Source: *Vittoria Biotherapeutics*

December 07, 2023 08:00 ET

Vittoria Biotherapeutics Announces FDA Clearance of IND Application for VIPER-101 to Treat T-Cell Lymphoma

- *VIPER-101 is an autologous, CD5 knock-out CAR-T therapy for the treatment of T-cell lymphoma*

- *Initiating first-in-human Phase 1 trial in H1 of 2024*

PHILADELPHIA, Dec. 07, 2023 (GLOBE NEWSWIRE) -- Vittoria Biotherapeutics has announced the clearance of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for the initiation of a first-in-human Phase 1 clinical trial to evaluate the Company's lead candidate, VIPER-101, a gene-edited, autologous, CAR-T cell therapy for treatment of patients with relapsed or refractory T-cell lymphoma.

"The FDA clearance of our investigational new drug application for VIPER-101 marks a pivotal milestone for Vittoria Biotherapeutics and our mission to transform therapeutic outcomes for patients battling difficult to treat diseases," said Dr. Nicholas Siciliano, Ph.D., chief executive officer of Vittoria. "With limited advancements in T-cell lymphoma treatment over the last decade, this signifies a crucial step toward bringing an innovative treatment option to T-cell lymphoma patients with the potential to transform patient outcomes - an opportunity enabled by our proprietary Senza5 platform technology, designed to both enhance efficacy and improve safety."

Marco Ruella, MD, scientific co-founder of Vittoria and an assistant professor of Medicine in the Perelman School of Medicine at the University of Pennsylvania commented, "As a physician-scientist, I have seen first-hand the need for new therapies when treating T-cell lymphoma patients and as such, it is deeply gratifying to advance the first cell therapy candidate from our novel Senza5 technology into first-in-human studies. VIPER-101 is the first autologous CD5-targeting therapy designed to circumvent fratricide, improve anti-tumor efficacy, and mitigate inherent safety challenges associated with targeting T-cell malignancies with CAR-T therapies, thus creating the opportunity to deliver a potentially ground-breaking treatment for patients with T-cell lymphoma."

VIPER-101 is an autologous, CD5 deleted CAR-T therapy for the treatment of T-cell lymphoma produced using Vittoria's proprietary cell therapy engineering and manufacturing platform, Senza5^{TM}. CD5 is a pan-T cell marker that also regulates an immunosuppressive signaling pathway, however, conventional CAR-T cell therapies targeting CD5 for T cell malignancies can elicit fratricidal T-cell responses, diminishing treatment efficacy. VIPER-101 is uniquely engineered to both avoid fratricide and unlock the benefit of circumventing the inhibitory CD5 signaling pathway. Engineered using a proprietary five-day process to preserve cell stemness, the features of VIPER-101 synergize to maximize potency, safety, and manufacturing efficiency.

At the upcoming 2023 American Society of Hematology (ASH) Annual Meeting, multiple abstracts will be presented that highlight the compelling preclinical data generated with the VIPER-101 cell therapy candidate, and that showcase the broad utility and enhanced anti-tumor efficacy of the Senza5 platform across distinct tumor models.

Dr. Siciliano added: “We will continue to draw upon the same vigorous dedication of our team that enabled our rapid and cost-efficient evolution from a preclinical to clinical stage Company, as we advance VIPER-101 through clinical trials with phase 1 initiation expected in early 2024.”

The Company anticipates announcing data from its Phase 1 trial in early 2025.

About Senza5

Senza5 is a proprietary cell therapy engineering and manufacturing platform that combines the power of genetic engineering and a proprietary five-day manufacturing process to maximize stemness, durability, and efficacy of its produced cell therapies by disabling the CD5 signaling pathway on engineered CAR-T cells, and bypassing CD5's immunosuppressive effects to amplify the therapy’s antitumor activity. Stemness is further enhanced by the expedited five-day manufacturing process which promotes greater *in vivo* expansion and durability, and the potential for longer-lasting responses. By acting on the fundamental biology of T cells, Senza5 can be widely utilized to improve the efficacy of engineered T-cell therapies.

About Vittoria Biotherapeutics

Vittoria Biotherapeutics, Inc., is developing novel CAR-T cell therapies that transcend the limitations of current cell therapies. Based on technology exclusively licensed from the University of Pennsylvania, the Company’s proprietary Senza5 platform unlocks the antitumor potential of engineered T cells and utilizes a five-day manufacturing process to maximize stemness, durability, and target cell cytotoxicity. By acting on the fundamental biology of T cells, Senza5 can be used to improve the efficacy of engineered T cell therapies with pipeline applications in oncology and autoimmune diseases. To learn more, visit vittoriabio.com and follow us on LinkedIn.

Editor’s Note

Dr. Ruella is the scientific founder of, and an equity holder in, Vittoria Biotherapeutics. The University of Pennsylvania holds equity in Vittoria Biotherapeutics, has received sponsored research funding from Vittoria, has licensed certain intellectual property to Vittoria and may receive future funding and financial consideration based on development and commercialization of certain products by Vittoria. Dr. Ruella is also a paid consultant for Vittoria Biotherapeutics.

Investor Contact

Vittoria Biotherapeutics
Nicholas A. Siciliano, Ph.D.
Chief Executive Officer
+1 215-600-1380

Media Contact

LifeSci Communications
Jason Braco, Ph.D.
jbraco@lifescicomms.com
+1 646-876-4932