



Century Therapeutics Announces Investigator-Initiated Phase 1/2 Trial of its iPSC-derived iNK Cell Therapy CNTY-101 in B-cell Mediated Autoimmune Diseases Sponsored by Internationally Renowned Key Opinion Leaders

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- Investigator-initiated trial (IIT) to be led by pioneers of cell therapy in B-cell mediated autoimmune disease, the Schett/Mackensen group at Friedrich-Alexander University Erlangen-Nürnberg -

- Trial to evaluate and enhance clinical experience with CNTY-101 in patients with systemic lupus erythematosus, lupus nephritis, idiopathic inflammatory myopathy, and diffuse cutaneous systemic sclerosis -

PHILADELPHIA, Jan. 21, 2025 (GLOBE NEWSWIRE) -- [Century Therapeutics](#), Inc. (NASDAQ: IPSC), an innovative biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immuno-oncology and autoimmune disease, has entered into an agreement for an investigator-initiated Phase 1/2 trial by Professors Georg Schett and Andreas Mackensen of its CD19 CAR-iNK investigational cell therapy candidate CNTY-101 in patients with B-cell mediated autoimmune diseases. The IIT, which is sponsored by the Friedrich-Alexander University Erlangen-Nürnberg, represents the first evaluation by the internationally recognized Schett/Mackensen group of an allogeneic iPSC-derived CD19-directed NK cell therapy for the treatment of autoimmune diseases.

Consistent with Century's ongoing Phase 1 CALiPSO-1 trial ([NCT06255028](#)), the IIT (known as the CAMEL trial) will evaluate safety, efficacy, and key translational data of CNTY-101 in systemic lupus erythematosus, lupus nephritis, idiopathic inflammatory myopathy, and diffuse cutaneous systemic sclerosis.

"The decision by these internationally recognized experts to conduct their first evaluation of allogeneic iPSC-derived cell therapies in autoimmune indications with Century represents important recognition of the unique potential for CNTY-101 in this setting. We believe CNTY-101 is well positioned to address autoimmune diseases as an iPSC-derived NK cell therapy incorporating our Allo-Evasion™ technology for precise control over drug exposure, as supported by pre-clinical and clinical data demonstrating clear anti-B cell activity and an encouraging safety profile. We look forward to insights from Dr. Schett and Mackensen's research into Century's allogeneic iNK cell therapy to complement and enhance clinical experience in our ongoing Phase 1 CALiPSO-1 trial of CNTY-101, setting us up for important milestones in the year ahead," said Brent Pfeifferberger, Pharm.D., Chief Executive Officer of Century Therapeutics.

Dr. Andreas Mackensen, Director of Medical Clinic 5 – Hematology & Internal Oncology at Friedrich-Alexander University Erlangen-Nürnberg, commented: "We believe allogeneic iPSC-derived cell therapy with a consistent, off-the-shelf product like CNTY-101 holds immense promise in the treatment of autoimmune diseases, driven by the elimination of logistical hurdles such as apheresis, removal of washout concerns, and the potential for administration in outpatient settings. We look forward to our partnership with Century on this study as we seek to address significant unmet needs for patients across these serious diseases."

The Schett/Mackensen group at Erlangen has pioneered the development of cell therapy in autoimmune diseases, having first presented data in 2022¹ showing that autologous CD19 CAR-T cell therapy achieved deep depletion of B-cells in patients with severe autoimmune disease leading to groundbreaking clinical outcomes. Their data continues to provide evidence of long-term, drug-free remission, and has paved the way for broader clinical investigation of cell therapies in these indications. The CAMEL trial with Century is intended to commence in mid-2025 following CTA approval.

In addition to the Schett/Mackensen CAMEL trial, the company plans also to expand the CALiPSO-1 clinical trial to include sites in select European countries. Century will provide timing on initial clinical data from its ongoing CALiPSO-1 clinical trial once a clear cadence of patient enrollment has been established across indications.

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 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 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 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 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; our ability to progress CNTY-101 through our CALIPSO and ELIPSE Phase 1 clinical trials; our ability to meet development milestones on anticipated timelines; 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; 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:

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