Geographic region					
Europe	44/ 90 (48.9)	12/ 45 (26.7)	2.30	[1.20, 4.42]	0.013
Others	30/ 67 (44.8)	7/ 31 (22.6)	2.27	[1.01, 5.10]	0.048

MMR: Major molecular response

*HR and two-sided p-value estimated by sub-distribution hazard model

(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).

Subgroup "Missing" will not be analyzed for any of the attributes.

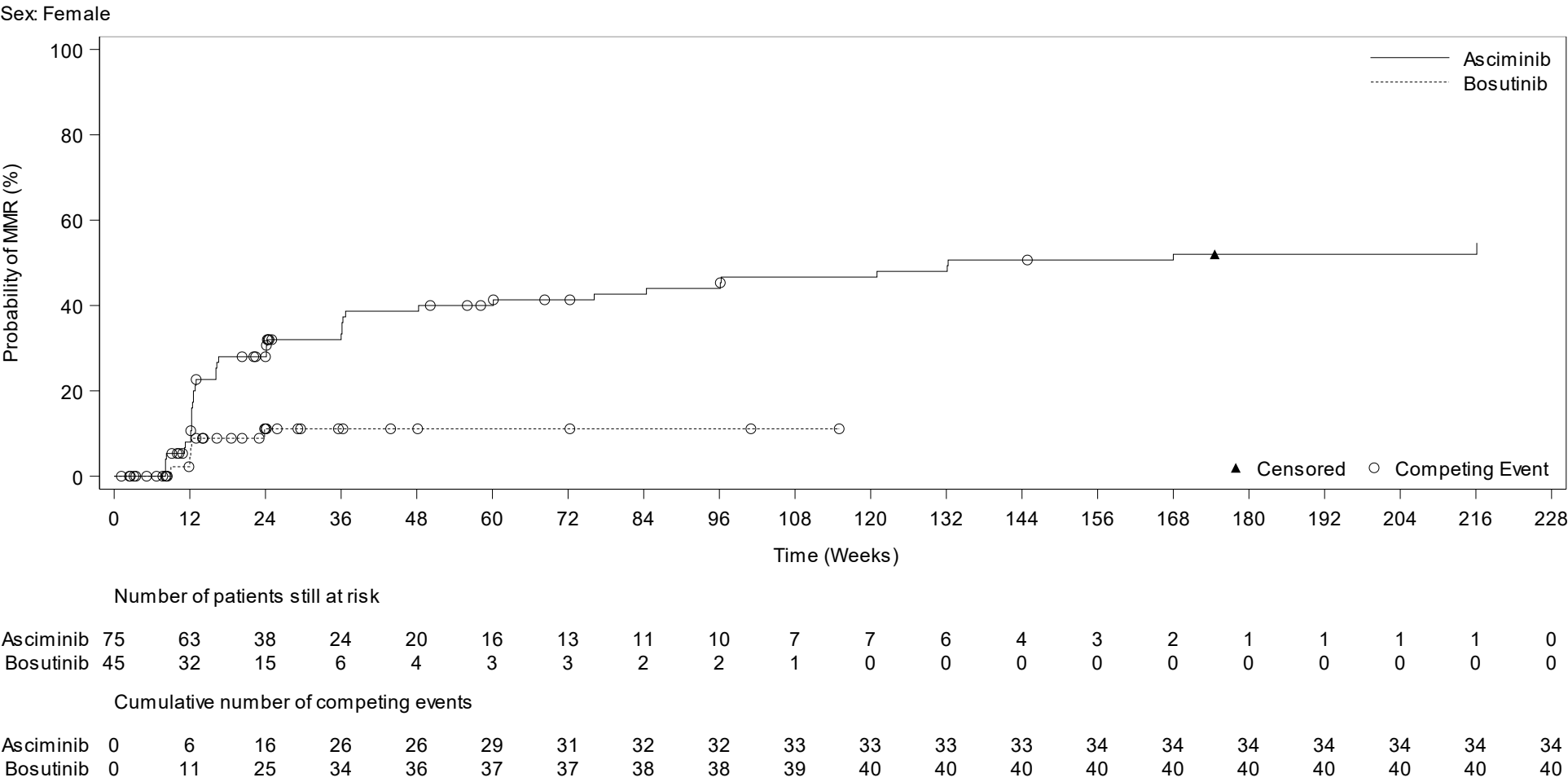
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,

N*: Number of patients included in the analysis. - NE: Not Estimable.

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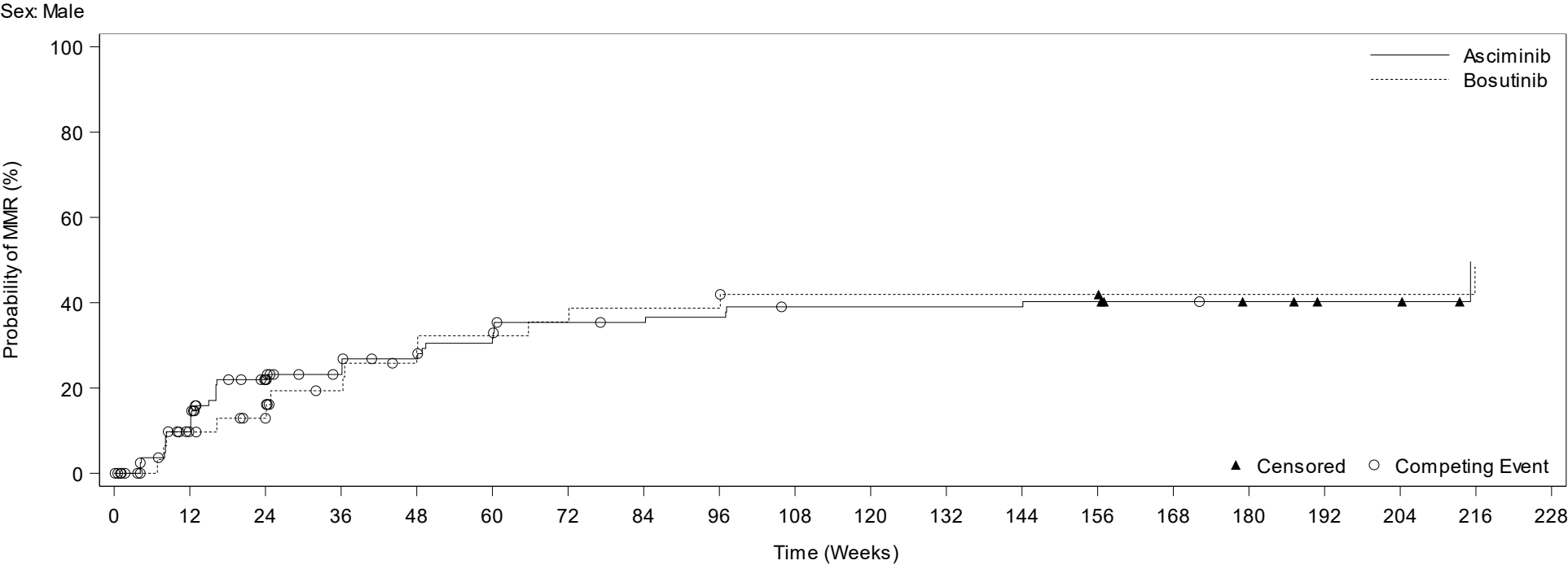
Final

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
(Page 1 of 10)



The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
(Page 2 of 10)

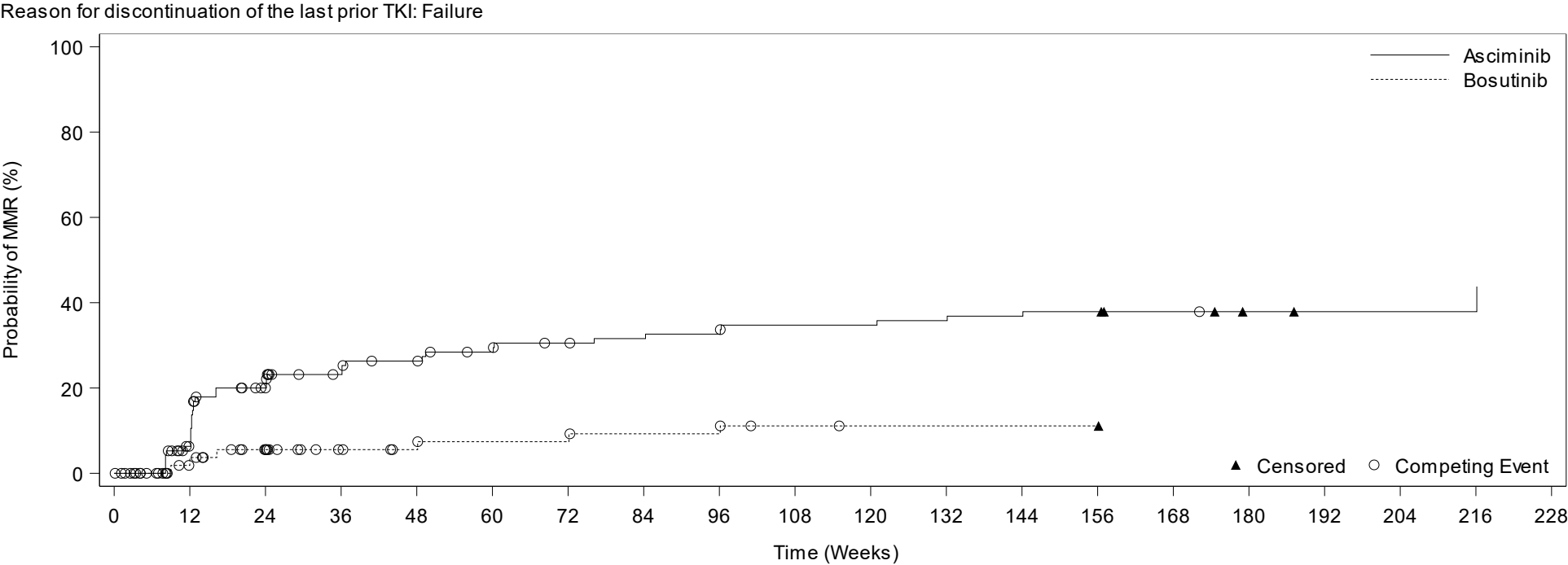


Number of patients still at risk																			
Asciminib	82	64	44	31	26	20	15	14	13	10	10	10	10	9	7	5	3	3	0
Bosutinib	31	24	19	11	7	6	5	4	4	2	2	2	2	2	1	1	1	1	0

Cumulative number of competing events																			
Asciminib	0	10	20	32	34	36	38	39	39	40	40	40	40	40	40	41	41	41	41
Bosutinib	0	4	8	14	15	15	15	15	15	16	16	16	16	16	16	16	16	16	16

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

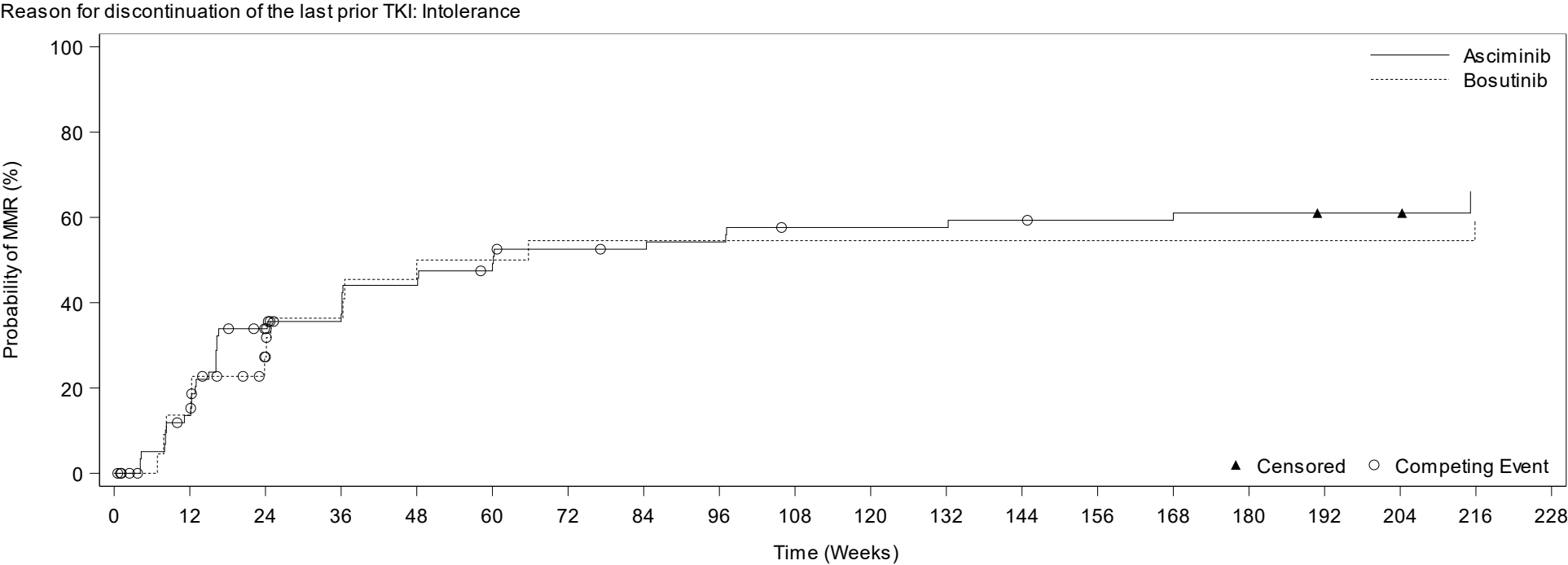
Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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Number of patients still at risk																				
Asciminib	95	77	52	32	27	21	16	14	13	10	10	9	8	7	5	2	1	1	1	0
Bosutinib	54	39	26	12	9	7	7	5	5	2	1	1	1	1	0	0	0	0	0	0
Cumulative number of competing events																				
Asciminib	0	12	24	41	43	47	50	51	51	52	52	52	52	52	52	53	53	53	53	53
Bosutinib	0	13	25	39	42	43	43	44	44	46	47	47	47	47	47	47	47	47	47	47

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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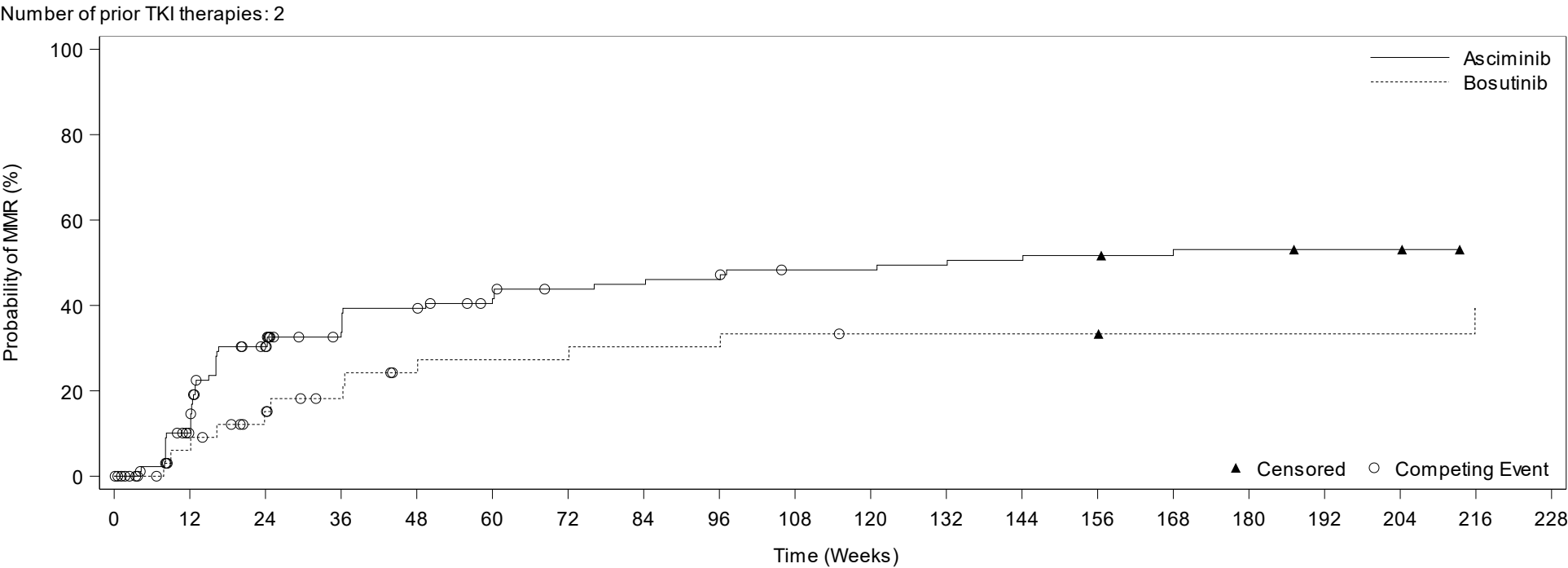


Number of patients still at risk																			
Asciminib	59	47	29	22	18	14	11	10	9	6	6	6	5	4	3	3	2	2	0
Bosutinib	22	17	8	5	2	2	1	1	1	1	1	1	1	1	1	1	1	1	0

Cumulative number of competing events																			
Asciminib	0	4	10	15	15	16	17	18	18	19	19	19	19	20	20	20	20	20	20
Bosutinib	0	2	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

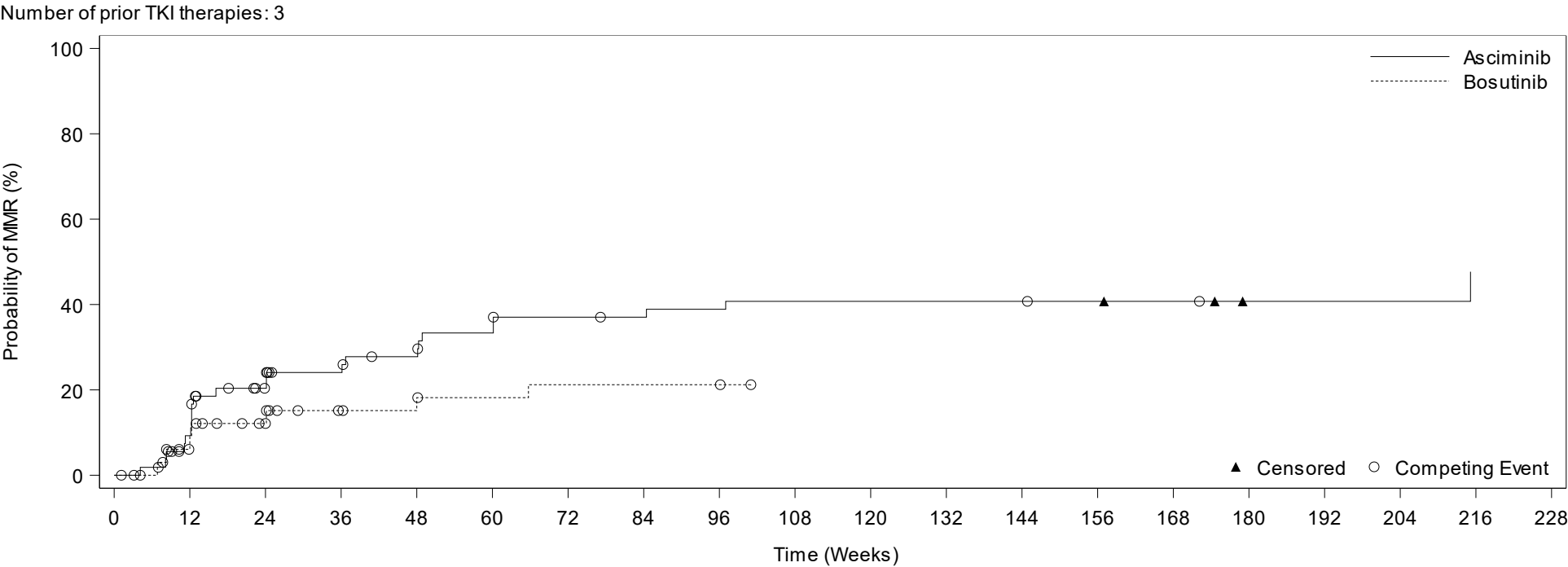
Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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Number of patients still at risk																				
Asciminib	89	72	42	29	24	18	14	13	12	8	8	7	6	5	3	3	2	2	0	0
Bosutinib	33	22	15	10	6	5	5	4	4	3	2	2	2	2	1	1	1	1	0	0
Cumulative number of competing events																				
Asciminib	0	8	20	30	30	34	36	36	36	38	38	38	38	38	38	38	38	38	38	38
Bosutinib	0	9	13	17	19	19	19	19	19	19	20	20	20	20	20	20	20	20	20	20

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

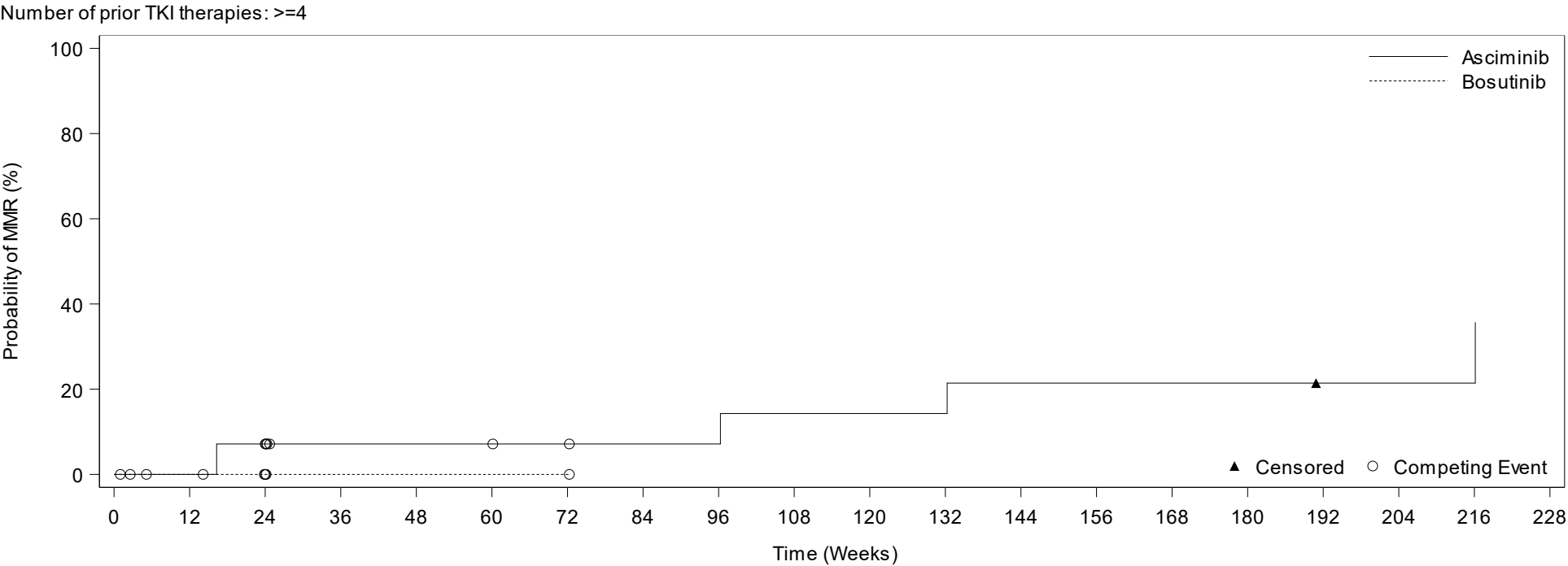
Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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Number of patients still at risk																			
Asciminib	54	43	30	20	16	12	9	8	7	6	6	6	6	5	4	1	1	1	0
Bosutinib	33	25	16	6	4	3	2	2	2	0	0	0	0	0	0	0	0	0	0
Cumulative number of competing events																			
Asciminib	0	6	13	21	23	24	25	26	26	26	26	26	26	27	27	28	28	28	28
Bosutinib	0	5	13	22	23	24	24	24	24	26	26	26	26	26	26	26	26	26	26

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

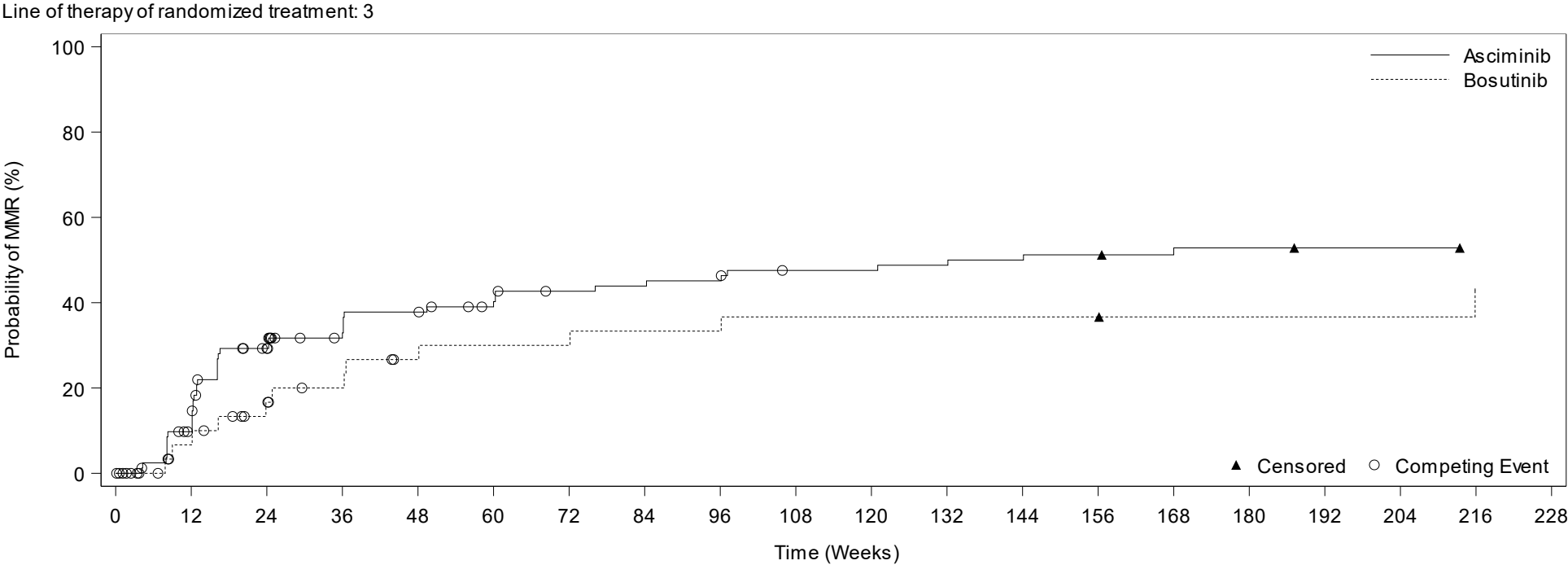
Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
(Page 7 of 10)



Number of patients still at risk																				
Asciminib	14	12	10	6	6	6	5	4	4	3	3	3	2	2	2	2	1	1	1	0
Bosutinib	10	9	3	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Cumulative number of competing events																				
Asciminib	0	2	3	7	7	7	8	9	9	9	9	9	9	9	9	9	9	9	9	9
Bosutinib	0	1	7	9	9	9	9	10	10	10	10	10	10	10	10	10	10	10	10	10

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
(Page 8 of 10)

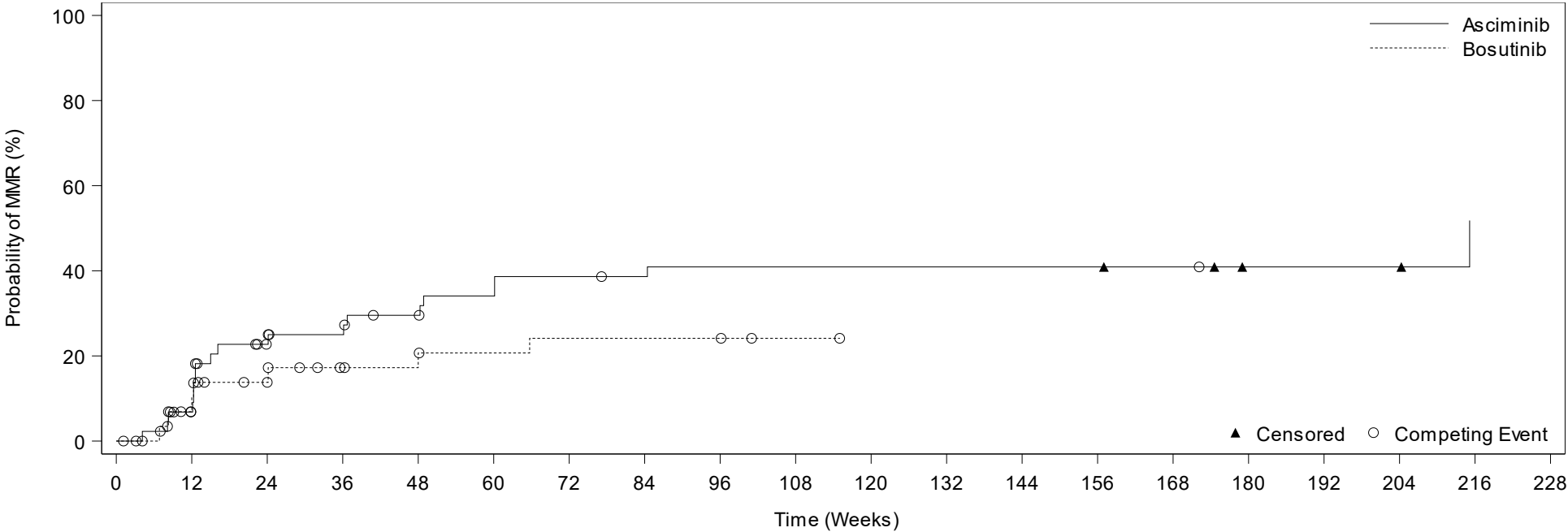


Number of patients still at risk																			
Asciminib	82	67	40	27	23	17	13	12	11	7	7	6	5	4	2	2	1	1	0
Bosutinib	30	20	13	9	5	4	4	3	3	2	2	2	2	2	1	1	1	1	0
Cumulative number of competing events																			
Asciminib	0	7	18	28	28	32	34	34	34	36	36	36	36	36	36	36	36	36	36
Bosutinib	0	8	12	15	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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Line of therapy of randomized treatment: 4



Number of patients still at risk																			
Asciminib	44	35	22	17	13	10	8	7	6	6	6	6	6	6	5	2	2	2	0
Bosutinib	29	21	14	7	5	4	3	3	3	1	0	0	0	0	0	0	0	0	0

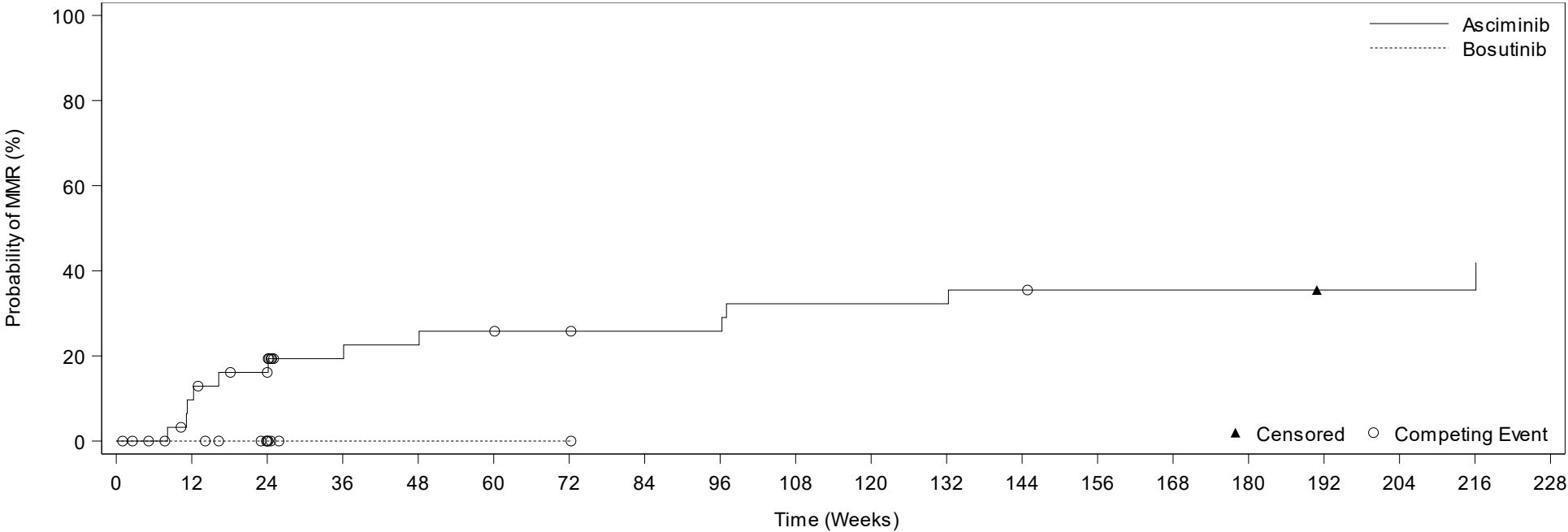
Cumulative number of competing events																			
Asciminib	0	6	12	16	18	19	19	20	20	20	20	20	20	20	20	21	21	21	21
Bosutinib	0	5	11	17	18	19	19	19	19	21	22	22	22	22	22	22	22	22	22

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.
/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_f523_2_2.sas@@/main/5 23NOV23:07:17

Final

Figure 5-2.3.2 MMR: Cumulative incidence plot of time to event adjusting for competing risks - Subgroups
Full Analysis Set
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Line of therapy of randomized treatment: >=5



Number of patients still at risk																				
Asciminib	31	25	20	11	10	9	7	6	6	4	4	4	3	2	2	2	1	1	1	0
Bosutinib	17	15	7	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Cumulative number of competing events																				
Asciminib	0	3	6	14	14	14	16	17	17	17	17	17	17	18	18	18	18	18	18	18
Bosutinib	0	2	10	16	16	16	16	17	17	17	17	17	17	17	17	17	17	17	17	17

The competing risks include discontinuations from treatment due to any reason, without prior achievement of MMR.
/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_f523_2_2.sas@@/main/5 23NOV23:07:17

Final

Table 5-2.3.3.1 MMR: Duration of event - Subgroups
MMR Responder Set
(Page 1 of 1)

Treatment Groups				Comparison	
Asciminib N=74		Bosutinib N=19		HR	p-value
n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		

None of the attribute
have at least 10
events occurred in
one of the subgroups

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
Subgroup "Missing" will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable, MMR: Major molecular response

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t523_3_1.sas@@/main/3 22NOV23:10:40

Final

Table 5-2.5.1 Progression to BC: Time to event - Subgroups
Full Analysis Set
(Page 1 of 1)

Treatment Groups				Comparison	
Asciminib N=157		Bosutinib N=76		HR	p-value
n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	

None of the attribute
have at least 10
events occurred in
one of the subgroups

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
Subgroup "Missing" will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable, BC: Blast Crisis

/vob/CABL001A/haq/haq_eu_4/pgm/eff/germ_t52_5_1.sas@@/main/3 22NOV23:10:38

Final

Figure 5-2.5.1 Progression to BC: Kaplan Meier plot - Subgroups
Full Analysis Set
(Page 1 of 1)

None of the attribute have at least 10 events occurred in one of the subgroups

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test
(both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT).
Subgroup "Missing" will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event,
N*: Number of patients included in the analysis.
- NE: Not Estimable, BC: Blast Crisis

Table 5-3.1.1 Any AE: time to first event - subgroup analysis
 Safety Set
 (Page 1 of 3)

	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Stratification factor by IRT							
Major Cytogenetic Response	44/ 46 (95.7)	0.71 [0.13, 1.41]	21/ 22 (95.5)	0.07 [0.03, 0.30]	0.50	[0.29, 0.86]	0.011
No Major Cytogenetic Response	98/110 (89.1)	0.34 [0.26, 0.95]	53/ 54 (98.1)	0.16 [0.03, 0.26]	0.60	[0.43, 0.84]	0.002
Age category							
18 - 65 years	114/127 (89.8)	0.30 [0.16, 0.92]	59/ 61 (96.7)	0.07 [0.03, 0.16]	0.61	[0.44, 0.84]	0.002
>=65 years	28/ 29 (96.6)	0.95 [0.26, 1.84]	15/ 15 (100)	0.26 [0.03, 0.49]	0.51	[0.26, 1.01]	0.052
Sex							
Female	69/ 75 (92.0)	0.30 [0.13, 0.92]	43/ 45 (95.6)	0.13 [0.03, 0.26]	0.67	[0.45, 0.98]	0.034
Male	73/ 81 (90.1)	0.79 [0.26, 0.95]	31/ 31 (100)	0.07 [0.03, 0.26]	0.48	[0.31, 0.75]	<0.001
Race							
Asian	20/ 22 (90.9)	0.95 [0.16, 3.81]	11/ 11 (100)	0.26 [0.03, 0.30]	0.45	[0.19, 1.06]	0.066
Caucasian	106/118 (89.8)	0.53 [0.26, 0.95]	55/ 57 (96.5)	0.07 [0.03, 0.26]	0.62	[0.44, 0.86]	0.004
Others	16/ 16 (100)	0.15 [0.03, 0.95]	8/ 8 (100)	0.05 [0.03, 0.20]	0.49	[0.19, 1.29]	0.101

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.1.1 Any AE: time to first event - subgroup analysis
 Safety Set
 (Page 2 of 3)

	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Reason for discontinuation of the last prior TKI							
Failure	82/ 94 (87.2)	0.92 [0.30, 0.95]	52/ 54 (96.3)	0.15 [0.03, 0.26]	0.47	[0.32, 0.67]	<0.001
Intolerance	57/ 59 (96.6)	0.13 [0.03, 0.30]	22/ 22 (100)	0.07 [0.03, 0.26]	0.72	[0.43, 1.21]	0.193
Number of prior TKI therapies							
2	81/ 88 (92.0)	0.95 [0.26, 0.99]	31/ 33 (93.9)	0.07 [0.03, 0.30]	0.59	[0.38, 0.90]	0.014
3	49/ 54 (90.7)	0.25 [0.07, 0.69]	33/ 33 (100)	0.07 [0.03, 0.16]	0.64	[0.41, 1.01]	0.050
≥4	12/ 14 (85.7)	0.57 [0.03, 2.79]	10/ 10 (100)	0.26 [0.03, 0.39]	0.57	[0.22, 1.44]	0.214
Line of therapy of randomized treatment							
3	75/ 81 (92.6)	0.95 [0.26, 0.95]	28/ 30 (93.3)	0.07 [0.03, 0.30]	0.65	[0.41, 1.01]	0.059
4	39/ 44 (88.6)	0.26 [0.10, 0.95]	29/ 29 (100)	0.10 [0.03, 0.33]	0.62	[0.38, 1.03]	0.051
≥5	28/ 31 (90.3)	0.30 [0.07, 0.92]	17/ 17 (100)	0.13 [0.03, 0.26]	0.40	[0.20, 0.79]	0.008

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.1.1 Any AE: time to first event - subgroup analysis
 Safety Set
 (Page 3 of 3)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	118/125 (94.4)	0.30 [0.26, 0.92]	63/ 63 (100)	0.07 [0.03, 0.20]	0.51[0.37, 0.71]	<0.001
Mutant	13/ 17 (76.5)	1.25 [0.03, 2.46]	8/ 8 (100)	0.59 [0.03, 3.19]	0.70[0.28, 1.72]	0.426
BCR-ABL ratio at baseline						
>= 1%	128/141 (90.8)	0.72 [0.26, 0.95]	70/ 72 (97.2)	0.07 [0.03, 0.20]	0.56[0.42, 0.76]	<0.001
< 1%	14/ 15 (93.3)	0.13 [0.03, 0.69]	4/ 4 (100)	0.20 [0.03, NE]	0.59[0.18, 1.97]	0.370
Geographic region						
Europe	78/ 89 (87.6)	0.95 [0.26, 0.99]	43/ 45 (95.6)	0.07 [0.03, 0.16]	0.56[0.38, 0.82]	0.003
Others	64/ 67 (95.5)	0.26 [0.07, 0.62]	31/ 31 (100)	0.20 [0.03, 0.26]	0.68[0.43, 1.07]	0.074

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.1.1 Any AE: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_f54_1_1.sas@@/main/2 22NOV23:10:50

Final

Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Gastrointestinal disorders						
Stratification factor by IRT						
Major Cytogenetic Response	22/ 46 (47.8)	37.98 [10.87, NE]	19/ 22 (86.4)	0.18 [0.03, 0.62]	0.13[0.06, 0.27]	<0.001
No Major Cytogenetic Response	47/110 (42.7)	35.75 [11.99, NE]	42/ 54 (77.8)	0.26 [0.07, 0.49]	0.27[0.18, 0.42]	<0.001
Age category						
18 - 65 years	56/127 (44.1)	35.75 [13.77, NE]	48/ 61 (78.7)	0.20 [0.07, 0.36]	0.24[0.16, 0.36]	<0.001
>=65 years	13/ 29 (44.8)	19.65 [7.29, NE]	13/ 15 (86.7)	0.26 [0.03, 0.76]	0.18[0.07, 0.45]	<0.001
Sex						
Female	35/ 75 (46.7)	21.19 [8.34, NE]	33/ 45 (73.3)	0.20 [0.07, 0.36]	0.29[0.17, 0.48]	<0.001
Male	34/ 81 (42.0)	37.98 [13.77, NE]	28/ 31 (90.3)	0.26 [0.07, 0.49]	0.17[0.10, 0.29]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_2.sas@@/main/2 22NOV23:11:19

Final

Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
 Safety Set
 (Page 2 of 8)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	9/ 22 (40.9)	NE [8.34, NE]	9/ 11 (81.8)	0.26 [0.03, 0.30]	0.14[0.05, 0.45]	<0.001
Caucasian	49/118 (41.5)	36.83 [13.83, NE]	45/ 57 (78.9)	0.20 [0.07, 0.53]	0.23[0.15, 0.35]	<0.001
Others	11/ 16 (68.8)	2.86 [0.07, 21.19]	7/ 8 (87.5)	0.16 [0.03, 1.02]	0.30[0.10, 0.89]	0.023
Reason for discontinuation of the last prior TKI						
Failure	36/ 94 (38.3)	NE [17.64, NE]	41/ 54 (75.9)	0.26 [0.07, 0.49]	0.22[0.14, 0.36]	<0.001
Intolerance	30/ 59 (50.8)	20.73 [8.34, NE]	20/ 22 (90.9)	0.21 [0.03, 0.49]	0.20[0.11, 0.38]	<0.001
Number of prior TKI therapies						
2	34/ 88 (38.6)	NE [19.65, NE]	26/ 33 (78.8)	0.26 [0.03, 0.72]	0.18[0.10, 0.31]	<0.001
3	29/ 54 (53.7)	10.15 [3.81, NE]	28/ 33 (84.8)	0.10 [0.03, 0.36]	0.28[0.16, 0.48]	<0.001
>=4	6/ 14 (42.9)	36.83 [0.79, NE]	7/ 10 (70.0)	0.28 [0.03, NE]	0.23[0.06, 0.91]	0.025

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_2.sas@@/main/2 22NOV23:11:19

Final

Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
 Safety Set
 (Page 3 of 8)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	30/ 81 (37.0)	NE [17.25, NE]	23/ 30 (76.7)	0.23 [0.03, 0.76]	0.19[0.10, 0.33]	<0.001
4	24/ 44 (54.5)	9.40 [2.04, 32.33]	25/ 29 (86.2)	0.20 [0.07, 0.49]	0.32[0.17, 0.57]	<0.001
>=5	15/ 31 (48.4)	35.75 [1.74, NE]	13/ 17 (76.5)	0.26 [0.03, 0.72]	0.24[0.10, 0.59]	<0.001
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	59/125 (47.2)	21.19 [11.17, NE]	54/ 63 (85.7)	0.20 [0.07, 0.30]	0.20[0.13, 0.30]	<0.001
Mutant	3/ 17 (17.6)	NE [6.47, NE]	5/ 8 (62.5)	4.68 [0.03, NE]	0.16[0.03, 0.83]	0.014
BCR-ABL ratio at baseline						
>= 1%	61/141 (43.3)	32.33 [11.99, NE]	57/ 72 (79.2)	0.26 [0.07, 0.33]	0.24[0.16, 0.35]	<0.001
< 1%	8/ 15 (53.3)	35.75 [1.64, NE]	4/ 4 (100)	0.30 [0.03, NE]	0.07[0.01, 0.42]	<0.001
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Europe	30/ 89 (33.7)	NE [32.33, NE]	32/ 45 (71.1)	0.16 [0.07, 0.53]	0.19	[0.11, 0.33]	<0.001
Others	39/ 67 (58.2)	8.34 [3.81, 20.73]	29/ 31 (93.5)	0.26 [0.07, 0.30]	0.26	[0.15, 0.44]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_2.sas@@/main/2 22NOV23:11:19

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Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Investigations						
Stratification factor by IRT						
Major Cytogenetic Response	12/ 46 (26.1)	NE [NE, NE]	13/ 22 (59.1)	4.60 [1.25, NE]	0.26[0.12, 0.60]	<0.001
No Major Cytogenetic Response	44/110 (40.0)	38.70 [10.18, NE]	27/ 54 (50.0)	6.60 [2.79, NE]	0.64[0.39, 1.03]	0.066
Age category						
18 - 65 years	43/127 (33.9)	NE [NE, NE]	30/ 61 (49.2)	7.46 [3.78, 25.10]	0.51[0.32, 0.82]	0.005
>=65 years	13/ 29 (44.8)	33.08 [9.23, NE]	10/ 15 (66.7)	2.10 [0.95, NE]	0.50[0.21, 1.19]	0.106
Sex						
Female	25/ 75 (33.3)	NE [17.54, NE]	24/ 45 (53.3)	4.60 [2.04, NE]	0.41[0.23, 0.74]	0.002
Male	31/ 81 (38.3)	NE [21.22, NE]	16/ 31 (51.6)	8.31 [2.79, NE]	0.63[0.34, 1.16]	0.140

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	7/ 22 (31.8)	NE [1.87, NE]	7/ 11 (63.6)	2.23 [0.66, NE]	0.57[0.19, 1.67]	0.290
Caucasian	45/118 (38.1)	NE [21.22, NE]	27/ 57 (47.4)	8.31 [3.75, NE]	0.61[0.38, 1.00]	0.045
Others	4/ 16 (25.0)	NE [7.06, NE]	6/ 8 (75.0)	2.33 [0.23, NE]	0.23[0.06, 0.83]	0.015
Reason for discontinuation of the last prior TKI						
Failure	28/ 94 (29.8)	NE [33.38, NE]	25/ 54 (46.3)	11.99 [3.78, NE]	0.42[0.24, 0.73]	0.002
Intolerance	28/ 59 (47.5)	38.70 [3.25, NE]	15/ 22 (68.2)	2.76 [0.95, 8.31]	0.63[0.33, 1.18]	0.145
Number of prior TKI therapies						
2	30/ 88 (34.1)	NE [33.08, NE]	16/ 33 (48.5)	8.31 [2.79, NE]	0.57[0.31, 1.05]	0.070
3	19/ 54 (35.2)	NE [10.18, NE]	20/ 33 (60.6)	3.75 [1.87, 11.99]	0.44[0.23, 0.84]	0.010
>=4	7/ 14 (50.0)	13.86 [0.26, NE]	4/ 10 (40.0)	NE [0.72, NE]	1.11[0.30, 4.15]	0.859

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	27/ 81 (33.3)	NE [33.08, NE]	15/ 30 (50.0)	8.31 [2.79, NE]	0.56[0.30, 1.06]	0.071
4	16/ 44 (36.4)	NE [17.54, NE]	20/ 29 (69.0)	2.79 [0.95, 7.46]	0.32[0.16, 0.64]	<0.001
>=5	13/ 31 (41.9)	NE [3.71, NE]	5/ 17 (29.4)	NE [1.41, NE]	1.28[0.43, 3.80]	0.646
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	49/125 (39.2)	NE [21.22, NE]	33/ 63 (52.4)	7.46 [2.73, NE]	0.60[0.38, 0.93]	0.022
Mutant	5/ 17 (29.4)	NE [7.43, NE]	5/ 8 (62.5)	4.63 [0.92, NE]	0.25[0.06, 1.07]	0.044
BCR-ABL ratio at baseline						
>= 1%	51/141 (36.2)	NE [33.08, NE]	36/ 72 (50.0)	6.60 [2.79, NE]	0.54[0.35, 0.83]	0.005
< 1%	5/ 15 (33.3)	NE [0.49, NE]	4/ 4 (100)	1.99 [1.15, NE]	0.19[0.05, 0.81]	0.013
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.2 Any AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Europe	30/ 89 (33.7)	NE [33.08, NE]	22/ 45 (48.9)	8.31 [2.79, NE]	0.48	[0.27, 0.83]	0.008
Others	26/ 67 (38.8)	NE [13.73, NE]	18/ 31 (58.1)	5.55 [0.95, NE]	0.60	[0.32, 1.11]	0.097

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Figure 5-3.1.2 Any AE by SOC: Kaplan Meier plot of time to first event - subgroup analysis

Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Abdominal pain						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.30[0.06, 1.43]	0.112
No Major Cytogenetic Response	10/110 (9.1)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	0.43[0.17, 1.07]	0.063
Age category						
18 - 65 years	13/127 (10.2)	NE [NE, NE]	11/ 61 (18.0)	NE [NE, NE]	0.37[0.16, 0.84]	0.014
>=65 years	1/ 29 (3.4)	NE [NE, NE]	1/ 15 (6.7)	NE [NE, NE]	0.50[0.03, 7.99]	0.617
Sex						
Female	6/ 75 (8.0)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.38[0.12, 1.25]	0.102
Male	8/ 81 (9.9)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.41[0.14, 1.19]	0.091

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	1/ 22 (4.5)	NE [NE, NE]	1/ 11 (9.1)	NE [3.71, NE]	NE [NE, NE]	0.206
Caucasian	11/118 (9.3)	NE [NE, NE]	9/ 57 (15.8)	NE [NE, NE]	0.43[0.17, 1.05]	0.056
Others	2/ 16 (12.5)	NE [NE, NE]	2/ 8 (25.0)	NE [0.03, NE]	0.33[0.05, 2.39]	0.250
Reason for discontinuation of the last prior TKI						
Failure	5/ 94 (5.3)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	0.22[0.07, 0.68]	0.004
Intolerance	7/ 59 (11.9)	NE [NE, NE]	3/ 22 (13.6)	NE [19.68, NE]	0.68[0.17, 2.67]	0.576
Number of prior TKI therapies						
2	7/ 88 (8.0)	NE [NE, NE]	6/ 33 (18.2)	NE [NE, NE]	0.28[0.09, 0.85]	0.017
3	6/ 54 (11.1)	NE [NE, NE]	6/ 33 (18.2)	NE [19.68, NE]	0.52[0.16, 1.68]	0.270
>=4	1/ 14 (7.1)	NE [18.53, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	5/ 81 (6.2)	NE [NE, NE]	6/ 30 (20.0)	NE [NE, NE]	0.22[0.07, 0.73]	0.007
4	5/ 44 (11.4)	NE [NE, NE]	4/ 29 (13.8)	NE [19.68, NE]	0.58[0.15, 2.24]	0.421
>=5	4/ 31 (12.9)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	1.06[0.18, 6.33]	0.951
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	12/125 (9.6)	NE [NE, NE]	10/ 63 (15.9)	NE [NE, NE]	0.41[0.17, 0.97]	0.038
Mutant	0/ 17	NE [NE, NE]	1/ 8 (12.5)	NE [3.55, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	12/141 (8.5)	NE [NE, NE]	12/ 72 (16.7)	NE [NE, NE]	0.37[0.16, 0.83]	0.013
< 1%	2/ 15 (13.3)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Europe	3/ 89 (3.4)	NE [NE, NE]	8/ 45 (17.8)	NE [NE, NE]	0.13[0.03, 0.50]	<0.001
Others	11/ 67 (16.4)	NE [NE, NE]	4/ 31 (12.9)	NE [NE, NE]	1.07[0.33, 3.47]	0.904

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Alanine aminotransferase increased						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	8/ 22 (36.4)	NE [3.75, NE]	0.06[0.01, 0.29]	<0.001
No Major Cytogenetic Response	6/110 (5.5)	NE [NE, NE]	15/ 54 (27.8)	NE [NE, NE]	0.15[0.06, 0.39]	<0.001
Age category						
18 - 65 years	7/127 (5.5)	NE [NE, NE]	17/ 61 (27.9)	NE [NE, NE]	0.13[0.05, 0.31]	<0.001
>=65 years	1/ 29 (3.4)	NE [NE, NE]	6/ 15 (40.0)	NE [1.41, NE]	0.07[0.01, 0.59]	0.001
Sex						
Female	4/ 75 (5.3)	NE [NE, NE]	17/ 45 (37.8)	NE [3.71, NE]	0.08[0.03, 0.26]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Male	4/ 81 (4.9)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.20[0.06, 0.73]	0.007
Race						
Asian	0/ 22	NE [NE, NE]	2/ 11 (18.2)	NE [0.92, NE]	NE [NE, NE]	NE
Caucasian	6/118 (5.1)	NE [NE, NE]	18/ 57 (31.6)	NE [6.47, NE]	0.11[0.04, 0.28]	<0.001
Others	2/ 16 (12.5)	NE [NE, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.29[0.05, 1.75]	0.150
Reason for discontinuation of the last prior TKI						
Failure	6/ 94 (6.4)	NE [NE, NE]	15/ 54 (27.8)	NE [NE, NE]	0.14[0.05, 0.39]	<0.001
Intolerance	2/ 59 (3.4)	NE [NE, NE]	8/ 22 (36.4)	NE [3.25, NE]	0.07[0.01, 0.32]	<0.001
Number of prior TKI therapies						
2	3/ 88 (3.4)	NE [NE, NE]	8/ 33 (24.2)	NE [6.47, NE]	0.11[0.03, 0.41]	<0.001
3	3/ 54 (5.6)	NE [NE, NE]	13/ 33 (39.4)	NE [3.75, NE]	0.08[0.02, 0.34]	<0.001
>=4	2/ 14 (14.3)	NE [27.66, NE]	2/ 10 (20.0)	NE [0.72, NE]	0.38[0.03, 4.19]	0.411

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Line of therapy of randomized treatment						
3	2/ 81 (2.5)	NE [NE, NE]	7/ 30 (23.3)	NE [6.47, NE]	0.08[0.02, 0.39]	<0.001
4	2/ 44 (4.5)	NE [NE, NE]	13/ 29 (44.8)	NE [2.04, NE]	0.08[0.02, 0.35]	<0.001
>=5	4/ 31 (12.9)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	0.44[0.07, 2.64]	0.357
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	7/125 (5.6)	NE [NE, NE]	19/ 63 (30.2)	NE [NE, NE]	0.13[0.05, 0.31]	<0.001
Mutant	1/ 17 (5.9)	NE [9.23, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.13[0.01, 1.27]	0.040
BCR-ABL ratio at baseline						
>= 1%	7/141 (5.0)	NE [NE, NE]	21/ 72 (29.2)	NE [NE, NE]	0.12[0.05, 0.29]	<0.001
< 1%	1/ 15 (6.7)	NE [NE, NE]	2/ 4 (50.0)	4.60 [2.73, NE]	0.07[0.01, 0.83]	0.007
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Europe	5/ 89 (5.6)	NE [NE, NE]	15/ 45 (33.3)	NE [4.60, NE]	0.11[0.04, 0.31]	<0.001
Others	3/ 67 (4.5)	NE [NE, NE]	8/ 31 (25.8)	NE [NE, NE]	0.16[0.04, 0.59]	0.002

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Arthralgia						
Stratification factor by IRT						
Major Cytogenetic Response	12/ 46 (26.1)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
No Major Cytogenetic Response	11/110 (10.0)	NE [NE, NE]	2/ 54 (3.7)	NE [NE, NE]	2.09[0.46, 9.51]	0.328
Age category						
18 - 65 years	19/127 (15.0)	NE [NE, NE]	2/ 61 (3.3)	NE [NE, NE]	3.40[0.78, 14.76]	0.082
>=65 years	4/ 29 (13.8)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	11/ 75 (14.7)	NE [NE, NE]	1/ 45 (2.2)	NE [NE, NE]	3.85[0.48, 30.82]	0.173
Male	12/ 81 (14.8)	NE [NE, NE]	1/ 31 (3.2)	NE [NE, NE]	4.22[0.55, 32.63]	0.133

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	1/ 22 (4.5)	NE [NE, NE]	0/ 11	NE [NE, NE]	NE [NE, NE]	NE
Caucasian	21/118 (17.8)	NE [NE, NE]	1/ 57 (1.8)	NE [NE, NE]	8.75[1.17, 65.40]	0.011
Others	1/ 16 (6.3)	NE [NE, NE]	1/ 8 (12.5)	NE [1.41, NE]	0.51[0.03, 8.31]	0.627
Reason for discontinuation of the last prior TKI						
Failure	11/ 94 (11.7)	NE [NE, NE]	2/ 54 (3.7)	NE [NE, NE]	2.39[0.51, 11.12]	0.254
Intolerance	12/ 59 (20.3)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
Number of prior TKI therapies						
2	13/ 88 (14.8)	NE [NE, NE]	0/ 33	NE [NE, NE]	NE [NE, NE]	NE
3	8/ 54 (14.8)	NE [NE, NE]	1/ 33 (3.0)	NE [NE, NE]	4.49[0.56, 36.39]	0.123
>=4	2/ 14 (14.3)	NE [32.26, NE]	1/ 10 (10.0)	NE [0.82, NE]	NE [NE, NE]	0.273

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	13/ 81 (16.0)	NE [NE, NE]	0/ 30	NE [NE, NE]	NE [NE, NE]	NE
4	7/ 44 (15.9)	NE [NE, NE]	0/ 29	NE [NE, NE]	NE [NE, NE]	NE
>=5	3/ 31 (9.7)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	0.29[0.03, 2.54]	0.247
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	20/125 (16.0)	NE [NE, NE]	2/ 63 (3.2)	NE [NE, NE]	3.87[0.90, 16.74]	0.051
Mutant	2/ 17 (11.8)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	20/141 (14.2)	NE [NE, NE]	2/ 72 (2.8)	NE [NE, NE]	4.10[0.95, 17.71]	0.041
< 1%	3/ 15 (20.0)	NE [14.23, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Europe	15/ 89 (16.9)	NE [NE, NE]	1/ 45 (2.2)	NE [NE, NE]	6.76[0.88, 51.76]	0.034
Others	8/ 67 (11.9)	NE [NE, NE]	1/ 31 (3.2)	NE [NE, NE]	2.45[0.30, 20.19]	0.389

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Aspartate aminotransferase increased						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	7/ 22 (31.8)	NE [6.54, NE]	0.08[0.02, 0.40]	<0.001
No Major Cytogenetic Response	7/110 (6.4)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	0.33[0.12, 0.88]	0.020
Age category						
18 - 65 years	8/127 (6.3)	NE [NE, NE]	11/ 61 (18.0)	NE [NE, NE]	0.25[0.10, 0.63]	0.002
>=65 years	1/ 29 (3.4)	NE [NE, NE]	5/ 15 (33.3)	NE [1.91, NE]	0.09[0.01, 0.75]	0.005
Sex						
Female	2/ 75 (2.7)	NE [NE, NE]	9/ 45 (20.0)	NE [NE, NE]	0.08[0.02, 0.41]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Male	7/ 81 (8.6)	NE [NE, NE]	7/ 31 (22.6)	NE [NE, NE]	0.34[0.12, 0.98]	0.037
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	2/ 11 (18.2)	NE [0.92, NE]	0.50[0.06, 4.34]	0.527
Caucasian	5/118 (4.2)	NE [NE, NE]	11/ 57 (19.3)	NE [NE, NE]	0.16[0.06, 0.48]	<0.001
Others	2/ 16 (12.5)	NE [NE, NE]	3/ 8 (37.5)	NE [1.87, NE]	0.33[0.06, 1.99]	0.205
Reason for discontinuation of the last prior TKI						
Failure	5/ 94 (5.3)	NE [NE, NE]	8/ 54 (14.8)	NE [NE, NE]	0.25[0.08, 0.85]	0.017
Intolerance	4/ 59 (6.8)	NE [NE, NE]	8/ 22 (36.4)	NE [6.54, NE]	0.14[0.04, 0.46]	<0.001
Number of prior TKI therapies						
2	3/ 88 (3.4)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.13[0.03, 0.50]	<0.001
3	5/ 54 (9.3)	NE [NE, NE]	9/ 33 (27.3)	NE [7.33, NE]	0.30[0.10, 0.89]	0.022
>=4	1/ 14 (7.1)	NE [27.66, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	2/ 81 (2.5)	NE [NE, NE]	6/ 30 (20.0)	NE [6.60, NE]	0.10[0.02, 0.49]	<0.001
4	5/ 44 (11.4)	NE [NE, NE]	9/ 29 (31.0)	NE [6.54, NE]	0.33[0.11, 0.99]	0.037
>=5	2/ 31 (6.5)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	0.76[0.05, 12.11]	0.844
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	7/125 (5.6)	NE [NE, NE]	13/ 63 (20.6)	NE [NE, NE]	0.20[0.08, 0.52]	<0.001
Mutant	2/ 17 (11.8)	NE [9.23, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.27[0.04, 1.62]	0.124
BCR-ABL ratio at baseline						
>= 1%	9/141 (6.4)	NE [NE, NE]	14/ 72 (19.4)	NE [NE, NE]	0.26[0.11, 0.60]	<0.001
< 1%	0/ 15	NE [NE, NE]	2/ 4 (50.0)	7.33 [2.73, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Europe	4/ 89 (4.5)	NE [NE, NE]	9/ 45 (20.0)	NE [NE, NE]	0.17[0.05, 0.57]	0.001
Others	5/ 67 (7.5)	NE [NE, NE]	7/ 31 (22.6)	NE [NE, NE]	0.29[0.09, 0.92]	0.026

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Diarrhoea						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	17/ 22 (77.3)	0.20 [0.03, 0.95]	0.05[0.02, 0.15]	<0.001
No Major Cytogenetic Response	16/110 (14.5)	NE [NE, NE]	38/ 54 (70.4)	0.28 [0.16, 0.72]	0.11[0.06, 0.20]	<0.001
Age category						
18 - 65 years	16/127 (12.6)	NE [NE, NE]	44/ 61 (72.1)	0.26 [0.10, 0.72]	0.09[0.05, 0.16]	<0.001
>=65 years	4/ 29 (13.8)	NE [NE, NE]	11/ 15 (73.3)	0.33 [0.03, 6.44]	0.12[0.04, 0.39]	<0.001
Sex						
Female	9/ 75 (12.0)	NE [NE, NE]	30/ 45 (66.7)	0.26 [0.07, 0.72]	0.09[0.04, 0.20]	<0.001
Male	11/ 81 (13.6)	NE [NE, NE]	25/ 31 (80.6)	0.49 [0.10, 0.95]	0.08[0.04, 0.16]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	9/ 11 (81.8)	0.26 [0.07, 2.79]	0.03[0.00, 0.24]	<0.001
Caucasian	15/118 (12.7)	NE [NE, NE]	40/ 57 (70.2)	0.30 [0.10, 0.76]	0.10[0.05, 0.18]	<0.001
Others	3/ 16 (18.8)	NE [NE, NE]	6/ 8 (75.0)	0.28 [0.03, NE]	0.04[0.00, 0.34]	<0.001
Reason for discontinuation of the last prior TKI						
Failure	10/ 94 (10.6)	NE [NE, NE]	37/ 54 (68.5)	0.30 [0.10, 1.02]	0.08[0.04, 0.17]	<0.001
Intolerance	9/ 59 (15.3)	NE [NE, NE]	18/ 22 (81.8)	0.21 [0.07, 0.76]	0.09[0.04, 0.21]	<0.001
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	24/ 33 (72.7)	0.30 [0.07, 0.95]	0.07[0.03, 0.15]	<0.001
3	8/ 54 (14.8)	NE [NE, NE]	24/ 33 (72.7)	0.10 [0.07, 0.49]	0.12[0.05, 0.26]	<0.001
>=4	3/ 14 (21.4)	NE [19.94, NE]	7/ 10 (70.0)	0.51 [0.03, NE]	0.15[0.03, 0.72]	0.007

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Line of therapy of randomized treatment							
3	8/ 81 (9.9)	NE [NE, NE]	22/ 30 (73.3)	0.39 [0.07, 4.44]	0.06	[0.03, 0.14]	<0.001
4	6/ 44 (13.6)	NE [NE, NE]	21/ 29 (72.4)	0.26 [0.07, 1.02]	0.12	[0.05, 0.29]	<0.001
>=5	6/ 31 (19.4)	NE [NE, NE]	12/ 17 (70.6)	0.26 [0.03, 2.79]	0.17	[0.06, 0.49]	<0.001
With or without Week1 Day 1 BCR-ABL1 mutation							
Wild type	18/125 (14.4)	NE [NE, NE]	49/ 63 (77.8)	0.26 [0.10, 0.49]	0.09	[0.05, 0.15]	<0.001
Mutant	1/ 17 (5.9)	NE [NE, NE]	4/ 8 (50.0)	6.44 [0.03, NE]	0.11	[0.01, 0.96]	0.016
BCR-ABL ratio at baseline							
>= 1%	19/141 (13.5)	NE [NE, NE]	51/ 72 (70.8)	0.28 [0.13, 0.72]	0.10	[0.06, 0.17]	<0.001
< 1%	1/ 15 (6.7)	NE [NE, NE]	4/ 4 (100)	0.30 [0.03, NE]	0.03	[0.00, 0.32]	<0.001
Geographic region							

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Europe	7/ 89 (7.9)	NE [NE, NE]	30/ 45 (66.7)	0.36 [0.07, 4.44]	0.06	[0.02, 0.14]	<0.001
Others	13/ 67 (19.4)	NE [NE, NE]	25/ 31 (80.6)	0.26 [0.07, 0.72]	0.12	[0.06, 0.25]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Nausea						
Stratification factor by IRT						
Major Cytogenetic Response	5/ 46 (10.9)	NE [NE, NE]	11/ 22 (50.0)	NE [0.07, NE]	0.12[0.04, 0.36]	<0.001
No Major Cytogenetic Response	13/110 (11.8)	NE [NE, NE]	24/ 54 (44.4)	NE [1.87, NE]	0.19[0.09, 0.37]	<0.001
Age category						
18 - 65 years	14/127 (11.0)	NE [NE, NE]	29/ 61 (47.5)	4.60 [1.35, NE]	0.15[0.08, 0.29]	<0.001
>=65 years	4/ 29 (13.8)	NE [NE, NE]	6/ 15 (40.0)	NE [0.03, NE]	0.27[0.08, 0.96]	0.031
Sex						
Female	10/ 75 (13.3)	NE [NE, NE]	22/ 45 (48.9)	4.60 [0.62, NE]	0.16[0.07, 0.35]	<0.001
Male	8/ 81 (9.9)	NE [NE, NE]	13/ 31 (41.9)	NE [0.92, NE]	0.17[0.07, 0.41]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	1/ 22 (4.5)	NE [NE, NE]	3/ 11 (27.3)	NE [0.26, NE]	0.12[0.01, 1.23]	0.040
Caucasian	15/118 (12.7)	NE [NE, NE]	27/ 57 (47.4)	NE [0.62, NE]	0.18[0.10, 0.35]	<0.001
Others	2/ 16 (12.5)	NE [NE, NE]	5/ 8 (62.5)	1.87 [0.49, NE]	0.11[0.02, 0.61]	0.003
Reason for discontinuation of the last prior TKI						
Failure	5/ 94 (5.3)	NE [NE, NE]	22/ 54 (40.7)	NE [3.02, NE]	0.10[0.04, 0.28]	<0.001
Intolerance	13/ 59 (22.0)	NE [NE, NE]	13/ 22 (59.1)	1.43 [0.26, NE]	0.22[0.10, 0.50]	<0.001
Number of prior TKI therapies						
2	10/ 88 (11.4)	NE [NE, NE]	13/ 33 (39.4)	NE [0.49, NE]	0.20[0.08, 0.45]	<0.001
3	5/ 54 (9.3)	NE [NE, NE]	19/ 33 (57.6)	2.37 [0.49, NE]	0.09[0.03, 0.27]	<0.001
>=4	3/ 14 (21.4)	NE [11.99, NE]	3/ 10 (30.0)	NE [0.26, NE]	0.37[0.05, 2.49]	0.290

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	8/ 81 (9.9)	NE [NE, NE]	13/ 30 (43.3)	NE [0.30, NE]	0.15[0.06, 0.37]	<0.001
4	5/ 44 (11.4)	NE [NE, NE]	15/ 29 (51.7)	3.02 [0.36, NE]	0.16[0.06, 0.45]	<0.001
>=5	5/ 31 (16.1)	NE [NE, NE]	7/ 17 (41.2)	NE [0.99, NE]	0.25[0.07, 0.92]	0.026
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	17/125 (13.6)	NE [NE, NE]	30/ 63 (47.6)	NE [0.95, NE]	0.18[0.10, 0.34]	<0.001
Mutant	0/ 17	NE [NE, NE]	4/ 8 (50.0)	NE [0.07, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	17/141 (12.1)	NE [NE, NE]	32/ 72 (44.4)	NE [1.64, NE]	0.18[0.10, 0.33]	<0.001
< 1%	1/ 15 (6.7)	NE [NE, NE]	3/ 4 (75.0)	0.43 [0.03, NE]	NE [NE, NE]	<0.001
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Europe	5/ 89 (5.6)	NE [NE, NE]	20/ 45 (44.4)	NE [0.49, NE]	0.08[0.03, 0.23]	<0.001
Others	13/ 67 (19.4)	NE [NE, NE]	15/ 31 (48.4)	3.45 [1.35, NE]	0.30[0.14, 0.66]	0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Rash						
Stratification factor by IRT						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	8/ 22 (36.4)	NE [1.22, NE]	0.07[0.01, 0.30]	<0.001
No Major Cytogenetic Response	12/110 (10.9)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.50[0.21, 1.16]	0.098
Age category						
18 - 65 years	14/127 (11.0)	NE [NE, NE]	15/ 61 (24.6)	NE [NE, NE]	0.32[0.15, 0.68]	0.002
>=65 years	1/ 29 (3.4)	NE [NE, NE]	3/ 15 (20.0)	NE [7.10, NE]	0.14[0.01, 1.33]	0.045
Sex						
Female	8/ 75 (10.7)	NE [NE, NE]	13/ 45 (28.9)	NE [7.10, NE]	0.20[0.07, 0.52]	<0.001
Male	7/ 81 (8.6)	NE [NE, NE]	5/ 31 (16.1)	NE [NE, NE]	0.53[0.17, 1.66]	0.264

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	0/ 22	NE [NE, NE]	3/ 11 (27.3)	NE [0.95, NE]	NE [NE, NE]	NE
Caucasian	12/118 (10.2)	NE [NE, NE]	15/ 57 (26.3)	NE [NE, NE]	0.28[0.13, 0.62]	<0.001
Others	3/ 16 (18.8)	NE [32.56, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	9/ 94 (9.6)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.36[0.13, 0.94]	0.029
Intolerance	6/ 59 (10.2)	NE [NE, NE]	8/ 22 (36.4)	NE [6.37, NE]	0.20[0.07, 0.58]	0.001
Number of prior TKI therapies						
2	6/ 88 (6.8)	NE [NE, NE]	8/ 33 (24.2)	NE [NE, NE]	0.22[0.07, 0.63]	0.002
3	7/ 54 (13.0)	NE [NE, NE]	6/ 33 (18.2)	NE [NE, NE]	0.54[0.17, 1.69]	0.282
>=4	2/ 14 (14.3)	NE [20.01, NE]	4/ 10 (40.0)	NE [0.13, NE]	0.13[0.01, 1.22]	0.038

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

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- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Final

Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Line of therapy of randomized treatment						
3	5/ 81 (6.2)	NE [NE, NE]	8/ 30 (26.7)	NE [7.10, NE]	0.18[0.06, 0.55]	<0.001
4	4/ 44 (9.1)	NE [NE, NE]	5/ 29 (17.2)	NE [NE, NE]	0.46[0.12, 1.73]	0.238
>=5	6/ 31 (19.4)	NE [32.56, NE]	5/ 17 (29.4)	NE [3.29, NE]	0.32[0.07, 1.35]	0.102
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	12/125 (9.6)	NE [NE, NE]	15/ 63 (23.8)	NE [NE, NE]	0.29[0.13, 0.64]	0.001
Mutant	3/ 17 (17.6)	NE [32.56, NE]	2/ 8 (25.0)	NE [1.64, NE]	0.51[0.07, 3.63]	0.493
BCR-ABL ratio at baseline						
>= 1%	15/141 (10.6)	NE [NE, NE]	16/ 72 (22.2)	NE [NE, NE]	0.34[0.16, 0.71]	0.003
< 1%	0/ 15	NE [NE, NE]	2/ 4 (50.0)	7.10 [0.82, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Europe	6/ 89 (6.7)	NE [NE, NE]	12/ 45 (26.7)	NE [NE, NE]	0.18[0.07, 0.50]	<0.001
Others	9/ 67 (13.4)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.48[0.16, 1.40]	0.170

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

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/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

Final

Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Vomiting						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	6/ 22 (27.3)	NE [3.55, NE]	0.08[0.02, 0.45]	<0.001
No Major Cytogenetic Response	10/110 (9.1)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	0.29[0.13, 0.66]	0.002
Age category						
18 - 65 years	11/127 (8.7)	NE [NE, NE]	16/ 61 (26.2)	NE [NE, NE]	0.25[0.11, 0.54]	<0.001
>=65 years	1/ 29 (3.4)	NE [NE, NE]	4/ 15 (26.7)	NE [0.36, NE]	0.11[0.01, 1.01]	0.019
Sex						
Female	9/ 75 (12.0)	NE [NE, NE]	14/ 45 (31.1)	NE [NE, NE]	0.26[0.11, 0.61]	0.001
Male	3/ 81 (3.7)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.18[0.04, 0.71]	0.006

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	1/ 22 (4.5)	NE [NE, NE]	3/ 11 (27.3)	NE [0.33, NE]	0.15[0.01, 1.59]	0.077
Caucasian	10/118 (8.5)	NE [NE, NE]	14/ 57 (24.6)	NE [NE, NE]	0.27[0.12, 0.61]	<0.001
Others	1/ 16 (6.3)	NE [NE, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.17[0.02, 1.71]	0.092
Reason for discontinuation of the last prior TKI						
Failure	5/ 94 (5.3)	NE [NE, NE]	12/ 54 (22.2)	NE [NE, NE]	0.19[0.07, 0.54]	<0.001
Intolerance	7/ 59 (11.9)	NE [NE, NE]	8/ 22 (36.4)	NE [0.46, NE]	0.27[0.10, 0.76]	0.008
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	8/ 33 (24.2)	NE [NE, NE]	0.34[0.13, 0.89]	0.023
3	2/ 54 (3.7)	NE [NE, NE]	10/ 33 (30.3)	NE [4.63, NE]	0.08[0.02, 0.40]	<0.001
>=4	1/ 14 (7.1)	NE [10.94, NE]	2/ 10 (20.0)	NE [0.39, NE]	NE [NE, NE]	0.118

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	7/ 81 (8.6)	NE [NE, NE]	7/ 30 (23.3)	NE [NE, NE]	0.30[0.10, 0.86]	0.018
4	4/ 44 (9.1)	NE [NE, NE]	10/ 29 (34.5)	NE [2.96, NE]	0.19[0.06, 0.64]	0.003
>=5	1/ 31 (3.2)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	NE [NE, NE]	0.036
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	11/125 (8.8)	NE [NE, NE]	19/ 63 (30.2)	NE [NE, NE]	0.22[0.10, 0.46]	<0.001
Mutant	0/ 17	NE [NE, NE]	1/ 8 (12.5)	NE [4.63, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	11/141 (7.8)	NE [NE, NE]	19/ 72 (26.4)	NE [NE, NE]	0.24[0.11, 0.50]	<0.001
< 1%	1/ 15 (6.7)	NE [NE, NE]	1/ 4 (25.0)	NE [0.39, NE]	0.17[0.01, 3.04]	0.178
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.1.3 Any AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Europe	3/ 89 (3.4)	NE [NE, NE]	10/ 45 (22.2)	NE [NE, NE]	0.10[0.03, 0.39]	<0.001
Others	9/ 67 (13.4)	NE [NE, NE]	10/ 31 (32.3)	NE [2.96, NE]	0.39[0.16, 0.97]	0.036

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

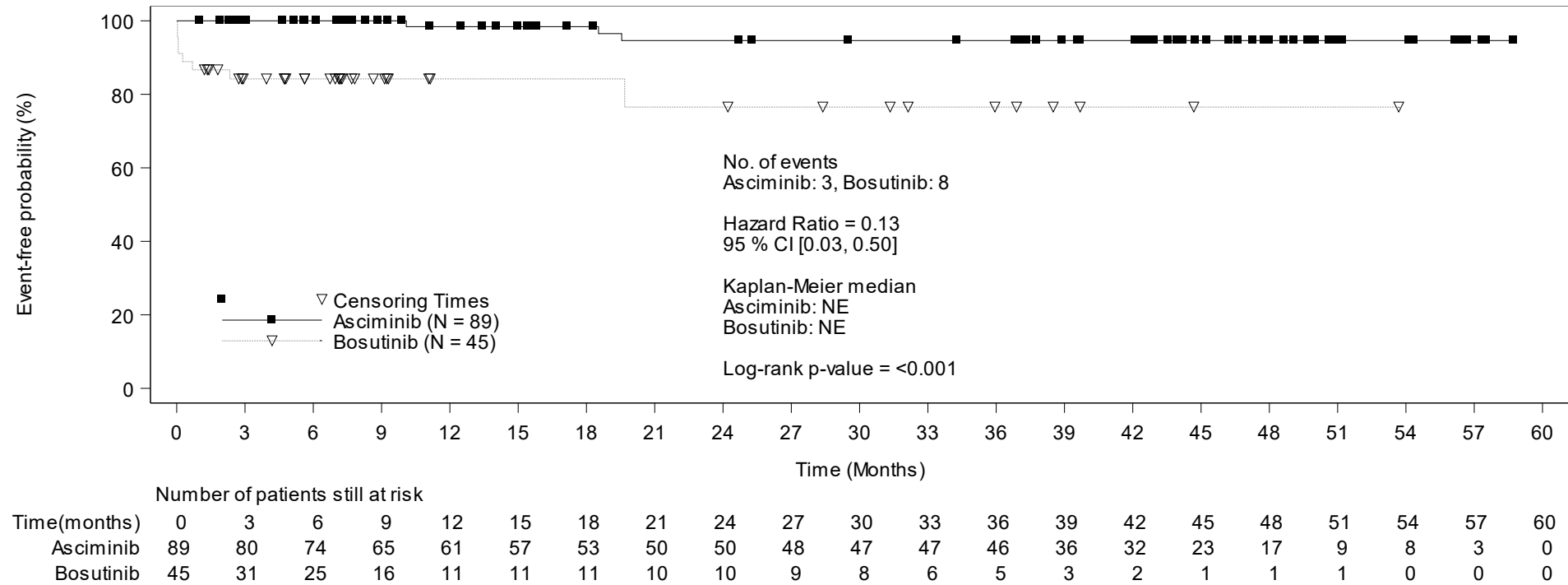
Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_1_3.sas@@/main/2 22NOV23:15:28

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Figure 5-3.1.3 Any AE by PT: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

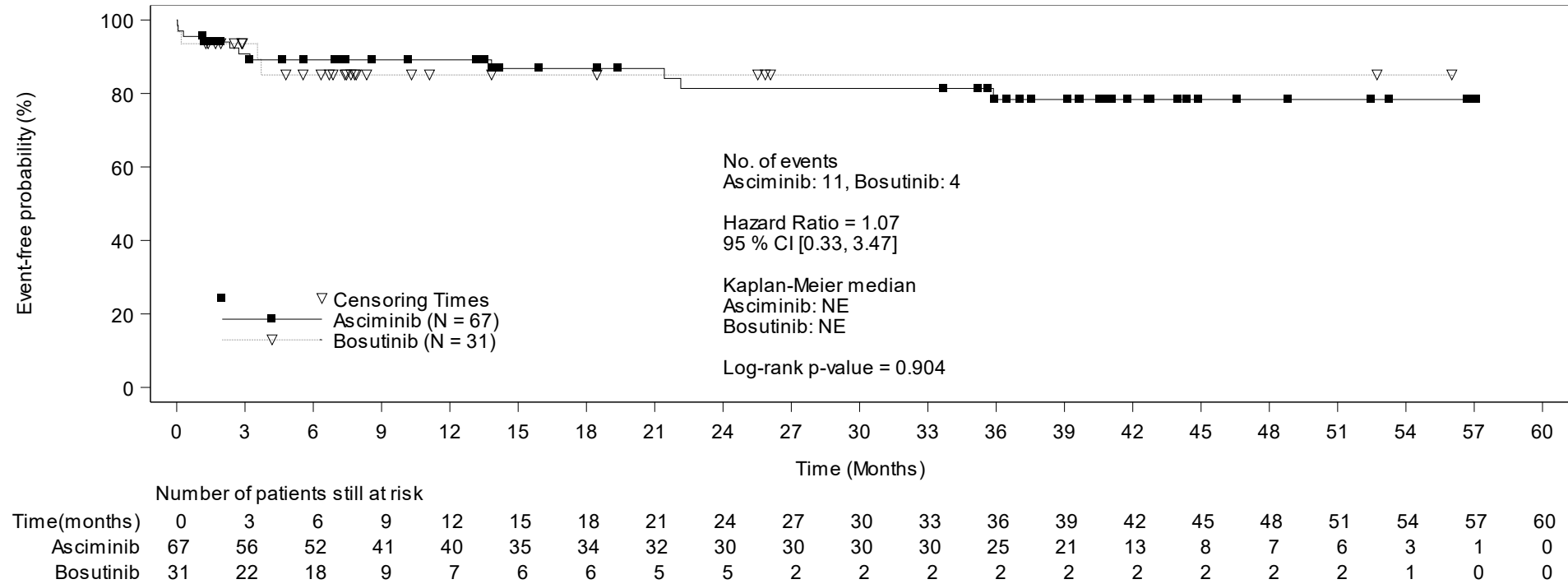
PT: Abdominal pain - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup Missing will not be analyzed for any of the attributes.
Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

Figure 5-3.1.3 Any AE by PT: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

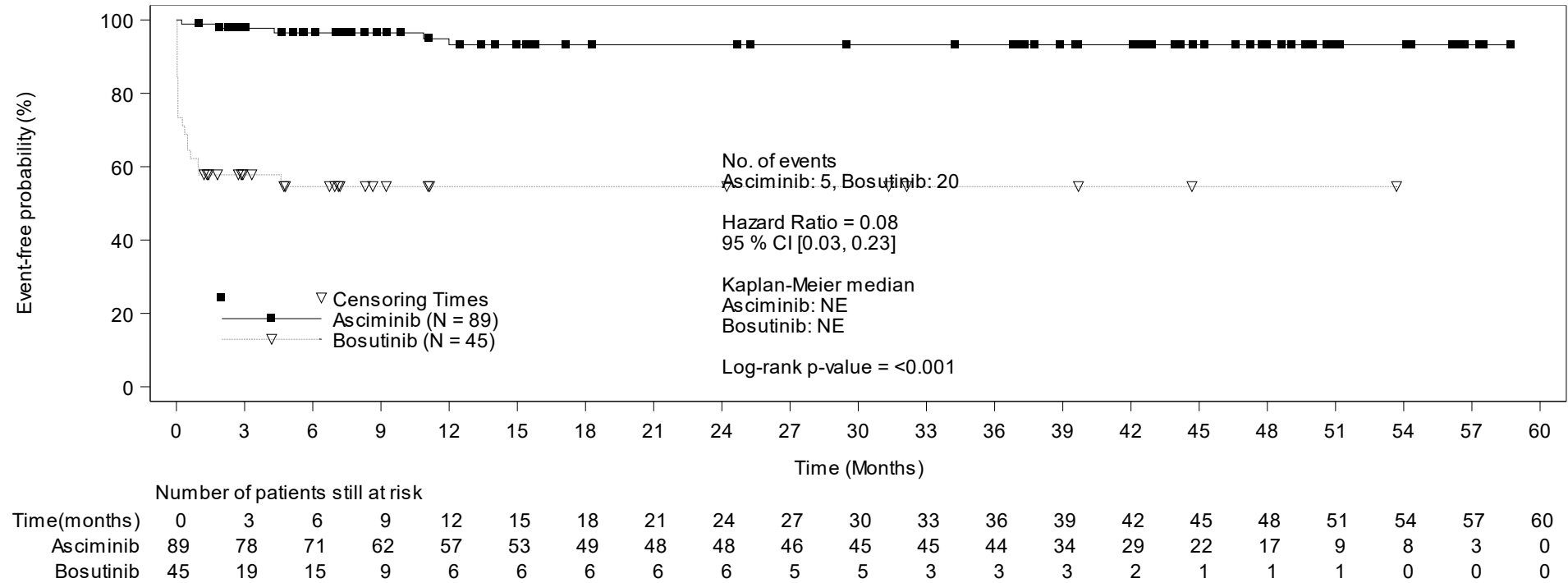
PT: Abdominal pain - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup Missing will not be analyzed for any of the attributes.
Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

Figure 5-3.1.3 Any AE by PT: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

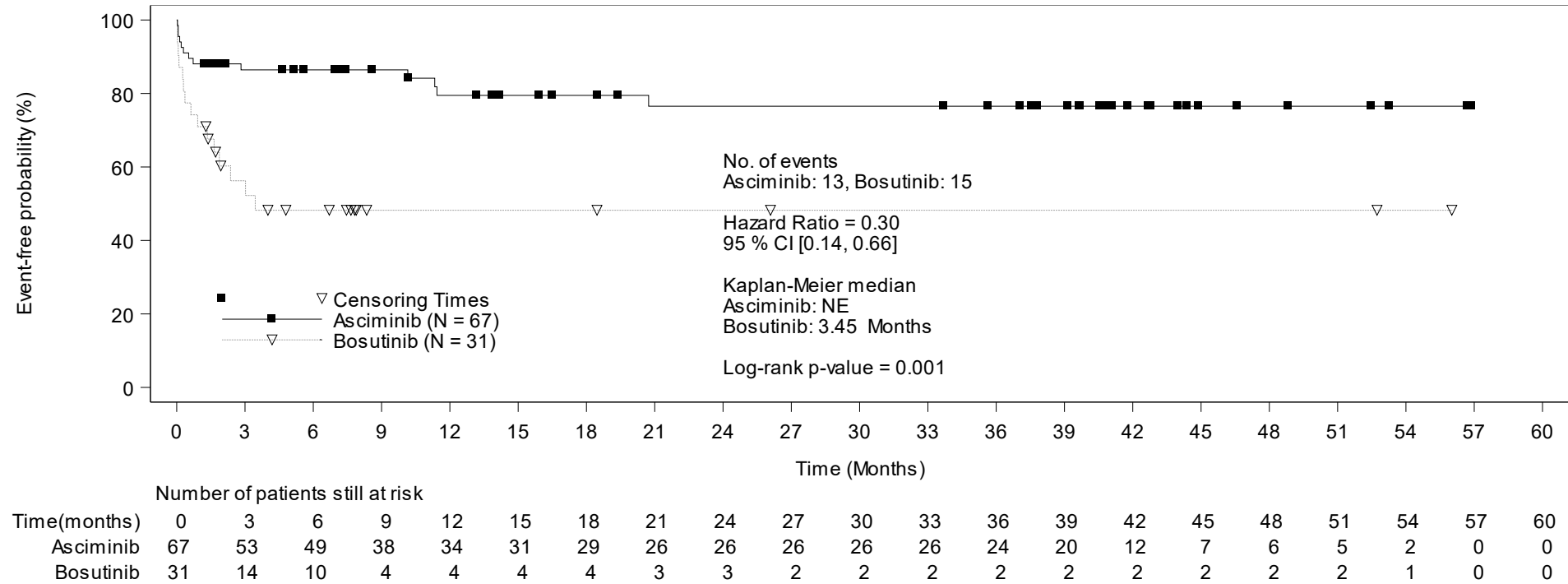
PT: Nausea - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup Missing will not be analyzed for any of the attributes.
Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

Figure 5-3.1.3 Any AE by PT: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

PT: Nausea - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.
- events in at least 10% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup Missing will not be analyzed for any of the attributes.
Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

Table 5-3.2.1 Grade ≥3 AE: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Stratification factor by IRT						
Major Cytogenetic Response	22/ 46 (47.8)	43.73 [15.21, NE]	14/ 22 (63.6)	6.03 [0.95, 18.43]	0.46[0.23, 0.91]	0.023
No Major Cytogenetic Response	71/110 (64.5)	3.68 [1.87, 10.05]	38/ 54 (70.4)	3.48 [1.41, 7.39]	0.79[0.53, 1.17]	0.226
Age category						
18 - 65 years	73/127 (57.5)	10.05 [3.68, 36.80]	38/ 61 (62.3)	3.48 [1.41, 9.26]	0.73[0.49, 1.08]	0.111
≥65 years	20/ 29 (69.0)	9.23 [1.41, 21.19]	14/ 15 (93.3)	4.17 [0.36, 7.39]	0.62[0.31, 1.26]	0.176
Sex						
Female	43/ 75 (57.3)	15.21 [4.83, 37.75]	30/ 45 (66.7)	3.06 [0.95, 8.31]	0.56[0.35, 0.90]	0.015
Male	50/ 81 (61.7)	7.39 [2.10, 15.64]	22/ 31 (71.0)	5.68 [1.84, 18.43]	0.88[0.53, 1.47]	0.628
Race						
Asian	12/ 22 (54.5)	24.21 [1.41, NE]	7/ 11 (63.6)	0.66 [0.30, NE]	0.63[0.22, 1.80]	0.376
Caucasian	71/118 (60.2)	9.40 [2.79, 18.43]	37/ 57 (64.9)	4.17 [1.84, 16.89]	0.75[0.50, 1.13]	0.166
Others	10/ 16 (62.5)	6.57 [0.95, NE]	8/ 8 (100)	2.68 [0.16, 8.31]	0.50[0.19, 1.31]	0.152

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.2.1 Grade ≥3 AE: time to first event - subgroup analysis
 Safety Set
 (Page 2 of 3)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Reason for discontinuation of the last prior TKI						
Failure	52/ 94 (55.3)	14.82 [6.08, 36.80]	34/ 54 (63.0)	3.65 [1.84, 9.26]	0.64 [0.41, 1.00]	0.047
Intolerance	39/ 59 (66.1)	3.25 [1.41, 30.98]	18/ 22 (81.8)	2.37 [0.62, 9.23]	0.73 [0.42, 1.29]	0.274
Number of prior TKI therapies						
2	51/ 88 (58.0)	10.74 [4.93, 31.38]	24/ 33 (72.7)	6.60 [0.95, 18.43]	0.63 [0.38, 1.02]	0.057
3	36/ 54 (66.7)	3.68 [1.84, 14.82]	24/ 33 (72.7)	2.10 [0.95, 5.68]	0.67 [0.39, 1.15]	0.140
≥4	6/ 14 (42.9)	NE [0.20, NE]	4/ 10 (40.0)	NE [0.36, NE]	1.51 [0.43, 5.38]	0.526
Line of therapy of randomized treatment						
3	47/ 81 (58.0)	10.05 [4.83, 24.21]	21/ 30 (70.0)	7.39 [1.84, 18.43]	0.75 [0.45, 1.25]	0.261
4	30/ 44 (68.2)	7.39 [1.64, 36.80]	22/ 29 (75.9)	1.84 [0.82, 5.68]	0.54 [0.30, 0.96]	0.033
≥5	16/ 31 (51.6)	9.40 [1.87, NE]	9/ 17 (52.9)	4.17 [0.95, NE]	1.15 [0.49, 2.68]	0.758

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.2.1 Grade ≥3 AE: time to first event - subgroup analysis
 Safety Set
 (Page 3 of 3)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	82/125 (65.6)	4.93 [2.10, 14.82]	45/ 63 (71.4)	2.83 [1.18, 9.23]	0.75[0.52, 1.08]	0.117
Mutant	7/ 17 (41.2)	21.19 [3.68, NE]	5/ 8 (62.5)	4.93 [0.95, NE]	0.56[0.17, 1.81]	0.320
BCR-ABL ratio at baseline						
≥ 1%	86/141 (61.0)	7.43 [2.37, 18.43]	48/ 72 (66.7)	3.48 [1.84, 8.31]	0.75[0.52, 1.06]	0.102
< 1%	7/ 15 (46.7)	NE [1.64, NE]	4/ 4 (100)	5.03 [0.30, NE]	0.26[0.07, 0.99]	0.031
Geographic region						
Europe	52/ 89 (58.4)	10.05 [3.25, 30.98]	31/ 45 (68.9)	4.70 [1.87, 16.89]	0.66[0.42, 1.03]	0.063
Others	41/ 67 (61.2)	7.39 [1.84, 36.80]	21/ 31 (67.7)	2.10 [0.82, 6.60]	0.80[0.47, 1.37]	0.415

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.2.1 Grade ≥ 3 AE: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Table 5-3.2.2 Grade ≥3 AE by SOC: time to first event - subgroup analysis
 Safety Set
 (Page 1 of 8)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Gastrointestinal disorders						
Stratification factor by IRT						
Major Cytogenetic Response	1/ 46 (2.2)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.11[0.01, 1.15]	0.029
No Major Cytogenetic Response	7/110 (6.4)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	0.25[0.09, 0.70]	0.005
Age category						
18 - 65 years	6/127 (4.7)	NE [NE, NE]	9/ 61 (14.8)	NE [NE, NE]	0.21[0.07, 0.62]	0.002
≥65 years	2/ 29 (6.9)	NE [NE, NE]	3/ 15 (20.0)	NE [0.82, NE]	0.23[0.04, 1.45]	0.092
Sex						
Female	5/ 75 (6.7)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.32[0.09, 1.11]	0.061
Male	3/ 81 (3.7)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.13[0.03, 0.55]	0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	2/ 11 (18.2)	NE [0.36, NE]	0.28[0.02, 3.21]	0.277
Caucasian	6/118 (5.1)	NE [NE, NE]	9/ 57 (15.8)	NE [NE, NE]	0.22[0.08, 0.64]	0.003
Others	0/ 16	NE [NE, NE]	1/ 8 (12.5)	NE [3.06, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	6/ 94 (6.4)	NE [NE, NE]	8/ 54 (14.8)	NE [NE, NE]	0.27[0.09, 0.83]	0.016
Intolerance	2/ 59 (3.4)	NE [NE, NE]	4/ 22 (18.2)	NE [NE, NE]	0.14[0.02, 0.78]	0.010
Number of prior TKI therapies						
2	5/ 88 (5.7)	NE [NE, NE]	5/ 33 (15.2)	NE [NE, NE]	0.17[0.04, 0.68]	0.006
3	2/ 54 (3.7)	NE [NE, NE]	6/ 33 (18.2)	NE [NE, NE]	0.15[0.03, 0.78]	0.010
≥ 4	1/ 14 (7.1)	NE [NE, NE]	1/ 10 (10.0)	NE [0.36, NE]	0.82[0.05, 13.06]	0.886

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_2_2.sas@@/main/2 22NOV23:15:28

Final

Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
 Safety Set
 (Page 3 of 8)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Line of therapy of randomized treatment						
3	3/ 81 (3.7)	NE [NE, NE]	4/ 30 (13.3)	NE [NE, NE]	0.18[0.04, 0.88]	0.018
4	3/ 44 (6.8)	NE [46.55, NE]	7/ 29 (24.1)	NE [NE, NE]	0.19[0.05, 0.77]	0.010
≥ 5	2/ 31 (6.5)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	0.86[0.06, 11.52]	0.911
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	8/125 (6.4)	NE [NE, NE]	10/ 63 (15.9)	NE [NE, NE]	0.24[0.09, 0.64]	0.002
Mutant	0/ 17	NE [NE, NE]	1/ 8 (12.5)	NE [3.55, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	8/141 (5.7)	NE [NE, NE]	12/ 72 (16.7)	NE [NE, NE]	0.23[0.09, 0.57]	<0.001
< 1%	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Europe	2/ 89 (2.2)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.11[0.02, 0.58]	0.003
Others	6/ 67 (9.0)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.37[0.12, 1.16]	0.076

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_2_2.sas@@/main/2 22NOV23:15:28

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Table 5-3.2.2 Grade ≥3 AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Investigations						
Stratification factor by IRT						
Major Cytogenetic Response	5/ 46 (10.9)	NE [NE, NE]	8/ 22 (36.4)	NE [2.10, NE]	0.20[0.06, 0.62]	0.002
No Major Cytogenetic Response	23/110 (20.9)	NE [NE, NE]	16/ 54 (29.6)	NE [6.60, NE]	0.59[0.31, 1.12]	0.104
Age category						
18 - 65 years	22/127 (17.3)	NE [NE, NE]	17/ 61 (27.9)	NE [9.23, NE]	0.48[0.25, 0.90]	0.020
≥65 years	6/ 29 (20.7)	NE [33.38, NE]	7/ 15 (46.7)	NE [1.87, NE]	0.40[0.13, 1.21]	0.094
Sex						
Female	11/ 75 (14.7)	NE [NE, NE]	14/ 45 (31.1)	NE [4.17, NE]	0.40[0.18, 0.89]	0.020
Male	17/ 81 (21.0)	NE [NE, NE]	10/ 31 (32.3)	NE [6.60, NE]	0.55[0.25, 1.20]	0.128

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Race						
Asian	6/ 22 (27.3)	NE [7.39, NE]	4/ 11 (36.4)	NE [0.92, NE]	0.81[0.21, 3.03]	0.750
Caucasian	21/118 (17.8)	NE [NE, NE]	16/ 57 (28.1)	NE [NE, NE]	0.49[0.26, 0.95]	0.032
Others	1/ 16 (6.3)	NE [NE, NE]	4/ 8 (50.0)	NE [0.26, NE]	0.11[0.01, 0.99]	0.018
Reason for discontinuation of the last prior TKI						
Failure	11/ 94 (11.7)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	0.32[0.14, 0.74]	0.005
Intolerance	17/ 59 (28.8)	NE [NE, NE]	10/ 22 (45.5)	NE [1.91, NE]	0.57[0.26, 1.24]	0.146
Number of prior TKI therapies						
2	14/ 88 (15.9)	NE [NE, NE]	11/ 33 (33.3)	NE [6.47, NE]	0.38[0.17, 0.84]	0.012
3	10/ 54 (18.5)	NE [NE, NE]	11/ 33 (33.3)	NE [3.75, NE]	0.45[0.19, 1.06]	0.060
≥ 4	4/ 14 (28.6)	NE [1.74, NE]	2/ 10 (20.0)	NE [2.23, NE]	2.00[0.36, 10.92]	0.417

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Line of therapy of randomized treatment						
3	13/ 81 (16.0)	NE [NE, NE]	10/ 30 (33.3)	NE [6.47, NE]	0.39[0.17, 0.89]	0.020
4	8/ 44 (18.2)	NE [NE, NE]	11/ 29 (37.9)	NE [1.91, NE]	0.34[0.14, 0.85]	0.016
≥ 5	7/ 31 (22.6)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	1.73[0.44, 6.85]	0.427
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	24/125 (19.2)	NE [NE, NE]	20/ 63 (31.7)	NE [9.23, NE]	0.50[0.28, 0.91]	0.020
Mutant	3/ 17 (17.6)	NE [7.43, NE]	2/ 8 (25.0)	NE [0.95, NE]	0.68[0.11, 4.06]	0.667
BCR-ABL ratio at baseline						
$\geq 1\%$	27/141 (19.1)	NE [NE, NE]	22/ 72 (30.6)	NE [NE, NE]	0.51[0.29, 0.89]	0.017
$< 1\%$	1/ 15 (6.7)	NE [NE, NE]	2/ 4 (50.0)	NE [1.25, NE]	0.13[0.01, 1.44]	0.050
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.2 Grade ≥ 3 AE by SOC: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Europe	11/ 89 (12.4)	NE [NE, NE]	13/ 45 (28.9)	NE [9.23, NE]	0.30[0.13, 0.67]	0.002
Others	17/ 67 (25.4)	NE [NE, NE]	11/ 31 (35.5)	NE [3.65, NE]	0.68[0.32, 1.47]	0.331

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

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Figure 5-3.2.2 Grade ≥ 3 AE by SOC: Kaplan Meier plot of time to first event - subgroup analysis

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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.3 Grade ≥ 3 AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Alanine aminotransferase increased						
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	1/125 (0.8)	NE [NE, NE]	9/ 63 (14.3)	NE [NE, NE]	0.05[0.01, 0.40]	<0.001
Mutant	0/ 17	NE [NE, NE]	2/ 8 (25.0)	NE [0.95, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	1/141 (0.7)	NE [NE, NE]	11/ 72 (15.3)	NE [NE, NE]	0.04[0.01, 0.32]	<0.001
< 1%	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.3 Grade ≥3 AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Thrombocytopenia						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
No Major Cytogenetic Response	26/110 (23.6)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	2.60[1.00, 6.77]	0.042
Age category						
18 - 65 years	22/127 (17.3)	NE [NE, NE]	5/ 61 (8.2)	NE [NE, NE]	2.10[0.79, 5.55]	0.126
≥65 years	6/ 29 (20.7)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	11/ 75 (14.7)	NE [NE, NE]	3/ 45 (6.7)	NE [NE, NE]	2.03[0.57, 7.30]	0.267
Male	17/ 81 (21.0)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	3.64[0.84, 15.75]	0.065

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.3 Grade ≥ 3 AE by PT: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Race						
Asian	0/ 22	NE [NE, NE]	1/ 11 (9.1)	NE [NE, NE]	NE [NE, NE]	NE
Caucasian	23/118 (19.5)	NE [NE, NE]	3/ 57 (5.3)	NE [NE, NE]	3.74[1.12, 12.45]	0.021
Others	5/ 16 (31.3)	NE [1.77, NE]	1/ 8 (12.5)	NE [8.31, NE]	2.61[0.30, 22.38]	0.364
Reason for discontinuation of the last prior TKI						
Failure	16/ 94 (17.0)	NE [NE, NE]	4/ 54 (7.4)	NE [NE, NE]	2.05[0.68, 6.13]	0.190
Intolerance	11/ 59 (18.6)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	4.95[0.64, 38.37]	0.090
Number of prior TKI therapies						
2	17/ 88 (19.3)	NE [NE, NE]	1/ 33 (3.0)	NE [NE, NE]	6.12[0.81, 46.02]	0.044
3	8/ 54 (14.8)	NE [NE, NE]	4/ 33 (12.1)	NE [NE, NE]	1.22[0.37, 4.06]	0.741
≥ 4	3/ 14 (21.4)	NE [1.91, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.3 Grade ≥ 3 AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Line of therapy of randomized treatment						
3	16/ 81 (19.8)	NE [NE, NE]	1/ 30 (3.3)	NE [NE, NE]	5.87[0.78, 44.28]	0.051
4	7/ 44 (15.9)	NE [NE, NE]	3/ 29 (10.3)	NE [NE, NE]	1.35[0.35, 5.23]	0.658
≥ 5	5/ 31 (16.1)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	3.86[0.45, 33.05]	0.184
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	25/125 (20.0)	NE [NE, NE]	5/ 63 (7.9)	NE [NE, NE]	2.49[0.95, 6.52]	0.053
Mutant	2/ 17 (11.8)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	28/141 (19.9)	NE [NE, NE]	5/ 72 (6.9)	NE [NE, NE]	2.87[1.11, 7.45]	0.023
$< 1\%$	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.2.3 Grade ≥ 3 AE by PT: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Europe	20/ 89 (22.5)	NE [NE, NE]	2/ 45 (4.4)	NE [NE, NE]	4.98[1.16, 21.30]	0.016
Others	8/ 67 (11.9)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	1.39[0.37, 5.24]	0.624

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

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Figure 5-3.2.3 Grade ≥ 3 AE by PT: Kaplan Meier plot of time to first event - subgroup analysis

Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) PT terms from related total population output are included. MedDRA version 26.0

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Table 5-3.3.1 SAE: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Stratification factor by IRT						
Major Cytogenetic Response	9/ 46 (19.6)	NE [NE, NE]	3/ 22 (13.6)	NE [18.43, NE]	0.61[0.15, 2.41]	0.477
No Major Cytogenetic Response	25/110 (22.7)	NE [49.38, NE]	17/ 54 (31.5)	30.95 [16.89, NE]	0.52[0.28, 0.97]	0.036
Age category						
18 - 65 years	24/127 (18.9)	NE [49.38, NE]	11/ 61 (18.0)	NE [30.95, NE]	0.67[0.32, 1.40]	0.286
>=65 years	10/ 29 (34.5)	50.10 [19.06, NE]	9/ 15 (60.0)	18.43 [0.46, 27.24]	0.33[0.13, 0.89]	0.021
Sex						
Female	16/ 75 (21.3)	NE [50.10, NE]	12/ 45 (26.7)	25.10 [9.53, NE]	0.42[0.19, 0.92]	0.027
Male	18/ 81 (22.2)	NE [49.38, NE]	8/ 31 (25.8)	NE [27.24, NE]	0.70[0.30, 1.64]	0.408
Race						
Asian	4/ 22 (18.2)	NE [NE, NE]	4/ 11 (36.4)	NE [0.36, NE]	0.27[0.05, 1.50]	0.109
Caucasian	25/118 (21.2)	NE [49.38, NE]	14/ 57 (24.6)	NE [18.43, NE]	0.53[0.27, 1.03]	0.058
Others	5/ 16 (31.3)	NE [6.08, NE]	2/ 8 (25.0)	NE [0.16, NE]	1.09[0.21, 5.63]	0.917

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.3.1 SAE: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Reason for discontinuation of the last prior TKI						
Failure	19/ 94 (20.2)	NE [50.10, NE]	12/ 54 (22.2)	NE [25.10, NE]	0.62[0.30, 1.30]	0.204
Intolerance	14/ 59 (23.7)	NE [43.73, NE]	8/ 22 (36.4)	27.24 [16.89, NE]	0.43[0.18, 1.06]	0.061
Number of prior TKI therapies						
2	17/ 88 (19.3)	NE [49.38, NE]	12/ 33 (36.4)	30.95 [16.89, NE]	0.36[0.17, 0.76]	0.005
3	14/ 54 (25.9)	50.10 [43.73, NE]	6/ 33 (18.2)	NE [NE, NE]	0.97[0.35, 2.70]	0.953
≥4	3/ 14 (21.4)	NE [2.37, NE]	2/ 10 (20.0)	NE [0.36, NE]	1.25[0.21, 7.49]	0.807
Line of therapy of randomized treatment						
3	15/ 81 (18.5)	NE [NE, NE]	10/ 30 (33.3)	30.95 [16.89, NE]	0.41[0.18, 0.92]	0.025
4	13/ 44 (29.5)	49.38 [33.71, NE]	5/ 29 (17.2)	NE [25.10, NE]	1.09[0.37, 3.22]	0.873
≥5	6/ 31 (19.4)	NE [NE, NE]	5/ 17 (29.4)	NE [3.48, NE]	0.61[0.17, 2.20]	0.448

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.3.1 SAE: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	31/125 (24.8)	NE [49.38, NE]	15/ 63 (23.8)	NE [25.10, NE]	0.66[0.35, 1.26]	0.205
Mutant	2/ 17 (11.8)	NE [10.18, NE]	3/ 8 (37.5)	NE [3.55, NE]	0.23[0.04, 1.41]	0.084
BCR-ABL ratio at baseline						
>= 1%	31/141 (22.0)	NE [50.10, NE]	18/ 72 (25.0)	NE [25.10, NE]	0.60[0.33, 1.08]	0.087
< 1%	3/ 15 (20.0)	NE [30.98, NE]	2/ 4 (50.0)	18.43 [0.30, NE]	0.24[0.04, 1.48]	0.096
Geographic region						
Europe	16/ 89 (18.0)	NE [50.10, NE]	11/ 45 (24.4)	NE [16.89, NE]	0.39[0.17, 0.86]	0.015
Others	18/ 67 (26.9)	NE [49.38, NE]	9/ 31 (29.0)	NE [25.10, NE]	0.78[0.34, 1.75]	0.543

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.3.1 SAE: Kaplan Meier plot of time to first event - subgroup analysis

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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_f54_3_1.sas@@/main/2 22NOV23:10:53

Final

Table 5-3.3.2 SAE by SOC: time to first event - subgroup analysis
 Safety Set
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Treatment Groups				Comparison	
Asciminib N=156		Bosutinib N=76		HR	p-value
n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	

None of the attribute
 have at least 10 events
 occurred in one of the
 subgroups

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant (p<0.05) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_3_2.sas@@/main/2 22NOV23:15:29

Final

Figure 5-3.3.2 SAE by SOC: Kaplan Meier plot of time to first event - subgroup analysis

Safety Set
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None of the attribute have at least 10 events occurred in one of the subgroups

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) SOC terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_f54_3_2.sas@@/main/3 22NOV23:10:53

Final

Table 5-3.3.3 SAE by PT: time to first event - subgroup analysis
 Safety Set
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Treatment Groups				Comparison	
Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		

No data selected for
 this analysis based on
 threshold criteria
 requirement of
 treatment arm

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm

Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_t54_3_3.sas@@/main/2 22NOV23:15:30

Final

Figure 5-3.3.3 SAE by PT: Kaplan Meier plot of time to first event - subgroup analysis

Safety Set
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No data selected for this analysis based on threshold criteria requirement of treatment arm

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

- events in at least 5% of patients in at least one of the treatment arms OR events in at least 10 patients and in at least 1% of patients in one treatment arm. Subgroup "Missing" will not be analyzed for any of the attributes. Only statistically significant ($p < 0.05$) PT terms from related total population output are included. MedDRA version 26.0

/vob/CABL001A/haq/haq_eu_4/pgm/saf/germ_f54_3_3.sas@@/main/2 22NOV23:10:53

Final

Table 5-3.4.1 AE leading to discontinuation: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Stratification factor by IRT						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	7/ 22 (31.8)	NE [7.62, NE]	0.10[0.02, 0.40]	<0.001
No Major Cytogenetic Response	10/110 (9.1)	NE [NE, NE]	14/ 54 (25.9)	NE [25.10, NE]	0.27[0.12, 0.61]	<0.001
Age category						
18 - 65 years	8/127 (6.3)	NE [NE, NE]	12/ 61 (19.7)	NE [30.95, NE]	0.22[0.09, 0.55]	<0.001
>=65 years	5/ 29 (17.2)	NE [NE, NE]	9/ 15 (60.0)	25.10 [2.83, 34.92]	0.23[0.08, 0.69]	0.005
Sex						
Female	4/ 75 (5.3)	NE [NE, NE]	13/ 45 (28.9)	34.92 [9.69, NE]	0.11[0.03, 0.34]	<0.001
Male	9/ 81 (11.1)	NE [NE, NE]	8/ 31 (25.8)	NE [27.24, NE]	0.36[0.14, 0.94]	0.029
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	3/ 11 (27.3)	23.03 [1.41, NE]	0.20[0.02, 1.96]	0.127
Caucasian	10/118 (8.5)	NE [NE, NE]	17/ 57 (29.8)	NE [25.10, NE]	0.20[0.09, 0.45]	<0.001
Others	1/ 16 (6.3)	NE [NE, NE]	1/ 8 (12.5)	NE [3.71, NE]	0.62[0.04, 10.74]	0.741

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.4.1 AE leading to discontinuation: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Reason for discontinuation of the last prior TKI						
Failure	4/ 94 (4.3)	NE [NE, NE]	12/ 54 (22.2)	NE [23.03, NE]	0.13[0.04, 0.41]	<0.001
Intolerance	9/ 59 (15.3)	NE [NE, NE]	9/ 22 (40.9)	34.92 [7.62, NE]	0.30[0.12, 0.77]	0.008
Number of prior TKI therapies						
2	4/ 88 (4.5)	NE [NE, NE]	13/ 33 (39.4)	30.95 [23.03, NE]	0.08[0.03, 0.25]	<0.001
3	8/ 54 (14.8)	NE [NE, NE]	8/ 33 (24.2)	NE [8.31, NE]	0.38[0.13, 1.11]	0.067
≥4	1/ 14 (7.1)	NE [NE, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	4/ 81 (4.9)	NE [NE, NE]	11/ 30 (36.7)	34.92 [23.03, NE]	0.10[0.03, 0.31]	<0.001
4	5/ 44 (11.4)	NE [NE, NE]	7/ 29 (24.1)	NE [25.10, NE]	0.31[0.10, 1.03]	0.045
≥5	4/ 31 (12.9)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	0.73[0.15, 3.61]	0.697

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.4.1 AE leading to discontinuation: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	12/125 (9.6)	NE [NE, NE]	21/ 63 (33.3)	34.92 [23.03, NE]	0.20[0.10, 0.41]	<0.001
Mutant	0/ 17	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	11/141 (7.8)	NE [NE, NE]	18/ 72 (25.0)	NE [25.10, NE]	0.23[0.11, 0.50]	<0.001
< 1%	2/ 15 (13.3)	NE [NE, NE]	3/ 4 (75.0)	21.62 [0.30, NE]	0.14[0.02, 0.85]	0.013
Geographic region						
Europe	6/ 89 (6.7)	NE [NE, NE]	15/ 45 (33.3)	34.92 [9.69, NE]	0.14[0.05, 0.36]	<0.001
Others	7/ 67 (10.4)	NE [NE, NE]	6/ 31 (19.4)	NE [23.03, NE]	0.43[0.14, 1.32]	0.129

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.4.1 AE leading to discontinuation: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Final

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Edema and fluid retention						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [32.62, NE]	0.34[0.07, 1.60]	0.155
No Major Cytogenetic Response	13/110 (11.8)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	1.04[0.37, 2.95]	0.933
Age category						
18 - 65 years	13/127 (10.2)	NE [NE, NE]	4/ 61 (6.6)	NE [NE, NE]	1.14[0.37, 3.56]	0.818
>=65 years	4/ 29 (13.8)	NE [NE, NE]	4/ 15 (26.7)	32.62 [22.08, NE]	0.43[0.11, 1.74]	0.224
Sex						
Female	5/ 75 (6.7)	NE [NE, NE]	5/ 45 (11.1)	NE [32.62, NE]	0.32[0.09, 1.17]	0.072
Male	12/ 81 (14.8)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	1.42[0.40, 5.06]	0.586
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	1/ 22 (4.5)	NE [NE, NE]	1/ 11 (9.1)	NE [22.08, NE]	0.32[0.02, 5.15]	0.394
Caucasian	14/118 (11.9)	NE [NE, NE]	7/ 57 (12.3)	NE [NE, NE]	0.76[0.30, 1.90]	0.556
Others	2/ 16 (12.5)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	7/ 94 (7.4)	NE [NE, NE]	6/ 54 (11.1)	NE [22.08, NE]	0.45[0.15, 1.39]	0.157
Intolerance	10/ 59 (16.9)	NE [NE, NE]	2/ 22 (9.1)	NE [32.62, NE]	1.70[0.37, 7.84]	0.491
Number of prior TKI therapies						
2	7/ 88 (8.0)	NE [NE, NE]	5/ 33 (15.2)	NE [32.62, NE]	0.38[0.12, 1.19]	0.083
3	8/ 54 (14.8)	NE [NE, NE]	2/ 33 (6.1)	NE [NE, NE]	2.23[0.46, 10.69]	0.304
>=4	2/ 14 (14.3)	NE [11.99, NE]	1/ 10 (10.0)	NE [4.53, NE]	0.56[0.04, 7.96]	0.668
Line of therapy of randomized treatment						
3	7/ 81 (8.6)	NE [NE, NE]	4/ 30 (13.3)	NE [32.62, NE]	0.49[0.14, 1.68]	0.249
4	5/ 44 (11.4)	NE [NE, NE]	3/ 29 (10.3)	NE [NE, NE]	0.87[0.20, 3.79]	0.850

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	5/ 31 (16.1)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	1.96[0.20, 18.86]	0.554
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	15/125 (12.0)	NE [NE, NE]	7/ 63 (11.1)	NE [32.62, NE]	0.77[0.31, 1.92]	0.574
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [4.53, NE]	0.97[0.09, 10.74]	0.983
BCR-ABL ratio at baseline						
>= 1%	16/141 (11.3)	NE [NE, NE]	6/ 72 (8.3)	NE [NE, NE]	1.07[0.42, 2.77]	0.881
< 1%	1/ 15 (6.7)	NE [NE, NE]	2/ 4 (50.0)	32.62 [1.15, NE]	0.11[0.01, 1.24]	0.031
Geographic region						
Europe	5/ 89 (5.6)	NE [NE, NE]	6/ 45 (13.3)	NE [32.62, NE]	0.29[0.09, 0.98]	0.036
Others	12/ 67 (17.9)	NE [NE, NE]	2/ 31 (6.5)	NE [22.08, NE]	2.51[0.55, 11.37]	0.217

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
GI toxicity						
Stratification factor by IRT						
Major Cytogenetic Response	16/ 46 (34.8)	NE [17.64, NE]	19/ 22 (86.4)	0.18 [0.03, 0.62]	0.10 [0.05, 0.22]	<0.001
No Major Cytogenetic Response	36/110 (32.7)	NE [21.19, NE]	41/ 54 (75.9)	0.23 [0.07, 0.49]	0.22 [0.14, 0.35]	<0.001
Age category						
18 - 65 years	44/127 (34.6)	NE [21.19, NE]	48/ 61 (78.7)	0.20 [0.07, 0.36]	0.19 [0.12, 0.29]	<0.001
>=65 years	8/ 29 (27.6)	NE [8.34, NE]	12/ 15 (80.0)	0.26 [0.03, 0.76]	0.18 [0.07, 0.47]	<0.001
Sex						
Female	26/ 75 (34.7)	NE [20.76, NE]	32/ 45 (71.1)	0.20 [0.07, 0.33]	0.21 [0.12, 0.37]	<0.001
Male	26/ 81 (32.1)	NE [20.73, NE]	28/ 31 (90.3)	0.26 [0.07, 0.62]	0.14 [0.08, 0.25]	<0.001
Race						
Asian	5/ 22 (22.7)	NE [13.77, NE]	9/ 11 (81.8)	0.26 [0.03, 2.79]	0.09 [0.02, 0.34]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Caucasian	39/118 (33.1)	NE [20.76, NE]	44/ 57 (77.2)	0.20 [0.07, 0.49]	0.20	[0.13, 0.31]	<0.001
Others	8/ 16 (50.0)	30.39 [0.79, NE]	7/ 8 (87.5)	0.16 [0.03, 1.02]	0.17	[0.05, 0.59]	0.002
Reason for discontinuation of the last prior TKI							
Failure	24/ 94 (25.5)	NE [NE, NE]	40/ 54 (74.1)	0.28 [0.07, 0.62]	0.17	[0.10, 0.28]	<0.001
Intolerance	25/ 59 (42.4)	NE [11.99, NE]	20/ 22 (90.9)	0.18 [0.03, 0.33]	0.16	[0.09, 0.32]	<0.001
Number of prior TKI therapies							
2	26/ 88 (29.5)	NE [NE, NE]	25/ 33 (75.8)	0.26 [0.03, 0.72]	0.17	[0.10, 0.30]	<0.001
3	21/ 54 (38.9)	NE [12.65, NE]	28/ 33 (84.8)	0.10 [0.03, 0.33]	0.18	[0.10, 0.34]	<0.001
>=4	5/ 14 (35.7)	NE [0.79, NE]	7/ 10 (70.0)	0.51 [0.03, NE]	0.25	[0.06, 0.96]	0.030
Line of therapy of randomized treatment							
3	23/ 81 (28.4)	NE [NE, NE]	23/ 30 (76.7)	0.23 [0.03, 0.76]	0.15	[0.08, 0.28]	<0.001
4	15/ 44 (34.1)	NE [12.65, NE]	24/ 29 (82.8)	0.20 [0.07, 0.49]	0.22	[0.11, 0.43]	<0.001
>=5	14/ 31 (45.2)	20.76 [1.74, NE]	13/ 17 (76.5)	0.26 [0.03, 2.79]	0.24	[0.10, 0.60]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	46/125 (36.8)	NE [20.76, NE]	53/ 63 (84.1)	0.20 [0.07, 0.30]	0.17[0.11, 0.26]	<0.001
Mutant	2/ 17 (11.8)	NE [17.64, NE]	5/ 8 (62.5)	4.73 [0.03, NE]	0.08[0.01, 0.72]	0.004
BCR-ABL ratio at baseline						
>= 1%	46/141 (32.6)	NE [30.39, NE]	56/ 72 (77.8)	0.23 [0.07, 0.33]	0.19[0.13, 0.29]	<0.001
< 1%	6/ 15 (40.0)	NE [1.64, NE]	4/ 4 (100)	0.30 [0.03, NE]	0.07[0.01, 0.42]	<0.001
Geographic region						
Europe	17/ 89 (19.1)	NE [NE, NE]	32/ 45 (71.1)	0.16 [0.07, 0.49]	0.10[0.06, 0.20]	<0.001
Others	35/ 67 (52.2)	13.77 [3.91, NE]	28/ 31 (90.3)	0.26 [0.07, 0.33]	0.31[0.18, 0.52]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Hemorrhage						
Stratification factor by IRT						
Major Cytogenetic Response	7/ 46 (15.2)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	1.97[0.23, 16.53]	0.526
No Major Cytogenetic Response	13/110 (11.8)	NE [NE, NE]	7/ 54 (13.0)	NE [NE, NE]	0.79[0.32, 1.99]	0.619
Age category						
18 - 65 years	15/127 (11.8)	NE [NE, NE]	6/ 61 (9.8)	NE [NE, NE]	0.96[0.37, 2.50]	0.931
>=65 years	5/ 29 (17.2)	NE [NE, NE]	2/ 15 (13.3)	NE [21.06, NE]	0.98[0.18, 5.19]	0.980
Sex						
Female	11/ 75 (14.7)	NE [NE, NE]	7/ 45 (15.6)	NE [NE, NE]	0.76[0.29, 1.97]	0.566
Male	9/ 81 (11.1)	NE [NE, NE]	1/ 31 (3.2)	NE [NE, NE]	2.65[0.33, 21.30]	0.342
Race						
Asian	3/ 22 (13.6)	NE [NE, NE]	1/ 11 (9.1)	NE [21.06, NE]	0.53[0.03, 8.69]	0.651

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Caucasian	14/118 (11.9)	NE [NE, NE]	5/ 57 (8.8)	NE [NE, NE]	1.12[0.40, 3.12]		0.834
Others	3/ 16 (18.8)	NE [6.08, NE]	2/ 8 (25.0)	NE [5.42, NE]	0.68[0.11, 4.07]		0.670
Reason for discontinuation of the last prior TKI							
Failure	12/ 94 (12.8)	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	0.82[0.30, 2.23]		0.693
Intolerance	8/ 59 (13.6)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	1.35[0.28, 6.40]		0.705
Number of prior TKI therapies							
2	10/ 88 (11.4)	NE [NE, NE]	3/ 33 (9.1)	NE [NE, NE]	0.90[0.25, 3.29]		0.874
3	8/ 54 (14.8)	NE [NE, NE]	5/ 33 (15.2)	NE [NE, NE]	0.86[0.28, 2.68]		0.799
>=4	2/ 14 (14.3)	NE [4.47, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]		NE
Line of therapy of randomized treatment							
3	10/ 81 (12.3)	NE [NE, NE]	2/ 30 (6.7)	NE [NE, NE]	1.42[0.31, 6.50]		0.651
4	6/ 44 (13.6)	NE [NE, NE]	5/ 29 (17.2)	NE [NE, NE]	0.63[0.19, 2.10]		0.445
>=5	4/ 31 (12.9)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	2.37[0.25, 22.09]		0.437

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	18/125 (14.4)	NE [NE, NE]	8/ 63 (12.7)	NE [NE, NE]	0.90[0.39, 2.08]	0.796
Mutant	0/ 17	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	19/141 (13.5)	NE [NE, NE]	8/ 72 (11.1)	NE [NE, NE]	0.96[0.41, 2.21]	0.917
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	7/ 89 (7.9)	NE [NE, NE]	3/ 45 (6.7)	NE [NE, NE]	1.05[0.27, 4.12]	0.940
Others	13/ 67 (19.4)	NE [NE, NE]	5/ 31 (16.1)	NE [21.06, NE]	0.96[0.33, 2.78]	0.940

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Hepatotoxicity (including laboratory terms)						
Stratification factor by IRT						
Major Cytogenetic Response	5/ 46 (10.9)	NE [NE, NE]	9/ 22 (40.9)	NE [2.73, NE]	0.13[0.04, 0.42]	<0.001
No Major Cytogenetic Response	14/110 (12.7)	NE [NE, NE]	16/ 54 (29.6)	NE [6.60, NE]	0.33[0.16, 0.67]	0.001
Age category						
18 - 65 years	17/127 (13.4)	NE [NE, NE]	18/ 61 (29.5)	NE [6.60, NE]	0.29[0.15, 0.58]	<0.001
>=65 years	2/ 29 (6.9)	NE [NE, NE]	7/ 15 (46.7)	NE [1.25, NE]	0.12[0.03, 0.60]	0.002
Sex						
Female	7/ 75 (9.3)	NE [NE, NE]	17/ 45 (37.8)	NE [3.71, NE]	0.13[0.05, 0.34]	<0.001
Male	12/ 81 (14.8)	NE [NE, NE]	8/ 31 (25.8)	NE [NE, NE]	0.49[0.20, 1.22]	0.119

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	5/ 22 (22.7)	NE [19.35, NE]	2/ 11 (18.2)	NE [0.92, NE]	1.14[0.20, 6.44]	0.882
Caucasian	12/118 (10.2)	NE [NE, NE]	19/ 57 (33.3)	NE [6.47, NE]	0.21[0.10, 0.43]	<0.001
Others	2/ 16 (12.5)	NE [NE, NE]	4/ 8 (50.0)	6.60 [0.95, NE]	0.22[0.04, 1.24]	0.061
Reason for discontinuation of the last prior TKI						
Failure	8/ 94 (8.5)	NE [NE, NE]	15/ 54 (27.8)	NE [NE, NE]	0.20[0.08, 0.50]	<0.001
Intolerance	11/ 59 (18.6)	NE [NE, NE]	10/ 22 (45.5)	NE [2.73, NE]	0.31[0.13, 0.74]	0.005
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	10/ 33 (30.3)	NE [6.47, NE]	0.23[0.09, 0.57]	<0.001
3	8/ 54 (14.8)	NE [NE, NE]	13/ 33 (39.4)	NE [3.75, NE]	0.25[0.10, 0.66]	0.003
>=4	2/ 14 (14.3)	NE [27.66, NE]	2/ 10 (20.0)	NE [0.72, NE]	0.38[0.03, 4.19]	0.411
Line of therapy of randomized treatment						
3	5/ 81 (6.2)	NE [NE, NE]	9/ 30 (30.0)	NE [6.47, NE]	0.15[0.05, 0.46]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
4	8/ 44 (18.2)	NE [NE, NE]	13/ 29 (44.8)	NE [2.04, NE]	0.36[0.15, 0.87]		0.018
>=5	6/ 31 (19.4)	NE [30.39, NE]	3/ 17 (17.6)	NE [NE, NE]	0.44[0.07, 2.64]		0.357
With or without Week1							
Day 1 BCR-ABL1							
mutation							
Wild type	16/125 (12.8)	NE [NE, NE]	21/ 63 (33.3)	NE [6.60, NE]	0.26[0.14, 0.51]		<0.001
Mutant	2/ 17 (11.8)	NE [9.23, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.28[0.05, 1.68]		0.136
BCR-ABL ratio at							
baseline							
>= 1%	16/141 (11.3)	NE [NE, NE]	22/ 72 (30.6)	NE [NE, NE]	0.27[0.14, 0.53]		<0.001
< 1%	3/ 15 (20.0)	NE [33.15, NE]	3/ 4 (75.0)	3.66 [1.25, NE]	0.15[0.03, 0.77]		0.009
Geographic region							
Europe	9/ 89 (10.1)	NE [NE, NE]	16/ 45 (35.6)	NE [4.60, NE]	0.19[0.08, 0.43]		<0.001
Others	10/ 67 (14.9)	NE [NE, NE]	9/ 31 (29.0)	NE [6.60, NE]	0.42[0.17, 1.05]		0.055

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Hypersensitivity						
Stratification factor by IRT						
Major Cytogenetic Response	9/ 46 (19.6)	NE [NE, NE]	11/ 22 (50.0)	6.47 [0.95, NE]	0.20[0.08, 0.51]	<0.001
No Major Cytogenetic Response	23/110 (20.9)	NE [NE, NE]	15/ 54 (27.8)	NE [NE, NE]	0.63[0.33, 1.22]	0.166
Age category						
18 - 65 years	27/127 (21.3)	NE [NE, NE]	22/ 61 (36.1)	NE [6.21, NE]	0.43[0.24, 0.76]	0.003
>=65 years	5/ 29 (17.2)	NE [NE, NE]	4/ 15 (26.7)	NE [1.64, NE]	0.45[0.11, 1.79]	0.245
Sex						
Female	17/ 75 (22.7)	NE [NE, NE]	19/ 45 (42.2)	NE [3.19, NE]	0.36[0.18, 0.71]	0.002
Male	15/ 81 (18.5)	NE [NE, NE]	7/ 31 (22.6)	NE [NE, NE]	0.64[0.25, 1.59]	0.332
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	8/ 11 (72.7)	0.95 [0.30, NE]	0.08[0.02, 0.41]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Caucasian	27/118 (22.9)	NE [NE, NE]	18/ 57 (31.6)	NE [6.47, NE]	0.54[0.29, 0.98]	0.041
Others	3/ 16 (18.8)	NE [32.56, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	17/ 94 (18.1)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	0.55[0.27, 1.13]	0.096
Intolerance	15/ 59 (25.4)	NE [41.07, NE]	12/ 22 (54.5)	6.21 [0.95, NE]	0.31[0.14, 0.69]	0.002
Number of prior TKI therapies						
2	17/ 88 (19.3)	NE [NE, NE]	11/ 33 (33.3)	NE [4.57, NE]	0.44[0.20, 0.95]	0.033
3	11/ 54 (20.4)	NE [NE, NE]	10/ 33 (30.3)	NE [4.90, NE]	0.52[0.21, 1.27]	0.143
>=4	4/ 14 (28.6)	NE [6.47, NE]	5/ 10 (50.0)	6.21 [0.13, NE]	0.24[0.05, 1.26]	0.069
Line of therapy of randomized treatment						
3	16/ 81 (19.8)	NE [NE, NE]	9/ 30 (30.0)	NE [6.47, NE]	0.52[0.23, 1.18]	0.115
4	7/ 44 (15.9)	NE [NE, NE]	9/ 29 (31.0)	NE [4.90, NE]	0.43[0.16, 1.17]	0.088
>=5	9/ 31 (29.0)	NE [32.56, NE]	8/ 17 (47.1)	6.21 [0.33, NE]	0.31[0.10, 0.97]	0.035

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	28/125 (22.4)	NE [NE, NE]	23/ 63 (36.5)	NE [6.47, NE]	0.44[0.25, 0.78]	0.004
Mutant	4/ 17 (23.5)	NE [32.56, NE]	2/ 8 (25.0)	NE [1.64, NE]	0.76[0.13, 4.57]	0.766
BCR-ABL ratio at baseline						
>= 1%	30/141 (21.3)	NE [NE, NE]	24/ 72 (33.3)	NE [NE, NE]	0.46[0.26, 0.80]	0.005
< 1%	2/ 15 (13.3)	NE [NE, NE]	2/ 4 (50.0)	4.57 [0.82, NE]	0.26[0.04, 1.88]	0.152
Geographic region						
Europe	15/ 89 (16.9)	NE [NE, NE]	16/ 45 (35.6)	NE [6.21, NE]	0.34[0.16, 0.70]	0.002
Others	17/ 67 (25.4)	NE [NE, NE]	10/ 31 (32.3)	NE [3.29, NE]	0.58[0.26, 1.30]	0.182

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Ischemic heart and CNS conditions						
Stratification factor by IRT						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	0.91[0.09, 8.81]	0.934
No Major Cytogenetic Response	7/110 (6.4)	NE [NE, NE]	3/ 54 (5.6)	NE [NE, NE]	0.91[0.23, 3.56]	0.896
Sex						
Female	3/ 75 (4.0)	NE [NE, NE]	1/ 45 (2.2)	NE [NE, NE]	1.63[0.17, 15.80]	0.668
Male	7/ 81 (8.6)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	0.75[0.19, 2.92]	0.680
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	9/125 (7.2)	NE [NE, NE]	2/ 63 (3.2)	NE [NE, NE]	1.69[0.36, 7.87]	0.499
Mutant	1/ 17 (5.9)	NE [NE, NE]	2/ 8 (25.0)	NE [5.68, NE]	0.25[0.02, 2.77]	0.223

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
BCR-ABL ratio at baseline						
>= 1%	10/141 (7.1)	NE [NE, NE]	4/ 72 (5.6)	NE [NE, NE]	0.95[0.30, 3.06]	0.934
< 1%	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Erythropenia)						
Stratification factor by IRT						
Major Cytogenetic Response	1/ 46 (2.2)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	0.21[0.02, 2.36]	0.166
No Major Cytogenetic Response	15/110 (13.6)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	1.39[0.51, 3.85]	0.520
Age category						
18 - 65 years	10/127 (7.9)	NE [NE, NE]	7/ 61 (11.5)	NE [NE, NE]	0.63[0.24, 1.65]	0.340
>=65 years	6/ 29 (20.7)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	10/ 75 (13.3)	NE [NE, NE]	5/ 45 (11.1)	NE [19.35, NE]	1.10[0.37, 3.23]	0.869
Male	6/ 81 (7.4)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	1.22[0.25, 6.06]	0.808
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	3/ 22 (13.6)	NE [NE, NE]	2/ 11 (18.2)	19.35 [1.87, NE]	0.86[0.14, 5.39]	0.871
Caucasian	11/118 (9.3)	NE [NE, NE]	3/ 57 (5.3)	NE [NE, NE]	1.68[0.47, 6.03]	0.420
Others	2/ 16 (12.5)	NE [NE, NE]	2/ 8 (25.0)	NE [1.41, NE]	0.41[0.06, 2.91]	0.356
Reason for discontinuation of the last prior TKI						
Failure	9/ 94 (9.6)	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	0.72[0.25, 2.03]	0.526
Intolerance	7/ 59 (11.9)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	2.82[0.35, 23.03]	0.312
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	2/ 33 (6.1)	NE [NE, NE]	1.42[0.31, 6.57]	0.653
3	4/ 54 (7.4)	NE [NE, NE]	5/ 33 (15.2)	NE [19.35, NE]	0.49[0.13, 1.83]	0.279
>=4	3/ 14 (21.4)	NE [2.50, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	8/ 81 (9.9)	NE [NE, NE]	2/ 30 (6.7)	NE [NE, NE]	1.29[0.27, 6.08]	0.746
4	4/ 44 (9.1)	NE [NE, NE]	3/ 29 (10.3)	NE [19.35, NE]	0.83[0.19, 3.72]	0.808

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	4/ 31 (12.9)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	1.26[0.22, 7.26]	0.794
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	14/125 (11.2)	NE [NE, NE]	5/ 63 (7.9)	NE [NE, NE]	1.34[0.48, 3.73]	0.574
Mutant	1/ 17 (5.9)	NE [NE, NE]	1/ 8 (12.5)	NE [19.35, NE]	0.43[0.03, 6.92]	0.542
BCR-ABL ratio at baseline						
>= 1%	16/141 (11.3)	NE [NE, NE]	6/ 72 (8.3)	NE [NE, NE]	1.27[0.50, 3.26]	0.614
< 1%	0/ 15	NE [NE, NE]	1/ 4 (25.0)	NE [1.15, NE]	NE [NE, NE]	NE
Geographic region						
Europe	9/ 89 (10.1)	NE [NE, NE]	5/ 45 (11.1)	NE [NE, NE]	0.83[0.28, 2.48]	0.735
Others	7/ 67 (10.4)	NE [NE, NE]	2/ 31 (6.5)	NE [19.35, NE]	1.54[0.32, 7.50]	0.588

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Neutropenia)						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.61[0.14, 2.74]	0.519
No Major Cytogenetic Response	32/110 (29.1)	NE [NE, NE]	13/ 54 (24.1)	NE [NE, NE]	1.15[0.60, 2.19]	0.669
Age category						
18 - 65 years	30/127 (23.6)	NE [NE, NE]	13/ 61 (21.3)	NE [NE, NE]	1.04[0.54, 2.00]	0.894
>=65 years	6/ 29 (20.7)	NE [NE, NE]	3/ 15 (20.0)	NE [4.70, NE]	1.04[0.26, 4.18]	0.946
Sex						
Female	16/ 75 (21.3)	NE [NE, NE]	10/ 45 (22.2)	NE [NE, NE]	0.86[0.39, 1.91]	0.722
Male	20/ 81 (24.7)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	1.24[0.50, 3.10]	0.631
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	8/ 22 (36.4)	NE [0.95, NE]	4/ 11 (36.4)	NE [0.92, NE]	1.34[0.39, 4.56]	0.650
Caucasian	24/118 (20.3)	NE [NE, NE]	10/ 57 (17.5)	NE [NE, NE]	1.07[0.51, 2.23]	0.863
Others	4/ 16 (25.0)	NE [13.37, NE]	2/ 8 (25.0)	NE [1.87, NE]	0.77[0.14, 4.35]	0.775
Reason for discontinuation of the last prior TKI						
Failure	20/ 94 (21.3)	NE [NE, NE]	12/ 54 (22.2)	NE [NE, NE]	0.86[0.42, 1.77]	0.681
Intolerance	16/ 59 (27.1)	NE [NE, NE]	4/ 22 (18.2)	NE [NE, NE]	1.56[0.52, 4.67]	0.419
Number of prior TKI therapies						
2	22/ 88 (25.0)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	1.06[0.45, 2.48]	0.896
3	11/ 54 (20.4)	NE [NE, NE]	9/ 33 (27.3)	NE [NE, NE]	0.73[0.30, 1.77]	0.491
>=4	3/ 14 (21.4)	NE [2.79, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	20/ 81 (24.7)	NE [NE, NE]	6/ 30 (20.0)	NE [NE, NE]	1.12[0.45, 2.79]	0.814
4	9/ 44 (20.5)	NE [NE, NE]	7/ 29 (24.1)	NE [NE, NE]	0.76[0.28, 2.03]	0.575

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	7/ 31 (22.6)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	1.16[0.28, 4.80]	0.838
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	32/125 (25.6)	NE [NE, NE]	15/ 63 (23.8)	NE [NE, NE]	1.02[0.55, 1.88]	0.951
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [0.92, NE]	0.86[0.08, 9.52]	0.904
BCR-ABL ratio at baseline						
>= 1%	35/141 (24.8)	NE [NE, NE]	16/ 72 (22.2)	NE [NE, NE]	1.05[0.58, 1.90]	0.860
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	18/ 89 (20.2)	NE [NE, NE]	8/ 45 (17.8)	NE [NE, NE]	1.00[0.43, 2.31]	0.995
Others	18/ 67 (26.9)	NE [NE, NE]	8/ 31 (25.8)	NE [NE, NE]	1.13[0.49, 2.59]	0.772

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Leucopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.61[0.14, 2.74]	0.519
No Major Cytogenetic Response	32/110 (29.1)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	1.06[0.56, 1.98]	0.858
Age category						
18 - 65 years	30/127 (23.6)	NE [NE, NE]	14/ 61 (23.0)	NE [NE, NE]	0.96[0.51, 1.81]	0.901
>=65 years	6/ 29 (20.7)	NE [NE, NE]	3/ 15 (20.0)	NE [4.70, NE]	1.04[0.26, 4.18]	0.946
Sex						
Female	16/ 75 (21.3)	NE [NE, NE]	11/ 45 (24.4)	NE [NE, NE]	0.77[0.36, 1.67]	0.524
Male	20/ 81 (24.7)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	1.24[0.50, 3.10]	0.631
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	8/ 22 (36.4)	NE [0.95, NE]	4/ 11 (36.4)	NE [0.92, NE]	1.34[0.39, 4.56]	0.650
Caucasian	24/118 (20.3)	NE [NE, NE]	11/ 57 (19.3)	NE [NE, NE]	0.96[0.47, 1.95]	0.910
Others	4/ 16 (25.0)	NE [13.37, NE]	2/ 8 (25.0)	NE [1.87, NE]	0.77[0.14, 4.35]	0.775
Reason for discontinuation of the last prior TKI						
Failure	20/ 94 (21.3)	NE [NE, NE]	13/ 54 (24.1)	NE [NE, NE]	0.79[0.39, 1.59]	0.500
Intolerance	16/ 59 (27.1)	NE [NE, NE]	4/ 22 (18.2)	NE [NE, NE]	1.56[0.52, 4.67]	0.419
Number of prior TKI therapies						
2	22/ 88 (25.0)	NE [NE, NE]	8/ 33 (24.2)	NE [NE, NE]	0.90[0.40, 2.03]	0.804
3	11/ 54 (20.4)	NE [NE, NE]	9/ 33 (27.3)	NE [NE, NE]	0.73[0.30, 1.77]	0.491
>=4	3/ 14 (21.4)	NE [2.79, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	20/ 81 (24.7)	NE [NE, NE]	7/ 30 (23.3)	NE [NE, NE]	0.93[0.39, 2.21]	0.868
4	9/ 44 (20.5)	NE [NE, NE]	7/ 29 (24.1)	NE [NE, NE]	0.76[0.28, 2.03]	0.575

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	7/ 31 (22.6)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	1.16[0.28, 4.80]	0.838
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	32/125 (25.6)	NE [NE, NE]	16/ 63 (25.4)	NE [NE, NE]	0.94[0.52, 1.72]	0.856
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [0.92, NE]	0.86[0.08, 9.52]	0.904
BCR-ABL ratio at baseline						
>= 1%	35/141 (24.8)	NE [NE, NE]	17/ 72 (23.6)	NE [NE, NE]	0.98[0.55, 1.76]	0.959
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	18/ 89 (20.2)	NE [NE, NE]	9/ 45 (20.0)	NE [NE, NE]	0.87[0.39, 1.95]	0.743
Others	18/ 67 (26.9)	NE [NE, NE]	8/ 31 (25.8)	NE [NE, NE]	1.13[0.49, 2.59]	0.772

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Myelosuppression (Thrombocytopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	6/ 46 (13.0)	NE [NE, NE]	3/ 22 (13.6)	NE [11.99, NE]	0.91[0.22, 3.69]	0.889
No Major Cytogenetic Response	40/110 (36.4)	NE [NE, NE]	13/ 54 (24.1)	NE [30.39, NE]	1.52[0.82, 2.85]	0.186
Age category						
18 - 65 years	37/127 (29.1)	NE [NE, NE]	12/ 61 (19.7)	NE [30.39, NE]	1.47[0.76, 2.82]	0.248
>=65 years	9/ 29 (31.0)	NE [1.91, NE]	4/ 15 (26.7)	NE [2.10, NE]	1.23[0.38, 4.01]	0.733
Sex						
Female	21/ 75 (28.0)	NE [NE, NE]	9/ 45 (20.0)	NE [NE, NE]	1.36[0.62, 2.97]	0.448
Male	25/ 81 (30.9)	NE [NE, NE]	7/ 31 (22.6)	NE [30.39, NE]	1.43[0.62, 3.30]	0.412
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	4/ 22 (18.2)	NE [NE, NE]	4/ 11 (36.4)	NE [0.92, NE]	0.64[0.16, 2.61]	0.510
Caucasian	36/118 (30.5)	NE [NE, NE]	10/ 57 (17.5)	NE [NE, NE]	1.73[0.86, 3.49]	0.124
Others	6/ 16 (37.5)	NE [1.41, NE]	2/ 8 (25.0)	NE [2.33, NE]	1.63[0.33, 8.11]	0.545
Reason for discontinuation of the last prior TKI						
Failure	24/ 94 (25.5)	NE [NE, NE]	13/ 54 (24.1)	NE [30.39, NE]	0.92[0.46, 1.81]	0.791
Intolerance	21/ 59 (35.6)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	3.42[1.02, 11.48]	0.035
Number of prior TKI therapies						
2	23/ 88 (26.1)	NE [NE, NE]	4/ 33 (12.1)	NE [30.39, NE]	2.02[0.70, 5.85]	0.189
3	16/ 54 (29.6)	NE [NE, NE]	9/ 33 (27.3)	NE [11.99, NE]	1.15[0.51, 2.62]	0.750
>=4	7/ 14 (50.0)	13.83 [1.74, NE]	3/ 10 (30.0)	NE [0.26, NE]	1.58[0.39, 6.46]	0.518
Line of therapy of randomized treatment						
3	22/ 81 (27.2)	NE [NE, NE]	3/ 30 (10.0)	NE [30.39, NE]	2.69[0.80, 8.98]	0.096
4	10/ 44 (22.7)	NE [NE, NE]	8/ 29 (27.6)	NE [11.99, NE]	0.73[0.29, 1.87]	0.507

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	14/ 31 (45.2)	NE [1.74, NE]	5/ 17 (29.4)	NE [2.23, NE]	1.75[0.61, 5.01]	0.283
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	41/125 (32.8)	NE [NE, NE]	14/ 63 (22.2)	NE [30.39, NE]	1.49[0.81, 2.75]	0.195
Mutant	2/ 17 (11.8)	NE [NE, NE]	2/ 8 (25.0)	NE [0.26, NE]	0.39[0.05, 2.75]	0.309
BCR-ABL ratio at baseline						
>= 1%	45/141 (31.9)	NE [NE, NE]	16/ 72 (22.2)	NE [30.39, NE]	1.43[0.81, 2.54]	0.220
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	29/ 89 (32.6)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	2.57[1.07, 6.21]	0.029
Others	17/ 67 (25.4)	NE [NE, NE]	10/ 31 (32.3)	30.39 [11.99, NE]	0.77[0.35, 1.70]	0.521

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Pancreatic toxicity						
Stratification factor by IRT						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
No Major Cytogenetic Response	10/110 (9.1)	NE [NE, NE]	7/ 54 (13.0)	NE [NE, NE]	0.58[0.22, 1.53]	0.264
Age category						
18 - 65 years	9/127 (7.1)	NE [NE, NE]	7/ 61 (11.5)	NE [NE, NE]	0.52[0.19, 1.42]	0.195
>=65 years	4/ 29 (13.8)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	4/ 75 (5.3)	NE [NE, NE]	4/ 45 (8.9)	NE [11.99, NE]	0.40[0.10, 1.66]	0.194
Male	9/ 81 (11.1)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	1.16[0.31, 4.28]	0.826
Race						
Asian	0/ 22	NE [NE, NE]	1/ 11 (9.1)	NE [6.47, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Final

Table 5-3.5.1 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Caucasian	12/118 (10.2)	NE [NE, NE]	5/ 57 (8.8)	NE [NE, NE]	0.99[0.35, 2.83]	0.986
Others	1/ 16 (6.3)	NE [NE, NE]	1/ 8 (12.5)	NE [0.26, NE]	0.42[0.03, 6.76]	0.529
Reason for discontinuation of the last prior TKI						
Failure	7/ 94 (7.4)	NE [NE, NE]	7/ 54 (13.0)	NE [NE, NE]	0.43[0.15, 1.24]	0.110
Intolerance	6/ 59 (10.2)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
Number of prior TKI therapies						
2	8/ 88 (9.1)	NE [NE, NE]	4/ 33 (12.1)	NE [NE, NE]	0.63[0.19, 2.11]	0.454
3	4/ 54 (7.4)	NE [NE, NE]	2/ 33 (6.1)	NE [11.99, NE]	0.90[0.16, 5.04]	0.900
>=4	1/ 14 (7.1)	NE [9.23, NE]	1/ 10 (10.0)	NE [3.65, NE]	0.34[0.01, 7.57]	0.482
Line of therapy of randomized treatment						
3	8/ 81 (9.9)	NE [NE, NE]	4/ 30 (13.3)	NE [NE, NE]	0.64[0.19, 2.11]	0.455
4	2/ 44 (4.5)	NE [NE, NE]	2/ 29 (6.9)	NE [11.99, NE]	0.54[0.07, 3.96]	0.541
>=5	3/ 31 (9.7)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	0.98[0.08, 11.48]	0.985

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.1 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	12/125 (9.6)	NE [NE, NE]	5/ 63 (7.9)	NE [NE, NE]	1.04[0.37, 2.98]	0.939
Mutant	1/ 17 (5.9)	NE [7.43, NE]	1/ 8 (12.5)	NE [6.47, NE]	0.37[0.02, 6.36]	0.474
BCR-ABL ratio at baseline						
>= 1%	11/141 (7.8)	NE [NE, NE]	7/ 72 (9.7)	NE [NE, NE]	0.66[0.26, 1.72]	0.395
< 1%	2/ 15 (13.3)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	6/ 89 (6.7)	NE [NE, NE]	2/ 45 (4.4)	NE [NE, NE]	1.20[0.24, 5.99]	0.830
Others	7/ 67 (10.4)	NE [NE, NE]	5/ 31 (16.1)	NE [NE, NE]	0.58[0.18, 1.84]	0.346

Median (time to event) and its 95% CI are generated by KM estimation.

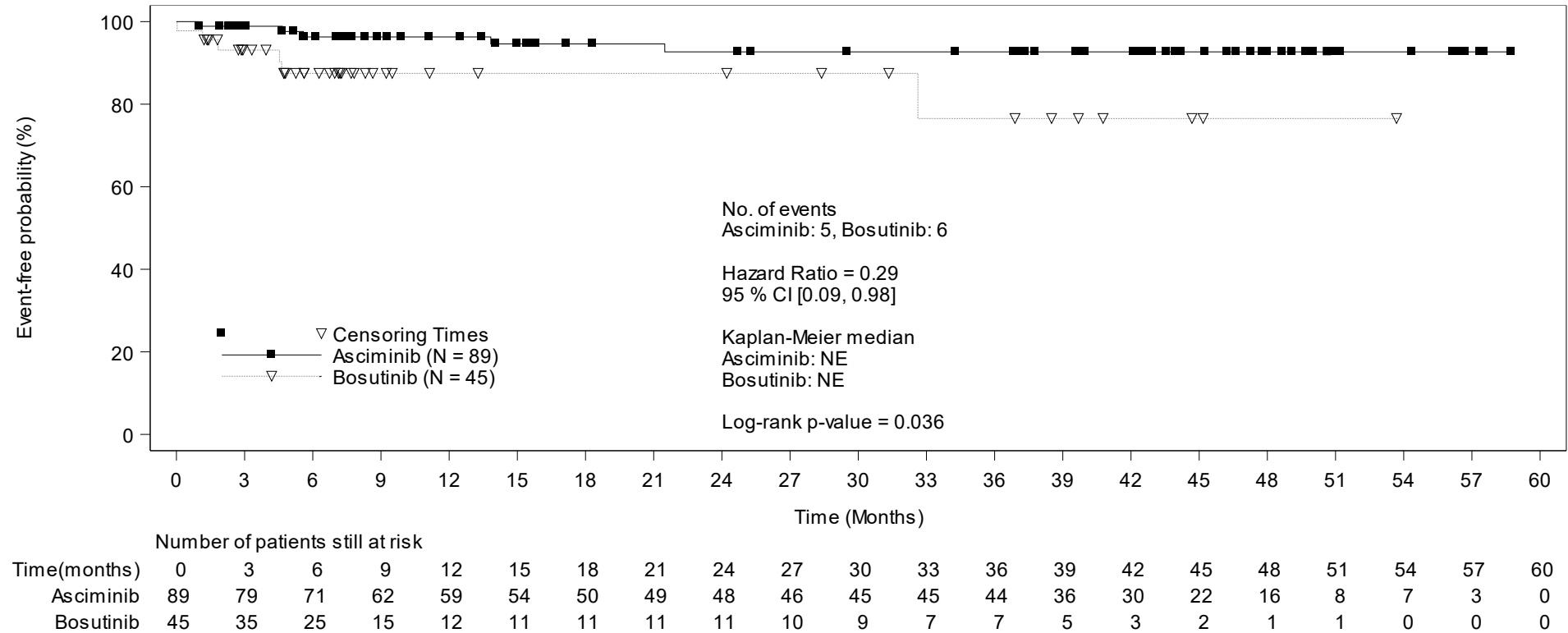
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

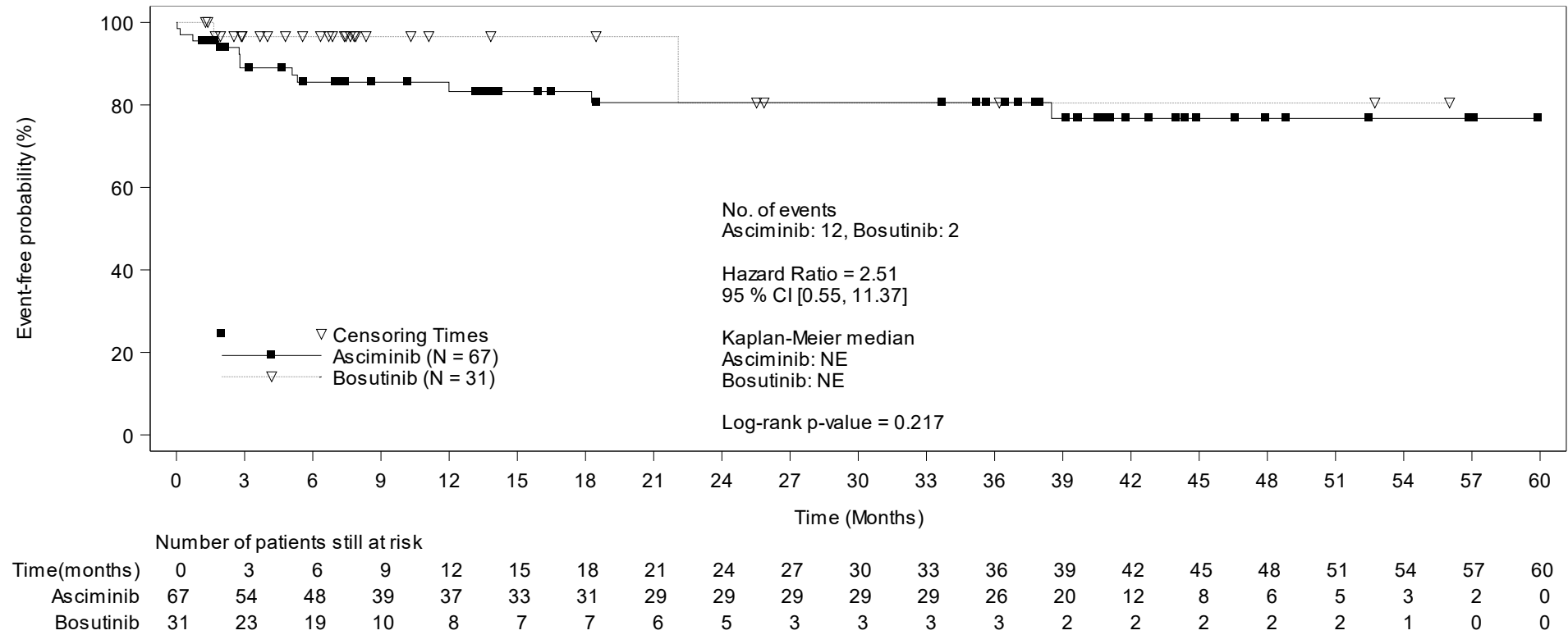
AESI: Edema and fluid retention - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

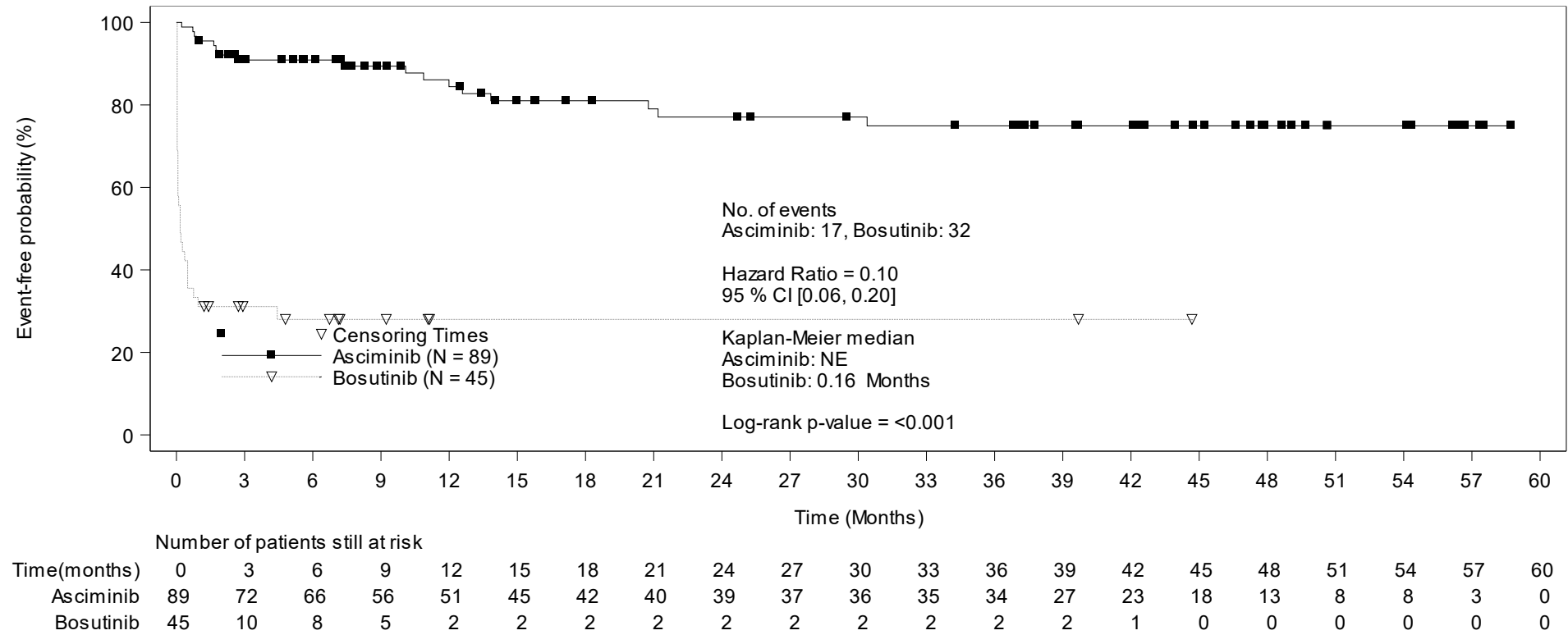
AESI: Edema and fluid retention - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

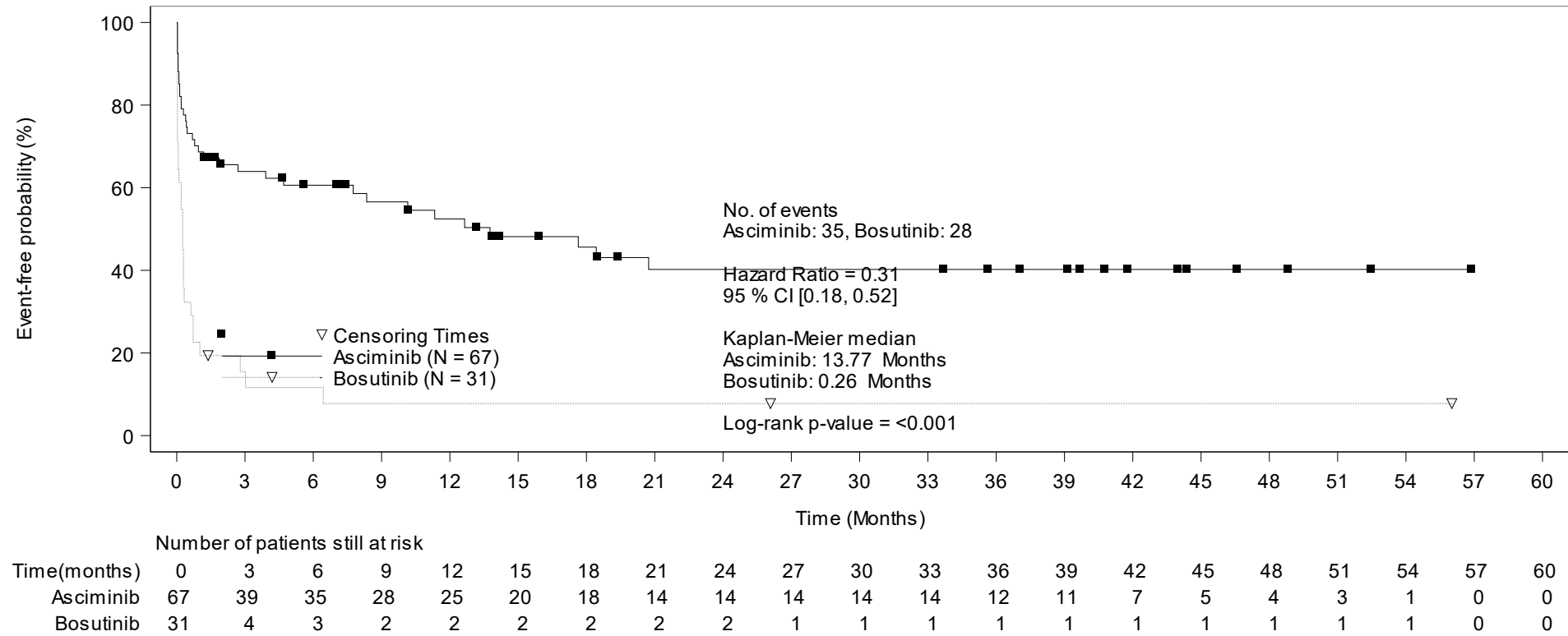
AESI: GI toxicity - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

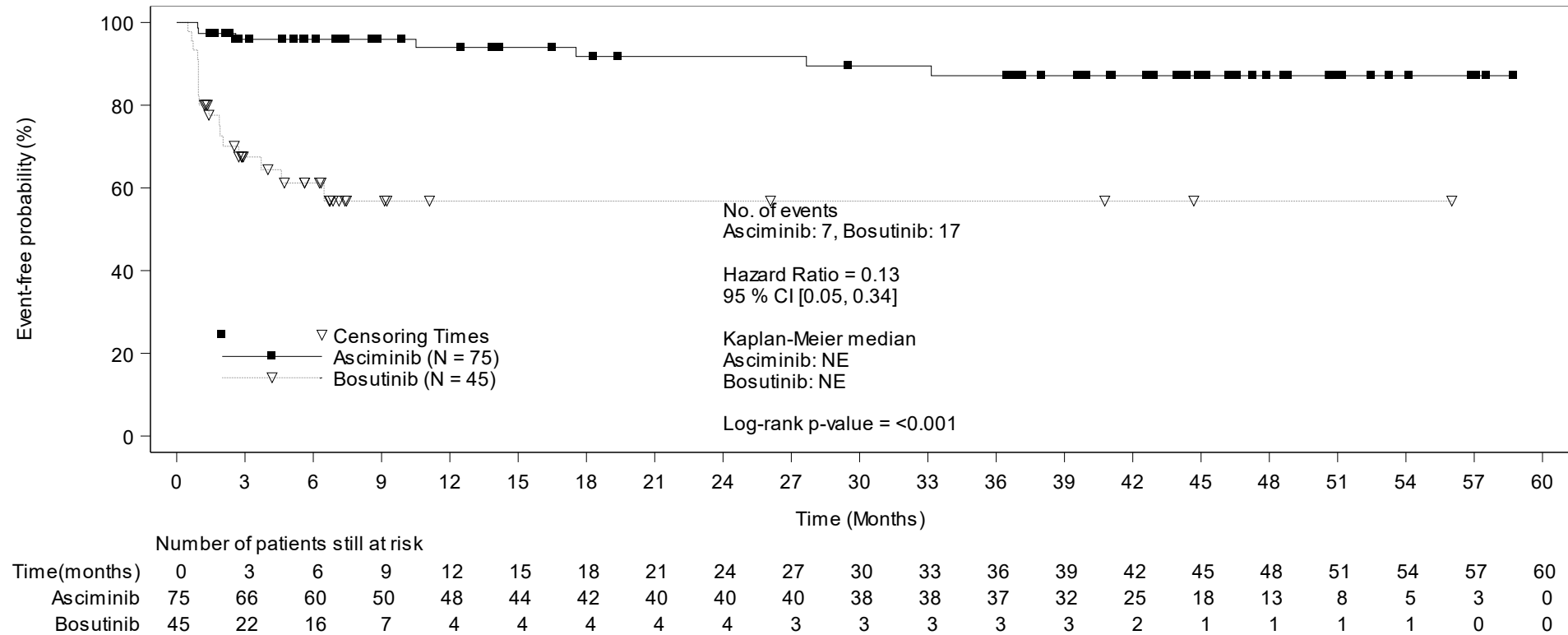
AESI: GI toxicity - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

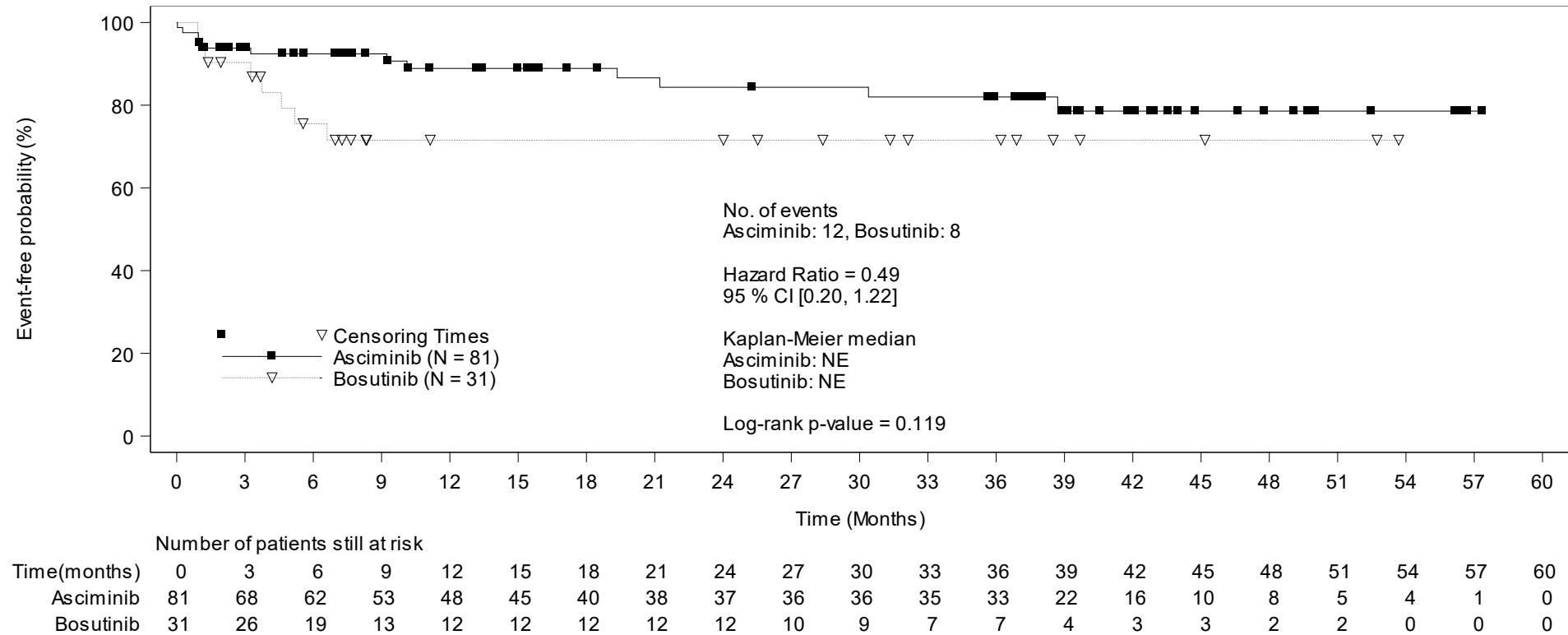
AESI: Hepatotoxicity (including laboratory terms) - Sex: Female



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

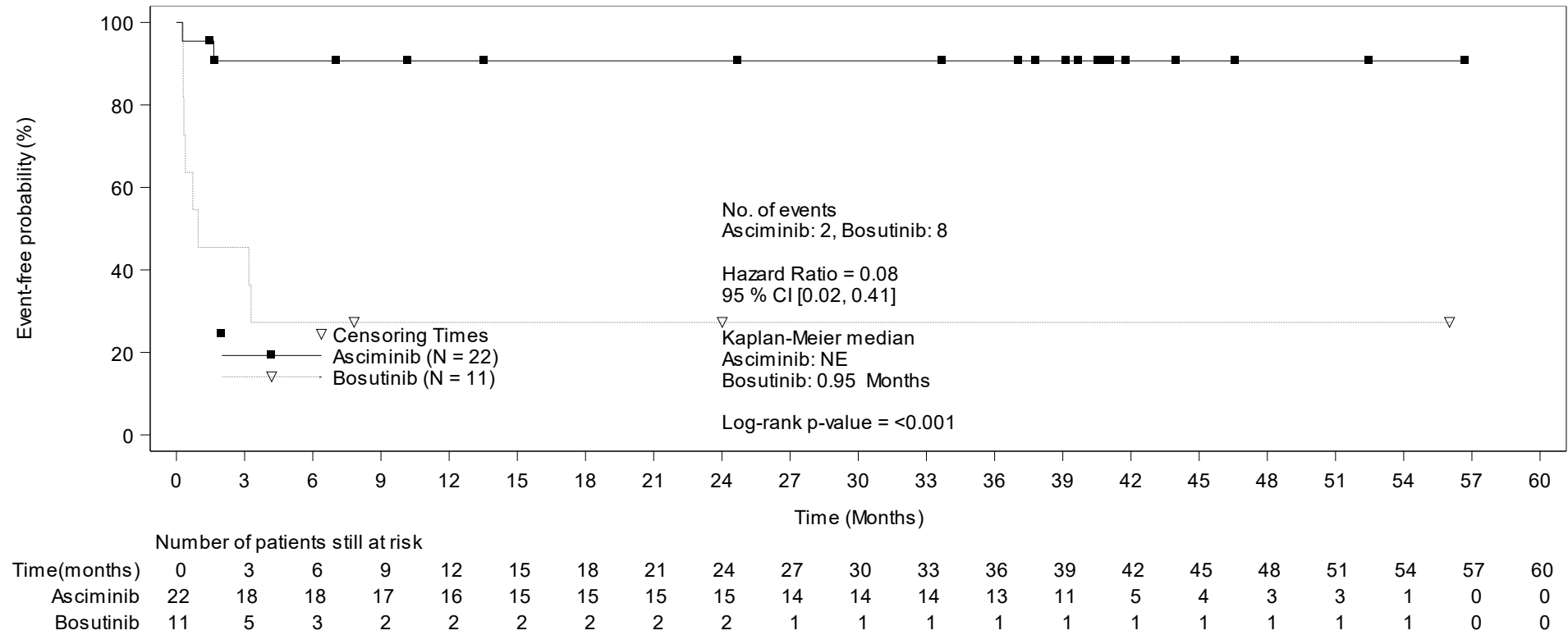
AESI: Hepatotoxicity (including laboratory terms) - Sex: Male



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

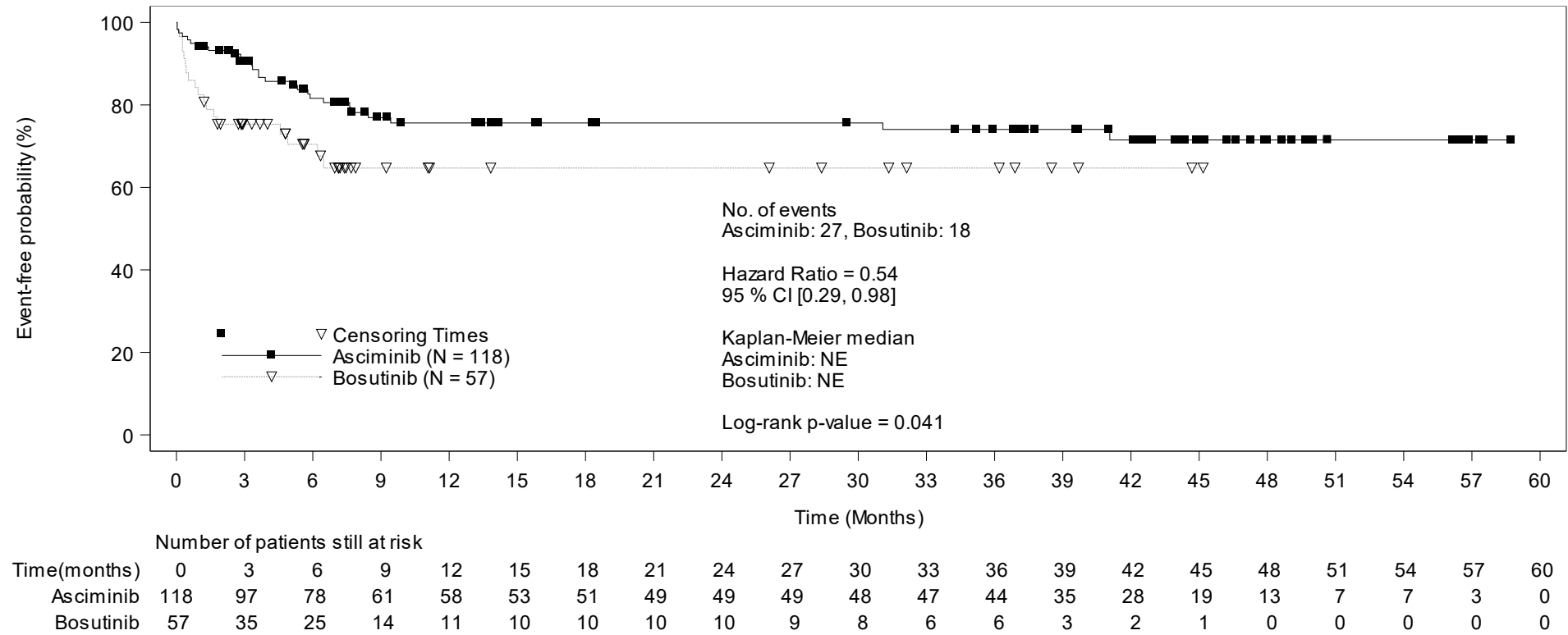
AESI: Hypersensitivity - Race: Asian



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

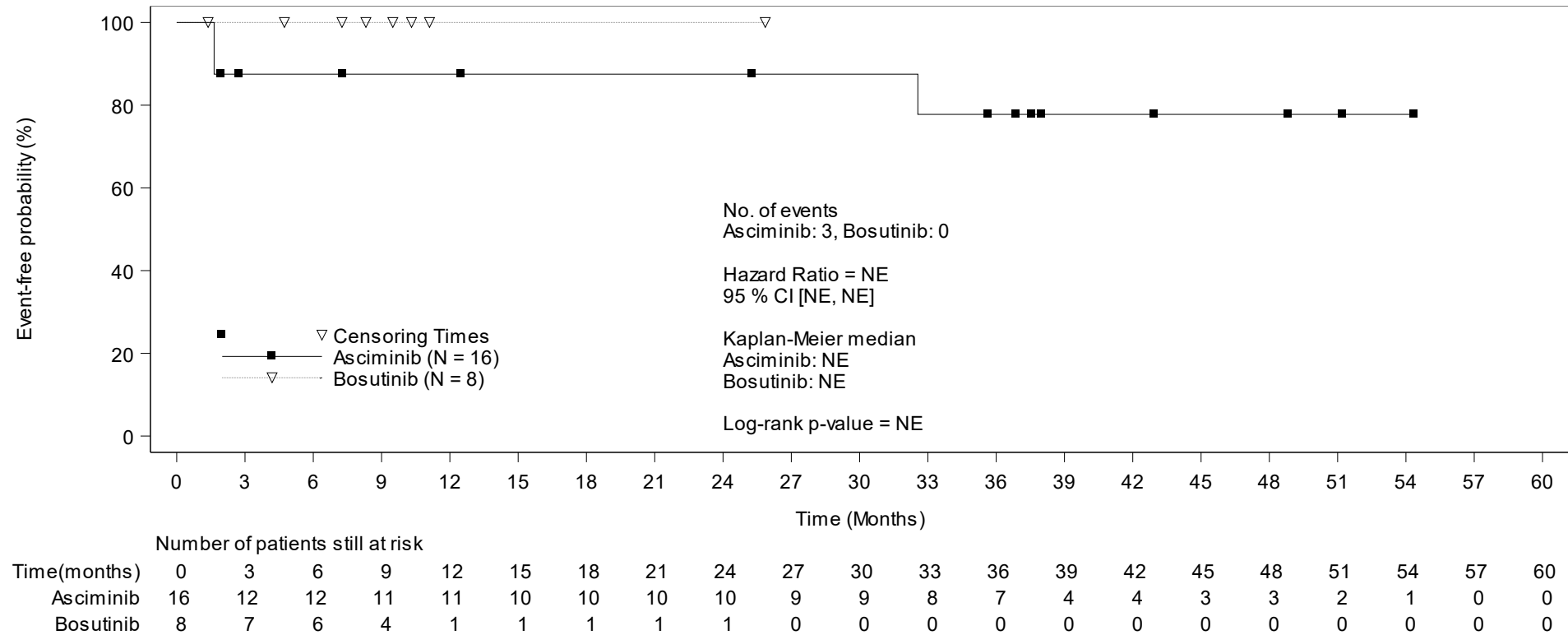
AESI: Hypersensitivity - Race: Caucasian



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

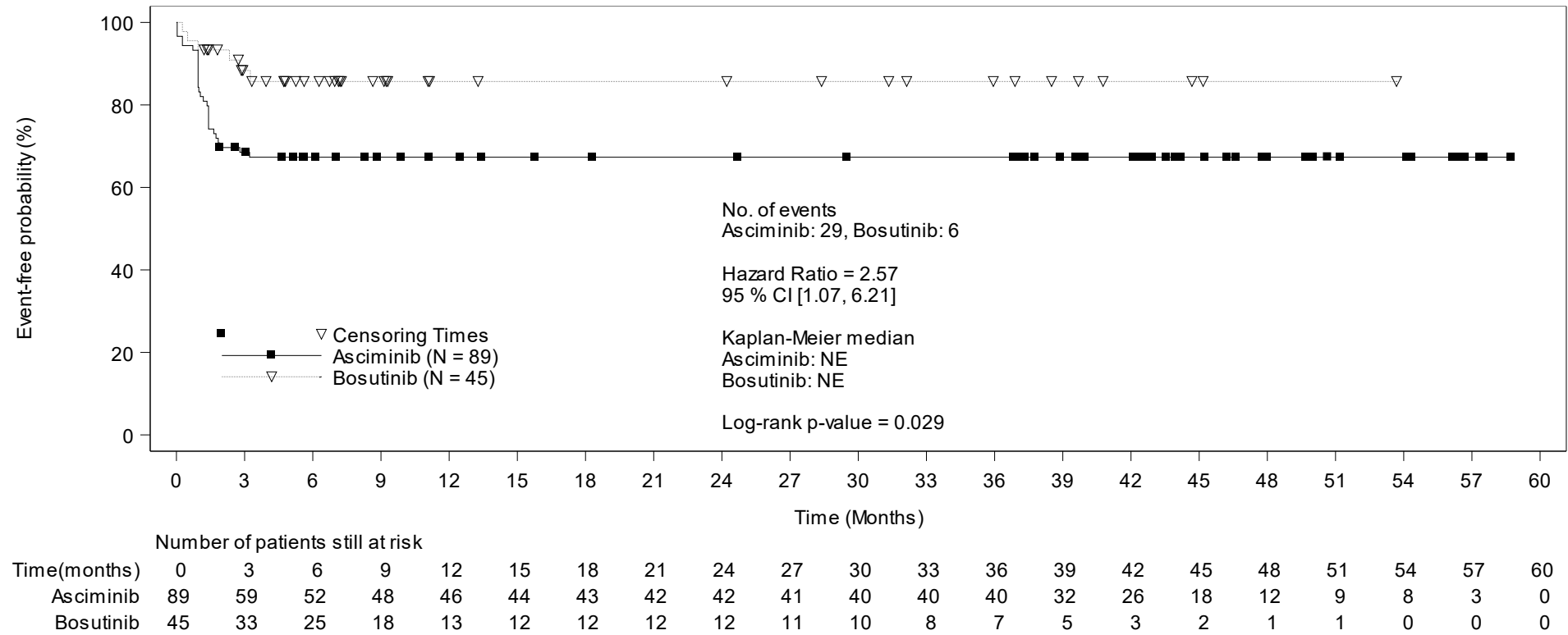
AESI: Hypersensitivity - Race: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

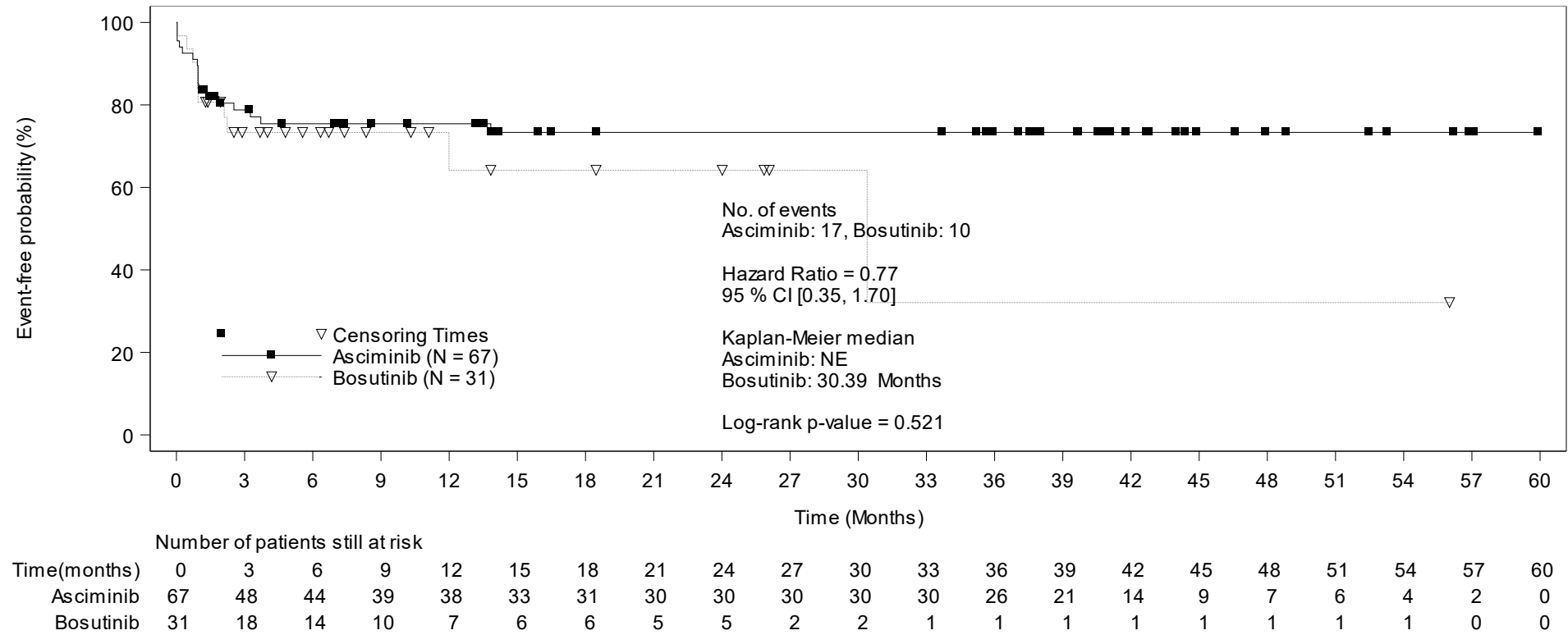
AESI: Myelosuppression (Thrombocytopenia) - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.1 AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set

AESI: Myelosuppression (Thrombocytopenia) - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Edema and fluid retention						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [32.69, NE]	0.34[0.07, 1.60]	0.155
No Major Cytogenetic Response	13/110 (11.8)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	1.04[0.37, 2.95]	0.933
Age category						
18 - 65 years	13/127 (10.2)	NE [NE, NE]	4/ 61 (6.6)	NE [NE, NE]	1.14[0.37, 3.56]	0.818
>=65 years	4/ 29 (13.8)	NE [NE, NE]	4/ 15 (26.7)	32.69 [22.08, NE]	0.43[0.11, 1.74]	0.224
Sex						
Female	5/ 75 (6.7)	NE [NE, NE]	5/ 45 (11.1)	NE [32.69, NE]	0.32[0.09, 1.17]	0.072
Male	12/ 81 (14.8)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	1.42[0.40, 5.06]	0.586
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	1/ 22 (4.5)	NE [NE, NE]	1/ 11 (9.1)	NE [22.08, NE]	0.32[0.02, 5.15]	0.394
Caucasian	14/118 (11.9)	NE [NE, NE]	7/ 57 (12.3)	NE [NE, NE]	0.76[0.30, 1.90]	0.556
Others	2/ 16 (12.5)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	7/ 94 (7.4)	NE [NE, NE]	6/ 54 (11.1)	NE [22.08, NE]	0.45[0.15, 1.39]	0.157
Intolerance	10/ 59 (16.9)	NE [NE, NE]	2/ 22 (9.1)	NE [32.69, NE]	1.70[0.37, 7.84]	0.491
Number of prior TKI therapies						
2	7/ 88 (8.0)	NE [NE, NE]	5/ 33 (15.2)	NE [32.69, NE]	0.38[0.12, 1.19]	0.083
3	8/ 54 (14.8)	NE [NE, NE]	2/ 33 (6.1)	NE [NE, NE]	2.23[0.46, 10.69]	0.304
>=4	2/ 14 (14.3)	NE [11.99, NE]	1/ 10 (10.0)	NE [4.53, NE]	0.56[0.04, 7.96]	0.668
Line of therapy of randomized treatment						
3	7/ 81 (8.6)	NE [NE, NE]	4/ 30 (13.3)	NE [32.69, NE]	0.49[0.14, 1.68]	0.249
4	5/ 44 (11.4)	NE [NE, NE]	3/ 29 (10.3)	NE [NE, NE]	0.87[0.20, 3.79]	0.850

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	5/ 31 (16.1)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	1.96[0.20, 18.86]	0.554
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	15/125 (12.0)	NE [NE, NE]	7/ 63 (11.1)	NE [32.69, NE]	0.77[0.31, 1.92]	0.574
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [4.53, NE]	0.97[0.09, 10.74]	0.983
BCR-ABL ratio at baseline						
>= 1%	16/141 (11.3)	NE [NE, NE]	6/ 72 (8.3)	NE [NE, NE]	1.07[0.42, 2.77]	0.881
< 1%	1/ 15 (6.7)	NE [NE, NE]	2/ 4 (50.0)	32.69 [1.15, NE]	0.11[0.01, 1.24]	0.031
Geographic region						
Europe	5/ 89 (5.6)	NE [NE, NE]	6/ 45 (13.3)	NE [32.69, NE]	0.29[0.09, 0.98]	0.036
Others	12/ 67 (17.9)	NE [NE, NE]	2/ 31 (6.5)	NE [22.08, NE]	2.51[0.55, 11.37]	0.217

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
GI toxicity							
Stratification factor by IRT							
Major Cytogenetic Response	16/ 46 (34.8)	NE [17.64, NE]	19/ 22 (86.4)	0.18 [0.03, 0.62]	0.10	[0.05, 0.22]	<0.001
No Major Cytogenetic Response	35/110 (31.8)	NE [30.39, NE]	41/ 54 (75.9)	0.23 [0.07, 0.49]	0.21	[0.13, 0.34]	<0.001
Age category							
18 - 65 years	43/127 (33.9)	NE [30.39, NE]	48/ 61 (78.7)	0.20 [0.07, 0.46]	0.18	[0.12, 0.28]	<0.001
>=65 years	8/ 29 (27.6)	NE [8.34, NE]	12/ 15 (80.0)	0.26 [0.03, 0.76]	0.18	[0.07, 0.47]	<0.001
Sex							
Female	25/ 75 (33.3)	NE [21.19, NE]	32/ 45 (71.1)	0.20 [0.07, 0.36]	0.20	[0.11, 0.36]	<0.001
Male	26/ 81 (32.1)	NE [20.73, NE]	28/ 31 (90.3)	0.30 [0.07, 0.62]	0.14	[0.08, 0.25]	<0.001
Race							
Asian	5/ 22 (22.7)	NE [13.77, NE]	9/ 11 (81.8)	0.30 [0.03, 2.79]	0.09	[0.02, 0.34]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
 (Page 5 of 30)

	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Caucasian	38/118 (32.2)	NE [NE, NE]	44/ 57 (77.2)	0.20 [0.07, 0.49]	0.19[0.12, 0.30]	<0.001	
Others	8/ 16 (50.0)	30.39 [0.79, NE]	7/ 8 (87.5)	0.16 [0.03, 1.02]	0.17[0.05, 0.59]	0.002	
Reason for discontinuation of the last prior TKI							
Failure	23/ 94 (24.5)	NE [NE, NE]	40/ 54 (74.1)	0.28 [0.07, 0.62]	0.16[0.09, 0.27]	<0.001	
Intolerance	25/ 59 (42.4)	NE [11.99, NE]	20/ 22 (90.9)	0.18 [0.03, 0.46]	0.17[0.09, 0.32]	<0.001	
Number of prior TKI therapies							
2	25/ 88 (28.4)	NE [NE, NE]	25/ 33 (75.8)	0.26 [0.03, 0.72]	0.16[0.09, 0.29]	<0.001	
3	21/ 54 (38.9)	NE [12.65, NE]	28/ 33 (84.8)	0.10 [0.03, 0.36]	0.18[0.10, 0.34]	<0.001	
>=4	5/ 14 (35.7)	NE [0.79, NE]	7/ 10 (70.0)	0.51 [0.03, NE]	0.25[0.06, 0.96]	0.030	
Line of therapy of randomized treatment							
3	22/ 81 (27.2)	NE [NE, NE]	23/ 30 (76.7)	0.23 [0.03, 0.76]	0.15[0.08, 0.27]	<0.001	
4	15/ 44 (34.1)	NE [12.65, NE]	24/ 29 (82.8)	0.20 [0.07, 0.49]	0.22[0.11, 0.43]	<0.001	
>=5	14/ 31 (45.2)	20.76 [1.74, NE]	13/ 17 (76.5)	0.26 [0.03, 2.79]	0.24[0.10, 0.60]	<0.001	

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	45/125 (36.0)	NE [21.19, NE]	53/ 63 (84.1)	0.20 [0.07, 0.30]	0.17[0.11, 0.25]	<0.001
Mutant	2/ 17 (11.8)	NE [17.64, NE]	5/ 8 (62.5)	4.73 [0.03, NE]	0.08[0.01, 0.72]	0.004
BCR-ABL ratio at baseline						
>= 1%	45/141 (31.9)	NE [NE, NE]	56/ 72 (77.8)	0.23 [0.07, 0.36]	0.19[0.12, 0.28]	<0.001
< 1%	6/ 15 (40.0)	NE [1.64, NE]	4/ 4 (100)	0.30 [0.03, NE]	0.07[0.01, 0.42]	<0.001
Geographic region						
Europe	17/ 89 (19.1)	NE [NE, NE]	32/ 45 (71.1)	0.16 [0.07, 0.49]	0.10[0.06, 0.20]	<0.001
Others	34/ 67 (50.7)	13.77 [3.91, NE]	28/ 31 (90.3)	0.26 [0.07, 0.46]	0.30[0.17, 0.50]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Hemorrhage						
Stratification factor by IRT						
Major Cytogenetic Response	6/ 46 (13.0)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	1.78[0.21, 15.34]	0.595
No Major Cytogenetic Response	11/110 (10.0)	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	0.79[0.29, 2.15]	0.644
Age category						
18 - 65 years	13/127 (10.2)	NE [NE, NE]	6/ 61 (9.8)	NE [NE, NE]	0.82[0.31, 2.18]	0.688
>=65 years	4/ 29 (13.8)	NE [NE, NE]	1/ 15 (6.7)	NE [21.06, NE]	1.88[0.21, 17.17]	0.569
Sex						
Female	9/ 75 (12.0)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.74[0.26, 2.10]	0.571
Male	8/ 81 (9.9)	NE [NE, NE]	1/ 31 (3.2)	NE [NE, NE]	2.46[0.30, 20.08]	0.385
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	1/ 11 (9.1)	NE [21.06, NE]	0.53[0.03, 8.69]	0.651

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Caucasian	13/118 (11.0)	NE [NE, NE]	4/ 57 (7.0)	NE [NE, NE]	1.31[0.42, 4.05]	0.637
Others	2/ 16 (12.5)	NE [NE, NE]	2/ 8 (25.0)	NE [5.42, NE]	0.47[0.07, 3.32]	0.435
Reason for discontinuation of the last prior TKI						
Failure	9/ 94 (9.6)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	0.76[0.25, 2.35]	0.637
Intolerance	8/ 59 (13.6)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	1.35[0.28, 6.40]	0.705
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	2/ 33 (6.1)	NE [NE, NE]	1.24[0.27, 5.79]	0.782
3	7/ 54 (13.0)	NE [NE, NE]	5/ 33 (15.2)	NE [NE, NE]	0.83[0.26, 2.62]	0.750
>=4	1/ 14 (7.1)	NE [NE, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	9/ 81 (11.1)	NE [NE, NE]	2/ 30 (6.7)	NE [NE, NE]	1.27[0.27, 5.88]	0.765
4	5/ 44 (11.4)	NE [NE, NE]	4/ 29 (13.8)	NE [NE, NE]	0.76[0.20, 2.85]	0.687
>=5	3/ 31 (9.7)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	1.61[0.16, 16.66]	0.686

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	15/125 (12.0)	NE [NE, NE]	7/ 63 (11.1)	NE [NE, NE]	0.88[0.36, 2.18]	0.786
Mutant	0/ 17	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
>= 1%	16/141 (11.3)	NE [NE, NE]	7/ 72 (9.7)	NE [NE, NE]	0.95[0.39, 2.33]	0.903
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	6/ 89 (6.7)	NE [NE, NE]	3/ 45 (6.7)	NE [NE, NE]	0.91[0.23, 3.70]	0.898
Others	11/ 67 (16.4)	NE [NE, NE]	4/ 31 (12.9)	NE [21.06, NE]	1.09[0.34, 3.52]	0.889

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Hepatotoxicity (including laboratory terms)						
Stratification factor by IRT						
Major Cytogenetic Response	5/ 46 (10.9)	NE [NE, NE]	8/ 22 (36.4)	NE [4.60, NE]	0.14[0.04, 0.47]	<0.001
No Major Cytogenetic Response	14/110 (12.7)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	0.39[0.18, 0.82]	0.010
Age category						
18 - 65 years	17/127 (13.4)	NE [NE, NE]	16/ 61 (26.2)	NE [NE, NE]	0.34[0.17, 0.69]	0.002
>=65 years	2/ 29 (6.9)	NE [NE, NE]	6/ 15 (40.0)	NE [1.41, NE]	0.15[0.03, 0.73]	0.007
Sex						
Female	7/ 75 (9.3)	NE [NE, NE]	16/ 45 (35.6)	NE [3.71, NE]	0.15[0.06, 0.38]	<0.001
Male	12/ 81 (14.8)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.67[0.25, 1.80]	0.423

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Race						
Asian	5/ 22 (22.7)	NE [19.35, NE]	2/ 11 (18.2)	NE [0.92, NE]	1.14[0.20, 6.44]	0.882
Caucasian	12/118 (10.2)	NE [NE, NE]	17/ 57 (29.8)	NE [6.47, NE]	0.23[0.11, 0.50]	<0.001
Others	2/ 16 (12.5)	NE [NE, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.33[0.05, 1.98]	0.200
Reason for discontinuation of the last prior TKI						
Failure	8/ 94 (8.5)	NE [NE, NE]	14/ 54 (25.9)	NE [NE, NE]	0.22[0.09, 0.55]	<0.001
Intolerance	11/ 59 (18.6)	NE [NE, NE]	8/ 22 (36.4)	NE [3.25, NE]	0.40[0.16, 1.00]	0.042
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	8/ 33 (24.2)	NE [6.47, NE]	0.29[0.11, 0.77]	0.009
3	8/ 54 (14.8)	NE [NE, NE]	12/ 33 (36.4)	NE [4.60, NE]	0.28[0.10, 0.74]	0.006
>=4	2/ 14 (14.3)	NE [27.66, NE]	2/ 10 (20.0)	NE [0.72, NE]	0.38[0.03, 4.19]	0.411
Line of therapy of randomized treatment						
3	5/ 81 (6.2)	NE [NE, NE]	7/ 30 (23.3)	NE [6.47, NE]	0.21[0.06, 0.65]	0.003

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
4	8/ 44 (18.2)	NE [NE, NE]	12/ 29 (41.4)	NE [3.25, NE]	0.41[0.17, 0.99]		0.042
>=5	6/ 31 (19.4)	NE [30.39, NE]	3/ 17 (17.6)	NE [NE, NE]	0.44[0.07, 2.64]		0.357
With or without Week1							
Day 1 BCR-ABL1							
mutation							
Wild type	16/125 (12.8)	NE [NE, NE]	18/ 63 (28.6)	NE [NE, NE]	0.32[0.16, 0.63]		<0.001
Mutant	2/ 17 (11.8)	NE [9.23, NE]	3/ 8 (37.5)	NE [0.95, NE]	0.28[0.05, 1.68]		0.136
BCR-ABL ratio at							
baseline							
>= 1%	16/141 (11.3)	NE [NE, NE]	20/ 72 (27.8)	NE [NE, NE]	0.31[0.16, 0.61]		<0.001
< 1%	3/ 15 (20.0)	NE [33.15, NE]	2/ 4 (50.0)	4.60 [2.73, NE]	0.20[0.03, 1.20]		0.051
Geographic region							
Europe	9/ 89 (10.1)	NE [NE, NE]	14/ 45 (31.1)	NE [6.47, NE]	0.21[0.09, 0.50]		<0.001
Others	10/ 67 (14.9)	NE [NE, NE]	8/ 31 (25.8)	NE [NE, NE]	0.49[0.19, 1.27]		0.133

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Hypersensitivity						
Stratification factor by IRT						
Major Cytogenetic Response	9/ 46 (19.6)	NE [NE, NE]	10/ 22 (45.5)	6.47 [1.22, NE]	0.23[0.09, 0.60]	0.001
No Major Cytogenetic Response	23/110 (20.9)	NE [NE, NE]	13/ 54 (24.1)	NE [NE, NE]	0.73[0.37, 1.45]	0.372
Age category						
18 - 65 years	27/127 (21.3)	NE [NE, NE]	20/ 61 (32.8)	NE [6.47, NE]	0.49[0.27, 0.87]	0.014
>=65 years	5/ 29 (17.2)	NE [NE, NE]	3/ 15 (20.0)	NE [4.57, NE]	0.62[0.14, 2.75]	0.523
Sex						
Female	17/ 75 (22.7)	NE [NE, NE]	17/ 45 (37.8)	NE [4.57, NE]	0.41[0.20, 0.81]	0.008
Male	15/ 81 (18.5)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.78[0.30, 2.05]	0.618
Race						
Asian	2/ 22 (9.1)	NE [NE, NE]	7/ 11 (63.6)	3.19 [0.39, NE]	0.09[0.02, 0.48]	<0.001

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Caucasian	27/118 (22.9)	NE [NE, NE]	16/ 57 (28.1)	NE [NE, NE]	0.62[0.33, 1.16]	0.129
Others	3/ 16 (18.8)	NE [32.56, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	17/ 94 (18.1)	NE [NE, NE]	12/ 54 (22.2)	NE [NE, NE]	0.64[0.30, 1.36]	0.243
Intolerance	15/ 59 (25.4)	NE [41.07, NE]	11/ 22 (50.0)	6.47 [1.64, NE]	0.36[0.16, 0.81]	0.010
Number of prior TKI therapies						
2	17/ 88 (19.3)	NE [NE, NE]	9/ 33 (27.3)	NE [6.47, NE]	0.55[0.24, 1.24]	0.145
3	11/ 54 (20.4)	NE [NE, NE]	9/ 33 (27.3)	NE [NE, NE]	0.60[0.24, 1.49]	0.264
>=4	4/ 14 (28.6)	NE [6.47, NE]	5/ 10 (50.0)	6.21 [0.13, NE]	0.24[0.05, 1.26]	0.069
Line of therapy of randomized treatment						
3	16/ 81 (19.8)	NE [NE, NE]	8/ 30 (26.7)	NE [6.47, NE]	0.59[0.25, 1.38]	0.221
4	7/ 44 (15.9)	NE [NE, NE]	7/ 29 (24.1)	NE [NE, NE]	0.57[0.20, 1.63]	0.281
>=5	9/ 31 (29.0)	NE [32.56, NE]	8/ 17 (47.1)	6.21 [0.33, NE]	0.31[0.10, 0.97]	0.035

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	28/125 (22.4)	NE [NE, NE]	20/ 63 (31.7)	NE [NE, NE]	0.52[0.29, 0.94]	0.027
Mutant	4/ 17 (23.5)	NE [32.56, NE]	2/ 8 (25.0)	NE [1.64, NE]	0.76[0.13, 4.57]	0.766
BCR-ABL ratio at baseline						
>= 1%	30/141 (21.3)	NE [NE, NE]	22/ 72 (30.6)	NE [NE, NE]	0.50[0.29, 0.88]	0.015
< 1%	2/ 15 (13.3)	NE [NE, NE]	1/ 4 (25.0)	NE [4.57, NE]	0.61[0.06, 6.72]	0.682
Geographic region						
Europe	15/ 89 (16.9)	NE [NE, NE]	14/ 45 (31.1)	NE [6.47, NE]	0.40[0.19, 0.84]	0.012
Others	17/ 67 (25.4)	NE [NE, NE]	9/ 31 (29.0)	NE [3.29, NE]	0.64[0.28, 1.49]	0.298

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Erythropenia)						
Stratification factor by IRT						
Major Cytogenetic Response	1/ 46 (2.2)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	0.21[0.02, 2.36]	0.166
No Major Cytogenetic Response	14/110 (12.7)	NE [NE, NE]	4/ 54 (7.4)	NE [NE, NE]	1.62[0.53, 4.92]	0.394
Age category						
18 - 65 years	9/127 (7.1)	NE [NE, NE]	6/ 61 (9.8)	NE [NE, NE]	0.65[0.23, 1.84]	0.416
>=65 years	6/ 29 (20.7)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	9/ 75 (12.0)	NE [NE, NE]	4/ 45 (8.9)	NE [19.35, NE]	1.21[0.37, 3.95]	0.759
Male	6/ 81 (7.4)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	1.21[0.24, 6.01]	0.815
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Asian	2/ 22 (9.1)	NE [NE, NE]	2/ 11 (18.2)	19.35 [1.87, NE]	0.48[0.06, 3.60]	0.468
Caucasian	11/118 (9.3)	NE [NE, NE]	2/ 57 (3.5)	NE [NE, NE]	2.54[0.56, 11.47]	0.209
Others	2/ 16 (12.5)	NE [NE, NE]	2/ 8 (25.0)	NE [1.41, NE]	0.41[0.06, 2.91]	0.356
Reason for discontinuation of the last prior TKI						
Failure	8/ 94 (8.5)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	0.76[0.24, 2.33]	0.624
Intolerance	7/ 59 (11.9)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	2.82[0.35, 23.03]	0.312
Number of prior TKI therapies						
2	9/ 88 (10.2)	NE [NE, NE]	1/ 33 (3.0)	NE [NE, NE]	2.87[0.36, 22.71]	0.294
3	3/ 54 (5.6)	NE [NE, NE]	5/ 33 (15.2)	NE [19.35, NE]	0.36[0.09, 1.50]	0.141
>=4	3/ 14 (21.4)	NE [3.25, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	13/125 (10.4)	NE [NE, NE]	4/ 63 (6.3)	NE [NE, NE]	1.55[0.50, 4.76]	0.442

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Mutant	1/ 17 (5.9)	NE [NE, NE]	1/ 8 (12.5)	NE [19.35, NE]	0.43[0.03, 6.92]	0.542
BCR-ABL ratio at baseline						
>= 1%	15/141 (10.6)	NE [NE, NE]	5/ 72 (6.9)	NE [NE, NE]	1.43[0.52, 3.93]	0.491
< 1%	0/ 15	NE [NE, NE]	1/ 4 (25.0)	NE [1.15, NE]	NE [NE, NE]	NE
Geographic region						
Europe	9/ 89 (10.1)	NE [NE, NE]	4/ 45 (8.9)	NE [NE, NE]	1.04[0.32, 3.40]	0.942
Others	6/ 67 (9.0)	NE [NE, NE]	2/ 31 (6.5)	NE [19.35, NE]	1.27[0.25, 6.34]	0.774

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Neutropenia)						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.62[0.14, 2.76]	0.524
No Major Cytogenetic Response	22/110 (20.0)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.99[0.47, 2.09]	0.973
Age category						
18 - 65 years	22/127 (17.3)	NE [NE, NE]	11/ 61 (18.0)	NE [NE, NE]	0.88[0.43, 1.82]	0.735
>=65 years	4/ 29 (13.8)	NE [NE, NE]	2/ 15 (13.3)	NE [5.09, NE]	1.00[0.18, 5.45]	0.997
Sex						
Female	12/ 75 (16.0)	NE [NE, NE]	9/ 45 (20.0)	NE [NE, NE]	0.66[0.28, 1.58]	0.352
Male	14/ 81 (17.3)	NE [NE, NE]	4/ 31 (12.9)	NE [NE, NE]	1.30[0.43, 3.94]	0.645
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	5/ 22 (22.7)	NE [NE, NE]	2/ 11 (18.2)	NE [1.41, NE]	1.32[0.25, 7.11]	0.743
Caucasian	19/118 (16.1)	NE [NE, NE]	10/ 57 (17.5)	NE [NE, NE]	0.80[0.37, 1.73]	0.578
Others	2/ 16 (12.5)	NE [NE, NE]	1/ 8 (12.5)	NE [2.33, NE]	0.85[0.08, 9.40]	0.894
Reason for discontinuation of the last prior TKI						
Failure	13/ 94 (13.8)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.64[0.28, 1.47]	0.283
Intolerance	13/ 59 (22.0)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	1.76[0.50, 6.20]	0.368
Number of prior TKI therapies						
2	14/ 88 (15.9)	NE [NE, NE]	6/ 33 (18.2)	NE [NE, NE]	0.76[0.29, 1.99]	0.584
3	9/ 54 (16.7)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.78[0.29, 2.08]	0.611
>=4	3/ 14 (21.4)	NE [3.09, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	13/ 81 (16.0)	NE [NE, NE]	6/ 30 (20.0)	NE [NE, NE]	0.70[0.27, 1.84]	0.467
4	6/ 44 (13.6)	NE [NE, NE]	4/ 29 (13.8)	NE [NE, NE]	0.92[0.26, 3.26]	0.890

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	7/ 31 (22.6)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	1.13[0.27, 4.66]	0.865
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	22/125 (17.6)	NE [NE, NE]	12/ 63 (19.0)	NE [NE, NE]	0.84[0.42, 1.70]	0.631
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [0.92, NE]	0.86[0.08, 9.52]	0.904
BCR-ABL ratio at baseline						
>= 1%	25/141 (17.7)	NE [NE, NE]	13/ 72 (18.1)	NE [NE, NE]	0.90[0.46, 1.76]	0.759
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	13/ 89 (14.6)	NE [NE, NE]	7/ 45 (15.6)	NE [NE, NE]	0.85[0.34, 2.13]	0.720
Others	13/ 67 (19.4)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.97[0.37, 2.57]	0.962

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Myelosuppression (Leucopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	4/ 46 (8.7)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	0.62[0.14, 2.76]	0.524
No Major Cytogenetic Response	23/110 (20.9)	NE [NE, NE]	11/ 54 (20.4)	NE [NE, NE]	0.93[0.45, 1.91]	0.846
Age category						
18 - 65 years	23/127 (18.1)	NE [NE, NE]	12/ 61 (19.7)	NE [NE, NE]	0.84[0.42, 1.68]	0.619
>=65 years	4/ 29 (13.8)	NE [NE, NE]	2/ 15 (13.3)	NE [5.09, NE]	1.00[0.18, 5.45]	0.997
Sex						
Female	12/ 75 (16.0)	NE [NE, NE]	10/ 45 (22.2)	NE [NE, NE]	0.59[0.25, 1.37]	0.218
Male	15/ 81 (18.5)	NE [NE, NE]	4/ 31 (12.9)	NE [NE, NE]	1.39[0.46, 4.20]	0.553
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	5/ 22 (22.7)	NE [NE, NE]	2/ 11 (18.2)	NE [1.41, NE]	1.32[0.25, 7.11]	0.743
Caucasian	20/118 (16.9)	NE [NE, NE]	11/ 57 (19.3)	NE [NE, NE]	0.76[0.36, 1.59]	0.469
Others	2/ 16 (12.5)	NE [NE, NE]	1/ 8 (12.5)	NE [2.33, NE]	0.85[0.08, 9.40]	0.894
Reason for discontinuation of the last prior TKI						
Failure	14/ 94 (14.9)	NE [NE, NE]	11/ 54 (20.4)	NE [NE, NE]	0.62[0.28, 1.37]	0.227
Intolerance	13/ 59 (22.0)	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	1.76[0.50, 6.20]	0.368
Number of prior TKI therapies						
2	15/ 88 (17.0)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.68[0.28, 1.67]	0.400
3	9/ 54 (16.7)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.78[0.29, 2.08]	0.611
>=4	3/ 14 (21.4)	NE [3.09, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	13/ 81 (16.0)	NE [NE, NE]	7/ 30 (23.3)	NE [NE, NE]	0.58[0.23, 1.46]	0.242
4	7/ 44 (15.9)	NE [NE, NE]	4/ 29 (13.8)	NE [NE, NE]	1.07[0.31, 3.67]	0.916

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	7/ 31 (22.6)	NE [NE, NE]	3/ 17 (17.6)	NE [NE, NE]	1.13[0.27, 4.66]	0.865
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	23/125 (18.4)	NE [NE, NE]	13/ 63 (20.6)	NE [NE, NE]	0.80[0.41, 1.59]	0.532
Mutant	2/ 17 (11.8)	NE [NE, NE]	1/ 8 (12.5)	NE [0.92, NE]	0.86[0.08, 9.52]	0.904
BCR-ABL ratio at baseline						
>= 1%	26/141 (18.4)	NE [NE, NE]	14/ 72 (19.4)	NE [NE, NE]	0.86[0.45, 1.65]	0.657
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	14/ 89 (15.7)	NE [NE, NE]	8/ 45 (17.8)	NE [NE, NE]	0.78[0.33, 1.87]	0.583
Others	13/ 67 (19.4)	NE [NE, NE]	6/ 31 (19.4)	NE [NE, NE]	0.97[0.37, 2.57]	0.962

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Thrombocytopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	6/ 46 (13.0)	NE [NE, NE]	3/ 22 (13.6)	NE [11.99, NE]	0.91[0.22, 3.69]	0.889
No Major Cytogenetic Response	31/110 (28.2)	NE [NE, NE]	12/ 54 (22.2)	NE [30.39, NE]	1.21[0.62, 2.37]	0.574
Age category						
18 - 65 years	29/127 (22.8)	NE [NE, NE]	12/ 61 (19.7)	NE [30.39, NE]	1.09[0.55, 2.14]	0.816
>=65 years	8/ 29 (27.6)	NE [5.26, NE]	3/ 15 (20.0)	NE [2.33, NE]	1.43[0.38, 5.41]	0.594
Sex						
Female	17/ 75 (22.7)	NE [NE, NE]	8/ 45 (17.8)	NE [NE, NE]	1.23[0.53, 2.85]	0.639
Male	20/ 81 (24.7)	NE [NE, NE]	7/ 31 (22.6)	NE [30.39, NE]	1.05[0.44, 2.48]	0.919
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	4/ 22 (18.2)	NE [NE, NE]	3/ 11 (27.3)	NE [0.92, NE]	0.87[0.19, 3.98]	0.841
Caucasian	29/118 (24.6)	NE [NE, NE]	10/ 57 (17.5)	NE [NE, NE]	1.35[0.66, 2.78]	0.413
Others	4/ 16 (25.0)	NE [3.02, NE]	2/ 8 (25.0)	NE [2.33, NE]	0.95[0.17, 5.23]	0.956
Reason for discontinuation of the last prior TKI						
Failure	21/ 94 (22.3)	NE [NE, NE]	13/ 54 (24.1)	NE [30.39, NE]	0.79[0.39, 1.58]	0.489
Intolerance	16/ 59 (27.1)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	3.41[0.78, 14.86]	0.081
Number of prior TKI therapies						
2	17/ 88 (19.3)	NE [NE, NE]	4/ 33 (12.1)	NE [30.39, NE]	1.42[0.48, 4.22]	0.532
3	13/ 54 (24.1)	NE [NE, NE]	9/ 33 (27.3)	NE [11.99, NE]	0.91[0.39, 2.15]	0.821
>=4	7/ 14 (50.0)	13.83 [1.87, NE]	2/ 10 (20.0)	NE [0.26, NE]	2.33[0.46, 11.75]	0.293
Line of therapy of randomized treatment						
3	17/ 81 (21.0)	NE [NE, NE]	3/ 30 (10.0)	NE [30.39, NE]	1.94[0.57, 6.64]	0.282
4	7/ 44 (15.9)	NE [NE, NE]	8/ 29 (27.6)	NE [11.99, NE]	0.49[0.18, 1.38]	0.168

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
>=5	13/ 31 (41.9)	NE [2.56, NE]	4/ 17 (23.5)	NE [2.33, NE]	1.98[0.63, 6.28]	0.233
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	33/125 (26.4)	NE [NE, NE]	13/ 63 (20.6)	NE [30.39, NE]	1.24[0.65, 2.36]	0.517
Mutant	2/ 17 (11.8)	NE [NE, NE]	2/ 8 (25.0)	NE [0.26, NE]	0.39[0.06, 2.80]	0.334
BCR-ABL ratio at baseline						
>= 1%	36/141 (25.5)	NE [NE, NE]	15/ 72 (20.8)	NE [30.39, NE]	1.17[0.64, 2.14]	0.621
< 1%	1/ 15 (6.7)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	22/ 89 (24.7)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	1.88[0.76, 4.64]	0.168
Others	15/ 67 (22.4)	NE [NE, NE]	9/ 31 (29.0)	30.39 [11.99, NE]	0.73[0.32, 1.69]	0.459

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Pancreatic toxicity						
Stratification factor by IRT						
Major Cytogenetic Response	3/ 46 (6.5)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
No Major Cytogenetic Response	9/110 (8.2)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	0.70[0.23, 2.10]	0.521
Age category						
18 - 65 years	8/127 (6.3)	NE [NE, NE]	5/ 61 (8.2)	NE [NE, NE]	0.63[0.20, 1.93]	0.412
>=65 years	4/ 29 (13.8)	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE
Sex						
Female	3/ 75 (4.0)	NE [NE, NE]	3/ 45 (6.7)	NE [11.99, NE]	0.36[0.07, 1.86]	0.206
Male	9/ 81 (11.1)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	1.73[0.37, 8.03]	0.477
Race						
Asian	0/ 22	NE [NE, NE]	1/ 11 (9.1)	NE [6.47, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Caucasian	11/118 (9.3)	NE [NE, NE]	4/ 57 (7.0)	NE [NE, NE]	1.12[0.36, 3.54]	0.846
Others	1/ 16 (6.3)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
Reason for discontinuation of the last prior TKI						
Failure	7/ 94 (7.4)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	0.59[0.19, 1.90]	0.373
Intolerance	5/ 59 (8.5)	NE [NE, NE]	0/ 22	NE [NE, NE]	NE [NE, NE]	NE
Number of prior TKI therapies						
2	7/ 88 (8.0)	NE [NE, NE]	3/ 33 (9.1)	NE [NE, NE]	0.74[0.19, 2.88]	0.665
3	4/ 54 (7.4)	NE [NE, NE]	2/ 33 (6.1)	NE [11.99, NE]	0.90[0.16, 5.04]	0.900
>=4	1/ 14 (7.1)	NE [9.23, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	7/ 81 (8.6)	NE [NE, NE]	3/ 30 (10.0)	NE [NE, NE]	0.74[0.19, 2.88]	0.667
4	2/ 44 (4.5)	NE [NE, NE]	2/ 29 (6.9)	NE [11.99, NE]	0.54[0.07, 3.96]	0.541
>=5	3/ 31 (9.7)	NE [NE, NE]	0/ 17	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.2 Grade 1/2 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	11/125 (8.8)	NE [NE, NE]	4/ 63 (6.3)	NE [NE, NE]	1.18[0.37, 3.72]	0.783
Mutant	1/ 17 (5.9)	NE [9.23, NE]	1/ 8 (12.5)	NE [6.47, NE]	0.39[0.02, 6.62]	0.499
BCR-ABL ratio at baseline						
>= 1%	10/141 (7.1)	NE [NE, NE]	5/ 72 (6.9)	NE [NE, NE]	0.82[0.28, 2.40]	0.710
< 1%	2/ 15 (13.3)	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	5/ 89 (5.6)	NE [NE, NE]	2/ 45 (4.4)	NE [NE, NE]	0.96[0.18, 5.03]	0.960
Others	7/ 67 (10.4)	NE [NE, NE]	3/ 31 (9.7)	NE [NE, NE]	0.94[0.24, 3.67]	0.929

Median (time to event) and its 95% CI are generated by KM estimation.

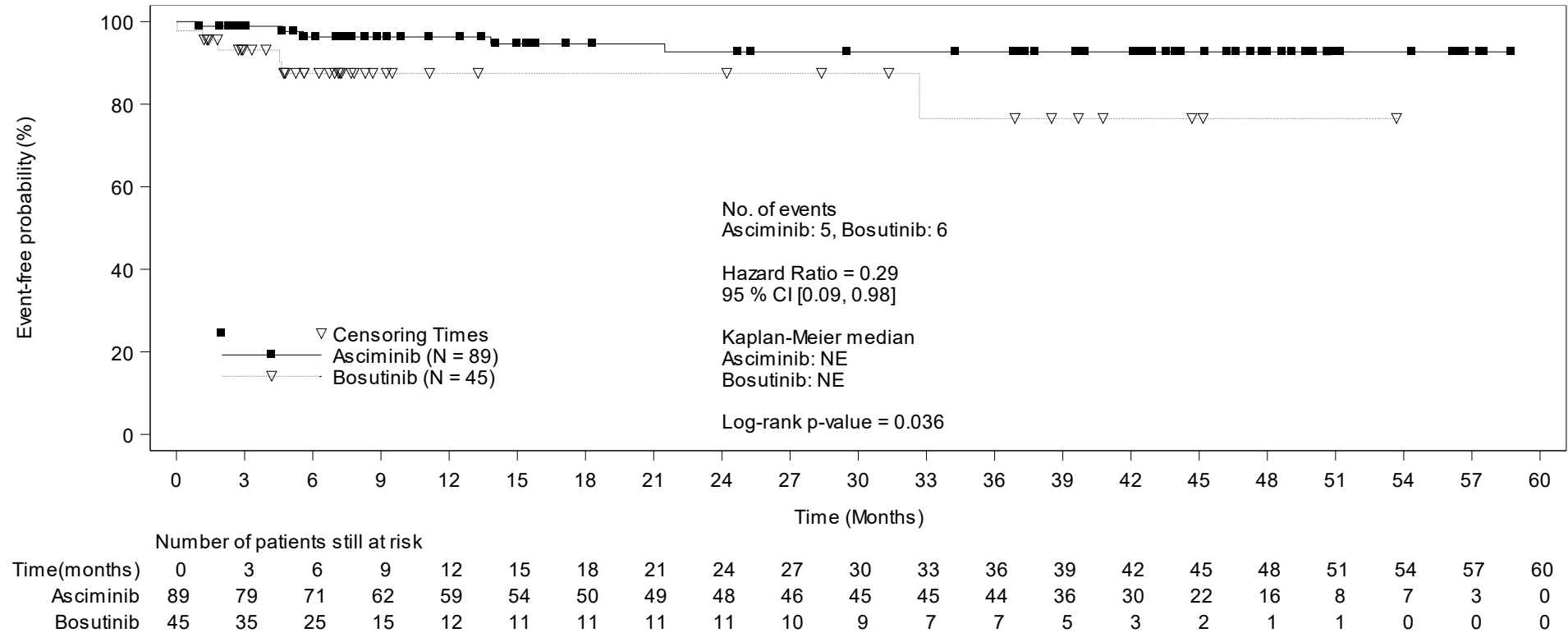
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

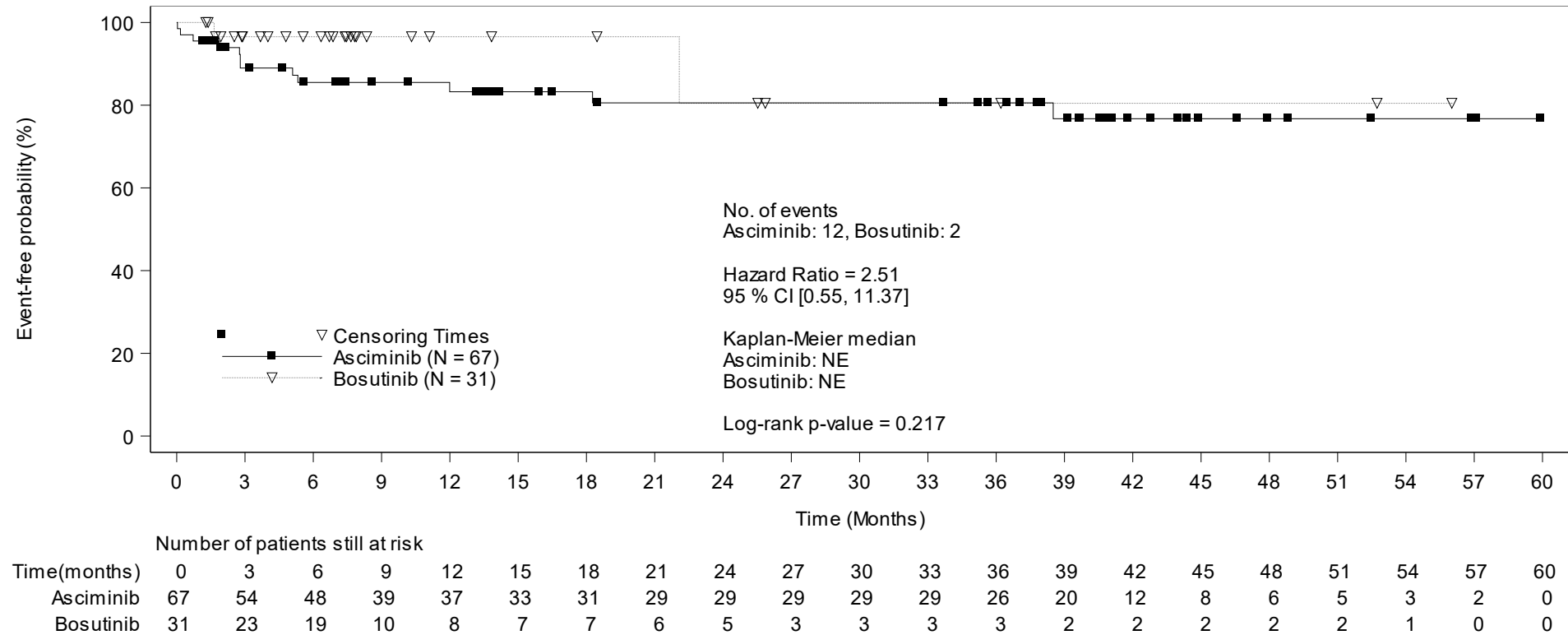
AEsI: Edema and fluid retention - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

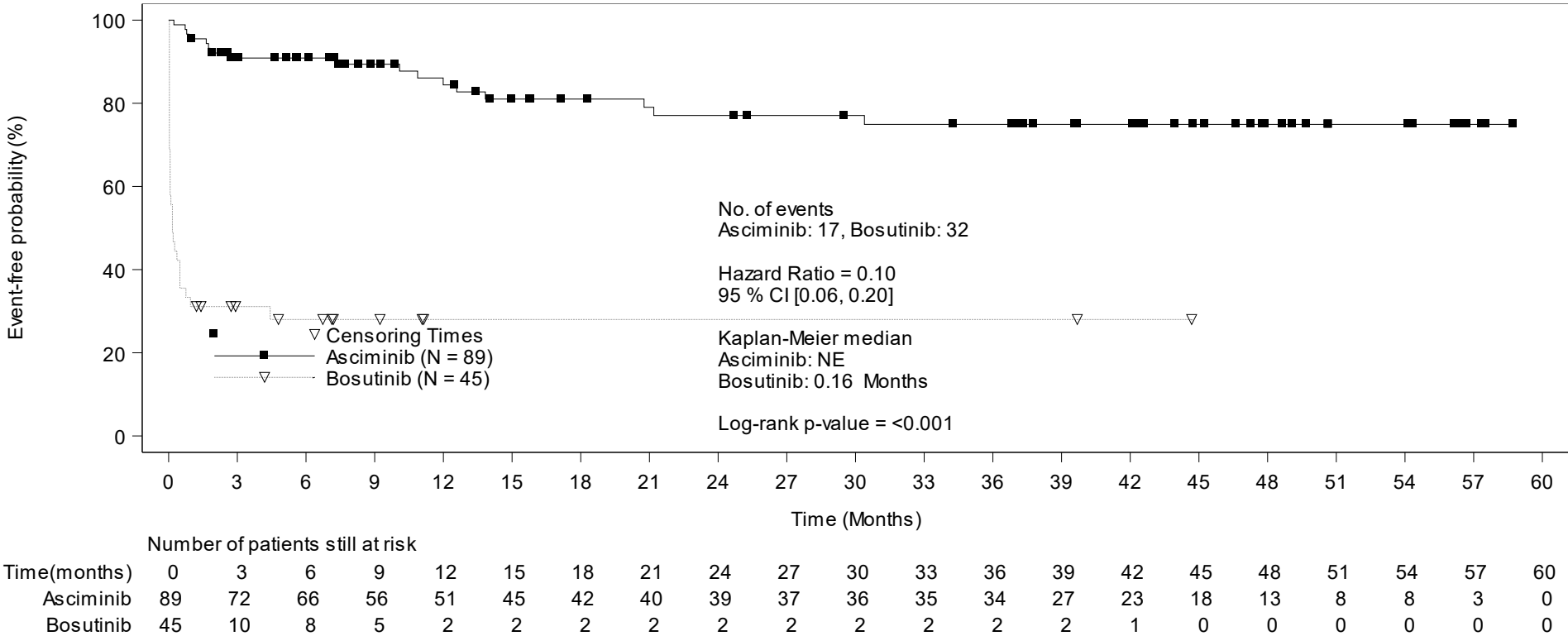
AEsI: Edema and fluid retention - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

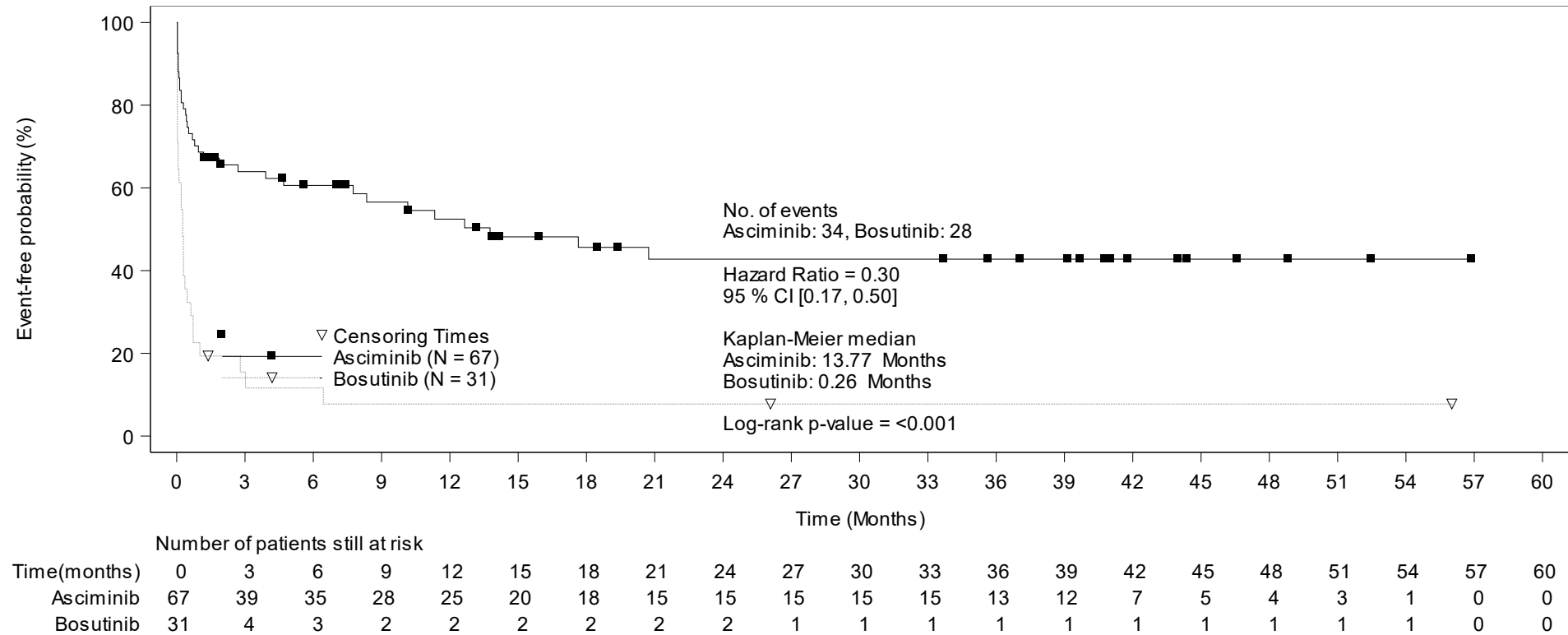
AEsI: GI toxicity - Geographic region: Europe



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AESI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

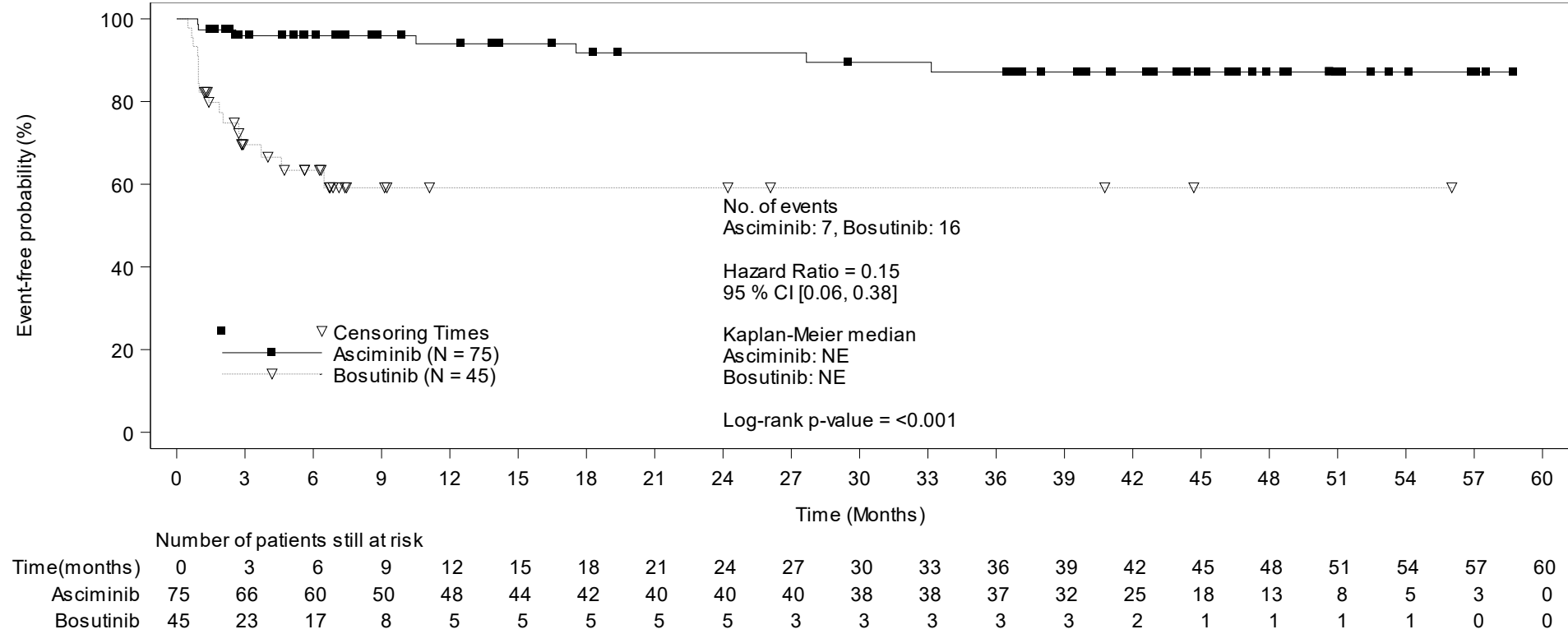
AESI: GI toxicity - Geographic region: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

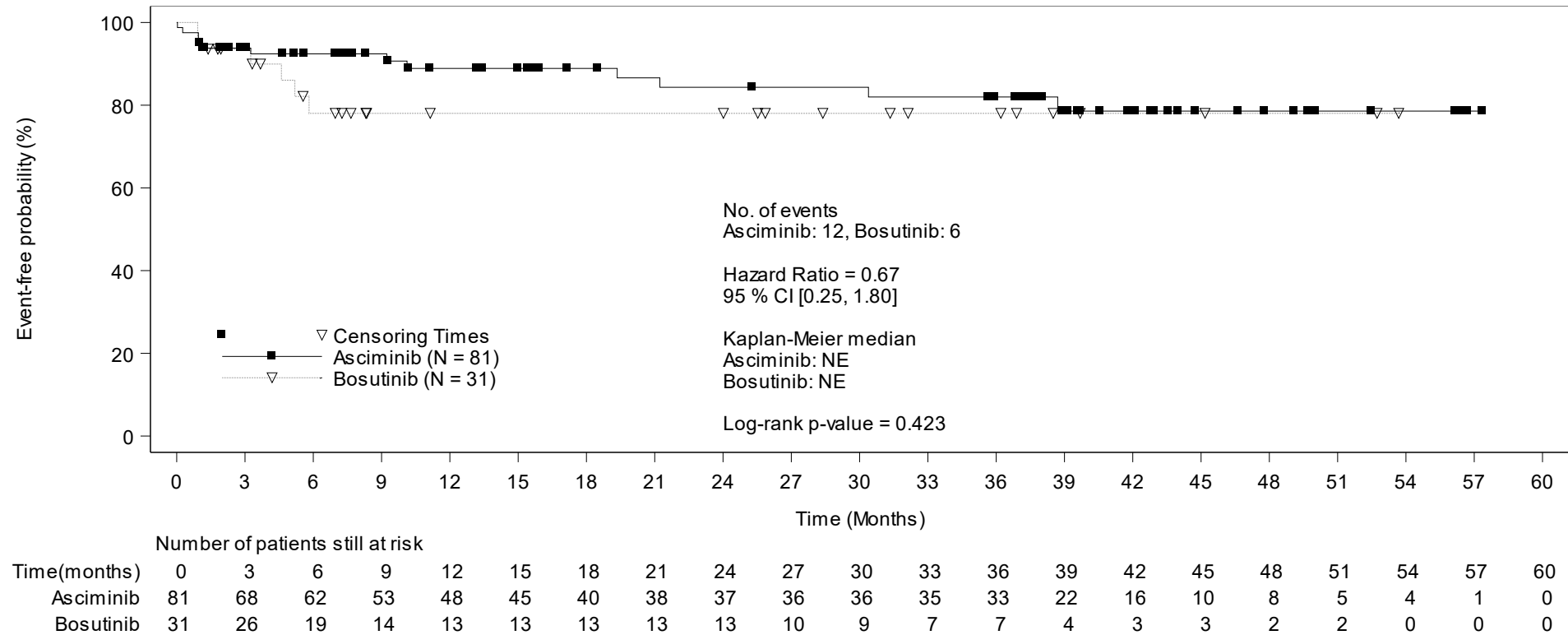
AEsI: Hepatotoxicity (including laboratory terms) - Sex: Female



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

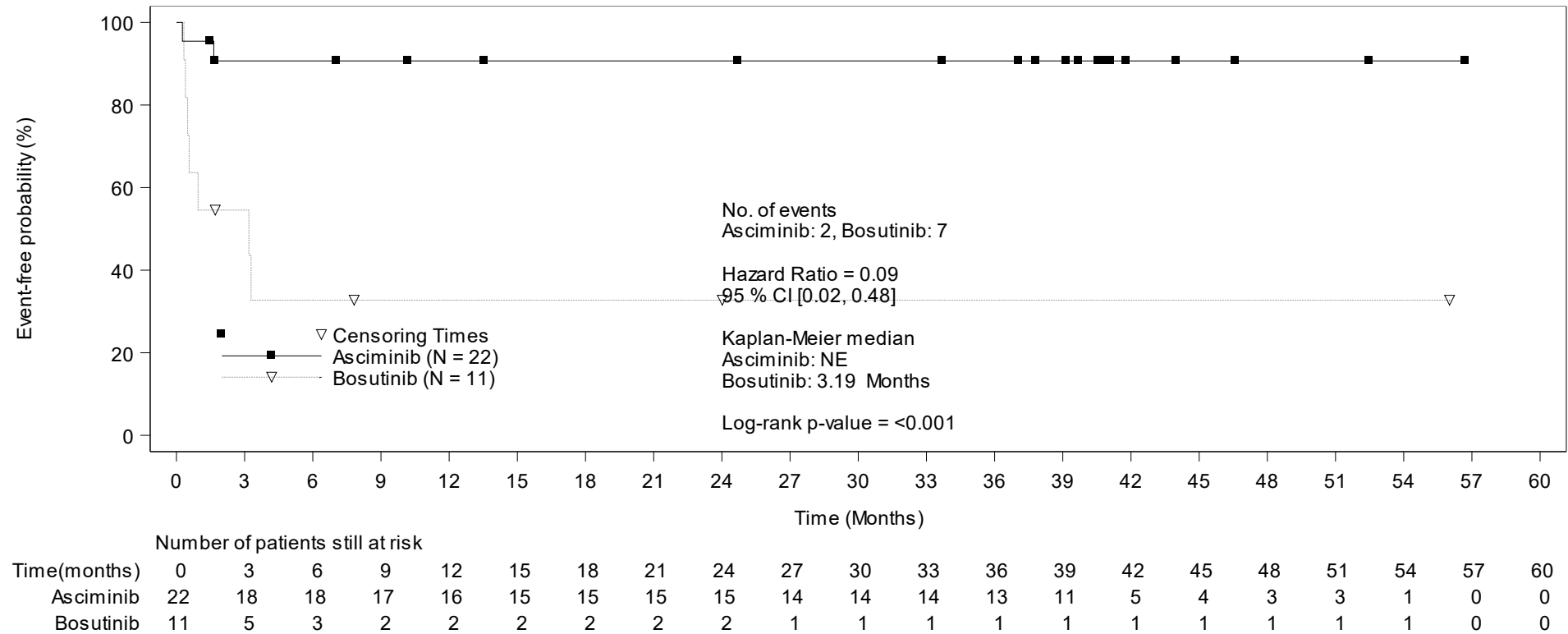
AEsI: Hepatotoxicity (including laboratory terms) - Sex: Male



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

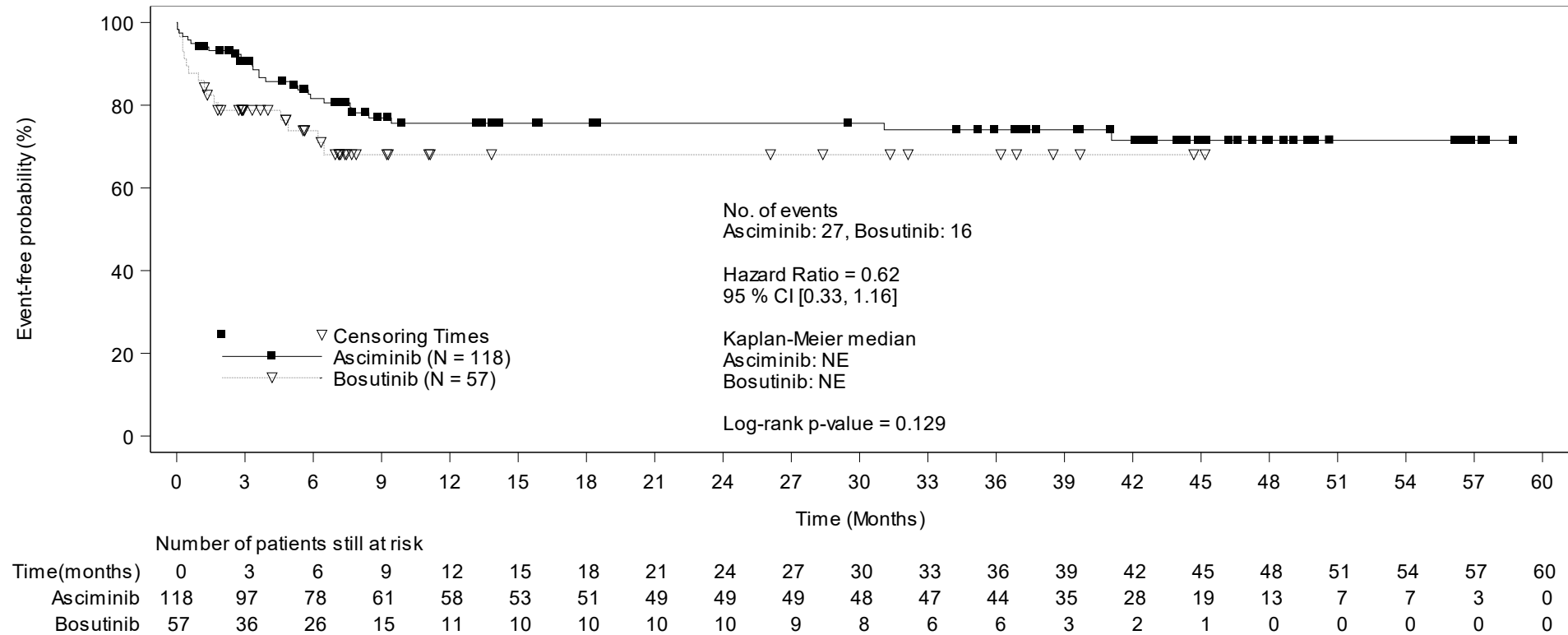
AEsI: Hypersensitivity - Race: Asian



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

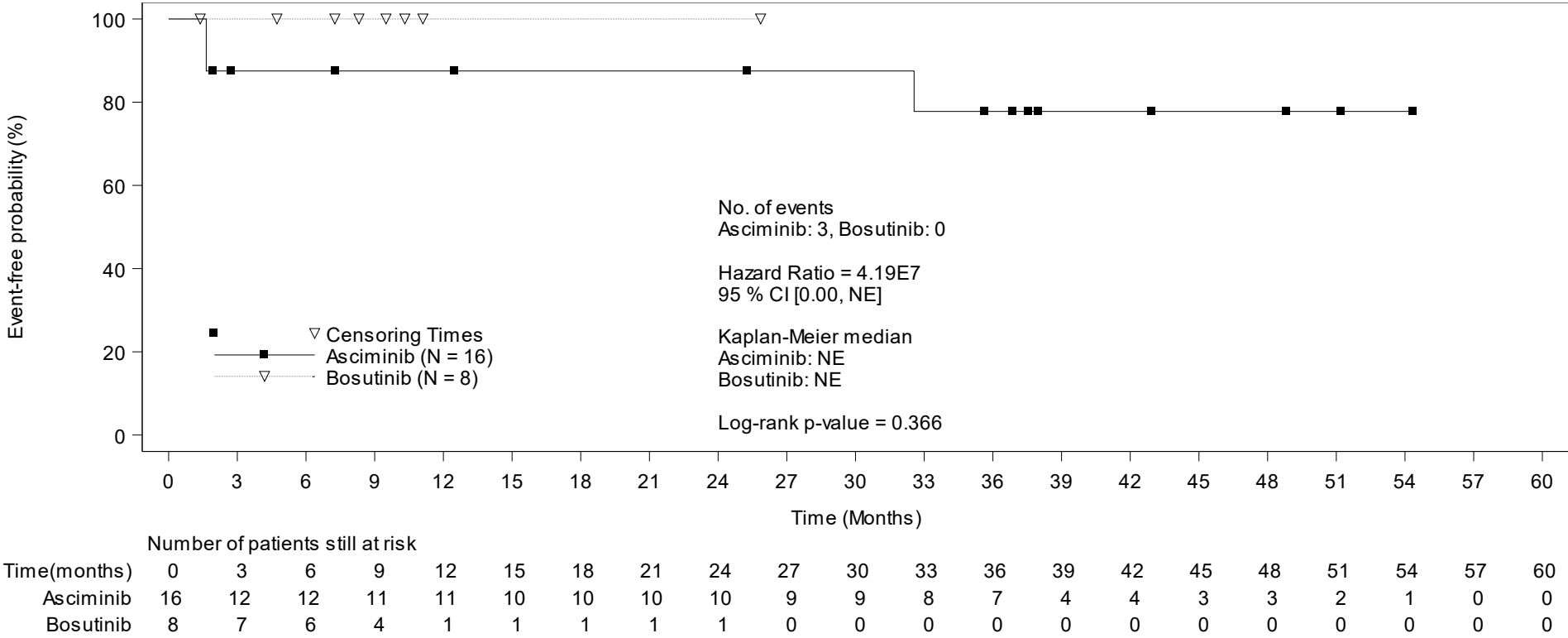
AEsI: Hypersensitivity - Race: Caucasian



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.2 Grade 1/2 AEsI: Kaplan Meier plot of time to first event- subgroup analysis
Safety Set

AEsI: Hypersensitivity - Race: Others



Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup Missing will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AE/SAE: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
GI toxicity						
Stratification factor by IRT						
Major Cytogenetic Response	0/ 46	NE [NE, NE]	3/ 22 (13.6)	NE [NE, NE]	NE [NE, NE]	NE
No Major Cytogenetic Response	5/110 (4.5)	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	0.29[0.08, 0.97]	0.034
Age category						
18 - 65 years	4/127 (3.1)	NE [NE, NE]	8/ 61 (13.1)	NE [NE, NE]	0.16[0.05, 0.57]	0.001
≥65 years	1/ 29 (3.4)	NE [NE, NE]	1/ 15 (6.7)	NE [NE, NE]	0.48[0.03, 7.63]	0.592
Race						
Asian	1/ 22 (4.5)	NE [NE, NE]	1/ 11 (9.1)	NE [NE, NE]	0.52[0.03, 8.83]	0.643
Caucasian	4/118 (3.4)	NE [NE, NE]	7/ 57 (12.3)	NE [NE, NE]	0.20[0.06, 0.73]	0.007
Others	0/ 16	NE [NE, NE]	1/ 8 (12.5)	NE [3.06, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	5/125 (4.0)	NE [NE, NE]	8/ 63 (12.7)	NE [NE, NE]	0.20[0.06, 0.67]	0.004
Mutant	0/ 17	NE [NE, NE]	1/ 8 (12.5)	NE [3.55, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	5/141 (3.5)	NE [NE, NE]	9/ 72 (12.5)	NE [NE, NE]	0.21[0.07, 0.64]	0.003
$< 1\%$	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Hepatotoxicity (including laboratory terms)							
Stratification factor by IRT							
Major Cytogenetic Response	1/ 46 (2.2)	NE [NE, NE]	5/ 22 (22.7)	NE [NE, NE]	0.08[0.01, 0.66]		0.003
No Major Cytogenetic Response	2/110 (1.8)	NE [NE, NE]	8/ 54 (14.8)	NE [NE, NE]	0.10[0.02, 0.48]		<0.001
Age category							
18 - 65 years	2/127 (1.6)	NE [NE, NE]	8/ 61 (13.1)	NE [NE, NE]	0.09[0.02, 0.43]		<0.001
≥65 years	1/ 29 (3.4)	NE [NE, NE]	5/ 15 (33.3)	NE [1.87, NE]	0.10[0.01, 0.84]		0.009
Race							
Asian	1/ 22 (4.5)	NE [NE, NE]	2/ 11 (18.2)	NE [0.92, NE]	0.16[0.01, 2.42]		0.154
Caucasian	2/118 (1.7)	NE [NE, NE]	9/ 57 (15.8)	NE [NE, NE]	0.09[0.02, 0.44]		<0.001
Others	0/ 16	NE [NE, NE]	2/ 8 (25.0)	NE [1.87, NE]	NE [NE, NE]		NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Reason for discontinuation of the last prior TKI						
Failure	0/ 94	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	NE [NE, NE]	NE
Intolerance	3/ 59 (5.1)	NE [NE, NE]	7/ 22 (31.8)	NE [3.75, NE]	0.13[0.03, 0.50]	<0.001
Number of prior TKI therapies						
2	1/ 88 (1.1)	NE [NE, NE]	5/ 33 (15.2)	NE [NE, NE]	0.07[0.01, 0.57]	0.001
3	2/ 54 (3.7)	NE [NE, NE]	8/ 33 (24.2)	NE [NE, NE]	0.13[0.03, 0.60]	0.002
≥4	0/ 14	NE [NE, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]	NE
Line of therapy of randomized treatment						
3	0/ 81	NE [NE, NE]	4/ 30 (13.3)	NE [NE, NE]	NE [NE, NE]	NE
4	2/ 44 (4.5)	NE [NE, NE]	8/ 29 (27.6)	NE [NE, NE]	0.13[0.03, 0.63]	0.003
≥5	1/ 31 (3.2)	NE [NE, NE]	1/ 17 (5.9)	NE [NE, NE]	0.76[0.05, 12.11]	0.844

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AESI: time to first event - subgroup analysis
 Safety Set
 (Page 5 of 15)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	3/125 (2.4)	NE [NE, NE]	11/ 63 (17.5)	NE [NE, NE]	0.11[0.03, 0.41]	<0.001
Mutant	0/ 17	NE [NE, NE]	2/ 8 (25.0)	NE [0.95, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	3/141 (2.1)	NE [NE, NE]	12/ 72 (16.7)	NE [NE, NE]	0.10[0.03, 0.37]	<0.001
< 1%	0/ 15	NE [NE, NE]	1/ 4 (25.0)	NE [1.25, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
 (Page 6 of 15)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Myelosuppression (Neutropenia)						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	0.47[0.07, 3.35]	0.442
No Major Cytogenetic Response	27/110 (24.5)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	1.47[0.69, 3.13]	0.314
Age category						
18 - 65 years	25/127 (19.7)	NE [NE, NE]	9/ 61 (14.8)	NE [NE, NE]	1.31[0.61, 2.81]	0.487
≥65 years	4/ 29 (13.8)	NE [NE, NE]	2/ 15 (13.3)	NE [NE, NE]	1.11[0.20, 6.05]	0.903
Sex						
Female	12/ 75 (16.0)	NE [NE, NE]	7/ 45 (15.6)	NE [NE, NE]	0.97[0.38, 2.47]	0.953
Male	17/ 81 (21.0)	NE [NE, NE]	4/ 31 (12.9)	NE [NE, NE]	1.79[0.60, 5.31]	0.289
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
 (Page 7 of 15)

	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Asian	7/ 22 (31.8)	NE [1.87, NE]	3/ 11 (27.3)	NE [0.95, NE]	1.56[0.39, 6.16]		0.519
Caucasian	18/118 (15.3)	NE [NE, NE]	6/ 57 (10.5)	NE [NE, NE]	1.42[0.56, 3.58]		0.452
Others	4/ 16 (25.0)	NE [13.37, NE]	2/ 8 (25.0)	NE [1.87, NE]	0.77[0.14, 4.35]		0.775
Reason for discontinuation of the last prior TKI							
Failure	16/ 94 (17.0)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.86[0.39, 1.89]		0.706
Intolerance	13/ 59 (22.0)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	5.65[0.74, 43.24]		0.060
Number of prior TKI therapies							
2	18/ 88 (20.5)	NE [NE, NE]	4/ 33 (12.1)	NE [NE, NE]	1.57[0.53, 4.64]		0.412
3	10/ 54 (18.5)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.88[0.34, 2.32]		0.804
≥4	1/ 14 (7.1)	NE [NE, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]		NE
Line of therapy of randomized treatment							
3	16/ 81 (19.8)	NE [NE, NE]	3/ 30 (10.0)	NE [NE, NE]	1.87[0.54, 6.42]		0.316
4	8/ 44 (18.2)	NE [NE, NE]	6/ 29 (20.7)	NE [NE, NE]	0.79[0.27, 2.28]		0.663

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AESI: time to first event - subgroup analysis
 Safety Set
 (Page 8 of 15)

	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
≥ 5	5/ 31 (16.1)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	1.63[0.31, 8.70]	0.564
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	28/125 (22.4)	NE [NE, NE]	11/ 63 (17.5)	NE [NE, NE]	1.27[0.63, 2.55]	0.501
Mutant	1/ 17 (5.9)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	29/141 (20.6)	NE [NE, NE]	11/ 72 (15.3)	NE [NE, NE]	1.33[0.67, 2.67]	0.417
$< 1\%$	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	12/ 89 (13.5)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.88[0.33, 2.36]	0.804
Others	17/ 67 (25.4)	NE [NE, NE]	5/ 31 (16.1)	NE [NE, NE]	1.93[0.71, 5.24]	0.189

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Myelosuppression (Leucopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	0.47[0.07, 3.35]	0.442
No Major Cytogenetic Response	27/110 (24.5)	NE [NE, NE]	9/ 54 (16.7)	NE [NE, NE]	1.47[0.69, 3.13]	0.314
Age category						
18 - 65 years	25/127 (19.7)	NE [NE, NE]	9/ 61 (14.8)	NE [NE, NE]	1.31[0.61, 2.81]	0.487
≥65 years	4/ 29 (13.8)	NE [NE, NE]	2/ 15 (13.3)	NE [NE, NE]	1.11[0.20, 6.05]	0.903
Sex						
Female	12/ 75 (16.0)	NE [NE, NE]	7/ 45 (15.6)	NE [NE, NE]	0.97[0.38, 2.47]	0.953
Male	17/ 81 (21.0)	NE [NE, NE]	4/ 31 (12.9)	NE [NE, NE]	1.79[0.60, 5.31]	0.289
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison		
	Asciminib N=156		Bosutinib N=76		HR	[95% CI]	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]			
Asian	7/ 22 (31.8)	NE [1.87, NE]	3/ 11 (27.3)	NE [0.95, NE]	1.56[0.39, 6.16]		0.519
Caucasian	18/118 (15.3)	NE [NE, NE]	6/ 57 (10.5)	NE [NE, NE]	1.42[0.56, 3.58]		0.452
Others	4/ 16 (25.0)	NE [13.37, NE]	2/ 8 (25.0)	NE [1.87, NE]	0.77[0.14, 4.35]		0.775
Reason for discontinuation of the last prior TKI							
Failure	16/ 94 (17.0)	NE [NE, NE]	10/ 54 (18.5)	NE [NE, NE]	0.86[0.39, 1.89]		0.706
Intolerance	13/ 59 (22.0)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	5.65[0.74, 43.24]		0.060
Number of prior TKI therapies							
2	18/ 88 (20.5)	NE [NE, NE]	4/ 33 (12.1)	NE [NE, NE]	1.57[0.53, 4.64]		0.412
3	10/ 54 (18.5)	NE [NE, NE]	7/ 33 (21.2)	NE [NE, NE]	0.88[0.34, 2.32]		0.804
≥4	1/ 14 (7.1)	NE [NE, NE]	0/ 10	NE [NE, NE]	NE [NE, NE]		NE
Line of therapy of randomized treatment							
3	16/ 81 (19.8)	NE [NE, NE]	3/ 30 (10.0)	NE [NE, NE]	1.87[0.54, 6.42]		0.316
4	8/ 44 (18.2)	NE [NE, NE]	6/ 29 (20.7)	NE [NE, NE]	0.79[0.27, 2.28]		0.663

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
≥ 5	5/ 31 (16.1)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	1.63[0.31, 8.70]	0.564
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	28/125 (22.4)	NE [NE, NE]	11/ 63 (17.5)	NE [NE, NE]	1.27[0.63, 2.55]	0.501
Mutant	1/ 17 (5.9)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	29/141 (20.6)	NE [NE, NE]	11/ 72 (15.3)	NE [NE, NE]	1.33[0.67, 2.67]	0.417
$< 1\%$	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	12/ 89 (13.5)	NE [NE, NE]	6/ 45 (13.3)	NE [NE, NE]	0.88[0.33, 2.36]	0.804
Others	17/ 67 (25.4)	NE [NE, NE]	5/ 31 (16.1)	NE [NE, NE]	1.93[0.71, 5.24]	0.189

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Myelosuppression (Thrombocytopenia)						
Stratification factor by IRT						
Major Cytogenetic Response	2/ 46 (4.3)	NE [NE, NE]	1/ 22 (4.5)	NE [NE, NE]	0.96[0.09, 10.62]	0.975
No Major Cytogenetic Response	33/110 (30.0)	NE [NE, NE]	6/ 54 (11.1)	NE [NE, NE]	2.85[1.19, 6.80]	0.014
Age category						
18 - 65 years	28/127 (22.0)	NE [NE, NE]	5/ 61 (8.2)	NE [NE, NE]	2.77[1.07, 7.18]	0.028
≥65 years	7/ 29 (24.1)	NE [NE, NE]	2/ 15 (13.3)	NE [NE, NE]	2.07[0.43, 9.99]	0.358
Sex						
Female	15/ 75 (20.0)	NE [NE, NE]	5/ 45 (11.1)	NE [NE, NE]	1.73[0.63, 4.75]	0.289
Male	20/ 81 (24.7)	NE [NE, NE]	2/ 31 (6.5)	NE [NE, NE]	4.45[1.04, 19.06]	0.028
Race						

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	
Asian	3/ 22 (13.6)	NE [NE, NE]	2/ 11 (18.2)	NE [2.23, NE]	1.08[0.18, 6.48]	0.953
Caucasian	26/118 (22.0)	NE [NE, NE]	4/ 57 (7.0)	NE [NE, NE]	3.23[1.13, 9.27]	0.021
Others	6/ 16 (37.5)	NE [1.41, NE]	1/ 8 (12.5)	NE [8.31, NE]	3.23[0.39, 26.89]	0.253
Reason for discontinuation of the last prior TKI						
Failure	18/ 94 (19.1)	NE [NE, NE]	5/ 54 (9.3)	NE [NE, NE]	1.90[0.70, 5.13]	0.197
Intolerance	16/ 59 (27.1)	NE [NE, NE]	2/ 22 (9.1)	NE [NE, NE]	4.05[0.93, 17.66]	0.044
Number of prior TKI therapies						
2	20/ 88 (22.7)	NE [NE, NE]	1/ 33 (3.0)	NE [NE, NE]	7.23[0.97, 53.91]	0.024
3	11/ 54 (20.4)	NE [NE, NE]	5/ 33 (15.2)	NE [NE, NE]	1.40[0.49, 4.04]	0.529
≥4	4/ 14 (28.6)	NE [1.74, NE]	1/ 10 (10.0)	NE [2.23, NE]	4.36[0.49, 39.08]	0.151
Line of therapy of randomized treatment						
3	19/ 81 (23.5)	NE [NE, NE]	1/ 30 (3.3)	NE [NE, NE]	6.99[0.94, 52.25]	0.027
4	9/ 44 (20.5)	NE [NE, NE]	4/ 29 (13.8)	NE [NE, NE]	1.40[0.43, 4.56]	0.573

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AEsI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
≥ 5	7/ 31 (22.6)	NE [NE, NE]	2/ 17 (11.8)	NE [NE, NE]	2.91[0.60, 14.04]	0.163
With or without Week1 Day 1 BCR-ABL1 mutation						
Wild type	32/125 (25.6)	NE [NE, NE]	7/ 63 (11.1)	NE [NE, NE]	2.38[1.05, 5.40]	0.032
Mutant	2/ 17 (11.8)	NE [NE, NE]	0/ 8	NE [NE, NE]	NE [NE, NE]	NE
BCR-ABL ratio at baseline						
$\geq 1\%$	35/141 (24.8)	NE [NE, NE]	7/ 72 (9.7)	NE [NE, NE]	2.66[1.18, 5.99]	0.014
$< 1\%$	0/ 15	NE [NE, NE]	0/ 4	NE [NE, NE]	NE [NE, NE]	NE
Geographic region						
Europe	22/ 89 (24.7)	NE [NE, NE]	2/ 45 (4.4)	NE [NE, NE]	5.55[1.30, 23.62]	0.009
Others	13/ 67 (19.4)	NE [NE, NE]	5/ 31 (16.1)	NE [NE, NE]	1.37[0.49, 3.86]	0.546

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Table 5-3.5.3 Grade ≥ 3 AESI: time to first event - subgroup analysis
 Safety Set
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	Treatment Groups				Comparison	
	Asciminib N=156		Bosutinib N=76		HR	[95% CI] p-value
	n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]		
Pancreatic toxicity						
Age category						
18 - 65 years	6/127 (4.7)	NE [NE, NE]	4/ 61 (6.6)	NE [NE, NE]	0.57[0.16, 2.04]	0.383
≥ 65 years	0/ 29	NE [NE, NE]	0/ 15	NE [NE, NE]	NE [NE, NE]	NE

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

Figure 5-3.5.3 Grade ≥ 3 AESI: Kaplan Meier plot of time to first event- subgroup analysis

Safety Set
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No Subgroup with significant interaction test (p-value < 0.05)

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.

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Final

Table 5-3.5.4 Serious AESI: time to first event - subgroup analysis
 Safety Set
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Treatment Groups				Comparison	
Asciminib N=156		Bosutinib N=76		HR	p-value
n/N* (%)	Median [95% CI]	n/N* (%)	Median [95% CI]	[95% CI]	

None of the attribute
 have at least 10 events
 occurred in one of the
 subgroups

Median (time to event) and its 95% CI are generated by KM estimation.

Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.

Subgroup "Missing" will not be analyzed for any of the attributes.

CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis., NE: Not Estimable.

Figure 5-3.5.4 Serious AESI: Kaplan Meier plot of time to first event - subgroup analysis
Safety Set
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None of the attribute have at least 10 events occurred in one of the subgroups

Median (time to event) and its 95% CI are generated by KM estimation.
Hazard Ratio estimated by Cox proportional hazards model and two-sided p-value based on a Log-rank test both adjusted for stratification factor, cytogenetic response status (MCyR vs no MCyR) at screening as per IRT.
Subgroup "Missing" will not be analyzed for any of the attributes.
CI: Confidence Interval, HR: Hazard Ratio, n: Number of patients with event, N*: Number of patients included in the analysis, NE: Not Estimable.