UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 25, 2022

Century Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40498**	**84-2040295**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

3675 Market Street **Philadelphia, Pennsylvania**	**19104**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(267) 817-5790**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.0001 per share	**IPSC**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 **Other Events**

On August 25, 2022, Century Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration notified the Company that its ELiPSE-1 study may proceed to assess CNTY-101 in patients with relapsed or refractory CD19 positive B-cell malignancies. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 **Financial Statements and Exhibits**

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Century Therapeutics, Inc., dated August 25, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CENTURY THERAPEUTICS, INC.

By: /s/ Osvaldo Flores, Ph.D.
Name: Osvaldo Flores, Ph.D.
Title: President and Chief Executive Officer

Date: August 25, 2022

Exhibit 99.1

Century Therapeutics Receives Study May Proceed Notification from FDA for CNTY-101, the First Allogeneic Cell Therapy Product Candidate Engineered to Overcome Three Major Pathways of Host vs Graft Rejection

- Investigational New Drug Application for CNTY-101, a CAR-iNK product candidate targeting CD19 for B-cell malignancies, cleared by FDA –

- First cell product candidate engineered with six precision gene edits including a CD19-CAR, Allo-Evasion™ technology, IL-15 cytokine support and a safety switch –

- Phase 1 ELiPSE-1 trial evaluating CNTY-101 in relapsed or refractory CD19 positive B-cell malignancies anticipated to begin in 2H22 –

PHILADELPHIA, August 25, 2022 -- Century Therapeutics, Inc., (NASDAQ: IPSC), an innovative biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immuno-oncology, announced today that the company has been notified by the U.S. Food and Drug Administration (FDA) that the Company's ELiPSE-1 clinical study may proceed to assess CNTY-101 in patients with relapsed or refractory CD19 positive B-cell malignancies. CNTY-101 is the first allogeneic cell therapy product candidate engineered with four powerful and complementary functionalities, including 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. CNTY-101 is manufactured from a clonal iPSC master cell bank that yields homogeneous product, in which all infused cells have the intended modifications.

"This IND clearance is a significant milestone for Century as we execute on our vision to merge two disruptive platforms, precision gene editing and the powerful potential of iPSCs, to potentially move the allogeneic cell therapy field forward, and continue on our path to becoming a leader in the space," said Lalo Flores, Chief Executive Officer, Century Therapeutics. "We believe that CNTY-101, our first and wholly owned product candidate, will be the most technically advanced and differentiated CD19-targeted cell product when it enters the clinic, which is anticipated to occur later this year. We look forward to assessing the potential of Allo-Evasion™ to prevent immunological rejection and enhance persistence of multiple dosing of CNTY-101 regimens with the aim to increase the proportion of patients that achieve durable responses."

"CNTY-101 is the first allogeneic cell product candidate with six genetic modifications incorporated using sequential rounds of CRISPR-mediated homologous recombination and repair that has received IND clearance by the FDA," said Luis Borges, Chief Scientific Officer, Century Therapeutics. "We believe CNTY-101 will demonstrate the power of Century's iPSC technology and cell engineering technology platforms. This accomplishment is a testament to the expertise and dedication of our team as we continue to make progress developing our pipeline of iPSC-derived NK and T cell product candidates."

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 malignancies. 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 FDA consent. We anticipate initiation of the Phase 1 trial later this year.

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 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 (FDA) for certain cancers. Initiation of the Phase 1, ELiPSE-1 trial in relapsed or refractory CD19-positive B-cell malignancies in multiple centers in the United States is anticipated to begin in the second half of 2022.

About Century Therapeutics

Century Therapeutics, Inc. (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 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 presentation 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.

For More Information:

Company: Elizabeth Krutoholow – investor.relations@centurytx.com

Investors: Melissa Forst/Maghan Meyers – century@argotpartners.com

Media: Joshua R. Mansbach – century@argotpartners.com