1510TiP The GATTO study: A phase I of the anti-EGFR tomuzotuximab (TO) in combination with the anti-MUC1 gatipotuzumab (GAT) in patients with EGFR positive solid tumors

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Background: TO (CetuGEX) is a second-generation anti-EGFR antibody that specifically binds to EGFR and acts as a competitive antagonist at the ligand binding site. GAT (PankoMab-GEX) is a novel humanized monoclonal antibody, which recognizes the tumor-specific epitope of mucin-1 (TA-MUC1) expressed on tumor cells. Both antibodies are glyco-engineered to potentiate antibody-dependent cellular cytotoxicity (ADCC). Compelling preclinical evidence suggests a complex interaction between EGFR and cell surface expressed TA-MUC1 in driving neoplastic processes and shows a synergistic antibody dependent cell cytotoxicity activity with the dual targeting of these molecules. Based on this evidence, this study aims to assess the tolerability, safety and preliminary activity of a combination with anti-EGFR and anti-TA-MUC1 glyco-engineered antibodies.

Trial design: The GATTO is an open label phase Ib dose evaluation study in patients with EGFR positive metastatic solid tumors, for whom no standard treatment is available. The proposed doses and schedule are 1200 mg Q2W for TO and 1400 mg Q2W for GAT. A staggered approach will be utilized in order to minimize the number of patients exposed and to evaluate the safety of the combination treatment. The first 6 patients will be enrolled into a safety run-in phase where the number of dose-limiting toxicities (DLTs) will be evaluated. Assuming that the safety criteria are met (ie. observation of 0 or 1 DLT), the dose will remain unchanged and further patients will be recruited at the highest dose level. If this is not the case, a step-wise dose reduction approach will be applied. The antitumor activity of the combined treatment will be evaluated as secondary endpoints including best overall response rate (ORR), duration of objective response (DOR), progression-free (PFS) and overall (OS) survival. Extensive pharmacokinetics (PK) and pharmacodynamics (PD) (cellular immune status, serum and tissue biomarkers) will be also analyzed. As of the beginning of May 2018 the study is ongoing and 6 patients are being treated.

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