ence of pancreatic metastases) and immune-mediated myocarditis (Grade 4) that contributed to respiratory failure. A complete response was reported as the best overall response for 1 patient (melanoma); partial responses were reported for 5 patients (2 melanoma, 2 NSCLC, 1 ovarian). The objective response rate was 13% overall and 21% at 10 mg/kg (6/46 and 6/29 evaluable patients, respectively). All responders had prior CI exposure. Responses were observed only at 10 mg/kg and, within the 10 mg/kg group, appeared to correlate with higher peak serum concentration and area under the curve.

Conclusions XmAb20717 induced T-cell proliferation in peripheral blood consistent with dual-checkpoint blockade. Preliminary data indicate XmAb20717 was generally well-tolerated and associated with evidence of antitumor activity in CI-pretreated patients with various types of advanced solid tumors.

Trial Registration NCT03517488
Ethics Approval The study was approved by each institution’s IRB.

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408 PHASE I, FIRST-IN-HUMAN TRIAL EVALUATING BI 1387446 (STIMULATOR OF INTERFERON GENES [STING] AGONIST) ALONE AND COMBINED WITH BI 754091 (ANTI-PROGRAMMED CELL DEATH [PD]-1) IN SOLID TUMORS

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Background Activation of the STING pathway in intratumoral immune cells leads to increased type I interferon production, promoting recruitment and priming of T-cells against tumor antigens, and providing anti-tumor activity.1 Intratumoral administration of STING agonists has resulted in notable therapeutic activity in animal models.1 STING agonists have also shown clinical activity in patients, which was more pronounced when combined with an anti-PD-1 antibody.2,3 BI 1387446 potently and highly selectively activates the STING pathway; BI 754091 is a humanized IgG4 anti-PD-1 monoclonal antibody. Intratumoral administration of BI 1387446 resulted in tumor regression, and enhanced the activity of anti-PD-1 therapy in syngeneic tumor models.4

Methods NCT04147234 is a first-in-human, Phase I, open-label, multicenter trial of BI 1387446 in patients aged ≥18 years with advanced, unresectable and/or metastatic malignant solid tumors. Patients (up to ~122) will be enrolled from ~six sites across Europe and the USA. The main objectives are to characterize safety and determine the maximum tolerated dose (MTD) for BI 1387446 ± BI 754091. BI 1387446 will be administered intratumorally at increasing doses as monotherapy in Arm A, and in combination with BI 754091 (240 mg every three weeks, intravenously) in Arm B. In both arms, BI 1387446 will be administered in superficial lesions. In a potential third arm, Arm C, BI 1387446 will be administered in deep/visceral lesions in combination with intravenous BI 754091. Dose escalation will be guided by a Bayesian Logistic Regression Model with overdose control. For trial eligibility, patients must have exhausted standard treatment options, have ≥1 tumor lesion suitable for injection, ≥1 additional tumor lesion amenable to biopsy, and ECOG performance status of 0/1. Treatment will continue until progressive disease, unacceptable toxicity, other withdrawal criteria, or a maximum treatment duration of 34 cycles (for cycle 19 and onwards, administration of BI 1387446 is applicable for patients with a partial response), whichever occurs first. Primary endpoints are the MTD based on number of dose-limiting toxicities (DLTs), and number of patients with DLTs in the MTD evaluation period. Secondary endpoints are objective response based on RECIST 1.1, and best percentage change from baseline in size of target and injected lesions. Paired pre- and post-treatment biopsies of injected- and non-injected lesions and peripheral blood will be collected to assess pharmacodynamic changes associated with treatment. The trial is currently open for recruitment.

Results N/A
Conclusions N/A
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Trial Registration NCT04147234
Ethics Approval Not applicable.
Consent Not applicable.

REFERENCES

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409 A PHASE I TRIAL OF TALIMOGENE LAHERPAREPVEC FOR THE TREATMENT OF PERITONEAL SURFACE MALIGNANCIES (TEMPO)

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Background...