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Forbius Announces First Patient Dosed in Phase 2a Squamous Cell Carcinoma of the Head and Neck (SCCHN) Trial of AVID100, a Novel Anti-EGFR ADC

- This trial will evaluate the efficacy of AVID100 in SCCHN patients with EGFR IHC 3+ tumors
- AVID100 is the most advanced, broadly active anti-EGFR ADC in clinical development
- 20% of SCCHN patients highly overexpress EGFR; no therapy is approved for these patients

Austin, TX, and Montreal, QC (Mar. 7, 2019) – Forbius, a clinical-stage company that develops novel biologics for the treatment of fibrosis and cancer, announced today that the first patient has been dosed in a Phase 2a squamous cell carcinoma of the head and neck (SCCHN) clinical trial.

The majority of SCCHN patients have tumors that overexpress epidermal growth factor receptor (EGFR) and approximately 20% have tumors that highly overexpress EGFR (more than 50% of cells with EGFR 3+ staining by a validated immunohistochemistry assay). No therapy is approved for the treatment of EGFR-overexpressing SCCHN.

The multicenter SCCHN trial (AVID100-01; NCT03094169) will evaluate the efficacy, safety, and tolerability of AVID100 in patients with EGFR IHC 3+ tumors and follows the previously announced Phase 2a trial of AVID100 in patients with advanced squamous non-small cell lung cancer.

About AVID100 and the AVID100-01 Trial

AVID100 is a highly potent EGFR-targeting antibody-drug conjugate (ADC) engineered to achieve enhanced anti-tumor efficacy without a corresponding increase in toxicity against skin and other EGFR-expressing normal tissues. In preclinical studies, AVID100 demonstrated significant anti-cancer activity in EGFR overexpressing tumor models resistant to marketed EGFR inhibitors. AVID100 is the only broadly active anti-EGFR ADC in clinical development.

A recommended Phase 2 dose (RP2D) of 240 mg/m^2 (~6mg/kg) was established for AVID100 in a completed Phase 1 study. This RP2D is expected to be in the therapeutically active range based on preclinical efficacy studies. The majority of treatment related adverse events in the Phase 1 trial at RP2D were well-tolerated and grade 1 or 2 in severity.

AVID100-01 is an open label, multicenter, dose-escalation study to evaluate the safety and efficacy of AVID100 in patients with confirmed EGFR-overexpressing tumors.

About Forbius: Targeting TGF-beta and EGFR Pathways in Fibrosis and Cancer

Forbius is a clinical-stage protein engineering company that designs and develops novel biologics for the treatment of fibrosis and cancer. Our current focus is on the development of agents that target the transforming growth factor-beta (TGF-beta) as well as the epidermal growth factor receptor (EGFR) pathways. For more information, please visit www.forbius.com.

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