Phase Ib study of BI 836880, a VEGF/Ang2-blocking nanobody®, in combination with BI 754091, an anti-PD-1 antibody: initial results in patients with advanced non-small cell lung cancer

Poster #332

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Introduction

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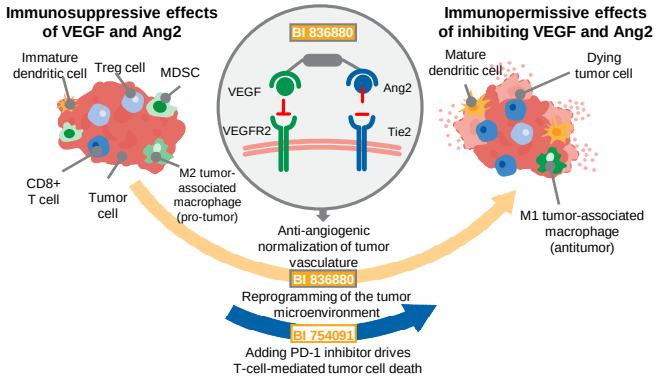

Ang2, angiopoietin-2; CD, cluster of differentiation; MDSC, myeloid-derived suppressor cell; PD-1, programmed cell death protein-1; Treg, regulatory T cell; VEGF, vascular endothelial growth factor; VEGFR2, VEGF receptor 2

Objectives

- In this Phase 1b trial (NCT03468426), the safety and antitumor activity of BI 836880 in combination with BI 754091 in patients with locally advanced or metastatic non-squamous NSCLC and in those with other solid tumors is being assessed

Methods

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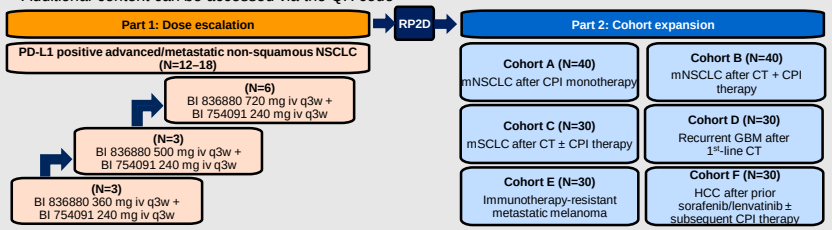

Part 1 endpoints	
Primary	Secondary
MTD/RP2D based on DLTs	AEs, PK

Part 2 endpoints	
Primary	Secondary
Shrinkage estimator of OR	AEs, DC, DoR, PFS, PK, tumor shrinkage

AE, adverse event; CPI, checkpoint inhibitor; CT, chemotherapy; DC, disease control; DLT, dose-limiting toxicity; DoR, duration of response; GBM, glioblastoma; HCC, hepatocellular carcinoma; iv, intravenous; mNSCLC, metastatic NSCLC; mSCLC, metastatic small-cell lung cancer; MTD, maximum tolerated dose; OR, objective response; PD-L1, programmed cell death ligand 1; PFS, progression-free survival; PK, pharmacokinetics; q3w, every 3 weeks; RP2D, recommended Phase II dose

Key findings and conclusions

- MTD/RP2D was BI 836880 720 mg plus BI 754091 240 mg q3w
- The combination had a manageable safety profile
- Preliminary antitumor activity was observed
  - Ten of 12 patients had best overall response of PR or SD
- Expansion cohorts are ongoing

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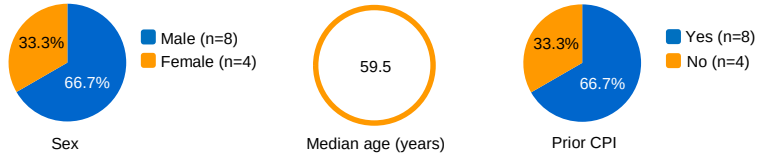
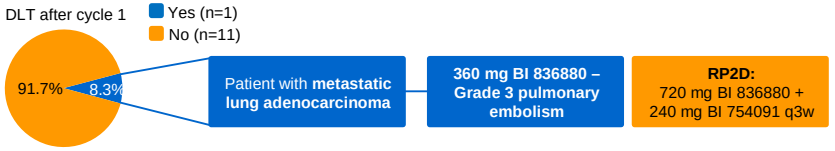
Results – Part 1: dose escalation (as of January 2020)

Baseline characteristics (N=12)



Safety (N=12)



Patients with:	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)
Any AE	12 (100.0)	1 (8.3)	5 (41.7)	5 (41.7)	0 (0.0)	1 (8.3)
Hypertension	7 (58.3)	0 (0.0)	4 (33.3)	3 (25.0)	0 (0.0)	0 (0.0)
Vomiting	5 (41.7)	3 (25.0)	2 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	4 (33.3)	1 (8.3)	3 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	4 (33.3)	2 (16.7)	2 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)

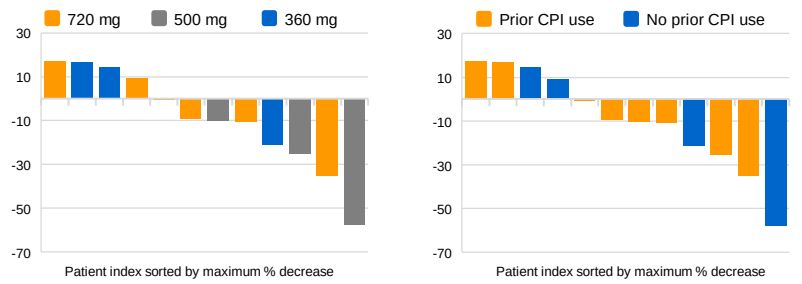
No Grade 4 AEs reported

One Grade 5 AE reported: general physical health deterioration

Five patients had immune-related AEs: hypothyroidism in two patients; pruritus, papular rash, and vomiting

Efficacy (N=12)

Percentage change from baseline in target lesions



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