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Forbius' AVID200, a novel TGF-beta 1 & 3 Inhibitor, Cleared by the FDA to Commence Phase 1 Clinical Trial in Solid Tumors

- AVID200 is a novel, rationally designed, highly potent TGF-beta 1 & 3 inhibitor
- Best-in-class efficacy and safety potential by selectively targeting principal oncogenic TGF-beta isoforms
- Reverses immunosuppression and renders tumors sensitive to checkpoint blockade in pre-clinical models

Austin, TX and Montreal, QC (Nov. 26, 2018) – Forbius, a clinical-stage company developing biologics for the treatment of cancer and fibrosis, announced today that the U.S. Food and Drug Administration (FDA) has approved its investigational new drug (IND) application to conduct a Phase 1 clinical trial in solid tumors with immuno-oncology candidate AVID200, a rationally designed inhibitor of TGF-beta 1 & 3.

The Phase 1 trial will evaluate safety, pharmacokinetics, pharmacodynamics, and antitumor effects of escalating doses of AVID200. This agent is the Company's second innovative biologic to enter clinical development.

AVID200 is designed to selectively neutralize TGF-beta 1 & 3 with best-in-class pM potency, thus neutralizing the principal immunosuppressive TGF-beta isoforms. AVID200's optimal selectivity is also designed to circumvent cardiac and other safety issues which have limited the applicability of older generation, non-selective TGF-beta inhibitors.

TGF-beta 1 & 3 are the main oncogenic TGF-beta isoforms expressed by many solid tumors. They are believed to play a major role in T-cell suppression, fibrosis, and resistance to immunotherapeutics such as nivolumab (Opdivo) and pembrolizumab (Keytruda) (Chakravarthy *et al.*, Nature Comm., 2018; Tauriello *et al.*, Nature, 2018; Mariathasan *et al.*, Nature, 2018).

AVID200's immuno-oncology mode of action centers on reversal of both immunosuppression and fibrosis in the tumor stroma. In syngeneic mouse tumor models, AVID200 treatment led to T-cell activation, increased immune tumor infiltration, and increased efficacy of immune checkpoint agents.

"TGF-beta signaling has emerged as a key target to overcome tumor immunosuppression and resistance to immunotherapies, a major unmet medical need. AVID200 has the potential to significantly expand the number of cancer patients that benefit from checkpoint blockade and other immunotherapies. I am keen to evaluate the effects of AVID200 in this clinical trial," commented Dr. Lillian Siu, a senior medical oncologist and Director of the Phase I Program at Princess Margaret Cancer Centre in Toronto. Dr. Siu is one of the investigators leading the AVID200 Phase 1 study in solid tumors.

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About AVID200

AVID200 is positioned to be an effective and well-tolerated therapeutic in a variety of clinical settings being rationally designed to selectively neutralize TGF-beta 1 & 3 with pM potency, thus avoiding TGF-beta 2 related cardiac and hematopoietic toxicity. Overexpression of TGF-beta isoforms 1 & 3 is closely associated with the progression of fibrosis and cancer.

AVID200's immuno-oncology mode of action centers on reversal of immunosuppression as well as a strong anti-fibrotic effect in the tumor stroma. Its development in this setting is supported by the previously announced peer-reviewed BioCanRx grant with a total project value of CAD$1,655,297.

AVID200 is undergoing Phase 1 clinical testing for the treatment of fibrotic diseases and immune oncology.

About Forbius

Forbius is a clinical stage company that designs and develops biotherapeutics for the treatment of cancer and fibrotic diseases. Forbius' medicines are designed to radically transform patients' lives. 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-beta) 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-beta 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.