Sana Biotechnology Publishes Early Clinical Data Showing that SC291, a CD19-directed Allogeneic CAR T Therapy, Evades Immune Detection in Presence of Intact Immune System

December 1, 2023

SEATTLE, Dec. 01, 2023 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced the publication in *Blood* of an abstract providing initial clinical data from the first patient treated at the lowest dose in the ongoing ARDENT Phase 1 clinical trial with SC291, a hypoimmune (HIP)-modified allogeneic CD19-directed CAR T cell therapy. SC291 appeared safe and well tolerated, evaded immune detection, and induced a partial response in a patient with chronic lymphocytic leukemia (CLL). ARDENT is a Phase 1 study evaluating safety and tolerability of SC291 in patients with CLL and non-Hodgkin lymphoma. Treatment in this dose escalation study is ongoing, and the company expects to present more data from this study at a later date in an appropriate venue.

“These are the first clinical data demonstrating that our HIP technology can engineer allogeneic cells to evade adaptive and innate immune detection and rejection in the context of an intact immune system, overcoming the key challenge in unlocking the potential of allogeneic cells,” said Gary Meininger, MD, Sana’s Chief Medical Officer. “These data suggest the potential of SC291 to persist and attack cancer cells in a manner consistent with autologous cells, which combined with scaled manufacturing, encourage us about both the opportunity for SC291 and our other HIP-modified cells to provide clinical benefit for patients. The data were published as part of an abstract submitted over the summer, and we look forward to sharing more data from this ongoing clinical trial that we expect will more clearly outline SC291’s profile.”

The full abstract is available for online viewing at https://doi.org/10.1182/blood-2023-179441.

About SC291 in B-cell Lymphomas or Leukemias
SC291 is a hypoimmune, CD19-directed allogeneic CAR T cell therapy derived from healthy donor CD4+ and CD8+ T cells that are genetically engineered. SC291 is developed with Sana’s hypoimmune platform, which is designed to overcome the immunologic rejection of allogeneic cells, which if true for SC291 may result in longer CAR T cell persistence and a higher rate of durable complete responses for patients with B-cell lymphomas or leukemias. 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 SC291 as a therapeutic for patients with B-cell malignancies. SC291 is being evaluated in a Phase 1 study called ARDENT for patients with chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL).

About Hypoimmune Platform
Sana’s hypoimmune platform is designed to create cells *ex vivo* that can evade 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 significance of initial data from the first patient treated in the ARDENT Phase 1 clinical trial; the Company’s expectations regarding the timing and substance of future data from the ARDENT trial; the ability to use the HIP platform to create cells *ex vivo* that can evade a patient’s immune system and enable the transplant of allogeneic cells without the need for immunosuppression and the potential benefits associated therewith; and the ability to apply the HIP technology to allogeneic T cells to make potent and persistent CAR T cells at scale and to 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