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Forbius Announces First Patient Dosed in Phase 2a Triple Negative Breast Cancer (TNBC) Trial of AVID100, a Novel, Tumor-Selective Anti-EGFR ADC

- This trial evaluates the efficacy of AVID100 in TNBC patients with EGFR-overexpression
- 20% of TNBC patients highly overexpress EGFR; there is no approved targeted therapy
- AVID100 is the most advanced, broadly active anti-EGFR ADC in clinical development, targeting both wild-type and mutant forms of EGFR

Austin, TX, and Montreal, QC (Apr. 22, 2019) – Forbius, a clinical-stage company that develops novel biologics for the treatment of cancer and fibrosis, announced today that the first patient has been dosed in a Phase 2a triple negative breast cancer (TNBC) clinical trial with AVID100, a novel, tumor-selective anti-epidermal growth factor receptor (EGFR) antibody-drug conjugate (ADC).

Approximately 20% of TNBC patients have tumors that highly overexpress EGFR. No targeted therapy is approved for EGFR-overexpressing TNBC.

The multicenter, dose-expansion Phase 2a trial (AVID100-01; NCT03094169) will evaluate the efficacy, safety, and tolerability of AVID100 in patients with advanced, EGFR-overexpressing TNBC (IHC 2+/3+). This is the third cohort that has been launched and follows the previously announced cohorts evaluating AVID100 in patients with advanced squamous non-small cell lung cancer (sqNSCLC) and squamous cell carcinoma of the head and neck (SCCHN). In total, approximately 100 patients will be evaluated across three EGFR-overexpressing tumor types: sqNSCLC, SCCHN, and TNBC.

About AVID100 and the AVID100-01 Trial

AVID100 is a highly potent EGFR-targeting ADC engineered to achieve enhanced anti-tumor efficacy without a corresponding increase in toxicity in skin or 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 most advanced, broadly active anti-EGFR ADC in clinical development and targets both wild-type and mutant forms of EGFR.

A recommended Phase 2 dose (RP2D) of 220 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 the RP2D were well-tolerated and grade 1 or 2 in severity.

AVID100-01 (NCT03094169) is an open-label, multicenter, dose-expansion study to evaluate the efficacy, safety, and tolerability of AVID100 in patients with confirmed EGFR-overexpressing sqNSCLC (IHC 3+), SCCHN (IHC 3+), and TNBC (IHC 2+/3+) (more than 50% of cells with EGFR 3+ or more than 75% of cells with EGFR 2+ staining).

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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) and the epidermal growth factor receptor (EGFR) pathways. For more information, please visit www.forbius.com.

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