Sana Biotechnology Announces Increased Focus on Type 1 Diabetes and B-cell Mediated Autoimmune Diseases with the Potential to Deliver Clinical Proof of Concept Data Across Multiple Studies in 2024 and 2025

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Prioritize clinical and preclinical development on type 1 diabetes (UP421 and SC451), B-cell mediated autoimmune diseases (SC291), refractory B-cell malignancies (SC262), and the fusogen platform for generating in vivo CAR T cells

Modified strategy extends expected cash runway into 2026 with potential for multiple data readouts in 2024 and 2025

SEATTLE, Nov. 04, 2024 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced it will prioritize future development activity for SC291, the company's CD19-directed allogeneic CAR T cell therapy, in B-cell mediated autoimmune diseases (AID). The company will suspend development of both SC291 in oncology and of SC379, its glial progenitor cell program, as it seeks partnerships for these programs. Sana will increase its investment in its type 1 diabetes program with the cash savings from these changes.

"Early clinical data with our hypoimmune platform (HIP) suggest HIP-modified cells evade immune detection, giving us confidence in the potential of the platform across multiple therapeutic areas. At the same time, we need to ensure that we are directing our investments into the areas where we believe we can have the greatest impact for patients," said Steve Harr, Sana's President and Chief Executive Officer. "Greater focus on type 1 diabetes, SC291 in AID, and SC262 in refractory blood cancers will enhance our ability to present robust clinical data over the next twelve to eighteen months. This modified strategy will also help us reduce our cash burn but comes with the necessity of parting with some talented and valued colleagues. We thank them for their contributions toward building Sana and thank the patients who have been treated in the SC291 oncology study."

With these changes, Sana extends its expected cash runway into 2026. Payments related to ongoing activities combined with the reduction in force may increase the 2024 operating cash burn above prior guidance of less than $200 million.

"Since joining Sana, I have actively engaged with the team to understand both Sana and competitor data and believe it is the right time to prioritize where we believe we have the most differentiated therapeutic candidates and the highest probability of success for patients," said Dhaval Patel, M.D., Ph.D., Chief Scientific Officer of Sana. "Type 1 diabetes is a significant unmet need, and we are optimistic that our program is novel and has the potential to offer patients meaningful benefit. The decision to prioritize SC291 in B-cell mediated autoimmune diseases is based on early clinical data with this drug in both oncology and autoimmune diseases, which show that therapy with SC291 can predictably lead to the deep B cell depletion that appears to drive an immune "reset" and significant clinical benefit in patients with B-cell mediated autoimmune diseases such as lupus. We look forward to generating and sharing more data from across our portfolio."

Select Program Review

UP421 (HIP-modified primary pancreatic islet cells) in type 1 diabetes: The investigator-sponsored trial exploring the potential of HIP modifications to allogeneic primary islet cells to enable immune evasion and overcome transplant rejection in type 1 diabetes is active; Sana expects to share proof of concept data in 2024 and/or 2025.

SC291 (HIP-modified CD19-directed allogeneic CAR T) in autoimmune diseases: Sana continues enrollment in the Phase 1 GLEAM trial for SC291 for the treatment of B-cell mediated autoimmune diseases and expects to share clinical data in 2024 and/or 2025.

SC262 (HIP-modified CD22-directed allogeneic CAR T) in oncology: Sana continues enrollment in the Phase 1 VIVID study for patients with refractory B-cell malignancies who have failed a previous CD19-directed CAR T therapy and expects to share data in 2025.

SC451 (HIP-modified stem cell-derived pancreatic islet cells) in type 1 diabetes: Sana continues preclinical development of this HIP-modified, stem-cell derived therapy for patients with type 1 diabetes.

SG299 (*in vivo* CAR T with CD8-targeted fusogen delivery of a CD19-directed CAR): Sana is continuing its preclinical development of this program, with potential in both B-cell mediated autoimmune diseases and oncology.

SC291 (HIP-modified CD19-directed allogeneic CAR T) in oncology: Given alternative opportunities within its pipeline as well as increased competition within blood cancers and uncertainty about the best path to regulatory and commercial success, Sana is halting enrollment and further internal investment in the Phase 1 ARDENT trial. It is actively seeking a licensing partner to support advancement.

SC379 (stem-cell derived glial progenitor cells) in various CNS diseases: Sana will actively seek a partner or opportunity to spin out this program into a new company.

About Sana Biotechnology
Sana Biotechnology, Inc. is focused on creating and delivering engineered cells as medicines for patients. We share a vision of 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, Bothell, 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; expectations regarding the impact of the Company's modified strategy on its cash burn and cash runway and its potential ability to present clinical data for the type 1 diabetes program, SC291 program in AID and SC262 program over the next twelve to eighteen months; expectations regarding how the Company will use the cash savings from the changes to its business; the potential ability of HIP-modified cells to evade immune detection; the potential of the HIP platform across a number of therapeutic areas; expectations regarding the Company's cash runway; expectations regarding the Company's 2024 operating cash burn; expectations regarding where the Company has the most differentiated therapeutic candidates and the highest probability of success; expectations regarding the type 1 diabetes program and its ability to offer patients meaningful benefits; the ability of deep B cell depletion to drive an immune "reset" and clinically benefit patients with B-cell mediated autoimmune diseases such as lupus; the Company's expectations regarding the timing, substance, and impact of the data from its clinical trials as well as the investigator sponsored trial exploring HIP-modified primarily islet cells in patients with type 1 diabetes; and the Company's future plans for the SC291 oncology and SC379 programs, including its ability to partner the SC291 oncology program or partner or spin out the SC379 program into a new company. 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 August 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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