New CNTY-813 Preclinical Data Demonstrate Durable Glucose Control, Immune Evasion Under Alloimmune Pressure, and Scalable Manufacturing at ADA 2026

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- Advancing CNTY-813 as a potential functional cure in Type 1 Diabetes
- CNTY-813 iPSC-derived islet replacement therapy demonstrates durable in-vivo glucose control maintained for more than eight months in preclinical models
- Allo-Evasion™ 5.0 maintains insulin secretion and maintained normoglycemia under allogeneic immune pressure in humanized mouse model without immunosuppression
- Phase 1 clinical manufacturing process has been established demonstrating consistent endocrine purity and optimal islet cell content
- CNTY-813 IND submission on track for 4Q 2026; initial clinical data expected in 2H 2027

PHILADELPHIA, June 08, 2026 (GLOBE NEWSWIRE) -- Century Therapeutics, Inc. ('Century', NASDAQ: IPSC), a biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies for autoimmune diseases, including type 1 diabetes (T1D), and cancer, today announced the presentation of new preclinical data from CNTY-813, Century's iPSC-derived islet replacement therapy engineered with Allo-Evasion™ 5.0, in an oral presentation at the American Diabetes Association (ADA) 86th Scientific Sessions in New Orleans, Louisiana.

T1D affects approximately nine million people worldwide. While islet cell transplantation has demonstrated the potential to restore insulin independence, with insulin independence achieved in approximately 70% of patients receiving cadaveric islet transplantation at one year, the current approach requires chronic systemic immunosuppression. The need for chronic immunosuppression limits the utility of cell transplantation for the majority of T1D patients. CNTY-813 is designed to address this directly: a potential off-the-shelf, iPSC-derived islet replacement therapy engineered with Allo-Evasion™ 5.0 to eliminate the need for immunosuppression and exogenous insulin. Based on preclinical data to date, Century believes CNTY-813 has the potential to deliver what no prior therapy has achieved, a functional cure for T1D without the need for chronic immunosuppression.

The presentation, titled "CNTY-813: Scalable Production of Allo-Evasion™ 5.0-Engineered iPSC Beta Islets for Off-the-Shelf Cell Therapies" (Abstract 1318-OR), was delivered by Leonardo Velazco-Cruz, Ph.D., at 2:45 p.m. CT. The data highlight CNTY-813's demonstrated functional potency, scalable manufacturing, engraftment with no evidence of abnormal outgrowth or tumorigenesis, and ability to maintain glucose control under allogeneic immune pressure, a combination of properties that Century believes distinguishes CNTY-813 as a completely novel approach to islet cell replacement.

"These preclinical data advance our case for a potentially functional cure for type 1 diabetes. Across a range of preclinical studies, CNTY-813 has now demonstrated what we believe are critical prerequisites for a potentially curative islet replacement therapy: glucose-responsive function comparable to primary islets, graft stability with no evidence of tumorigenesis, and immune evasion engineered to eliminate the need for chronic immunosuppression," said Brent Pfeiffenberger, Pharm.D., Chief Executive Officer of Century Therapeutics. "Having established our Phase 1 manufacturing process and demonstrated consistent product quality across independent batches, we are confident in our readiness for clinical trials and the potential to scale for broad patient access. With our IND submission on track for the fourth quarter of 2026 and initial clinical data anticipated in the second half of 2027, we are executing with discipline toward what we believe is a highly competitive and differentiated program."

Preclinical data highlights

The oral presentation highlighted new preclinical data from CNTY-813 studies as outlined below. The full presentation is available on the Presentations tab of Century's investor relations website at investors.centurytx.com/events-and-presentations.

Durable glucose control in vivo

CNTY-813 iPSC-derived islet cells rapidly restored normoglycemia in streptozotocin-rendered diabetic mice and maintained glucose control for greater than eight months following transplantation. New data demonstrate that Allo-Evasion™ 5.0-edited cells showed comparable glucose control to non-edited cells, confirming the immune evasion engineering modifications do not affect the islets' ability to control glucose. Islet performance in a glucose tolerance test demonstrated glucose normalization within 60 minutes in both edited and unedited islets.

Cell composition and acceptable post-mitotic safety profile

New single-cell RNA sequencing analysis demonstrated that CNTY-813 contains a consistent and optimal ratio of differentiated cell types in islet clusters, with beta cells comprising greater than 50% of total cell composition. Greater than 98% of cells were identified in G1 phase, indicating cell cycle exit on par with primary islets. In vivo graft analysis at two, four, and eight weeks post-infusion confirmed endocrine graft morphology was maintained with no evidence of cyst formation or abnormal outgrowth, as assessed by Ki67 staining over time. No tumorigenesis was observed in more than 140 mice with more than three months of follow-up across one billion cells infused.

Immune evasion: in vitro protection

Additional data from multiple in vitro assays demonstrated that CNTY-813 cells containing Allo-Evasion™ 5.0 edits provided significant protection from natural killer (NK) cell clearance, induced rapid IgG cleavage of a surrogate anti-drug antibody, and demonstrated protection from antibody-mediated phagocytosis. These results confirm functional activity across all three engineered immune protection layers: T cells, NK cells, and humoral evasion.

Immune evasion: in vivo protection in humanized mouse model

New data from a humanized mouse allogeneic graft rejection model engrafted with healthy donor peripheral blood mononuclear cells (PBMCs) to support survival of functional human T cells without graft-versus-host disease and human NK cells, demonstrated that mice transplanted with CNTY-813 maintained normal C-peptide secretion function through 42 days post-transplant. In contrast, mice transplanted with unedited islet grafts showed rapid functional deterioration and allo-rejection with PBMC co-engraftment. Consistent with immune evasion, Allo-Evasion™ 5.0-engineered islets maintained glucose tolerance in a glucose tolerance test under allogeneic immune pressure while unedited islets showed reduced function.

Consistent product quality from Phase 1 clinical manufacturing process

Century has established its manufacturing processes for Phase 1 clinical trial supply. New data demonstrated consistent product quality across three separate at-scale experiments from Century's GMP Master Cell Bank, comprising 11 samples, with optimal endocrine purity, islet cell content, and minimal islet cell impurities across all samples. The 29-day, bioreactor-based suspension differentiation process met pre-defined purity specifications at each stage. The process supports cryopreservation with retained post-thaw potency.

Upcoming CNTY-813 milestones

- **IND submission (4Q 2026):** Century expects to submit an Investigational New Drug application for CNTY-813 in the fourth quarter of 2026, subject to completion of remaining IND-enabling studies.
- **Initial clinical data (2H 2027):** Initial safety and early efficacy data from the first-in-human CNTY-813 study are anticipated in the second half of 2027.

About CNTY-813

CNTY-813 is Century's potential iPSC-derived islet replacement therapy for T1D. CNTY-813 is engineered with Allo-Evasion™ 5.0, Century's proprietary immune evasion technology, which is designed to enable durable engraftment without chronic systemic immunosuppression, the central unresolved limitation of every currently approved or late-stage cell therapy approach to T1D. Preclinical data demonstrated robust glucose-responsive function, favorable pre-clinical safety profile, scalable and reproducible manufacturing, and immune protection under alloimmune pressure. Century is targeting an IND submission for CNTY-813 in the fourth quarter of 2026.

About Century Therapeutics

Century Therapeutics (NASDAQ: IPSC) is a biotechnology company advancing a pipeline of induced pluripotent stem cell (iPSC)-derived cell therapies with the potential to meaningfully address autoimmune diseases, including type 1 diabetes, and cancer. Century's therapies are derived from its iPSC cell foundry and leverage its novel immune evasion engineering technology, Allo-Evasion™. Century believes its approach to developing off-the-shelf cell therapies will expand patient access and provide advantages over existing cell therapies which will ultimately advance the course of care. For more information on Century Therapeutics, please visit www.centurytx.com and connect with us on LinkedIn.

Forward-looking statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements about our timing and expectations regarding our preclinical and clinical development programs, including planned development of CNTY-813, therapeutic potential and market opportunity, ongoing and planned regulatory submissions and interactions, the achievement of developmental milestones, corporate strategies, and anticipated data readouts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this press release are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among others: our ability to successfully advance our current and future product candidates through development activities, preclinical studies, and clinical trials; our ability to meet development milestones on anticipated timelines; uncertainties inherent in the results of preliminary data, and pre-clinical studies , which may not be predictive of final results or the results of clinical trials; our ability to obtain clearance of our future IND or CTA submissions and commence and complete clinical trials on expected timelines, or at all; our reliance on the maintenance of certain key collaborative relationships for the manufacturing and development of our product candidates; the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates; the impact of geopolitical issues, trade disputes and tariffs, banking instability and inflation on our business and operations, supply chain and labor force; the performance of third parties in connection with the development of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers; our ability to successfully commercialize our product candidates and develop sales and marketing capabilities, if our product candidates are approved; our ability to recruit and maintain key members of management and our ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of our most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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