**Phase 1 Dose Escalation Study of MGC018, an anti-B7-H3 Antibody-Drug Conjugate (ADC), In Patients with Advanced Solid Tumors**

Szekiewicz, Jung, Jacobson, and others presented the study at the 2021 ASCO Annual Meeting.

**Background**

- MGC018 is a novel ADC that delivers an anti-B7-H3 antibody to tumor cells.
- B7-H3 is overexpressed in various tumors, including prostate, colon, melanoma, and sarcoma.

**Objectives**

1. **Primary Objective:**
   - Evaluate the maximum tolerated dose (MTD) and recommended phase II dose (RP2D) of MGC018.

2. **Secondary Objectives:**
   - Evaluate antitumor activity.
   - Assess tolerability.
   - Collect pharmacokinetic (PK) and pharmacodynamic (PD) data.
   - Assess post-baseline tumor evaluations.

**Study Design and Objectives**

- **Design:** Open-label, single-arm study.
- **Eligibility Criteria:**
  - Patients ≥ 18 years old with histologically or cytologically confirmed advanced solid tumors.
  - ECOG PS ≤ 2 and life expectancy ≥ 12 weeks.

**Enrollment Status**

- **Dose Escalation:**
  - 24 patients enrolled in 3 cohorts (6 patients per cohort).
  - Dose levels: 3.0 mg/kg, 4.0 mg/kg, 5.0 mg/kg.
  - Cohort expansion: 6 patients per dose level.

**Dose Escalation Results**

- **MGC018** arm: 24 patients enrolled.
  - 29 patients who received at least one dose and had at least one post-baseline tumor evaluation.
  - Best percent change of target lesions in evaluable population: 31.0% (SD -92%), 74% (SD -74%), 17% (SD +25%), and 99% (SD +70%).

**Update on mCRPC PSA Responders from ASCO 2020**

- Of the 7 patients, 4 had reductions in target lesion sums of 13%, 21%, 27%, and 35% (uPR).

**Conclusions**

- MGC018 shows promising antitumor activity and tolerability in patients with advanced solid tumors.
- Future studies will focus on optimizing the dose and expanding the patient population.