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Forbius Announces the First Patient Dosed in a Phase 1b Diffuse Cutaneous Systemic Sclerosis Trial of AVID200, a Novel TGF-beta 1 & 3 Inhibitor



Dr. Robert Lafyatis meeting Forbius team for the first time in 2017 (From left: Dr. Robert Lafyatis, Investigator in the SSc Trial; Maureen O'Connor, CSO; Ilia Tikhomirov, CEO; Paul Nadler, CMO)

- This trial will evaluate the safety and anti-fibrotic effects of AVID200 in diffuse cutaneous systemic sclerosis patients
- AVID200 is a rationally designed, highly potent inhibitor of TGF-beta 1 & 3
- TGF-beta 1 & 3 are the principal drivers of fibrosis in systemic sclerosis and other indications, supporting broad utility of AVID200

Austin, TX, and Montreal, QC (Mar. 4, 2019) – Forbius, a clinical-stage company that develops biologics for the treatment of fibrosis and cancer, announced today that the first patient has been dosed in a diffuse cutaneous systemic sclerosis (SSc) Phase 1b trial with AVID200, a rationally designed and highly potent inhibitor of TGF-beta 1 & 3.

"The basic defect in SSc and most other fibrotic diseases is increased TGF-beta signaling. Selective TGF-beta inhibition by AVID200 could rapidly reverse fibrosis, and I am keen to investigate the potential of AVID200 to transform the treatment of SSc," commented Coordinating Principal Investigator <u>Robert Lafyatis, M.D.</u>, Professor of Medicine, Medsger Professor and Director of the Scleroderma Center at the University of Pittsburgh Medical Center.

TGF-beta signaling is central to SSc pathogenesis (<u>Lafyatis, 2014</u>), and TGF-beta isoforms 1 & 3, but not 2, correlate positively with disease severity (<u>O'Connor *et al.*, 2018</u>). AVID200 selectively neutralizes TGF-beta 1 & 3 with best-in-class pM potency, thus simultaneously neutralizing the principal pro-fibrotic TGF-beta isoforms and providing optimal efficacy.

"For decades, safe and potent neutralization of TGF-beta has been the holy grail for the treatment of fibrotic diseases. To achieve this, our team of pioneers in the TGF-beta field identified the two principal disease-driving TGF-beta isoforms and designed selective inhibitors that simultaneously neutralize these isoforms, while sparing the isoform that is critical for safety," commented Mr. Ilia Tikhomirov, CEO of Forbius. "AVID200 has the potential to transform the treatment of many diseases and is the first of several new generation TGF-beta inhibitors being developed by Forbius."

About Diffuse Cutaneous Systemic Sclerosis and the AVID200-01 Trial

SSc is a rare, severe, and progressively debilitating fibrotic disease that predominately affects women in mid-life. The 10-year survival rate of SSc patients is approximately 55%. No therapeutic is currently approved for the treatment of SSc, which affects an estimated 50,000 people in the U.S. alone.

AVID200-01 (<u>NCT03831438</u>) is a Phase 1 open-label, dose-escalation study to evaluate safety, pharmacokinetics, pharmacodynamics, and anti-fibrotic activity of AVID200 in patients with documented SSc.

About AVID200: TGF-beta 1 & 3 Inhibitor

AVID200 is a rationally designed, highly potent TGF-beta 1 & 3 inhibitor undergoing Phase 1 clinical testing in fibrosis and solid tumors. TGF-beta 1 & 3 are the principal disease-driving

isoforms, while TGF-beta 2 is responsible for normal cardiac function and is a positive regulator of hematopoiesis. AVID200's selectivity for TGF-beta 1 & 3 was designed to achieve optimal efficacy, while circumventing cardiac and other safety issues that have limited the applicability of older-generation, non-selective TGF-beta inhibitors. Therefore, AVID200 is positioned to be an effective and well-tolerated therapeutic in a variety of clinical settings.

About Forbius:

Targeting TGF-beta and EGFR Pathways in Fibrosis and Cancer

Forbius is a clinical-stage protein engineering company that designs and develops biotherapeutics for the treatment of fibrosis and cancer. Our current focus is 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 <u>www.forbius.com</u>.

More News

February 14, 2019 <u>Forbius Announces a Clinical Trial Collaboration with the Myeloproliferative Neoplasm Research</u> <u>Consortium to Evaluate AVID200, a Novel TGF-beta Inhibitor, in Myelofibrosis</u>

January 7, 2019 Forbius Announces the First Patient Dosed in a Phase 1 Oncology Trial of AVID200, a Novel TGF-beta 1 & <u>3 Inhibitor</u>

January 2, 2019 Forbius to Present at the 37th Annual J.P. Morgan Healthcare Conference

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