A Phase 1b/2 Study of a Novel Anti-CTLA-4 NEObody™ ADG116 Monotherapy and in Combination with Toripalimab (TORI; Anti-PD-1 Antibody) in Patients with Advanced / Metastatic Solid Tumors

**Background**
ADG116 is a differentiated anti-CTLA-4 fully human IgG1 NEObody, targeting a unique and evolutionarily conserved epitope of CTLA-4 for antigen-specific tumor targeted therapy with comparable cross-reactivity from mouse, monkey to human. The drug was designed to be administered with subcutaneous, intramuscular, subcutaneous, intramuscular and tumor microenvironment (TME)

**Method**
We present interim data from a Phase 1b/2, open-label, non-randomized study in patients with advanced / metastatic solid tumors (ADG116-1193, NCT05091976/). Patients were enrolled across multiple solid tumors at escalating dose levels up to 60 mg/kg. The primary endpoints are safety and tolerability; determine MTDs and RP2Ds. A total of 36 patients (18 men; median age 49.8 years) were treated with ADG116 monotherapy or combination with toripalimab (200 mg, Q3W).

**Efficacy: ADG116 Monotherapy**
Across all dose levels, disease control rate (DCR) = 33% in 36 evaluable patients* treated by ADG116 (3 mg/kg) + TORI (240 mg, Q3W) + TORI (240 mg, Q3W). The full dataset is pending. Efficacy and safety will be presented at the next ASCO meeting.

**Efficacy: ADG116 + Toripalimab**
- Objective response rate (ORR) = 14%, and disease control rate (DCR) = 33%, among 7 evaluable patients who were treated with ADG116 (3 or 6mg/kg) + TORI (240 mg, Q3W).
- Among the 3 evaluable patients who received ADG116 3 mg/kg + TORI (240 mg, Q3W) + TORI (240 mg, Q3W), ORR = 25% and DCR = 100%.
- **Case Study:** Durable Complete Response to ADG116 3 mg/kg Q3W + TORI 240 mg Q3W in a Recurrent HNSCC Patient

**Conclusion**
ADG116 monotherapy showed improved safety and tolerability profile up to 15 mg/kg over the approved anti CTLA-4 therapy, with no DLTs and no apparent impact on PK of ADG116 across studied dose levels. Combination of ADG116 with toripalimab did not appear to change the PK of ADG116 when compared with PK profile of ADG116 monotherapy. Further dose optimization such as extended dosing interval for ADG116 in combination with anti-PD-1 therapy is being evaluated.