



Immunitas Therapeutics Receives FDA Clearance of IND Application for IMT-009 in Solid Tumors and Hematological Malignancies

IMT-009 Phase 1/2a clinical trial initiation expected in Q4 2022

Preclinical data indicate that IMT-009 restores tumor killing activity with potential for use as monotherapy or in combination with existing therapeutics

WALTHAM, Mass. September 21, 2022 – – [Immunitas Therapeutics](#) (“Immunitas”), a precision immunotherapy company committed to discovering and developing novel, differentiated therapeutics for patients with cancer, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for IMT-009, a fully human monoclonal antibody against a novel immuno-oncology target CD161. The Phase 1 study is designed to evaluate the safety, tolerability, pharmacodynamic biomarkers, and preliminary efficacy of IMT-009 as well as identify the Recommended Phase 2 Dose (RP2D). The trial will then transition into Phase 2 with multiple expansion cohorts to assess the safety and efficacy of IMT-009 alone or in combination with another antineoplastic agent.

“We are thrilled to advance IMT-009 to the clinic as we believe it represents a new wave of immuno-oncology agents with transformative potential in both hematological malignancies and solid tumors,” said Seng-Lai “Thomas” Tan, Ph.D., Chief Scientific Officer of Immunitas Therapeutics. “Based on compelling preclinical data demonstrating its dual-action mechanism and non-overlapping biology with other immune checkpoint pathways, IMT-009 will be investigated as a monotherapy and in combination with other cancer therapies.”

IMT-009 is an Fc-attenuated monoclonal antibody that binds with high affinity and selectivity to CD161, a receptor that is broadly expressed on NK and a subset of memory T cells, blocking interactions between the receptor and its cognate ligand, CLEC2D, which is expressed on the surface of both cancer cells and immune cells. Preclinical data confirm that CD161 blockade with IMT-009 results in enhanced anti-tumor activity.

“IMT-009 is a first-in-class therapeutic with exciting potential for efficacy in a broad range of tumor types. I applaud the team at Immunitas that has driven it forward, and our academic founders who originally identified CD161 as an inhibitory T-cell target. IMT-009 will be



progressed into the clinic using a biomarker-driven development plan designed to assess biological response and inform future patient selection,” said Amanda Wagner, M.B.A., Chief Executive Officer of Immunitas Therapeutics. “This development plan illustrates our commitment to the advancement of precision immunotherapies. In addition to IMT-009, we continue to discover and progress a pipeline of next-generation differentiated immunotherapies using our cross-functional discovery engine, which pairs advanced computational biology approaches with deep immunology expertise and in-house antibody capabilities.”

The IMT-009 Phase 1/2 clinical trial is anticipated to begin enrollment in Q4 2022.

About Immunitas Therapeutics

Immunitas is a precision immunotherapy company committed to discovering and developing novel, differentiated treatments for patients with cancer. A focus on human data, combined with fully integrated internal R&D capabilities and parallel discovery efforts, allows Immunitas to start with and stay closer to the most relevant and translatable biology for patients, accelerating the timeline from discovery to the clinic. The Immunitas discovery engine combines deep expertise in single-cell genomics with customized machine learning approaches to elucidate immune cell populations that are key actors in immuno-oncology. Its lead program, IMT-009, a CD161 mAb that modulates NK and T cell activity, is entering Phase 1/2a clinical evaluation for use as a monotherapy and combination treatment for solid tumor and hematological malignancies. The company was founded by Longwood Fund with leading scientists from Dana-Farber, MGH, the Broad, and MIT. Since being founded in 2019, Immunitas has raised a total of \$97 million in venture funding from a strong syndicate of investors including Agent Capital, Alexandria Venture Investments, Evotec, Leaps by Bayer, Longwood Fund, M Ventures, Medical Excellence Capital, and Novartis Venture Fund. To learn more, visit www.immunitastx.com.

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