

Puma Biotechnology

First Quarter 2026 Earnings Call

May 7, 2026



ALISCA™-Lung1 (PUMA-ALI-4201)

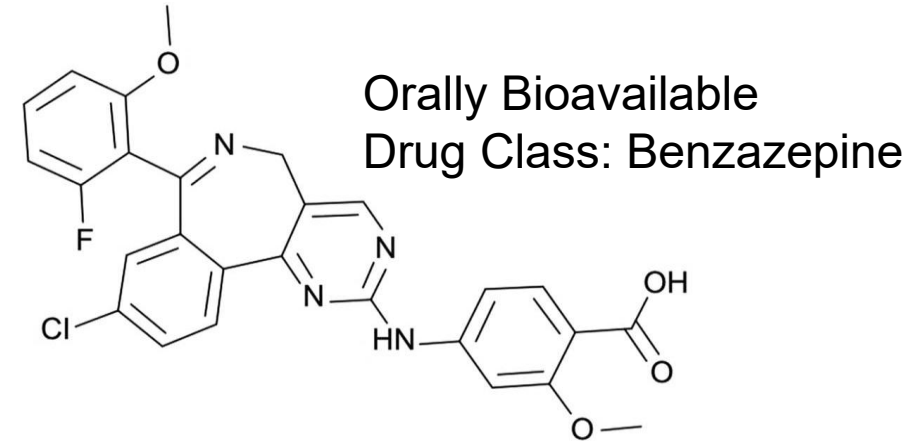
Interim Analysis

May 7, 2026



Alisertib (MLN 8237)

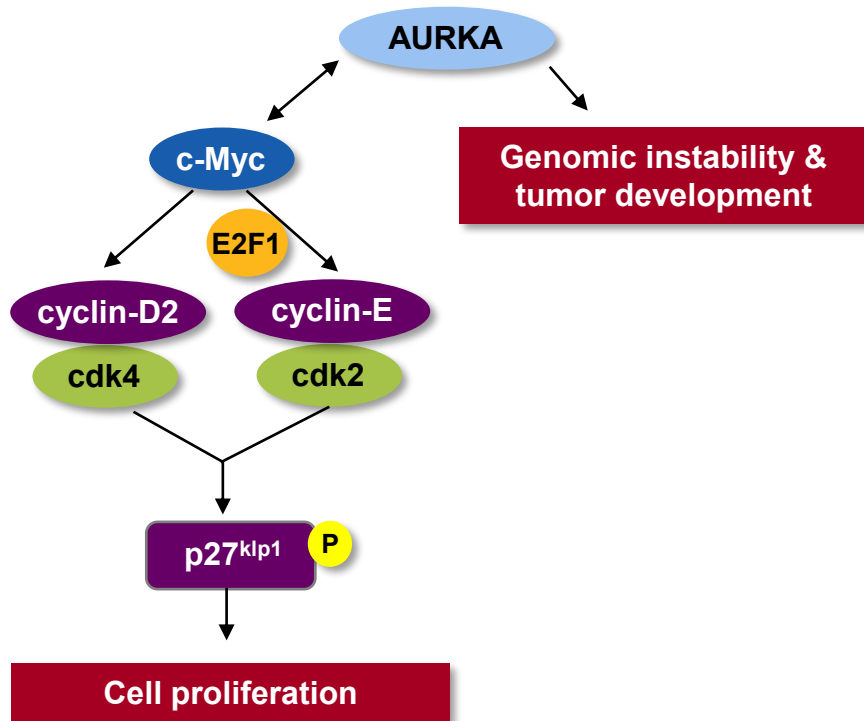
Aurora Kinase A
(AURKA) inhibitor



- Single-agent and combinational clinical activity in solid tumors including hormone receptor-positive breast cancer (HR+ MBC), triple negative breast cancer (TNBC), small cell lung cancer (SCLC), and head and neck cancer
- Single-agent clinical activity in hematologic malignancies including peripheral T-cell lymphoma (PTCL) and aggressive non-Hodgkin's lymphoma (NHL)
- Well-characterized safety profile: ~1,300 patients treated across 22 company-sponsored trials

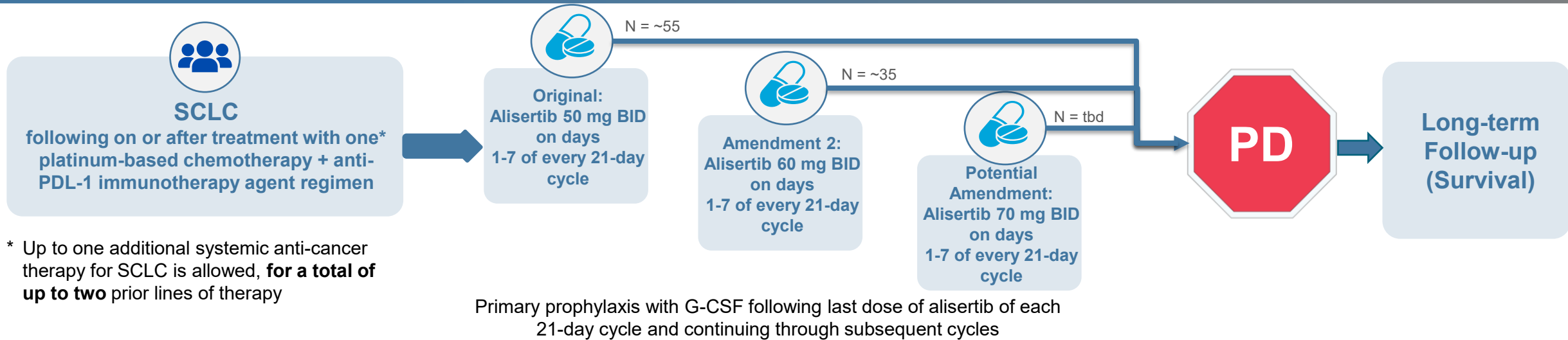
AURKA and c-Myc Co-regulate Each Other

Nuclear AURKA exerts kinase-independent functions by acting as a transcription factor



- AURKA and c-Myc transcriptionally upregulate each other, suggesting the existence of a positive feedback loop
- c-Myc upregulates Cyclin D2, CDK4, and cyclin-E, contributing to complex formation and subsequent phosphorylation of p27Kip1, which leads to cell proliferation

ALISCA™-Lung1 (PUMA-ALI-4201) Study Design – Alisertib Monotherapy



Study objectives and endpoints

Primary

- Determine whether any biomarker correlates with alisertib response by investigator-assessed ORR, DOR, DCR, PFS according to RECIST v1.1 within biomarker-defined subgroups from retrospectively evaluated patient samples

Secondary

- Determine investigator-assessed efficacy (ORR, DOR, DCR and PFS) according to RECIST v1.1
- Determine survival outcomes (OS)
- Determine the safety profile of alisertib (AE and SAEs per NCI CTCAE v 5.0)

ALISCA™-Lung1 SCLC History and Baseline Characteristics

	50 mg BID (N=52)	60 mg BID (N=27)	Total (N=79)
VALSG stage at initial diagnosis - n (%)			
Limited	7 (13.5)	6 (22.2)	13 (16.5)
Extensive	45 (86.5)	20 (74.1)	65 (82.3)
ECOG performance status at C1D1 – n (%)			
0	16 (30.8)	10 (37.0)	26 (32.9)
1	34 (65.4)	17 (63.0)	51 (64.6)
2	2 (3.8)	0	2 (2.5)
Tobacco smoking – n (%)			
Current	13 (25.0)	3 (11.1)	16 (20.3)
Never	2 (3.8)	2 (7.4)	4 (5.1)
Former	37 (71.2)	22 (81.5)	59 (74.7)
Location of disease at enrollment – n (%)			
Visceral	47 (90.4)	21 (77.8)	68 (86.1)
Not Visceral	5 (9.6)	3 (11.1)	8 (10.1)
Missing	0	3 (11.1)	3 (3.8)
Location of disease in the brain – n (%)			
Yes	21 (40.4)	9 (33.3)	30 (38.0)
No	31 (59.6)	15 (55.6)	46 (58.2)
Location of disease in the liver – n (%)			
Yes	25 (48.1)	13 (48.1)	38 (48.1)
No	27 (51.9)	11 (40.7)	38 (48.1)

ALISCA™-Lung1 Summary of Prior Anti-cancer Therapy

Prior anti-cancer therapy	50 mg BID (N=52)	60 mg BID (N=27)	Total (N=79)
Prior radiotherapy – n (%)			
No	16 (30.8)	12 (44.4)	28 (35.4)
Yes	36 (69.2)	15 (55.6)	51 (64.6)
Prior cancer-related surgery – n (%)			
No	44 (84.6)	25 (92.6)	69 (87.3)
Yes	8 (15.4)	2 (7.4)	10 (12.7)
Prior anti-cancer medication – n (%)			
No	0	1 (3.7)	1 (1.3)
Yes	52 (100.0)	26 (96.3)	78 (98.7)
Prior platinum based chemotherapy	52 (100.0)	24 (92.3)	76 (97.4)
Prior immunotherapy	52 (100.0)	24 (92.3)	76 (97.4)
Prior number of treatment regimens – n (%)			
1	40 (76.9)	16 (59.3)	56 (70.9)
2	12 (23.1)	10 (37.0)	22 (27.8)

Safety

ALISCA™-Lung1 Incidence of TEAEs – All Grades

	50 mg BID (N=52)	60 mg BID (N=27)	Total (N=79)
Subjects with at Least 1 Reported AE - n (%)	21 (40.4)	19 (70.4)	40 (50.6)
Neutropenia	10 (19.2)	6 (22.2)	16 (20.3)
Febrile neutropenia	2 (3.8)	2 (7.4)	4 (5.1)
Thrombocytopenia	4 (7.7)	4 (14.8)	8 (10.1)
Anemia	15 (28.8)	7 (25.9)	22 (27.8)
Diarrhea	12 (23.1)	11 (40.7)	23 (29.1)
Stomatitis	8 (15.4)	9 (33.3)	17 (21.5)
Somnolence	1 (1.9)	1 (3.7)	2 (2.5)

ALISCA™-Lung1 Incidence of Grade 3 or 4 TEAEs

	50 mg BID (N=52)	60 mg BID (N=27)	Total (N=79)
Subjects with at least one reported AE - n (%)	12 (23.1)	7 (25.9)	19 (24.1)
Neutropenia	7 (13.5)	3 (11.1)	10 (12.7)
Febrile neutropenia	2 (3.8)	2 (7.4)	4 (5.1)
Thrombocytopenia	2 (3.8)	1 (3.7)	3 (3.8)
Anemia	8 (15.4)	4 (14.8)	12 (15.2)
Diarrhea	0	0	0
Stomatitis	1 (1.9)	3 (11.1)	4 (5.1)
Somnolence	0	0	0

ALISCA™-Lung1 Incidence of Grade 3 or 4 TEAEs Compared to Study C14007

	C14007 Alisertib monotherapy 50 mg BID 7D (n=60) ¹	PUMA-ALI-4201 Alisertib monotherapy 50 mg BID 7D (n=52) ²	PUMA-ALI-4201 Alisertib monotherapy 60 mg BID 7D (n=27) ²
Subjects with at least one reported AESI - n (%)	28 (46.7)	12 (23.1)	7 (25.9)
Neutropenia	22 (36.7)	7 (13.5)	3 (11.1)
Febrile neutropenia	5 (8.3)	2 (3.8)	2 (7.4)
Thrombocytopenia	9 (15.0)	2 (3.8)	1 (3.7)
Anemia	11 (18.3)	8 (15.4)	4 (14.8)
Diarrhea	2 (3.3)	0	0
Stomatitis	4 (6.7)	1 (1.9)	3 (11.1)
Somnolence	1 (1.7)	0	0

¹Data on file. SCLC subjects only ²Source: Data Extract

Efficacy

ALISCA™-Lung1 Summary of Clinical Benefit (Subjects with at Least One Post-baseline Scan or Ended Treatment Prior to First Scan)

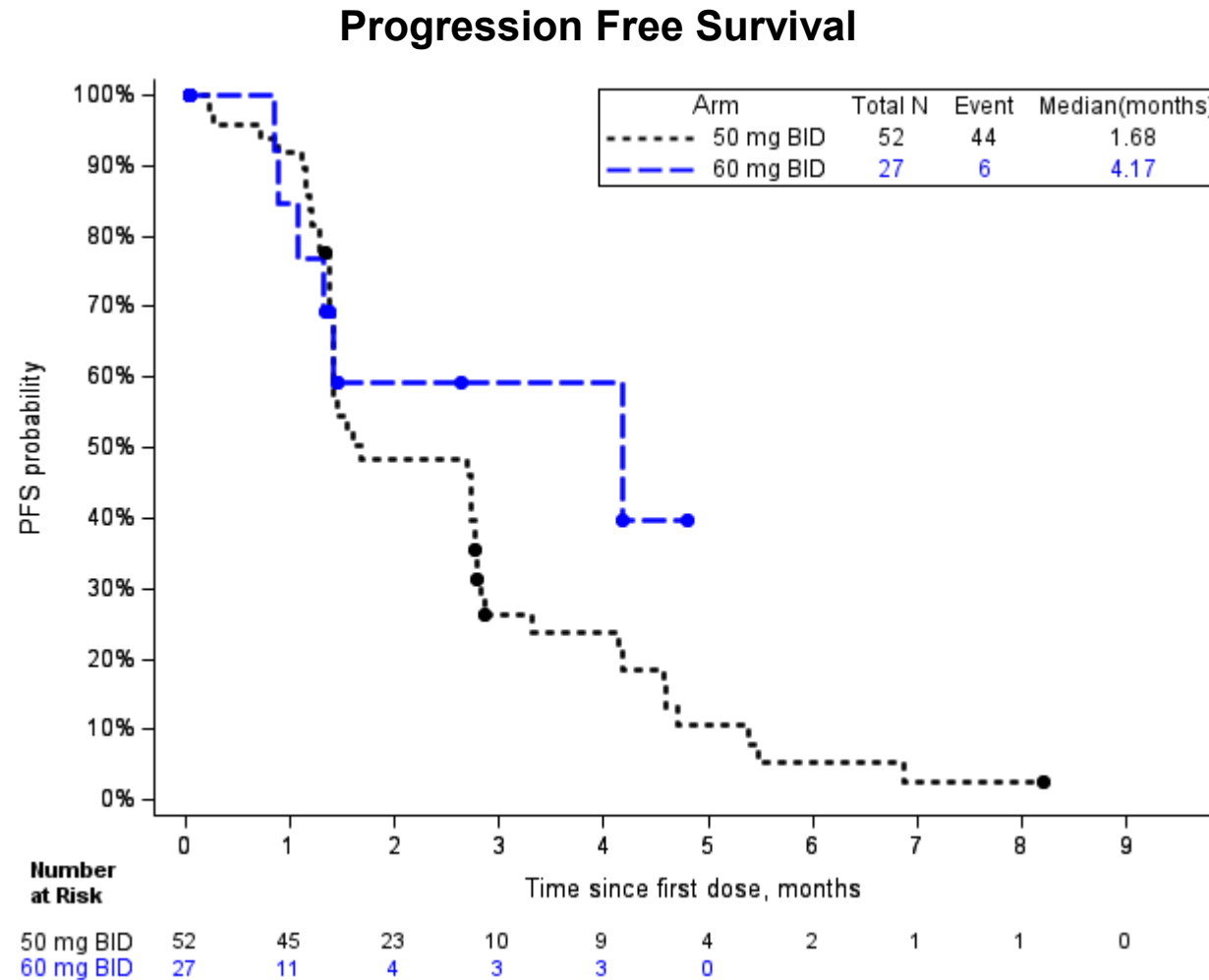
Response, n (%)	50 mg BID (N=52)	60 mg BID (N=15)
Best overall response		
Complete response (CR)	0	0
Partial response (PR)	6 (11.5)	1 (6.7)
Stable disease (SD)	18 (34.6)	7 (46.7)
Disease progression (PD)	22 (42.3)	2 (13.3)
Not evaluable (NE)	1 (1.9)	0
Unavailable*	5 (9.6)	5 (33.3)
Clinical benefit - n (%)		
Confirmed complete response (CR)	0	0
Confirmed partial response (PR)	3 (5.8)	1 (6.7)
Stable disease \geq 12 weeks (SD)	19 (36.5)	2 (13.3)
Objective response (Confirmed CR or PR) – n(%)	3 (5.8)	1 (6.7)
Disease control rate ^a (95% CI)	42.3 (28.7, 56.8)	20.0 (4.3, 48.1)
Median duration of response (months)	4.2	NA
Median PFS (months)	1.7	4.2

*Unavailable are subjects who ended treatment or died prior to any on-treatment scan

Best overall response (BOR) is not confirmed.

^aDCR=CR+PR+SD \geq 12 wks

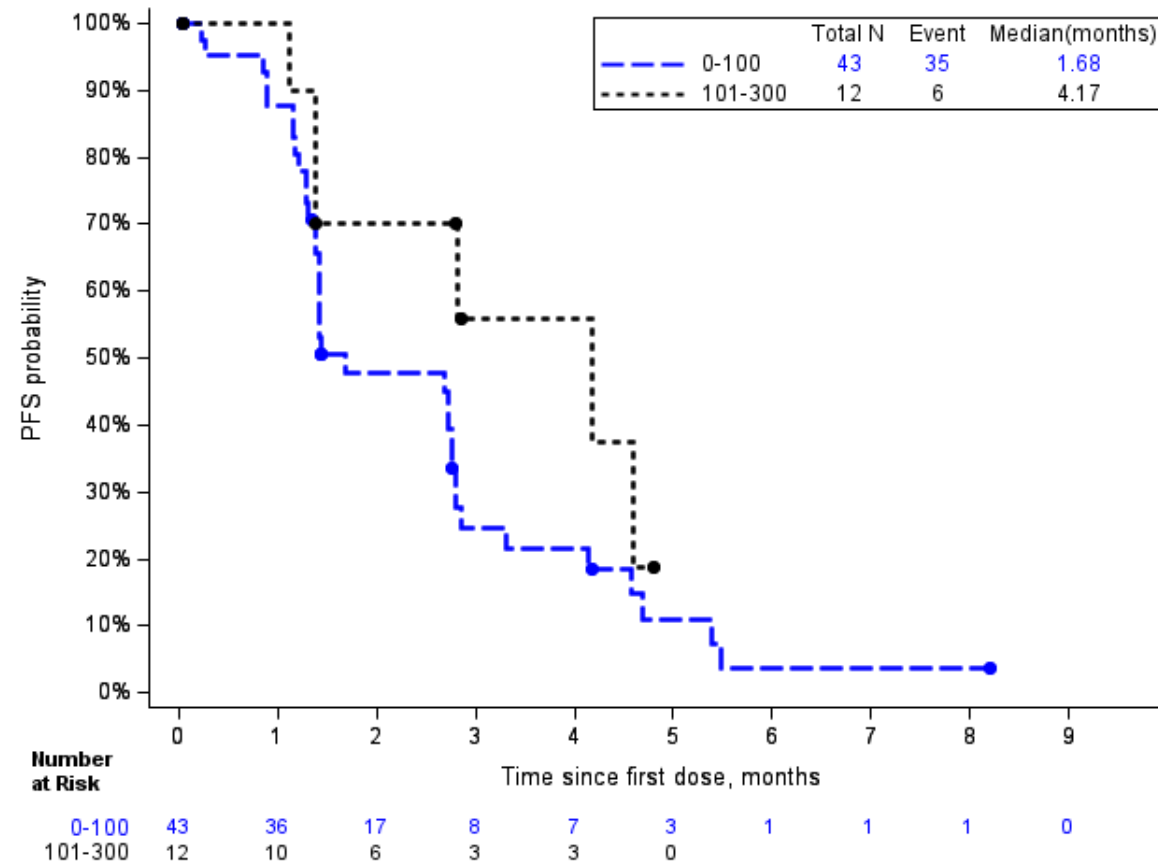
ALISCA™-Lung1 PFS – ITT Population by Treatment Group



Biomarkers

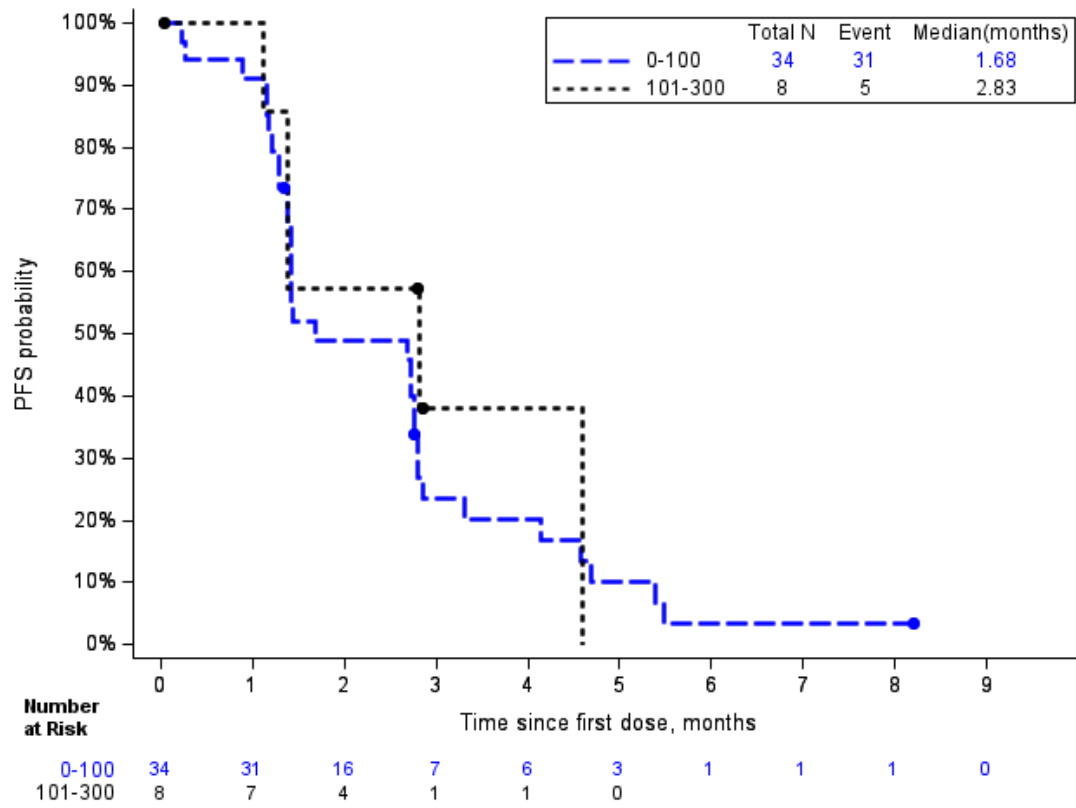
ALISCA™-Lung1 PFS by c-Myc H-score

Total

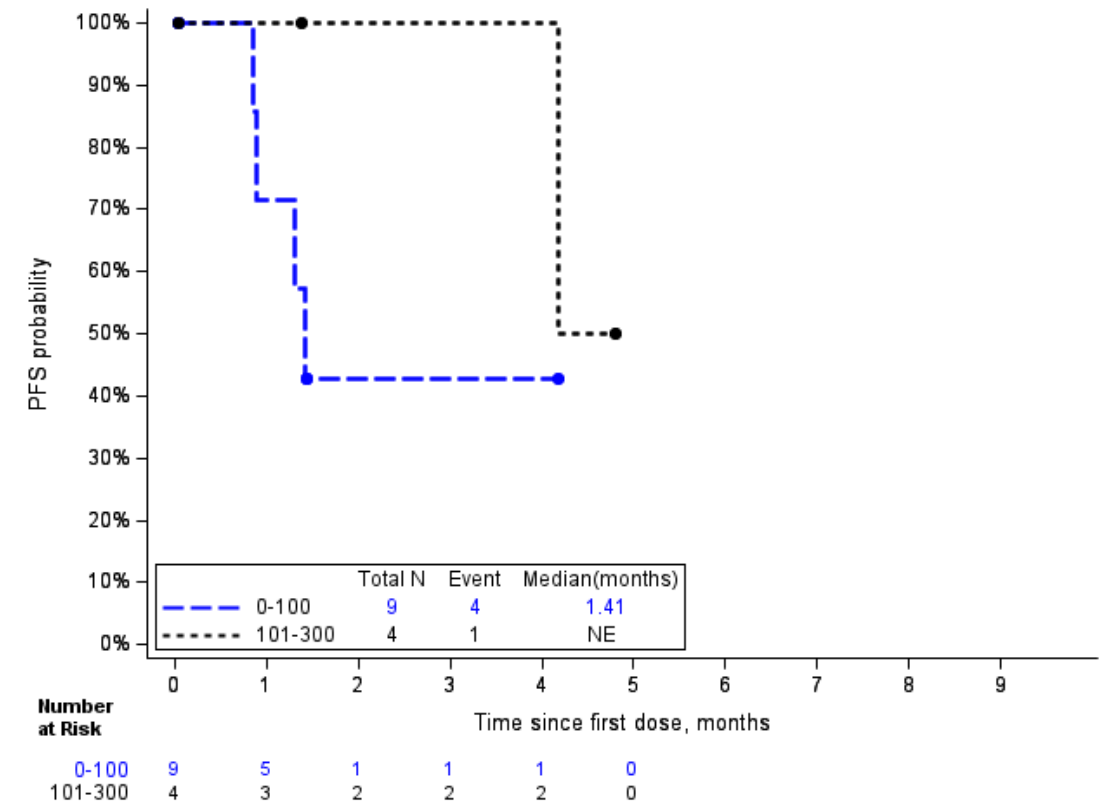


ALISCA™-Lung1 PFS by c-Myc H-score by Treatment Group

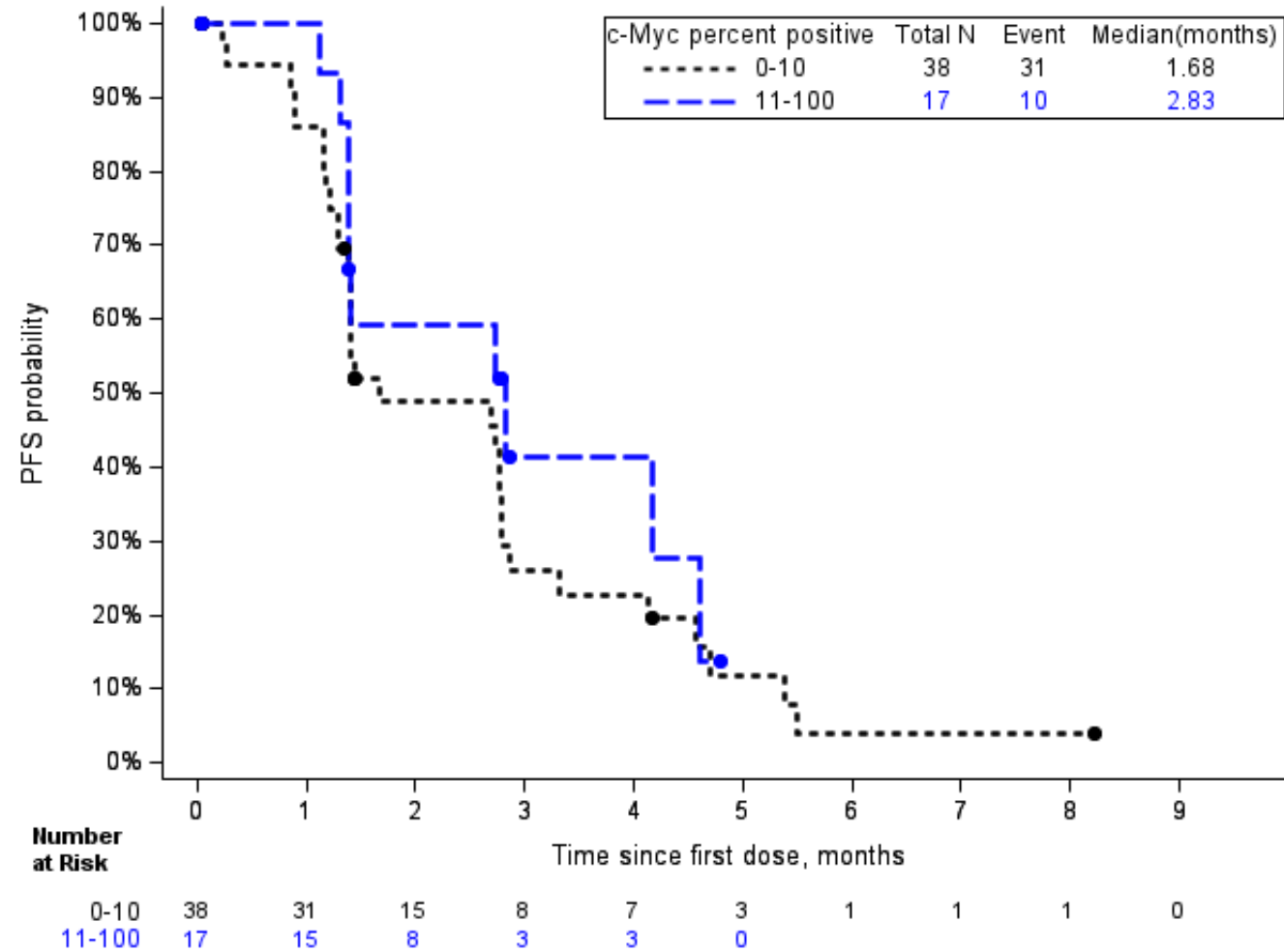
50 mg BID



60 mg BID

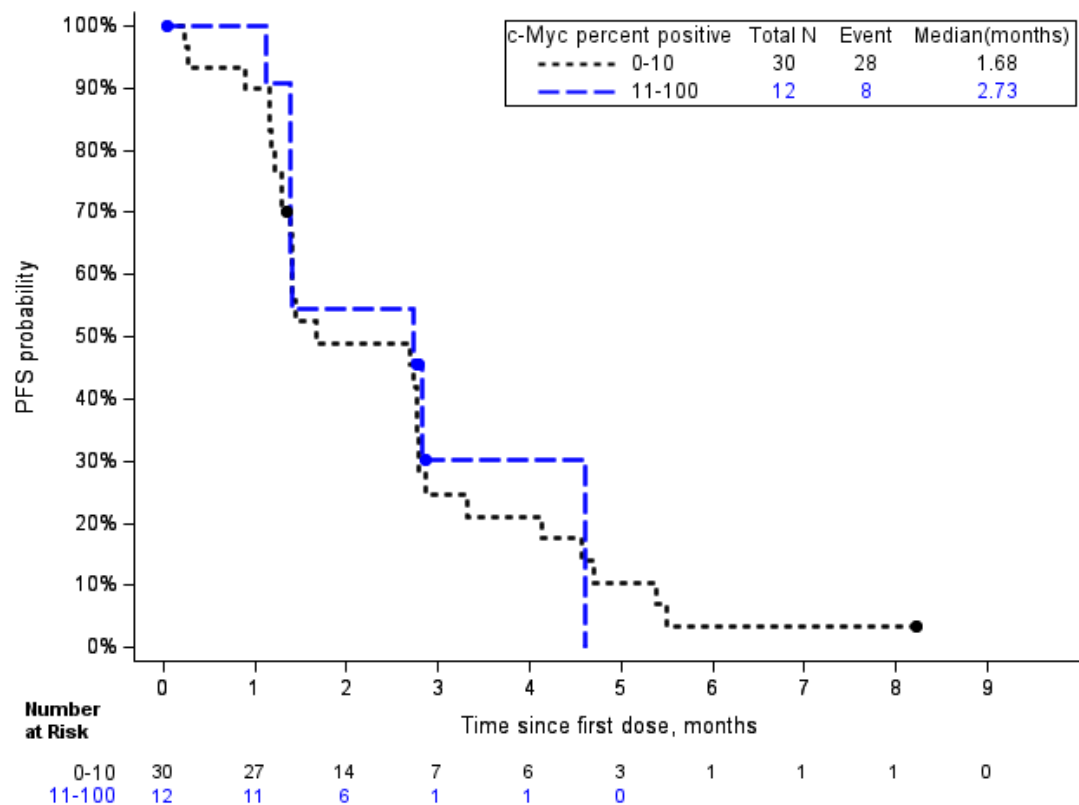


ALISCA™-Lung1 PFS by c-Myc % Positive Cells

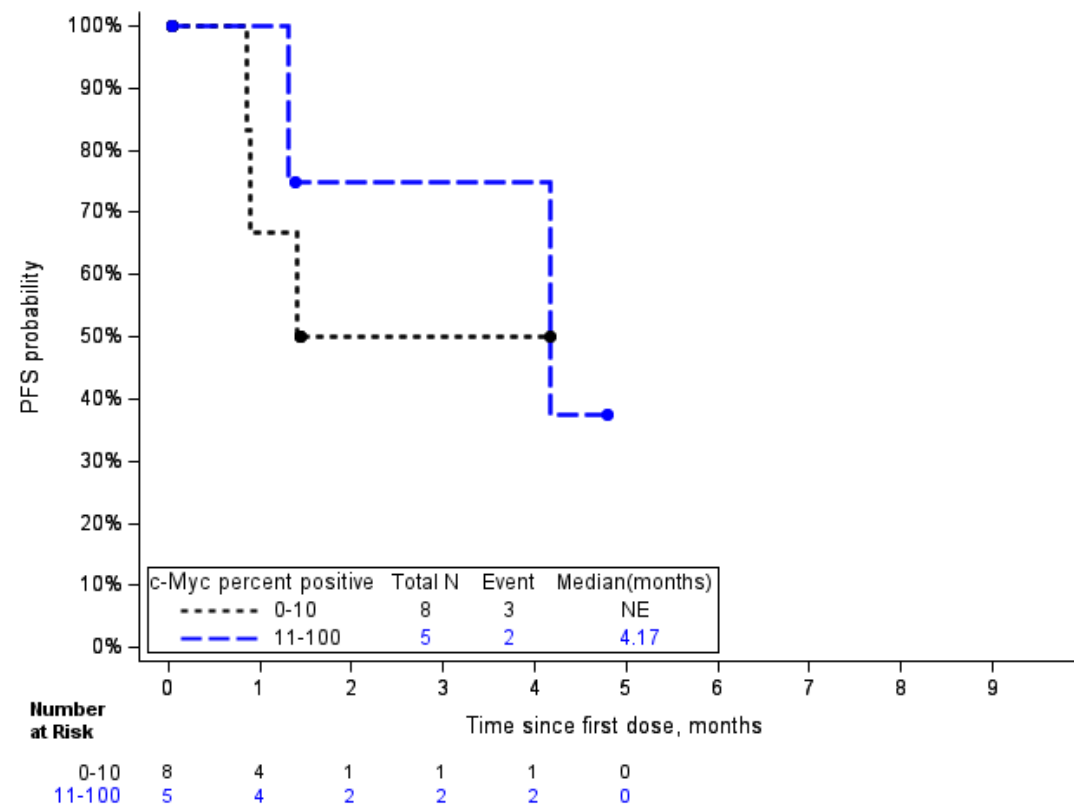


ALISCA™-Lung1 PFS by c-Myc % Positive Cells by Treatment Group

50 mg BID



60 mg BID



ALISCA™-Lung1 – Expected Milestones

- Initiate enrollment of 70 mg BID monotherapy cohort in ALISCA™-Lung1 (H2 2026)
- Initiate enrollment of ALISCA™ Lung2 – Phase I/II trial of alisertib in combination with paclitaxel (H2 26)
- Additional interim data from ALISCA™-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of extensive-stage small cell lung cancer (H2 2026/H1 2027)