

FORBIUS

Forbius Announces First Patient Dosed in Phase 2 Trial of anti-EGFR ADC AVID100 in EGFR-Overexpressing Squamous NSCLC

- First patient dosed in Phase 2 advanced squamous NSCLC, additional indications to be launched imminently
- High RP2D established, predicted to be therapeutically active
- AVID100 is the only broadly active anti-EGFR ADC in clinical development

(October 22, 2018) – Forbius, a clinical stage company developing biotherapeutics targeting EGFR and TGF- β pathways, today announced that the first patient has been dosed in a Phase 2a trial evaluating the efficacy and safety of AVID100 in patients with squamous non-small cell lung cancer (sqNSCLC) whose tumors overexpress epidermal growth factor receptor (EGFR).

Approximately 25% of patients with sqNSCLC have tumors that highly overexpress EGFR. Currently, no therapy is approved for the treatment of EGFR-overexpressing sqNSCLC.

An initial safety Phase 1 study for AVID100 was completed mid 2018, having enrolled 24 patients, and established a recommended Phase 2 dose (RP2D) of AVID100 of 240 mg/m² (~6 mg/kg). This is one of the highest RP2Ds reported for maytansinoid payload ADCs ([Deslandes, MAbs. 2014 Jul 1; 6\(4\): 859–870](#)) and is expected to be in the therapeutically active range based on preclinical efficacy studies. The majority of treatment related adverse events at RP2D were well-tolerated and grade 1 and 2 in severity. Of note, skin-related side-effects, that have been observed previously for therapeutic anti-EGFR antibodies, remained low grade and well tolerated.

“The sqNSCLC trial, along with additional soon-to-be launched Phase 2a trials, will provide us with important information about the efficacy of AVID100 in patients with confirmed EGFR overexpression. No therapy is approved for the treatment of EGFR-overexpressing malignancies, and AVID100 could be the first agent to address this significant unmet medical need,” commented Paul Nadler, M.D., Chief Medical Officer of Forbius.

The primary goal of the Phase 2a trial is to evaluate efficacy, safety, and tolerability of AVID100 when administered to sqNSCLC patients with confirmed EGFR-overexpression. The study is being conducted at multiple sites across North America and will initially enroll approximately 15 sqNSCLC patients who failed all prior lines of treatment. The number of patients will be increased pending preliminary signs of AVID100 efficacy. This Phase 2a study is being supported by the previously announced [\\$18.8M peer-reviewed grant from the Cancer Prevention Institute of Texas \(CPRIT\)](#).

About AVID100:

AVID100 is a highly potent EGFR-targeting antibody-drug conjugate (ADC) that was 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-

FORBIUS

cancer activity, including in EGFR overexpressing tumor models that are resistant to marketed EGFR inhibitors. AVID100 is the only broadly active anti-EGFR ADC in clinical development.

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

Forbius is a clinical stage company that designs and develops biotherapeutics for the treatment of cancer and fibrotic diseases. We use our strength in biological understanding and diverse protein engineering technologies to design superior inhibitors of validated pathways. We have particularly deep expertise in targeting the transforming growth factor-beta (TGF- β) and epidermal growth factor receptor (EGFR) pathways. For both of these pathways, there is a significant body of evidence validating their role as drivers of multiple life-threatening conditions, including cancer and fibrosis. However, in the case of the EGFR pathway, the majority of patients do not benefit from currently marketed EGFR inhibitors; in the case of the TGF- β pathway, no agent targeting this pathway has yet been approved. By using multiple complementary platform technologies, Forbius' team overcame barriers that prevented the development of effective therapeutics targeting these pathways. For more information, please visit www.forbius.com.