Sana Biotechnology Announces Fast Track Designation for SC291 in Relapsed/Refractory Systemic Lupus Erythematosus

December 2, 2024

Fast Track designation is designed to expedite clinical development and regulatory review timelines

Enrolling patients in the GLEAM trial for SC291 in B-cell mediated autoimmune diseases, including systemic lupus erythematosus; expect to report initial clinical data in 2025

SEATTLE, Dec. 02, 2024 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for SC291 in relapsed/refractory systemic lupus erythematosus (SLE), which includes extrarenal lupus and lupus nephritis. 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.

SC291, a hypoimmune (HIP)-modified CD19-directed allogeneic CAR T therapy, is being evaluated in Sana's GLEAM trial in patients with B-cell mediated autoimmune diseases including lupus nephritis, extrarenal lupus, and antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis. Sana is enrolling patients in this study and expects to share initial data in 2025.

"We are pleased to receive Fast Track designation from the FDA for SC291, which highlights the need for new treatment options for patients with relapsed/refractory SLE," said Dhaval Patel, M.D., Ph.D., Chief Scientific Officer of Sana. "As a HIP-modified allogeneic CAR T therapy with a scaled manufacturing process that produces hundreds of patient doses per manufacturing run, SC291 has the potential to serve as a universal off-the-shelf therapy that can address this large unmet need. We look forward to sharing initial data from the ongoing GLEAM trial."

About SC291 in B-cell mediated Autoimmune Diseases
SC291 is a CD19-directed allogeneic CAR T cell therapy developed using Sana's hypoimmune platform. Our allogeneic T cell programs use T cells from healthy donors to generate CAR T therapies that, in this case, target CD19, a protein expressed on the cell surface of B cells. B cells drive disease pathology in many autoimmune diseases, and therapies that target B cells have been efficacious across multiple autoimmune diseases. Emerging data in the field support the concept that deeper tissue B cell depletion can be associated with greater efficacy and a reasonable safety profile. CD19-directed CAR T therapy introduces a new option, in which the CAR T is the effector cell that depletes B cells throughout the body. Our goal is to develop SC291 in various settings, using our existing hypoimmune allogeneic CAR T manufacturing platform, to deliver with scale for these large unmet needs.

About Sana Biotechnology
Sana Biotechnology, Inc. is focused on creating and delivering engineered cells as medicines for patients. We share a vision of repairing and controlling genes, replacing missing or damaged cells, and making our therapies broadly available to patients. We are a passionate group of people working together to create an enduring company that changes how the world treats disease. Sana has operations in Seattle, WA, Cambridge, MA, South San Francisco, CA, Bothell, WA and Rochester, NY. For more information about Sana Biotechnology, please visit https://sana.com/.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements about Sana Biotechnology, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws, including those related to the Company's vision, progress, and business plans; expectations for its development programs, product candidates and technology platforms, including its preclinical, clinical and regulatory development plans and timing expectations; the potential of SC291 to serve as a universal off-the-shelf therapy for patients with relapsed/refractory SLE; expectations regarding the timing of initial data from the GLEAM trial; the association between deeper tissue B cell depletion and greater efficacy and a reasonable safety profile; and the ability to develop SC291 in various settings, using the Company's existing hypoimmune allogeneic CAR T manufacturing platform, to deliver with scale for B-cell mediated autoimmune diseases. All statements other than statements of historical facts contained in this press release, including, among others, statements regarding the Company's strategy, expectations, cash runway and future financial condition, future operations, and prospects, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results to vary materially, including, among others, the risks inherent in drug development such as those associated with the initiation, cost, timing, progress and results of the Company's current and future research and development programs, preclinical and clinical trials, as well as economic, market and social disruptions. For a detailed discussion of the risk factors that could affect the Company's actual results, please refer to the risk factors identified in the Company's SEC reports, including but not limited to its Annual Report on Form 10-Q dated November 8, 2024. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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