A PHASE 1 STUDY EVALUATING COM701 IN PATIENTS WITH ADVANCED SOLID TUMORS

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BACKGROUND

- Novel checkpoint therapies are needed for the treatment of patients who relapse/refractory to treatment with checkpoint inhibitors.
- COM701 is a novel first-in-class humanized IgG4 monoclonal antibody that binds with high affinity to poliovirus receptor related immunoglobulin domain containing (PVRIG) blocking its interaction with its ligand, PVRL2.
- We have demonstrated in preclinical experiments that inhibition of PVRIG leads to activation of T cells in the tumor microenvironment generating an anti-tumor immune response leading to tumor growth inhibition.
- We hypothesize that COM701 will be safe and tolerable and demonstrate antitumor activity in pts with R/R solid tumors.

METHODS

- Study NCT03667716 is in collaboration with Bristol Myers Squibb.
- Study objectives:
  - To evaluate preliminary antitumor activity of COM701.
  - To assess any association of DNAM axis members with clinical outcome.
  - To explore evidence of COM701-mediated PD effect in blood as monotherapy as well as in combination with Opdivo.

- To identify the maximum tolerated dose and/or the recommended dose for expansion.
- To evaluate the safety profile of COM701.
- To characterize the immunogenicity of COM701.
- To characterize the PK profile of COM701.
- To assess any association of DNAM axis members with clinical outcome.
- To explore evidence of COM701-mediated PD effect in blood as monotherapy as well as in combination with Opdivo.

- Key inclusion criteria:
  - Age ≥ 18 yrs
  - Histologically or cytologically confirmed, locally advanced or metastatic solid malignancy.
  - No dose-limiting toxicities have been observed in the 3rd single patient cohort and earlier dose cohorts.

- Key exclusion criteria:
  - Active autoimmune disease requiring systemic therapy in the last 2 years prior to the first dose of COM701.
  - Untreated or symptomatic central nervous system metastases.

- Accrual information:
  - As of the date of this presentation the 3rd single patient dose cohort has been filled.
  - No dose-limiting toxicities have been observed in the 3rd single patient cohort and earlier dose cohorts.
  - Clinical and laboratory assessment for safety and tolerability is ongoing for the 4th dosing cohort.

- Reference:
  - Ganguly and Pardoll, Johns Hopkins Univ. MC38 model.