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## **Forbius Reported Safety and Initial Anti-Fibrotic Effects of First-in-Class, Selective TGF-beta Inhibitor, AVID200, in Phase 1b Systemic Sclerosis Trial at EULAR 2020**

- Initial results demonstrate anti-fibrotic effects of AVID200 as indicated by rapid and sustained declines in skin fibrosis.
- AVID200 was well-tolerated, and no dose-limiting toxicities, SAEs or adverse events greater than Grade 2 were observed. The MTD was not reached.
- AVID200 demonstrated pharmacodynamic responses as shown by modulation of downstream targets of TGF-beta and biomarkers associated with scleroderma disease activity.

Austin, TX, and Montreal, QC (Jun. 5, 2020) – [Forbius](#), a clinical-stage protein engineering company that develops biotherapeutics to treat fibrosis and cancer, today presented the first AVID200 Phase 1b results from its scleroderma development program in a poster tour at the [Annual European Congress of Rheumatology \(EULAR\) 2020](#).

“The results seen to date in this Phase 1 trial with AVID200 are compelling. MRSS, a measure of skin fibrosis, declined in all patients and was supported by patient reported outcomes and biomarker modulation. These results, along with the favorable safety profile, demonstrate that AVID200 has the potential to be a disease modifying treatment of fibrotic diseases such as systemic sclerosis,” commented [Robert Lafyatis, M.D.](#), Medsger Professor and Director of the University of Pittsburgh Scleroderma Center at the University of Pittsburgh Medical Center, and coordinating PI in the trial.

Highlights of the presentation, “Safety, Target Engagement, and Initial Efficacy of AVID200, a First-in-Class Potent and Isoform-Selective Inhibitor of TGF-beta 1 and 3, in Patients with Diffuse Cutaneous Systemic Sclerosis (dcSSc): A Phase 1 Dose Escalation Study (Abstract # THU0329)”, included:

- A total of nine patients received escalating doses of AVID200 at 1, 3 and 9 mg/kg once every two weeks and have completed the initial treatment period (3 cycles). AVID200 was well-tolerated, and no dose-limiting toxicities, SAEs or adverse events greater than Grade 2 were observed. The MTD was not reached.
- All patients reported a reduction in skin fibrosis following the initial treatment period as measured by a decline in Modified Rodnan Skin Score (MRSS). 5 out of 9 patients reported declines between -8 and -10 points, representing a reduction between -25 and -45% from baseline.

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- AVID200 also demonstrated an improvement in patient reported outcomes in a majority of patients as well as pharmacodynamic responses as shown by modulation of downstream targets of TGF-beta and biomarkers associated with scleroderma disease activity.

AVID200 is a first-in-class, selective inhibitor of TGF-beta 1 & 3, the central mediators of fibrosis. AVID200 spares TGF-beta 2 for optimal safety.

The Phase 1b clinical study in patients with diffuse cutaneous systemic sclerosis (AVID200-01, [NCT03831438](#)) is designed to assess the safety and initial anti-fibrotic activity of escalating doses of AVID200.

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## **About TGF-beta 1 & 3**

TGF-beta 1 & 3 are central mediators of fibrosis, a leading cause of morbidity and mortality worldwide. TGF-beta 1 & 3 drive fibrosis by promoting the accumulation of extracellular matrix proteins in tissues; consequently, their inhibition is proposed to have broad potential as an anti-fibrotic therapy across several indications with high unmet need.

## **About AVID200 and the AVID200-01 Trial ([NCT03831438](#))**

Systemic Sclerosis (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 90,000 people in the U.S. alone.

AVID200-01 ([NCT03831438](#)) is a Phase 1 open-label, dose-escalation study to evaluate safety, pharmacokinetics, pharmacodynamics and anti-fibrotic activity of AVID200 in patients with documented diffuse cutaneous SSc.

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

[Forbius](#) is a clinical-stage protein engineering company that develops biotherapeutics to treat fibrosis and cancer. We are focused on the transforming growth factor-beta (TGF-beta) and epidermal growth factor receptor (EGFR) pathways.

Forbius' team of TGF-beta biology experts designed a proprietary platform of TGF-beta inhibitors with best-in-class potency and selectivity against the principal disease-driving isoforms 1 & 3. This novel class of TGF-beta inhibitors has proven highly active in preclinical models of fibrosis and cancer and was well-tolerated in long-term toxicology studies. Forbius' lead TGF-beta 1 & 3 inhibitor, AVID200, is undergoing Phase 1 clinical trials in two fibrotic indications as well as in solid tumors.

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Forbius' lead program targeting EGFR is AVID100. AVID100 is an anti-EGFR antibody-drug conjugate (ADC) with a novel tumor-selective mode of action. This program is undergoing Phase 2a clinical trials in EGFR-overexpressing solid tumors.