**Solu Therapeutics Granted FDA Fast Track Designation for STX-0712 for Treatment of Chronic Myelomonocytic Leukemia**

BOSTON, MA, May 27, 2026 – Solu Therapeutics, a biotechnology company pioneering novel therapies to eliminate disease-driving cells in cancer, immunology, and other therapeutic areas, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to STX-0712, the company's investigational therapy in development for the treatment of relapsed or refractory chronic myelomonocytic leukemia (CMML). CMML is an aggressive blood cancer with limited treatment options, particularly for patients whose disease has relapsed or become resistant to available therapies.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The designation also enables more frequent interactions with the FDA throughout the development and review process.

"Fast Track designation for STX-0712 reinforces the significant need for new treatment options for people living with CMML," said Philip Vickers, President and CEO of Solu Therapeutics. "By directly depleting CCR2-positive malignant monocytes and bone marrow blasts that drive disease in CMML, STX-0712 has the potential to offer a highly specific and targeted approach. We look forward to continuing to work closely with the FDA as we advance through clinical development and work to bring this potential therapy to patients as quickly as possible."

In addition to CMML, Solu is also exploring the potential of STX-0712 in other hematologic malignancies, including acute myeloid leukemia (AML). STX-0712 is a CyTAC™ (Cytotoxicity Targeting Chimera) targeting the G-Protein Coupled Receptor CCR2, a selective marker expressed at high levels on malignant monocytes and bone marrow blasts, which are key drivers of disease in CMML, AML, and other hematologic cancers. 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.

The Phase 1, open-label, multicenter study evaluating STX-0712 as monotherapy in patients with relapsed or refractory CMML and AML is ongoing. It is planned that initial clinical data from this study will be submitted to a hematology conference later this year.

**About Solu Therapeutics**

Solu Therapeutics is a biotechnology company dedicated to developing next-generation therapeutics to eliminate disease-driving cells in cancer, immunology, and other therapeutic areas. The company's proprietary CyTAC™ (Cytotoxicity Targeting Chimera) platform, exclusively licensed from GSK, enables the development of innovative medicines that combine the target-binding capability of small molecules with

the therapeutic power of biologics. Solu Therapeutics is committed to advancing the field of oncology, immunology, and other therapeutic areas by bringing transformative therapies to patients in need. For more information, visit www.solutherapeutics.com.

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