Sana Biotechnology Announces Continued Positive Clinical Results Through 14 Months from Type 1 Diabetes Study of Islet Cell Transplantation Without Immunosuppression

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Groundbreaking First-in-Human Study Demonstrates Potential to Treat Type 1 Diabetes by Transplanting Insulin-Secreting Cells Without Immunosuppression

14-Month Follow-up Data Show Hypoimmune (HIP)-Modified Islets are Safe, Evade Detection by the Immune System, Survive Long-Term, and Continue to Produce Insulin

C-Peptide Levels at Month 14 Comparable to Initial Six Months of Study; Results Highlight the Importance of Improved Glycemic Control on Islet Function

Full 14-Month Data to Be Presented Today at the Advanced Technologies & Treatments for Diabetes (ATTD) Conference

Sana is Leveraging Validated HIP Technology to Develop SC451, a HIP-Modified, Stem Cell-Derived Therapy, Designed as a One-Time Treatment for Patients with Type 1 Diabetes, with a Goal of Normal Blood Glucose without Insulin or Immunosuppression

Sana Expects to File Investigational New Drug (IND) Application for SC451 in Type 1 Diabetes and Initiate Phase 1 Trial as Early as This Year

SEATTLE, March 13, 2026 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced 14-month follow-up results from an investigator-sponsored, first-in-human study transplanting UP421, an allogeneic primary islet cell therapy engineered with Sana's hypoimmune platform (HIP) technology, into a patient with type 1 diabetes without any immunosuppression. The study is being conducted in partnership with Uppsala University Hospital.

Results from more than 1 year after cell transplantation demonstrate sustained survival and function of pancreatic beta cells, as measured by the presence of circulating C-peptide, a biomarker of endogenous insulin production by the transplanted beta cells. C-peptide levels also increase in response to a mixed meal tolerance test (MMTT), consistent with insulin secretion in response to a meal. Fasting and MMTT-stimulated C-peptide levels at month 14 are comparable to those observed in the first six months of the study and exceed levels measured at months 9 and 12. Between months 12 and 14, the patient achieved tighter glycemic control, and the improved insulin secretion at month 14 underscores the importance of glucose control in optimizing pancreatic beta cell function. No safety issues were identified in the study.

"We are pleased to share the results through 14 months from this first-in-human study transplanting hypoimmune-modified primary islet cells into a patient with type 1 diabetes," said Per-Ola Carlsson, MD, Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital. "These findings build upon previously presented data and continue to show no safety issues, along with continued immune evasion, survival, and function of the transplanted cells. Importantly, the results demonstrate the positive impact of improved glucose control on beta cell function and the dynamic functional capacity of beta cells transplanted in a single low dose without immunosuppression. This work suggests that the hypoimmune technology has the potential to enable a functional cure for type 1 diabetes without immunosuppression, and we look forward to working with Sana as it brings forward SC451, a more scalable approach, at higher doses."

"These data continue to highlight the potential for HIP-modified cells to survive, function, and evade immune detection long-term in people post-transplant, a finding that we believe could have broad impact in type 1 diabetes and beyond," said Steve Harr, MD, Sana's President and CEO. "The data presented today also demonstrate how improvement in glycemic control – which is anticipated with higher doses of hypoimmune islets – can further enhance the function of these cells. We remain focused on advancing SC451, a HIP-modified stem cell-derived islet cell therapy, into the clinic and expect to file an investigational new drug application (IND) and initiate a Phase 1 trial as early as this year. Our goal is to offer patients a single treatment that delivers durable, normal blood glucose without the need for exogenous insulin or immunosuppression, and we look forward to continuing our collaboration with Dr. Carlsson and his colleagues at Uppsala University to advance this vision."

Primary islet cell transplantation with immunosuppression is an established procedure in type 1 diabetes in which allogeneic pancreatic islet cells are isolated from a deceased donor's pancreas and transplanted into a patient with a goal of normal blood glucose and insulin independence. As with whole-organ transplants, suppression of the patient's immune system has historically been required to prevent immune rejection of allogeneic transplanted cells and resurgence of the inciting autoimmune attack. Sana's HIP technology is designed to overcome immunologic rejection of allogeneic cells and, in type 1 diabetes, to also evade autoimmune rejection of pancreatic beta cells. UP421 was derived from the islet cells of a deceased donor and transplanted with no immunosuppression, and the survival of the UP421 cells provides evidence that they evade both allogeneic and autoimmune detection.

About the Uppsala University Hospital Investigator-Sponsored Study of UP421 in Type 1 Diabetes
The investigator-sponsored study of UP421 is supported by a grant from The Leona M. and Harry B. Helmsley Charitable Trust. The study evaluates whether HIP-modified insulin-producing pancreatic cells can be transplanted safely and help to regain insulin production in individuals with type 1 diabetes without need of simultaneous treatment with immunosuppressive medicines. To do this, UP421 is engineered using Sana's HIP platform at Oslo University Hospital. The study involves intramuscular surgical transplantation of HIP-modified primary islet cells into the forearm of patients with type 1 diabetes. The primary objective of the study is to investigate the safety of UP421 transplantation in patients with type 1 diabetes, with secondary endpoints including cell survival, immune evasion, and C-peptide production. Circulating C-peptide is a measure of endogenous insulin production. This first-in-human study examines a low dose of HIP-modified primary islets to initially establish the safety and function of HIP-modified islets without immunosuppression and, as a result, is not intended to show improvement in glycemia and/or reduction in exogenous insulin administration.

Results of the study at 14 months after islet cell transplantation demonstrate the survival and function of pancreatic beta cells as measured by the presence of circulating C-peptide, a biomarker indicating that transplanted beta cells are producing insulin. C-peptide levels also increase during an MMTT, consistent with insulin secretion in response to a meal. At baseline, the patient had undetectable C-peptide both fasting and during an MMTT. 52-week PET-MRI scanning also demonstrated islet cells at the transplant site, a forearm muscle. The HIP platform has not only achieved proof-of-concept in humans but has also shown continuation of effect with long-term evasion of immune recognition, supporting its potential broad application for allogeneic transplantation without immunosuppression.

About the Sana Biotechnology Hypoimmune (HIP) Platform
Sana's HIP platform is designed to generate cells *ex vivo* that can evade the patient's immune system to enable the transplantation of allogeneic cells without the need for immunosuppression. We are applying our HIP technology to develop therapeutic candidates at scale, including pluripotent stem cells, which can then be differentiated into multiple cell types, including pancreatic islet cells. We and our collaborators have generated significant foundational intellectual property in the area. Early clinical data from Phase 1 trials and preclinical data published in peer-reviewed journals demonstrate across a variety of cell types that these transplanted allogeneic cells can evade both the adaptive and innate arms of the immune system while retaining their activity. Sana's most advanced program using this platform is its stem cell-derived pancreatic islet cell program for 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, WA, Cambridge, MA, and South San Francisco, CA. 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, including the potential timing of INDs and clinical trials for its SC451 program and the dose levels to be evaluated; the potential ability of SC451 to be administered as a one-time treatment for patients with type 1 diabetes, to provide a more scalable approach, and to achieve durable, normal blood glucose without exogenous insulin or immunosuppression; the potential impact and significance of data from the UP421 study of islet cell transplantation without immunosuppression in a patient with type 1 diabetes ("Study"), including the potential to transplant insulin-secreting cells and develop a functional cure for the treatment of type 1 diabetes without immunosuppression; expectations regarding the presentation at the Advanced Technologies & Treatments for Diabetes conference; the ability of the HIP platform to generate cells *ex vivo* that can evade the patient's immune system to enable the transplantation of allogeneic cells without the need for immunosuppression and, in type 1 diabetes, enable pancreatic beta cells to overcome autoimmune rejection, to have broad application for allogeneic transplantation without immunosuppression, including in diabetes, and to be applied to develop therapeutic candidates at scale, including pluripotent stem cells that can be differentiated into multiple cell types; the potential safety and long-term survival, function, and evasion of immune detection of HIP-modified cells with no immunosuppression, including the potential impact of glycemic control on islet and beta cell function and the dynamic functional capacity of beta cells transplanted in a single low dose without immunosuppression; expectations with respect to the impact of the dose level of hypoimmune islets on glycemic control; the potential application of the learnings from the Study to the Company's SC451 program; and statements made by Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital, and by the Company's President and CEO. 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 Securities and Exchange Commission (SEC) reports, including but not limited to its Annual Report on Form 10-K dated March 3, 2026. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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