

Verseau Therapeutics Announces FDA Clearance of Investigational New Drug Application for VTX-0811, a PSGL-1 Targeting Monoclonal Antibody

- Phase 1a/b Clinical Study of VTX-0811 in Solid Tumors Expected to Initiate in Q1 2022 -

BEDFORD Mass. – January 4, 2022 – [Verseau Therapeutics, Inc.](https://www.verseautx.com/) today announced that the U.S. Food and Drug Administration (FDA) has cleared the company’s investigational new drug (IND) application for its lead investigational product candidate, VTX-0811, a monoclonal antibody that binds to P-selectin glycoprotein ligand-1 (PSGL-1). VTX-0811 repolarizes macrophages, leading to coordinated anti-tumor immune responses. The FDA has completed its 30-day safety review and granted approval for the company to proceed with the proposed first-in-human clinical trial of VTX-0811.

“The clearance of our first IND is a major milestone for Versseau that brings us closer to our goal of providing a potent and broadly applicable approach for the treatment of solid tumors,” said John Edwards, Chief Executive Officer of Versseau Therapeutics. “We are incredibly excited to begin testing VTX-0811 safety and activity in patients and plan to continue this momentum with the filing of an additional IND for VTX-1218, our second macrophage repolarizer program, within the next year.”

The VTX-0811 two-part Phase 1 clinical trial will begin with an open label, dose-escalation study (Phase 1a) initially evaluating the safety profile of the drug administered intravenously (IV) to individuals with select solid tumor types that are predicted to have the highest probability of responding to treatment. This will be followed by a Phase 1b expansion portion of the trial, which will further evaluate VTX-0811 as a monotherapy and in combination with PD-1 therapy in select tumor types. The Phase 1b portion of the trial will focus on assessing anti-tumor activity of VTX-0811 in addition to safety.

About VTX-0811

VTX-0811 is an investigational first-in-class monoclonal antibody that binds to PSGL-1 (P-selectin glycoprotein ligand-1), an adhesion molecule involved in immune cell trafficking in response to tissue injury or inflammation. VTX-0811 binds to a specific epitope on PSGL-1 involved in controlling macrophage activation, without impacting selectin and VISTA mediated functions of PSGL-1. VTX-0811 enables a natural biological switch transforming immuno-suppressive tumor-associated macrophages into pro-inflammatory, anti-tumorigenic macrophages. These repolarized macrophages set in motion an immune response that attracts and turns on cancer-fighting immune cells in the tumor microenvironment.

About Versseau

Verseau Therapeutics is advancing a new class of cancer immunotherapies to stimulate the conversion of immuno-suppressive, pro-tumorigenic macrophages into pro-inflammatory macrophages. This transformation, called macrophage repolarization, induces a coordinated immune response to fight cancer. Preclinically this approach has been found to offer both a broader and more potent antitumor approach than with currently available T cell-based immunotherapies. Versseau’s macrophage repolarization target discovery engine leverages human and disease biology, as well as computational approaches in a patient-focused discovery process. This led to the discovery and validation over 20 novel macrophage targets. Versseau’s first-in-class monoclonal antibody candidates, VTX-0811 targeting PSGL-1 and VTX-1218 targeting VSIG4, are progressing toward clinical trials. <https://www.verseautx.com/>

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