Solu Therapeutics Closes $41M Series A Financing and Announces First Patient Dosed in Phase 1 Clinical Trial of STX-0712 in Patients with CMML and Other Advanced Hematologic Malignancies

Funding to support clinical evaluation of STX-0712, drive additional pipeline programs, and target new applications of company's proprietary CyTAC™ and TicTAC™ platforms.

Phase 1 trial of STX-0712 to assess safety and preliminary antitumor activity of novel CCR2-CyTAC therapy in patients with CMML.

BOSTON, Mass – April 9, 2024 – Solu Therapeutics, a biotechnology company pioneering therapies to eliminate disease-driving cells in cancer, immunology, and other therapeutic areas, today announced the successful completion of a $41 million Series A financing that included participation from five new investors – Eli Lilly and Company, Biovision Ventures, Pappas Capital, Hengdian Group Capital (HgC) and The Leukemia & Lymphoma Society Therapy Acceleration Program® – as well as continued support from existing Solu investors Longwood Fund, DCVC Bio, Santé Ventures, Astellas Venture Management, and Alexandria Venture Investments. The company also announced initiation of treatment of the first patient in its first-in-human Phase 1 clinical trial evaluating STX-0712 in patients with resistant/refractory chronic myelomonocytic leukemia (CMML) and other hematologic malignancies.

"In the short period since our initial seed funding, Solu Therapeutics has rapidly advanced to a clinical-stage company targeting areas of high unmet medical need for patients," said Philip J. Vickers, President and CEO at Solu Therapeutics. "With this Series A round we are grateful for the continued support from our existing investors and are excited to welcome several new investors who recognize the potential of our novel CyTAC (Cytotoxicity Targeting Chimera) and TicTAC (Therapeutic Index Control Targeting Chimera) platforms. These technologies have demonstrated an unprecedented ability to unlock high-value cell surface targets that are beyond the reach of traditional antibodies, making it possible to eliminate disease-driving cells with greater precision and efficacy."

Proceeds from the Series A financing will be used to complete dose escalation and expansion of the company's lead CCR2-CyTAC program, STX-0712, for the treatment of CMML. Additionally, the funding will support the generation of new development candidates, including a novel, first-in-class mast cell depletor for immunological diseases, initiation of new discovery programs targeting pathogenic cells, further pipeline expansion, and exploration of new applications for the CyTAC and TicTAC platforms.

STX-0712 is designed to selectively eliminate CCR2-positive malignant monocytes in patients with advanced hematologic malignancies, with an initial focus on CMML. The Phase 1 trial of STX-0712 is an open-label, multicenter study designed in two parts. Part A will focus on dose escalation to determine the maximum tolerated dose and/or minimum effective dose, enrolling participants with resistant/refractory CMML. Part B will further evaluate safety, tolerability, recommended Phase 2 dose and preliminary antitumor activity of STX-0712.

“Our team is thrilled to initiate this first-in-human clinical trial of STX-0712, marking a significant step forward in our mission to develop innovative therapies for patients with high unmet medical needs,” said Sergio Santillana MD, Chief Medical Officer. “By directly depleting the CCR2-positive malignant monocytes driving CMML, STX-0712 has the potential to offer a highly specific and targeted therapy for patients who currently have limited treatment options available. This trial represents an important milestone for Solu Therapeutics as we work to bring novel and potentially more effective targeted therapies to patients with CMML and other hematologic malignancies.”

In December 2024, Solu Therapeutics presented preclinical data at the 2024 American Society of Hematology (ASH) Annual Meeting showing robust ex-vivo activity of STX-0712 against CCR2-positive monocytes in CMML patient samples. CMML is characterized by elevated monocyte counts and dysplastic bone marrow features with limited treatment options.

About STX-0712

STX-0712 is a CyTAC designed to target the G-Protein Coupled Receptor CCR2, a selective marker expressed at high levels on malignant monocytes that are key drivers of disease in CMML and other hematologic malignancies. By eliminating CCR2-positive cells, STX-0712 has the potential to offer a more targeted and effective treatment option with minimal effects on non-malignant cells.

About Solu Therapeutics

Solu Therapeutics is a biotechnology company cofounded by Longwood Fund and committed to developing an innovative class of therapeutic agents that uniquely pair small molecules with monoclonal antibodies to eliminate disease-driving cells in cancer, immunology, and other therapeutic areas. By leveraging its proprietary CyTAC (Cytotoxicity Targeting Chimera) and TicTAC (Therapeutic Index Control Targeting Chimera) platforms, Solu is advancing therapies that combine the target-binding capability of small molecules with the therapeutic power of biologics. Our lead product candidate, STX-0712, is currently in Phase 1 clinical development for the treatment of advanced hematologic malignancies including CMML. For more information, visit www.solutherapeutics.com.

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