Sana Biotechnology Announces FDA Clearance of Investigational New Drug Application for SC291, a Hypoimmune-modified, CD19-directed Allogeneic CAR T Therapy, for Patients with Lupus Nephritis, Extrarenal Lupus, and ANCA-associated Vasculitis

November 9, 2023

Phase 1 trial to investigate multiple B-cell mediated autoimmune diseases

First healthy donor-derived allogeneic CAR T cell therapy to announce IND clearance

Expect to disclose initial clinical data next year

SEATTLE, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to initiate a study of SC291 in patients with multiple B-cell mediated autoimmune diseases, including lupus nephritis, extrarenal lupus, and antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis.

"Our goal is to develop SC291 for patients with multiple B-cell mediated autoimmune diseases, and the clearance of this IND is an important milestone," said Doug Williams, PhD, Sana's President of Research and Development. "SC291 is an allogeneic CAR T cell therapy with a scaled manufacturing process that produces hundreds of patient doses per manufacturing run, which we believe will be critical to addressing these large unmet needs. The use of allogeneic cells further simplifies the treatment paradigm for doctors and patients alike by eliminating apheresis and individualized patient-by-patient manufacturing of the drug product. We intend to begin treating patients in the near-term and expect to disclose initial safety and efficacy data across multiple diseases in 2024."

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 utilize 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. It has been shown that B cells drive disease pathology in many autoimmune diseases, and B-cell targeting therapies from several different modalities 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, where the CAR T is the effector cell that depletes B cells *in situ*. 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 Hypoimmune Platform
Sana's hypoimmune platform is designed to create cells *ex vivo* that can "hide" from the patient's immune system to enable the transplant of allogeneic cells without the need for immunosuppression. We are applying the hypoimmune technology to both donor-derived allogeneic T cells, with the goal of making potent and persistent CAR T cells at scale, and pluripotent stem cells, which can then be differentiated into multiple cell types at scale. Preclinical data published in peer-reviewed journals demonstrate across a variety of cell types that these transplanted allogeneic cells are able to evade both the innate and adaptive arms of the immune system while retaining their activity. Our most advanced programs utilizing this platform include an allogeneic CAR T program targeting CD19+ cancers, an allogeneic CAR T program for B-cell mediated autoimmune diseases, an allogeneic CAR T program targeting CD22+ cancers, and stem-cell derived pancreatic islet cells for patients with type 1 diabetes.

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, Cambridge, South San Francisco, and Rochester. 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 pre-clinical, clinical and regulatory development plans and timing expectations; the Company's expectations regarding the timing and significance of data from its clinical trials; the potential significance of the clearance of the SC291 IND in B-cell mediated autoimmune disease; the potential significance of the manufacturing scale for SC291; the potential benefits of using allogeneic cells with respect to the treatment paradigm; expectations regarding the timing and scope of the presentation of initial clinical data from the SC291 trial in B-cell mediated autoimmune disease; the goals for and potential benefits of the SC291 program; and the ability to use the Company's hypoimmune platform to evade immune recognition and overcome the immunologic rejection of allogeneic cells and the potential benefits associated therewith. 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. 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 Quarterly Report on Form 10-Q dated November 8, 2023. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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