Century Therapeutics and FUJIFILM Cellular Dynamics Announce Licenses for the Development and Commercialization of iPSC-Derived Cell Therapies in Autoimmune and Inflammatory Diseases

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PHILADELPHIA and MADISON, Wis., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Century Therapeutics, Inc. (NASDAQ: IPSC), an innovative clinical-stage biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immune-oncology, and FUJIFILM Cellular Dynamics, Inc., a leading global developer and manufacturer of human iPSCs and iPSC-derived cells, today announce a new worldwide license agreement and expansion of existing licenses for the development and commercialization of cell therapies derived from iPSCs for the treatment of autoimmune and inflammatory diseases, including type 1 diabetes, multiple sclerosis, lupus, and rheumatoid arthritis.

There are up to 100 autoimmune conditions which collectively impact more than 24 million Americans,[1] with studies indicating that both incidence and prevalence of autoimmune disease are rising for reasons that are poorly understood[2]. Treatment of autoimmune disease is currently limited to symptom management, and includes correcting resulting deficiencies in the body, along with reducing inflammation and the immune response. iPSCs have the capability to self-renew and differentiate into key cell types, providing regenerative and immune-modulating properties as a treatment modality.

The new licenses expand on the companies' existing collaboration initiated in 2018 for iPSC-derived cancer immunotherapeutics.

Under the terms of the agreements, FUJIFILM Cellular Dynamics will be eligible to receive certain development and regulatory milestone payments as well as royalties related to products developed in connection with the companies' agreements.

"Leveraging our proprietary Allo-Evasion™ technology, we believe we are uniquely positioned to develop differentiated, effective cell therapies that can be redosed to potentially deliver effective levels of drug exposure and immunologic pressure not only for the treatment of cancer, but also for immunologic diseases with high unmet need. These agreements enable further evaluation of Century's iPSC-derived NK, T cell, and monocyte/macrophage platforms," said Hy Levitsky, M.D., president of research and development, Century Therapeutics. "We look forward to sharing at ASH later this year our first clinical and translational dataset from the ongoing Phase 1 ELiPSE-1 trial of CNTY-101, an iPSC-derived CD19-specific CAR-NK cell therapy in patients with relapsed or refractory B cell lymphomas, supporting the potential of our platform to overcome the limitations that have historically prevented the successful application of off-the-shelf allogeneic NK cell approaches."

"As a global leader in the field of iPSCs, we are pleased to expand our partnership with Century as they seek to develop new and transformative allogeneic cell therapies for the treatment of immune-mediated diseases," said Tomoyuki Hasegawa, president and chief executive officer, FUJIFILM Cellular Dynamics, Inc. "FUJIFILM Cellular Dynamics supported Century Therapeutics in the manufacturing of CNTY-101 and we look forward to expanding our manufacturing partnership to address autoimmune and inflammatory diseases. We are committed to ensuring that iPSC-derived therapeutics realize their full potential, and we look forward to supporting Century Therapeutics' progress."

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.

About FUJIFILM Cellular Dynamics, Inc.

FUJIFILM Cellular Dynamics, Inc. is a leading developer and manufacturer of human iPSCs and iPSC-derived cells utilized in drug discovery, contract development and manufacturing services for cell therapies. For its partners, FUJIFILM Cellular Dynamics utilizes its iPSC platform to advance the progress of therapeutic candidates in the clinic and provides contract development and manufacturing (CDMO) services. In addition to cell therapy, FUJIFILM Cellular Dynamics also offers life science research tools including the company's inventoried iCell® products, which are available in almost any cell type and are sourced from multiple cell lines which can be applied for target identification as well as toxicity testing. The company also offers custom cell services and cell banking. FUJIFILM Cellular Dynamics' goal is to leverage the vast utility of iPSCs to advance human health and improve the quality of life for patients around the world. For more information, please visit: https://www.fujifilmcdi.com/

About FUJIFILM Holdings Corporation

FUJIFILM Holdings Corporation, Tokyo, leverages its depth of knowledge and proprietary core technologies to deliver "Value from Innovation" in our products and services in the business segments of healthcare, materials, business innovation, and imaging. Our relentless pursuit of innovation is focused on providing social value and enhancing the lives of people worldwide. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information about Fujifilm's Sustainable Value Plan 2030, click here. For the year ended March 31, 2023, the company had global revenues of approximately 2.9 trillion yen (21 billion USD at an exchange rate of 134 yen/dollar). For more information, please visit: www.fujifilmholdings.com.

Century Therapeutics 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 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.

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[1] National Institute of Allergy and Infectious Diseases (NIAID). Autoimmune Diseases [Website]. National Institutes of Health (NIH): Bethesda, MA. Available at: https://www.niaid.nih.gov/diseases-conditions/autoimmune-diseases [accessed 24 Oct 2023].

[2] Dinse GE et al. 2020. *Arthritis Rheumatol* 72(6):1026-1035, PMID: 32266792, https://doi.org/10.1002/art.41214.