Sana Biotechnology Announces Publication in New England Journal of Medicine of Groundbreaking Clinical Data from Transplantation Without Immunosuppression of Hypoimmune-Modified, Insulin-Producing Islet Cells in Patient with Type 1 Diabetes

August 4, 2025

Data Demonstrate that Sana's Hypoimmune (HIP)-Modified Pancreatic Islet Cells, Transplanted with No Immunosuppression, Persist and Function Over Time in Patient with Type 1 Diabetes

Study Establishes Ability to Genetically Modify and Transplant Pancreatic Islet Cells Without Immunosuppression and Overcome Both Allogeneic and Autoimmune Rejection

Six-Month Patient Follow-up Results Presented at the 85th Annual American Diabetes Association (ADA) Scientific Sessions Further Demonstrate that Sana's HIP-Modified Pancreatic Islet Cells are Safe and Well-tolerated, Survive, Evade Detection by the Immune System, and Continue to Produce Insulin in the Patient

Sana Is Incorporating its HIP Technology to Develop SC451, a HIP-Modified, Stem Cell-Derived Therapy as a One-Time Treatment for Patients with Type 1 Diabetes, with a Goal of Normal Blood Glucose with No Insulin and No Immunosuppression

Recent FDA INTERACT Meeting Increases Confidence in Moving Forward with GMP Master Cell Bank for SC451 and in Filing SC451 Investigational New Drug Application (IND) as Early as 2026

Sana Expects Study Data to Be Generalizable across Multiple Cell Types and Patient Populations

SEATTLE, Aug. 04, 2025 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced that the *New England Journal of Medicine* (NEJM) has published a journal article titled "Survival of Transplanted Allogeneic Beta Cells with No Immunosuppression" (DOI: 10.1056/NEJMoa2503822). The article discusses 12-week results from an investigator-sponsored trial, conducted at Uppsala University Hospital, evaluating the transplantation of UP421, a primary human pancreatic islet cell therapy engineered with Sana's hypoimmune (HIP) technology, without the use of immunosuppressive medications in a 42-year-old patient living with type 1 diabetes for over three decades. The intramuscular transplantation of HIP-modified pancreatic islet cells is safe and well-tolerated and demonstrates that these cells evade autoimmune and allogeneic immune recognition, persist, and secrete insulin in a glucose-dependent manner over the 12-week evaluation period reported in the article. 12-week PET-MRI scanning also confirmed islet cells at the transplant site. Six-month data, described below, were recently presented at the ADA meeting and presented today at the World Transplant Congress 2025 concurrently with the publication of the NEJM article.

"We are thrilled to have the results of this study, which we believe represent both a scientific and medical breakthrough, recognized in the *New England Journal of Medicine*," said Per-Ola Carlsson, MD, Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital. "Type 1 diabetes is a disease in which the immune system destroys the beta cells in pancreatic islets, requiring the patient to receive lifelong insulin therapy to control glucose levels. Although it is well established that pancreatic islet cell transplantation at a target therapeutic dose can predictably allow patients with type 1 diabetes to live without insulin therapy, until now these patients must take lifelong, significant immunosuppression, which is frequently toxic and difficult to tolerate. This study shows that Sana's novel HIP-modified pancreatic islets restore insulin production without the need for immunosuppression, a transformative outcome and significant step toward a broadly accessible, functional cure for patients with type 1 diabetes. The patient is making his own insulin for the first time in over 35 years."

"These peer-reviewed results, built upon the extensive preclinical and translational studies of Dr. Sonja Schrepfer and the team at Sana, reinforce our belief that Sana has the capability to develop a functional cure for the broad population of individuals living with type 1 diabetes," said Steve Harr, MD, Sana's President and Chief Executive Officer. "The data, together with recent FDA feedback regarding our HIP-edited master cell bank for GMP manufacturing and our non-clinical testing plan for SC451, increase our confidence in our goal for treating type 1 diabetes—a single treatment with no immunosuppression that leads to long-term normal blood glucose without exogeneous insulin. We expect to file an IND for SC451, a next generation HIP-modified, stem cell-derived pancreatic islet therapy, as early as 2026 and begin Phase 1 testing shortly thereafter. I want to thank the entire Sana team, the investigators at Uppsala, and the patient who volunteered for this transformative, first-in-human study."

James Shapiro, M.D., Professor of Surgery, Medicine, and Surgical Oncology at the University of Alberta and leader of the clinical team that developed the Edmonton Protocol for islet cell transplantation, added "Exogenous insulin therapy remains a lifesaving therapy in the short term, but it falls short of replicating the precise and dynamic glucose regulation of a healthy pancreas, leaving patients susceptible to both short- and long-term medical complications. This limitation motivated my team and me to pioneer a protocol for islet cell transplantation with immunosuppression and to continue innovating in this field. The data presented in the NEJM article—demonstrating that transplanted, engineered islet cells can both evade immune-mediated destruction and respond appropriately to insulin demands—represent a significant advancement in the ongoing pursuit of a definitive cure for type 1 diabetes and support my long-held belief that the future of type 1 diabetes treatment is in stem cell-based therapies."

Key Findings from Ongoing Study

1. No serious adverse events or adverse events possibly or probably related to UP421 were identified in the study.
2. HIP-modified pancreatic islet cells, transplanted with no immunosuppressive medicines, including no glucocorticoids, evade immune detection and rejection.

3. Pancreatic islet cells survive and function post-transplantation.
    a. The survival and function of the HIP-modified pancreatic beta cells was confirmed at each blood draw, as measured by the presence of circulating C-peptide, a biomarker indicating that transplanted beta cells are producing insulin.
    b. C-peptide levels increase during monthly mixed meal tolerance tests (MMTT), showing increased insulin secretion in response to a meal. Of note, prior to transplant, the patient had undetectable C-peptide both when fasting and during an MMTT.
    c. MRI scans at each month show a sustained and consistent signal at the site of cell transplantation, consistent with graft survival.
    d. A PET-MRI scan with a tracer targeting pancreatic beta cells confirms that the surviving cells are, in fact, pancreatic beta cells.

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-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 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.

The 12-week results have been published in the *New England Journal of Medicine*, and six-month results were presented at the 85th Annual American Diabetes Association (ADA) Scientific Sessions meeting on June 23, 2025, as well as at the World Transplant Congress 2025 on August 4, 2025.

Results of the study over six months after islet cell transplantation demonstrate the survival and function of pancreatic beta cells through the latest timepoint at month six, 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. 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 using this platform include a stem cell-derived pancreatic islet cell program for 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
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.

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 timing of filing investigational new drug applications and beginning Phase 1 testing, the impact of the FDA INTERACT meeting and feedback and the ability to move forward with the Company's HIP-edited master cell bank for GMP manufacturing and non-clinical testing plan for SC451, and the potential ability of SC451 to be a one-time treatment for patients with type 1 diabetes with no immunosuppression and to achieve normal blood glucose without exogenous insulin; the potential impact and significance of data from preclinical and clinical studies of the Company's product candidates and technologies, including the UP421 study of islet cell transplantation without immunosuppression in type 1 diabetes ("Study"), including the potential ability to develop a broadly accessible, functional cure for the broad population of individuals living with type 1 diabetes, the potential of the Study data to be generalizable across multiple cell types and patient populations, and the potential implications for the Company's SC451 program; expectations with respect to the role of stem cell-based therapies in the future of type 1 diabetes treatment; the potential ability of the HIP platform to have broad application and 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 to be applied to develop therapeutic candidates at scale, including pluripotent stem cells, which can be differentiated into multiple cell types, and donor-derived allogeneic CAR T cells; the potential safety and survival, function, and immune evasion of HIP-modified primary pancreatic islet cells transplanted intramuscularly with no immunosuppression; and statements made by Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital, statements made by the Company's President and CEO, and statements made by the Professor of Surgery, Medicine, and Surgical Oncology at the University of Alberta. All statements other than statements of historical facts contained in this press release, including, among others, statements regarding the Company's strategy, expectations, 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 May 8, 2025. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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