Sana Biotechnology Announces FDA Clearance of Investigational New Drug Application for SC262, a Hypoimmune-modified, CD22-directed Allogeneic CAR T Therapy, for Patients with Relapsed or Refractory B-cell Malignancies

January 5, 2024

Expect to disclose initial SC262 clinical data in 2024

SEATTLE, Jan. 05, 2024 (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 SC262 in patients with relapsed or refractory B-cell malignancies, initially in patients who have received prior CD19-directed CAR T therapy.

Engineered CAR T cell therapies for B-cell malignancies use binders to target proteins expressed on the surface of B cells. One such protein, CD19, has been the target of all approved autologous CAR T therapies for B-cell lymphoma and B-cell acute lymphoblastic leukemia to date. Unfortunately, incomplete responses or relapses occur in approximately 60% of CD19 CAR T-treated patients. CD22, which is also a B-cell surface protein, has emerged as an alternative to address failure to achieve durable complete responses with CD19-directed CAR T therapy. SC262 expresses the same CAR, including the same CD22 binder, used in CD22-directed CAR T therapies tested in multiple academic clinical trials. To date, these trials have shown durable complete responses in a substantial number of patients in the relapse setting following treatment with a CD19-directed CAR T therapy.

"Patients who have failed a CD19-directed CAR T therapy represent a significant unmet need, and this population is growing as more patients receive these therapies," said Doug Williams, PhD, Sana's President of Research and Development. "SC262 represents an important potential option for these patients and is the next step in building Sana's hypoimmune CAR T therapy platform. Over the past twelve months, Sana has received three IND regulatory clearances, as well as supported the authorization of an investigator-sponsored CTA, to begin new studies utilizing our hypoimmune platform in seven different indications in oncology, B-cell mediated autoimmune diseases, and type 1 diabetes. We look forward to presenting data from all of these studies this year, including initial proof of concept data for SC262 later this year."

About SC262 in B-cell Malignancies
SC262 is a hypoimmune, CD22-directed allogeneic CAR T cell therapy derived from healthy donor CD4+ and CD8+ T cells. SC262 is developed with Sana's hypoimmune platform, which is designed to overcome the immunologic rejection of allogeneic cells and may result in longer CAR T cell persistence and a higher rate of durable complete responses for patients with B-cell malignancies. CD22 is expressed on lymphoma and leukemia cells in most patients with these diseases, including those that have failed CD19- and/or a CD20-directed therapies. SC262 is initially being explored in patients that have failed a previous CD19-directed therapy. The hypoimmune technology includes disruption of major histocompatibility (MHC) class I and MHC class II expression to allow cells to evade the adaptive immune system, which includes antibody and T cell responses, as well as overexpression of CD47 to evade the innate immune cell system, in particular macrophages and natural killer (NK) cells. The company has presented data across multiple preclinical models highlighting the potential of this platform to cloak cells from immune recognition and the potential of SC262 as a therapeutic for patients with B-cell malignancies.

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 of CD22-directed CAR T therapies to address failure to achieve durable complete responses; expectations regarding the growth of the potential patient population for SC262; the potential significance of the IND clearance for SC262; the ability to use the Company's hypoimmune platform to evade immune recognition and overcome the immunologic rejection of allogeneic cells without immunosuppression and the potential benefits associated therewith; the potential of SC262 as a therapeutic for patients with B-cell malignancies; and the ability to apply the HIP technology to donor-derived allogeneic T cells to make potent and persistent CAR T cells at scale and pluripotent stem cells, which can then be differentiated into multiple cell types at scale. 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.

Investor Relations & Media:
Nicole Keith
investor.relations@sana.com
media@sana.com