Phase 1 with Expansion Cohorts in a Study of NEO-201 in Adults with Chemo-Resistant Solid Tumors

M. Pia Morelli1, Nicole Houston1, Stan Lipkowski1, Jung-min Lee1, Alexandra Zimmer1, Farah Zia1, Kathrine Treviñ1 Herr Nichols2, Mira Pavelova2, Steven Hewitt2, Massimo Fantini2, Philip M. Arlen3, Kwong Y. Tsang2 and Christina M. Annunziata1

1Women’s Malignancies Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD, USA; 2Precision Biologics, Inc., Rockville, MD, USA;

Abstract #283199

Background: NEO-201 is a humanized IgG1 monoclonal antibody (mAb) generated against tumor-associated antigens (TAA) derived from tumor membrane fractions pooled from colorectal cancer surgical specimens. In preclinical data generated in our laboratory, we demonstrated that NEO-201 exerts anti-tumor activity by natural killer (NK)-mediated antibody-dependent cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) against several tumor types. We identified NEO-201 antigen as a tumor-associated form of CEACAM5-6, which is expressed by tumor tissue but is not present in the surrounding healthy tissue.DL2.

Methods: This is a first-in-human phase 1 study to determine the maximum tolerated dose (MTD) and recommended phase II dose (RP2D) of NEO-201 in adults with advanced solid tumors that have high likelihood of expression NEO201 antigen and have progressed to standard of treatments. This is a classic 3+3 dose escalation, with cohort expansion at the MTD. NEO-201 is administered intravenously every two weeks, and at four dose levels (DL1=1mg/kg, DL2=2mg/kg, DL3=4mg/kg and DL4=6mg/kg).

Results: A total of 9 evaluable patients were enrolled. Prolonged neutropenia, defined as grade 3/4 prolonged neutropenia was the DLT, and was observed in the first two dose levels. At DL3 and DL4, NEO-201 antigen expression in patient tumor tissue, circulating (CEACAM5/6), and MICA will be evaluated to correlate with response and toxicity. This is a first-in-human clinical trial of the monoclonal Ab against a TAA form of CEACAM5/6. Promising activity data were observed at DL2. Activity may correlate with baseline CEA and/or MICA level.

Conclusion: NEO201 has shown some promising activity. PK and PD studies are ongoing to better understand dosing schedule, toxicity profile and to identify biomarkers for patient selection. Clinical trial NCT number: NCT03476681.

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Results: Here we report the safety data and pharmacokinetics from Phase 1 with Expansion Cohorts in a Study of NEO-201 in Adults with Chemo-Resistant Solid Tumors. A. In vitro ADCC activity. B. In vivo activity against CFPAC1 mouse model.

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