**Phase 1 dose escalation study of IMC-002, a novel anti-CD47 monoclonal antibody, in patients with advanced solid tumors**

**BACKGROUND**
- IMC-002 is a fully human IgG4 antibody targeting CD47. IMC-002 induces phagocytosis of tumor cells by macrophages and strongly suppresses tumor growth in preclinical models of hematologic and solid tumors.
- In order to mitigate on-target anemia caused by ubiquitous expression of CD47, IMC-002 was screened for a selective binding to CD47 on tumor cells, but not on RBCs. In line with this, IMC-002 showed no hemagglutination in vitro and no hematological toxicity up to 100 mg/kg in cynomolgus monkeys.
- Here, we present preliminary safety, pharmacokinetics (PK), and efficacy data from an ongoing phase 1 study of IMC-002 in patients with advanced solid tumors who have failed to standard therapy (without prior dose).

**OBJECTIVES**
- In order to mitigate on-target anemia caused by ubiquitous expression of CD47, IMC-002 was screened for a selective binding to CD47 on tumor cells, but not on RBCs. In line with this, IMC-002 showed no hemagglutination in vitro and no hematological toxicity up to 100 mg/kg in cynomolgus monkeys.
- Here, we present preliminary safety, pharmacokinetics (PK), and efficacy data from an ongoing phase 1 study of IMC-002 in patients with advanced solid tumors who have failed to standard therapy (without prior dose).

**METHODS**

- **Key Inclusion Criteria:**
  - Histologically or cytologically proven metastatic or locally advanced solid tumors that have progressed following any standard treatments or are not possible for standard treatment.
  - At least 1 measurable lesion according to RECIST v1.1.
  - ECOG performance status of 0-1.
  - According to the traditional 3+3 design, 3 to 8 subjects were enrolled at each escalating dose level.
  - The DLT evaluation period was 21 days.

**RESULTS**

- **Patient Disposition and Baseline Characteristics:**
  - From May 2022, 3 patients were enrolled in each dose level 1 to 3 (5 mg/kg, 10 mg/kg, 20 mg/kg) with no observed DLT. A total of 4 patients were enrolled in dose level 4 (30 mg/kg) because 1 patient was ineligible and not included in the DLT population. Analyses were conducted in the DLT population.

- **Safety Results:**
  - No DLTs were observed across all 4 dose levels. The majority of treatment-related adverse events (TRAEs) were grade 1-2. Most of these events occurred during the first cycle (94%). TRAEs observed in more than 2 patients included skin rash, transient vitreous floaters and anemia.
  - Notable to infusion-related reactions, thrombocytopenia, or neutropenia were reported.

- **PK Results:**
  - The serum exposure of IMC-002 (Cmax, and AUC) demonstrated a dose-dependent increase, and the predicted trough concentration for 20 and 30 mg/kg Q3W exceeded 24 ug/mL, the minimum efficacious concentration for IMC-002.

**CONCLUSIONS**

- Based on safety and PK profile, we have determined the recommended phase 2 dose (10 mg/kg) of IMC-002.

**ACKNOWLEDGEMENTS**

- Here, the authors thank the patients and their families and caregivers for their participation in this trial, as well as all investigators and site personnel.