Open-label, Phase I dose escalation/expansion trial of the anti-SIRPα monoclonal antibody BI 770371 in patients with advanced solid tumours, alone or in combination with the anti-PD-1 monoclonal antibody ezabenlimab

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Introduction
• The SIRPα (CD172a/CD47) axis is a critical regulator of myeloid cell activation and serves as a myeloid-specific immune checkpoint

Methods
• BI 770371 is currently undergoing investigation as monotherapy and in combination with ezabenlimab, a PD-1 inhibitor, in a Phase I, open-label, dose escalation/dose expansion trial (NCT05327946) in patients with advanced solid tumours

Baseline characteristics
BI 770371 (N=15) BI 770371 + ezabenlimab (N=3)
Median age, years (range) 64 (26–77) 67 (51–70)
Male, n (%) 8 (53) 2 (33)
Race, n (%) White 10 (67) 2 (67)
Black or African-American 1 (7) 0 (0)
ECOG PS at baseline, n (%) 0 8 (53) 2 (67)
1 7 (47) 1 (33)
Number of prior lines of systemic therapies ≥2, n (%) 15 (100) 2 (67)

Key findings and conclusions
• In this Phase I, open-label, dose escalation/dose expansion trial (NCT05327946) in patients with advanced solid tumours, BI 770371 ± ezabenlimab was well tolerated
• There were no DLTs during the MTD evaluation period. One DLT (encephalitis) occurred during the on-treatment period
• AE s were manageable during the on-treatment period

Patients
• As of 31 March 2023, a total of 18 patients (BI 770371 group, N=15; BI 770371 + ezabenlimab group, N=3) have been treated in Canada, Japan, and the USA
• The most common tumours were colorectal, ovarian, and prostate (n=2, each) in the BI 770371 group and pancreas (n=2) and bladder (n=1) in the BI 770371 + ezabenlimab group

Efficacy
• In 14 evaluable patients in the monotherapy group (N=15), 11 (75%) achieved a best response of stable disease in the combination therapy group (N=2), two patients evaluated (50%) achieved a best response of progressive disease; data were missing for one patient

Safety
• AEs in the BI 770371 group were manageable

References

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Download these slides to BI 770371 and a fixed dose of ezabenlimab given as IV infusion q3w for maintenance of myeloid-antigen-presenting cells and downregulation of Tumour ligand CD47 its interaction with its ligand CD47

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