Precision Biologics Commences Phase 2 Clinical Trial using NEO-201 and Pembrolizumab as a 2nd line Therapy in Patients with Solid Tumors

Bethesda, MD, October 14, 2021 - Precision Biologics today announces that a Phase 2 Clinical Trial with a safety lead in, combining its monoclonal antibody NEO-201 with the anti PD-1 monoclonal antibody Pembrolizumab (KEYTRUDA ®), is open and recruiting patients at the National Cancer Institute, National Institutes of Health (NIH) (USA).

In this Clinical Trial, up to 228 subjects with Non-Small Cell Lung Cancer (NSCLC), Head and Neck Squamous Cell Carcinoma (HNSCC), Cervical and Uterine Cancers who have received prior frontline therapy will be screened and, if eligible, treated with NEO-201 at 1.5 mg/kg every 2 weeks in combination with Pembrolizumab, given 1 day after the NEO-201, at 400 mg IV every 6 weeks.

RATIONALE OF THE STUDY:

- The low response rates and resistance to PD-1/PD-L1 blockade in the 2nd line treatment setting may be due to the action of Regulatory T (Tregs) cells in the tumor microenvironment (TME). Tregs have been demonstrated to play a role in increased resistance to PD-1/PD-L1 blockade.

- Preliminary data has shown that NEO-201 can target human Tregs.

- We hypothesize that the combination between NEO-201 and Pembrolizumab may overcome resistance to PD-1/PD-L1 checkpoint inhibitors by depleting Tregs and enhancing immune system mediated anti-tumor activity in subjects for whom Pembrolizumab is currently indicated in the second line setting.

PRIMARY ENDPOINT:

- Determine the safety of the combination of NEO-201 with standard of care Pembrolizumab

- Determine Objective Response Rate (ORR = CR, PR), as determined by RECIST v1.1 guidelines and Progression Free Survival (PFS), in four cohorts of subjects (NSCLC, HNSCC, Uterine and Cervical cancers) receiving NEO-201 in combination with Pembrolizumab at the FDA approved adult dose.

For more information on Precision Biologics, please visit http://www.precision-biologics.com/