



Century Therapeutics to Present Initial Clinical Data Supporting the Potential for a Multi-Dosing Strategy for CAR iNK Enabled by Allo-Evasion™ Edits at the 65th ASH Annual Meeting and Exposition

November 2, 2023

– CNTY-101 is the first cell therapy product candidate engineered with six precision gene edits including a CD19-CAR, Allo-Evasion™ technology, IL-15 cytokine support, and a safety switch –

– Preliminary clinical data from a case study featured in ASH abstract shows complete response maintained in Dose Cohort 1 patient following completion of four 28-day cycles of CNTY-101 in Phase 1 ELIPSE-1 trial, the two most recent of which did not include lymphodepletion –

– CNTY-101 well tolerated –

– Additional data from Dose Cohort 1 patients, as well as preliminary data from Dose Cohort 2, to be featured in ASH presentation –

PHILADELPHIA, Nov. 02, 2023 (GLOBE NEWSWIRE) -- [Century Therapeutics](#), Inc. (NASDAQ: IPSC), an innovative biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immune-oncology, today announced the upcoming presentation of initial data from its ongoing first-in-human Phase 1 ELIPSE-1 trial of CNTY-101 in relapsed/refractory CD19 positive B-cell lymphomas. The data, which support the potential for a multi-dosing strategy for CAR iNK enabled by Allo-Evasion™ edits, will be featured during a poster session at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition being held December 9-12, 2023 in San Diego.

CNTY-101 is the Company's first allogeneic cell therapy product candidate engineered with multiple complementary functionalities designed to enhance its product profile. These features include a CD19 CAR for tumor targeting, IL-15 support for enhanced persistence, Allo-Evasion™ technology to prevent host rejection and enhance persistence, and a safety switch to provide the option to eliminate the drug product if ever necessary.

A copy of the abstract, which highlights a case study of a patient with high risk relapsed/refractory follicular lymphoma who completed four 28-day cycles of CNTY-101 as of a July 10, 2023 data cutoff, is now available online via the ASH website at www.hematology.org. The patient, who received four prior lines of therapy, completed four 28-day cycles of CNTY-101 at the 100 million cell dose level (Dose Level 1), the first two of which were administered following lymphodepletion while the most recent two were administered without lymphodepletion. CNTY-101 was well tolerated, with no measurable functional pre-existing or induced anti-drug-antibodies observed. Pharmacokinetic measurements demonstrated that CNTY-101 cells were detected after each infusion with comparable kinetics, with a limited duration in circulation. The patient achieved a complete response that is ongoing as of five months following their first CNTY-101 infusion. The Company believes these preliminary data support the potential for a multi-dosing strategy for CAR iNK enabled by Allo-Evasion™ edits.

Updated data to be announced in December will include additional results from patients treated at Dose Level 1 as of a more recent cutoff date, as well as preliminary data from patients treated at the 300 million cell dose level (Dose Level 2).

"We are thrilled to share the first clinical evidence supporting the potential for our proprietary Allo-Evasion™ technology to engineer differentiated allogeneic cell therapies capable of delivering a multi-dosing regimen," said Adrienne Farid, Ph.D., Chief Operations Officer and Head of Early Development at Century Therapeutics. "While this is a significant achievement in and of itself, data also demonstrate that CNTY-101 is, to our knowledge, the first therapy of its kind to be re-dosed without lymphodepletion, a procedure commonly associated with high rates of toxicity. We look forward to sharing additional patient data next month which we believe will continue to support the potential for Century to deliver novel cell therapies with increased drug exposure via a multi-dosing approach to ultimately drive deeper and more durable responses. The potential of our platform to enable dosing without lymphodepletion is particularly exciting for both oncology and non-oncology indications, where the side effect profile of lymphodepletion may be prohibitive."

Details for the presentation are as follows:

- **Abstract:** 1654
- **Title:** Multiple Doses of CNTY-101, an iPSC-Derived Allogeneic CD19 Targeting CAR-NK Product, are Safe and Result in Tumor Microenvironment Changes Associated with Response: A Case Study
- **Session Name:** 622. Lymphomas: Translational – Non-Genetic: Poster I
- **Date:** Saturday, December 9, 2023
- **Session Time:** 5:30 PM - 7:30 PM PT

About ELIPSE-1 Trial

The Phase 1 ELIPSE-1 trial ([NCT05336409](#)) is intended to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of CNTY-101 in patients with relapsed or refractory CD19-positive B-cell lymphomas. All patients will receive an initial standard dose of conditioning chemotherapy consisting of cyclophosphamide (300 mg/m²) and fludarabine (30mg/m²) for 3 days. Schedule A of the trial includes a single-dose escalation of CNTY-101 and subcutaneous IL-2. Schedule B will evaluate a three-dose schedule per cycle of CNTY-101. Patients who demonstrate a clinical benefit are eligible for additional cycles of treatment with or without additional lymphodepletion.

About Allo-Evasion™

Century's proprietary Allo-Evasion™ technology is used to engineer cell therapy product candidates with the potential to evade identification by the host immune system so they can be dosed multiple times without rejection, enabling increased persistence of the cells during the treatment period and potentially leading to deeper and more durable responses. More specifically, Allo-Evasion™ 1.0 technology incorporates three gene edits designed to avoid recognition by patient/host CD8+ T cells, CD4+ T cells and NK cells. Knockout of beta-2-microglobulin or $\beta 2m$, designed to prevent CD8+ T cell recognition, knock-out of the Class II Major Histocompatibility Complex Transactivator, or CIITA, designed to prevent CD4+ T cell recognition, and knock-in of the HLA-E gene, designed to enable higher expression of the HLA-E protein to prevent killing of CNTY-101 cells by host NK cells. Allo-Evasion™ technology may allow the implementation of more flexible and effective repeat dosing protocols for off-the-shelf product candidates.

About CNTY-101

CNTY-101 is an investigational off-the-shelf cancer immunotherapy product candidate that utilizes iPSC-derived natural killer (NK) cells with a CD19-directed chimeric antigen receptor (CAR) and includes Century's core Allo-Evasion™ edits designed to overcome the three major pathways of host versus graft rejection - CD8+ T cells, CD4+ T cells and NK cells. In addition, the product candidate is engineered to express IL-15 to provide homeostatic cytokine support, which has been shown pre-clinically to improve functionality and persistence. Further, to potentially improve safety, the iNK cells were engineered with an EGFR safety switch, and proof-of-concept studies have demonstrated that the cells can be quickly eliminated by the administration of cetuximab, an antibody against EGFR approved by the U.S. Food and Drug Administration for certain cancers. Century is currently assessing CNTY-101 in patients with relapsed or refractory CD19-positive B-cell lymphomas in its Phase 1 ELiPSE-1 trial.

About Century Therapeutics

Century Therapeutics (NASDAQ: IPSC) is harnessing the power of adult stem cells to develop curative cell therapy products for cancer that we believe will allow us to overcome the limitations of first-generation cell therapies. Our genetically engineered, iPSC-derived iNK and iT cell product candidates are designed to specifically target hematologic and solid tumor cancers. We are leveraging our expertise in cellular reprogramming, genetic engineering, and manufacturing to develop therapies with the potential to overcome many of the challenges inherent to cell therapy and provide a significant advantage over existing cell therapy technologies. We believe our commitment to developing off-the-shelf cell therapies will expand patient access and provide an unparalleled opportunity to advance the course of cancer care. For more information on Century Therapeutics please visit www.centurytx.com.

Century Therapeutics Forward-Looking Statement

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 regarding our clinical development plans and timelines, 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 dependence on the success of our lead product candidate, CNTY-101; uncertainties inherent in the results of preliminary data, pre-clinical studies and earlier-stage clinical trials being predictive of the results of early or later-stage clinical trials; our ability to obtain FDA acceptance for our future IND submissions and commence 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 the COVID-19 pandemic, geopolitical issues, 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.

For More Information:

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