Supplementary slides

Oral presentation at: EHA2025 Congress; June 12-15, 2025; Milan, Italy.

Rates of adverse events (>5% in either arm) regardless of relationship to treatment

Preferred term, n (%)[a]	Asciminib n=284		Nilotinib n=282	
	All grades	Grade ≥3	All grades	Grade ≥3
Patients with ≥1 event	**228 (80.3)**	**71 (25.0)**	**244 (86.5)**	**90 (31.9)**
Thrombocytopenia[b]	43 (15.1)	26 (9.2)	39 (13.8)	18 (6.4)
Headache	29 (10.2)	0	37 (13.1)	1 (0.4)
Myalgia	29 (10.2)	0	23 (8.2)	0
Nausea	27 (9.5)	0	18 (6.4)	0
Neutropenia[c]	27 (9.5)	17 (6.0)	23 (8.2)	15 (5.3)
Anemia[d]	25 (8.8)	9 (3.2)	20 (7.1)	4 (1.4)
Fatigue	25 (8.8)	0	28 (9.9)	1 (0.4)
Rash	24 (8.5)	1 (0.4)	46 (16.3)	2 (0.7)
Diarrhea	23 (8.1)	0	21 (7.4)	0
Lipase increased	23 (8.1)	6 (2.1)	21 (7.4)	7 (2.5)
Pruritus	22 (7.7)	0	26 (9.2)	0
Hypertension	19 (6.7)	7 (2.5)	3 (1.1)	1 (0.4)
Asthenia	18 (6.3)	0	20 (7.1)	0
Back pain	18 (6.3)	0	10 (3.5)	0
Arthralgia	17 (6.0)	0	22 (7.8)	0
Alopecia	10 (3.5)	0	24 (8.5)	0
ALT increased	9 (3.2)	4 (1.4)	35 (12.4)	10 (3.5)
AST increased	9 (3.2)	2 (0.7)	22 (7.8)	6 (2.1)
GGT increased	7 (2.5)	1 (0.4)	17 (6.0)	3 (1.1)
Blood bilirubin increased	6 (2.1)	0	28 (9.9)	6 (2.1)
Constipation	5 (1.8)	0	16 (5.7)	0

- The most frequent AEs (>10% in either arm) were thrombocytopenia, headache, myalgia, rash, and ALT increased

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma glutamyl transferase.
[a] AEs occurring during treatment or within 30 days of the last study treatment are summarized. A patient with multiple severity grades for an AE was only counted under the maximum grade.
[b] Thrombocytopenia included platelet count decreased and thrombocytopenia. [c] Neutropenia included neutrophil count decreased and neutropenia. [d] Anemia included anemia, red blood cell count decreased, and hematocrit decreased.

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AEs leading to treatment discontinuation were less frequent with asciminib vs nilotinib

AEs leading to discontinuation[a]	Asciminib[b] n=284		Nilotinib[c] n=282	
	All grades	Grade ≥3	All grades	Grade ≥3
	Patients, n (%)[a]			
Patients with ≥1 event	**15 (5.3)**	**12 (4.2)**	**33 (11.7)**	**23 (8.2)**
Thrombocytopenia[d]	4 (1.4)	4 (1.4)	1 (0.4)	1 (0.4)
Lipase increased	2 (0.7)	0	6 (2.1)	4 (1.4)
ALT increased	1 (0.4)	1 (0.4)	2 (0.7)	2 (0.7)
AST increased	1 (0.4)	1 (0.4)	0	0
Blast cell crisis	1 (0.4)	1 (0.4)	0	0
Febrile neutropenia	1 (0.4)	1 (0.4)	0	0
Hepatobiliary disease	1 (0.4)	1 (0.4)	0	0
Hypertensive crisis	1 (0.4)	1 (0.4)	0	0
Musculoskeletal pain	1 (0.4)	1 (0.4)	0	0
Neutropenia[e]	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)
Optic ischemic neuropathy	1 (0.4)	0	0	0
Pancreatitis[f]	1 (0.4)	1 (0.4)	4 (1.4)	4 (1.4)
Rash	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)
Suspected drug-induced liver injury	1 (0.4)	1 (0.4)	0	0
Tendonitis	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)
Transient ischemic attack	1 (0.4)	1 (0.4)	0	0

AEs leading to discontinuation[a]	Asciminib[b] n=284		Nilotinib[c] n=282	
	All grades	Grade ≥3	All grades	Grade ≥3
	Patients, n (%)[a]			
Amylase increased	0	0	3 (1.1)	1 (0.4)
Arteriospasm coronary	0	0	1 (0.4)	1 (0.4)
Asthenia	0	0	2 (0.7)	0
Atrial fibrillation	0	0	2 (0.7)	0
Blood bilirubin increased	0	0	3 (1.1)	1 (0.4)
Blood creatine phosphokinase increased	0	0	1 (0.4)	1 (0.4)
Blood creatinine increased	0	0	1 (0.4)	1 (0.4)
Death	0	0	1 (0.4)	1 (0.4)
Decreased appetite	0	0	1 (0.4)	0
Drug-induced liver injury	0	0	2 (0.7)	2 (0.7)
Hypercholesterolemia	0	0	1 (0.4)	1 (0.4)
Intermittent claudication	0	0	1 (0.4)	0
Muscle spasms	0	0	1 (0.4)	0
Myocarditis	0	0	1 (0.4)	1 (0.4)
Nausea	0	0	1 (0.4)	0
Peripheral artery stenosis	0	0	1 (0.4)	0

[a] Included AEs occurring during treatment or within 30 days of the last study treatment. A patient may have multiple AEs leading to treatment disc. Events counting towards primary endpoint included 14 patients who disc due to AEs and 2 deaths 16/284 (5.6%) on asciminib; 33 patients disc due to AEs and 1 death 34/282 (12.1%) on nilotinib. [b] One patient on asciminib had AE blast cell crisis and treatment disc due to progressive disease (not contributing to primary endpoint). [c] One patient on nilotinib had death recorded as AE and treatment disc due to death (contributed to primary endpoint). One patient on nilotinib had treatment disc due to an AE, but the AE (thrombocytopenia) leading to disc occurred after 30 days of last dose (contributed to primary endpoint).
[d] Thrombocytopenia included platelet count decreased and thrombocytopenia. [e] Neutropenia included neutrophil count decreased and neutropenia. [f] Pancreatitis included acute pancreatitis and pancreatitis.

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AEs of special interest were generally less frequent with asciminib vs nilotinib

	Asciminib n=284		Nilotinib n=282	
Safety topic, n (%)[a]	**All grade**	**Grade ≥3**	**All grade**	**Grade ≥3**
Isolated pancreatic enzyme elevations[b]	23 (8.1)	6 (2.1)	27 (9.6)	11 (3.9)
Acute pancreatitis (clinical events)	1 (0.4)	1 (0.4)	7 (2.5)	4 (1.4)
Arterial occlusive events	2 (0.7)	1 (0.4)	6 (2.1)	2 (0.7)
Cardiac failure	1 (0.4)	1 (0.4)	1 (0.4)	1 (0.4)
Edema and fluid retention	8 (2.8)	0	12 (4.3)	0
Gastrointestinal toxicity	65 (22.9)	1 (0.4)	68 (24.1)	2 (0.7)
Hemorrhage	11 (3.9)	1 (0.4)	11 (3.9)	0
Hepatotoxicity (including laboratory terms)	23 (8.1)	5 (1.8)	70 (24.8)	22 (7.8)
Hepatotoxicity (clinical events)	6 (2.1)	3 (1.1)	13 (4.6)	3 (1.1)
Hypersensitivity	38 (13.4)	1 (0.4)	72 (25.5)	3 (1.1)
Ischemic heart and CNS conditions	6 (2.1)	3 (1.1)	13 (4.6)	3 (1.1)
Ischemic CNS conditions	1 (0.4)	1 (0.4)	0	0
Ischemic heart conditions	5 (1.8)	2 (0.7)	13 (4.6)	3 (1.1)
Myelosuppression[c]	77 (27.1)	39 (13.7)	68 (24.1)	34 (12.1)
Erythropenia	27 (9.5)	10 (3.5)	23 (8.2)	4 (1.4)
Leukopenia	44 (15.5)	21 (7.4)	34 (12.1)	18 (6.4)
Thrombocytopenia	55 (19.4)	30 (10.6)	44 (15.6)	19 (6.7)
Phototoxicity	1 (0.4)	0	2 (0.7)	0
QTc prolongation	4 (1.4)	2 (0.7)	5 (1.8)	1 (0.4)
Reproductive toxicity	1 (0.4)	0	3 (1.1)	0

CNS, central nervous system; QTc, corrected QT interval.

[a] AEs occurring during treatment or within 30 days of the last study treatment are summarized. A patient with multiple severity grades for an AE was only counted under the maximum grade.

[b] Included isolated enzyme elevations in the asciminib vs nilotinib arms were increased lipase (all-grade, 8.1% vs 7.4; grade ≥3, 2.1% vs 2.5%), increased amylase (all-grade, 1.8% vs 4.6%; grade ≥3, 0.4% vs 2.1%), and increased pancreatic enzymes (all-grade, 0% vs 0.4%; grade ≥3, 0% vs 0.4%). [c] Included erythropenia, leukopenia, thrombocytopenia, and cytopenias affecting >1 lineage.

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AOEs occurred less frequently in the asciminib arm

AOEs, n (%)[a]	Asciminib n=284		Nilotinib n=282	
	All grades	Grade ≥3	All grades	Grade ≥3
Patients with ≥1 event	**2 (0.7)**	**1 (0.4)**	**6 (2.1)**	**2 (0.7)**
Unstable angina	1 (0.4)	0	0	0
Coronary artery disease	1 (0.4)	0	0	0
Transient ischemic attack	1 (0.4)	1 (0.4)	0	0
Acute myocardial infarction	0	0	1 (0.4)	1 (0.4)
Angina pectoris	0	0	2 (0.7)	0
Arteriospasm coronary	0	0	1 (0.4)	1 (0.4)
Myocardial infarction	0	0	1 (0.4)	0
Increased troponin	0	0	2 (0.7)	0

- By data cutoff, fewer patients had all-grade AOEs with asciminib vs nilotinib

AOE, arterial occlusive event.

[a] A patient with multiple severity grades for an AE was only counted under the maximum grade.

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On-treatment deaths were reported in both treatment arms[a]

Primary reason (preferred term), n (%)	Asciminib n=284	Nilotinib n=282
No. of patients who died	2 (0.7)	1 (0.4)
Study indication	0	0
Adverse event	2 (0.7)	1 (0.4)
Cardiac arrest	1 (0.4)	1 (0.4)[b]
Completed suicide	1 (0.4)	0

- Of the 2 deaths in the asciminib arm, both were considered **unrelated to study treatment** by the investigator
- For the death in the nilotinib arm, **causality to study treatment could not be assessed** per investigator's judgement

[a] Deaths occurring during treatment or within 30 days after the last study treatment are summarized. [b] Cause of death at time of data cutoff was death unknown suspected cardiac cause, cardiac arrest was confirmed post cutoff.

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IA allowed for an early assessment of the primary endpoint

Observed No. of events for IA	α Spent during IA (γ family with γ=−6)[a]
44	.0035 or .35%
45	.0039 or .39%
46 (planned)	.0043 or .43%
47	.0047 or .47%
48	.0052 or .52%
49	.0057 or .57%
50 (actual)	.0062 or .62%

- IA was planned for when **46 treatment discontinuations** due to AEs (including deaths due to AEs) occurred
- If the actual observed number of events is not exactly 46, then **the boundary would be recalculated** based on the actual number of events

- By data cutoff, **50 events** (47 treatment discontinuations due to AEs and 3 deaths due to AEs) **were observed**
- The boundary expressed on the *P*-value scale at IA was **recalculated as .0062**
- The observed *P* value **must be less than the boundary of .0062 to conclude a significant result**

AE, adverse event; IA, interim analysis.
[a] An α spending function according to a 2-look (γ family) group sequential design with parameter γ=−6 was used to construct the boundary.

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