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

January 7, 2025

First-in-Human Study Provides Evidence that Sana's Hypoimmune (HIP) Technology Enables Transplanted Islet Cells to Avoid Immune Rejection and Produce Insulin Without Immunosuppression

Results Demonstrate HIP-Engineered Primary Pancreatic Islet Cells Avoid Immune Detection, Function, and Persist after Intramuscular Transplantation in First Treated Patient with Type 1 Diabetes

Function and Persistence of Pancreatic Islets Were Detectable by Production of Consistent Levels of Circulating C-Peptide, a Marker of Insulin Production, and Increased C-Peptide Levels with a Mixed Meal Tolerance Test (MMTT)

MRI Shows Signals Consistent with Graft Survival 28 Days after Transplantation

Study Continues to Evaluate Safety, Persistence, and Function of Transplanted Cells

Conference Call to be Webcast at 1:30pm PT

SEATTLE, Jan. 07, 2025 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced initial results from an investigator-sponsored, first-in-human study transplanting UP421, an allogeneic primary islet cell therapy engineered with Sana's hypoimmune (HIP) technology, into a patient with type 1 diabetes without the use of any immunosuppression. The study was conducted in partnership with Uppsala University Hospital. Results of the study at four weeks after 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 with a mixed meal tolerance test (MMTT), consistent with insulin secretion in response to a meal. MRI scanning also demonstrated a sustained signal at the site of transplanted cells over time, which is consistent with graft survival. The study identified no safety issues, and the HIP-modified islet cells evaded immune responses.

"These initial exciting results build upon the extensive preclinical and translational studies of Dr. Sonja Schrepfer and the team at Sana. The clinical data are highly promising for patients and provide the first evidence in humans for overcoming allogeneic and autoimmune rejection with pancreatic islet cell transplantation in type 1 diabetes with no immunosuppression," said Per-Ola Carlsson, MD, Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital. "In type 1 diabetes, a person's immune system attacks and destroys the beta cells. Today's data, when combined with progress elsewhere in the field, provide real hope that a scalable, curative treatment for patients with type 1 diabetes, meaning normal blood glucose with no insulin injections or immunosuppression, is possible. We look forward to longer follow-up and plan to submit study results for publication as well as for presentation at an upcoming scientific forum."

"We achieved our goals for the study, identifying no safety issues as well as demonstrating survival, function, and evasion of immune detection of HIP-modified primary pancreatic islet cells transplanted intramuscularly with no immunosuppression," said Steve Harr, Sana's President and Chief Executive Officer. "As far as we are aware, this is the first study showing survival of an allogeneic transplant with no immunosuppression or immune-protective device in a fully immune competent individual. Safe cell transplantation without immunosuppression has the potential to transform the treatment of type 1 diabetes and a number of other diseases. We view the insights from the current study as directly applicable to developing SC451, our HIP-modified, stem cell-derived pancreatic islet cell program for the treatment of type 1 diabetes. Thank you to everyone involved in this study."

"These initial clinical results show that cell therapies that replace insulin-producing cells without immunosuppression are approaching reality as a meaningful and potentially life-changing cure for type 1 diabetes," said Aaron J. Kowalski, Ph.D., CEO of Breakthrough T1D (previously known as JDRF). "We are proud to contribute to translational research endeavors such as those at Sana as a supporter and investor through the T1D Fund: A Breakthrough T1D Venture. We are extremely grateful for the collaborative efforts of the research teams at Sana, at Uppsala University Hospital, and all those involved, for their dedication to this work. We look forward to working with Sana and others to break down the remaining barriers to ensure all members of the T1D community can benefit from these life-changing breakthroughs."

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 control and insulin independence. As with whole-organ transplants, suppression of the recipient's immune system has historically been required to prevent immune rejection of the 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, also to evade the autoimmune rejection of pancreatic beta cells. UP421 cells were transplanted with no immunosuppression, and the survival of the islet cells provides evidence that these cells evade both allogeneic and autoimmune detection.

Webcast Conference Call Information
Sana will host a webcast conference call to discuss results today, January 7, 2025 at 1:30 p.m. PT. The live webcast and audio archive of the presentation will be accessible on the Investor Relations page of Sana's website at https://sana.com/. The call can be accessed by dialing (877)-346-6112 (domestic) or (848)-280-6350 (international) and referring to conference ID 9582416.

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 tests the hypothesis whether HIP-engineered 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 primary, or donor-derived, HIP-engineered islet cells into the forearm of patients with type 1 diabetes. The primary objective of the study is to investigate 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 over four weeks after islet cell transplantation demonstrate the survival and function of pancreatic beta cells at each weekly blood draw, 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. MRI scanning demonstrated a sustained signal at the site of the graft over time, consistent with graft survival. The HIP platform has achieved proof-of-concept in humans, showing evasion of immune recognition with the 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 the 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, and donor-derived allogeneic CAR T 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 are able to evade both the innate and adaptive arms of the immune system while retaining their activity. Sana's most advanced programs utilizing this platform include stem cell-derived pancreatic islet cells for patients with type 1 diabetes, an allogeneic CAR T program for B-cell mediated autoimmune diseases, and an allogeneic CAR T program targeting CD22+ cancers.

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, South San Francisco, CA, and Bothell, WA. 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; the ability of Sana's 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 transplanted islet cells to avoid immune rejection and produce insulin without immunosuppression; the potential implications of the data on the ability to find a scalable, curative treatment for patients with type 1 diabetes; expectations with respect to follow up and publication and presentation of the study results; the potential safety and survival, function, and evasion of immune detection of HIP-modified primary pancreatic islet cells transplanted intramuscularly with no immunosuppression; the potential of safe cell transplantation without immunosuppression to transform the treatment of type 1 diabetes and a number of other diseases; the potential application of the learnings from the study to the company's SC451 program; the potential significance of the survival of the islet cells in the study; and the ability to apply the HIP technology to develop therapeutic candidates at scale, including both pluripotent stem cells and donor-derived allogeneic CAR T cells. 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 Quarterly Report on Form 10-Q dated November 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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