



Century Therapeutics Announces First Patient Dosed in First-In-Human Phase 1 ELiPSE-1 Trial Evaluating CNTY-101 in Relapsed or Refractory CD19 Positive B-cell Lymphomas

February 8, 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 –

– ELiPSE-1 trial to test multi-dosing strategy for CAR iNK enabled by Allo-Evasion™ edits designed to resist 3 major pathways of rejection –

PHILADELPHIA, Feb. 08, 2023 (GLOBE NEWSWIRE) -- [Century Therapeutics](#), Inc., (NASDAQ: IPSC), an innovative clinical-stage biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immuno-oncology, announced today that the first patient has been dosed in the first-in-human Phase 1 ELiPSE-1 trial evaluating CNTY-101 in patients with relapsed or refractory CD19 positive B-cell lymphomas. CNTY-101 is the Company's first allogeneic cell therapy product candidate engineered with multiple complementary functionalities 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.

As a leading next-generation allogeneic cell therapy candidate, CNTY-101 is the first to test the potential of a finite, repeat dosing regimen and the ability to deliver more durable responses enabled by Allo-Evasion™ gene edits. CNTY-101 is manufactured from a clonal iPSC master cell bank that yields homogeneous product, in which all infused cells have the intended modifications.

"Today's achievement marks our transition to a clinical-stage company and represents an important milestone for both Century and for patients with relapsed or refractory CD19 positive B-cell lymphomas who are lacking efficacious therapeutic options," said Lalo Flores, Ph.D., Chief Executive Officer, Century Therapeutics. "With our vision of a finite multi-dosing regimen combined with core Allo-Evasion™ edits, we are attempting to pave the way for our future product candidates and a new paradigm for allogeneic cell therapies."

The Phase 1 trial, ELiPSE-1 ([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 pending U.S. Food and Drug Administration consent.

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, Inc. (NASDAQ: IPSC) is a clinical-stage biotechnology company 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 <https://www.centurytx.com/>.

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 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 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 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 future 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; 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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