Century Therapeutics Presents Interim Results from Phase 1 ELiPSE-1 Study at ASCO 2024 Annual Meeting

June 3, 2024

In ongoing dose escalation, CNTY-101 has demonstrated a manageable safety profile with no observed DLTs or GvHD and with majority of patients treated in outpatient setting

Encouraging preliminary efficacy in heavily pretreated R/R NHL at initial dose levels

Novel cell-free DNA method for detecting total body PK suggests CNTY-101 persists outside the bloodstream

Enrollment continues in dose escalation phase of ELiPSE-1 at dose levels 3B (three weekly infusions of 1 billion cells) and 4A (single infusion of 3 billion cells) per cycle

PHILADELPHIA, June 03, 2024 (GLOBE NEWSWIRE) -- Century Therapeutics (NASDAQ: IPSC), an innovative biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immuno-oncology and autoimmune and inflammatory disease, today announced a poster presentation highlighting interim results from the ongoing Phase 1 ELiPSE-1 study evaluating CNTY-101 in relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) at the American Society of Clinical Oncology (ASCO) Annual Meeting being held May 31 – June 4, 2024 in Chicago, Illinois.

CNTY-101 is an investigational CD19 targeting allogeneic, iPSC-derived natural killer (NK) cell therapy with six precision gene edits powered by Century's Allo-Evasion™ technology enabling repeat dosing without the need for continued lymphodepletion. ELiPSE-1 (NCT05336409) is an ongoing Phase 1, multicenter, open-label clinical trial to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of CNTY-101 in patients with R/R, CD19-positive B-cell malignancies.

"These interim results continue to support our belief in the potential of CNTY-101, which shows additional responses across escalating doses and different types of B-cell malignancies in heavily pretreated patients with predominantly aggressive or high-risk histologies," said Adrienne Farid, PhD, Chief Operations Officer and Head of Early Development. "We are also encouraged by the safety profile we are seeing at higher doses, with no dose-limiting toxicities to date, after multiple treatment cycles, which we believe was achieved by leveraging our proprietary Allo-Evasion™ technology to avoid host rejection. Further, the majority of these cycles have been administered in the outpatient setting, providing additional support for CNTY-101 as a new paradigm for allogeneic cell therapies. We look forward to completing dose escalation and moving into dose expansion in the coming months."

Interim Results from the ELiPSE-1 Study: A Phase 1, Multicenter, Open-Label Study of CNTY-101 in Subjects with Relapsed or Refractory CD19-Positive B-Cell Malignancies
Poster Board Number: 6
Session Title: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
Session Date & Time: Monday, June 3, 2024, from 9:00 am – 12:00 pm CDT

CNTY-101 is Century's lead iNK cell therapy and the first iPSC-derived NK cell therapy engineered with six precision gene edits, featuring antigen-specific killing of CD19+ B cells, homeostatic cytokine support for enhanced persistence, Allo-Evasion™ edits to prevent rejection by the patients' immune system, and a safety switch. CNTY-101 is being assessed in heavily pre-treated relapsed or refractory NHL patients with predominantly aggressive or high-risk indolent histologies who have received two to five prior therapies, four of whom received prior CAR-T therapy. The Company previously announced initial data in December 2023, demonstrating a favorable safety profile in the initial seven patients treated with Dose Level 1 (100 million cells) and Dose Level 2 (300 million cells) on a once monthly schedule. In these low dose levels, CNTY-101 demonstrated encouraging early response signals, including two complete responses (CRs) and one partial response (PR).

As of the interim data cutoff date of March 27, 2024, preliminary safety and efficacy were evaluated across Dose Level 1, Dose Level 2 and Dose Level 3 (one billion cells) and two dosing schedules (Schedule A with single infusion, and Schedule B with three weekly infusions, per cycle). CNTY-101 infusions of up to one billion cells per cycle (as a single infusion of one billion cells, or 3 weekly infusions of 300 million cells) demonstrated a favorable safety profile with no observations of graft-versus-host disease (GvHD) or dose-limiting toxicities (DLT), and 8/12 subjects received at least one cycle of CNTY-101 in an outpatient setting. Preliminary efficacy in all evaluable patients (n=10) across dose schedules and histologies demonstrated a complete response rate (CRR) of 30% and an objective response rate (ORR) of 40% in heavily pretreated patients, with a 40% CRR and 60% ORR observed in the five patients treated with the two higher Schedule A dose levels, 300 million cells and one billion cells.

Pharmacokinetics (PK) evaluated by a novel cell-free DNA (cfDNA) method for detecting total body PK showed that CNTY-101 rapidly traffics out of circulation and persists outside the bloodstream, with AUC trending to increase with dose level. In patients who received additional cycles of CNTY-101 without lymphodepleting chemotherapy, three out of four patients had positive detection of CNTY-101 on Day 3 and beyond. The ELiPSE-1 study is currently ongoing in the dose escalation phase and is enrolling in Dose Level 3B (one billion cells in three weekly infusions per cycle), and Dose Level 4A (single infusion of 3 billion cells per cycle).

The full poster will be available on the Scientific Resources page of Century's website at the start of the poster presentation.

About CNTY-101
CNTY-101 is an investigational off-the-shelf 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 preclinically to improve functionality and persistence. Further, to address potential safety considerations, the iNK cells

were engineered with an EGFR safety switch, and preclinical proof-of-concept studies have demonstrated that the cells can be quickly eliminated *in vivo* 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 clinical trial. The Company intends to initiate its second Phase 1 clinical trial assessing CNTY-101 in patients with moderate to severe systemic lupus erythematosus, in addition to pursuing additional regulatory filings in other prioritized autoimmune disease indications.

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 β2m, 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 Century Therapeutics

Century Therapeutics (NASDAQ: IPSC) is harnessing the power of adult stem cells to develop curative cell therapy products for cancer and autoimmune and inflammatory diseases that we believe will allow us to overcome the limitations of first-generation cell therapies. Our genetically engineered, iPSC-derived cell product candidates are designed to specifically target hematologic and solid tumor cancers, with a broadening application to autoimmune and inflammatory diseases. 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 and autoimmune and inflammatory disease 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 and the initial safety and efficacy profiles of CNTY-101 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; the ability of CNTY-101 to be administered as part of a multi-dose strategy and to enable responses without lymphodepletion; uncertainties inherent in the results of preliminary data, pre-clinical studies and earlier-stage clinical trials, which may not be predictive of final results or the results of later-stage clinical trials; the timing of and our ability to initiate and successfully enroll the Phase 1 SLE trial; our ability to obtain FDA clearance of our future IND 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, 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:
Investors/Media: Julie Seidel/ Noor Pahlavi – century@argotpartners.com