## **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): December 9, 2023

### Century Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

#### Delaware

(State or other jurisdiction of incorporation or organization)

001-40498 (Commission File Number) 84-2040295

(I.R.S. Employer Identification No.)

19104

(Zip Code)

25 North 38th Street, 11th Floor Philadelphia, Pennsylvania (Address of principal executive offices)

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:

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

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.  $\square$ 

#### Item 8.01 Other Events

On December 9, 2023, Century Therapeutics, Inc. (the "Company") issued a press release announcing the presentation of initial clinical data from a single-patient case study in which the Company believes support the potential for a multi-dosing strategy for CAR iNK enabled by Allo-Evasion<sup>TM</sup> edits at the  $65^{th}$  American Society of Hematology Annual Meeting and Exposition, being held December 9-12<sup>th</sup> in San Diego, California. 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.

On December 11, 2023, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

Item 9.01	Financial Statements and Exhibits
(d) Exhibits	
Exhibit No.	Document
<u>99.1</u>	Press Release of Century Therapeutics, Inc., dated December 9, 2023
99.2	Investor Presentation of Century Therapeutics, Inc., dated December 11, 2023
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/ Brent Pfeiffenberger, Pharm.D.

Name: Brent Pfeiffenberger, Pharm.D.

Title: President and Chief Executive Officer

Date: December 11, 2023



#### Century Therapeutics Presents Initial Data from CNTY-101 Phase 1 ELiPSE-1 Trial Supporting the Potential for a Multi-Dosing Strategy for CAR iNK Enabled by Allo-EvasionTM Edits

- Data presented at 65th ASH Annual Meeting show CNTY-101 was generally well tolerated at Dose Level 1 (100 million cells) in a high-risk, heavily pretreated R/R B-cell lymphoma patient -
  - Preliminary clinical data demonstrate six-month durable complete response in Dose Level 1 in a single patient following multiple cycles of CNTY-101 without lymphodepletion -
  - Pharmacokinetic data suggests CNTY-101 exposure may be maintained upon administration of additional cycles without lymphodepletion due to lack of observed allo-rejection -
- Company to host conference call on Monday, December 11 at 7:30 AM PT/10:30 AM ET to review ASH data including additional clinical results from Dose Level 1 (100 million cells) and Dose Level 2 (300 million cells), as well as clinical plans for CNTY-101 in systemic lupus erythematosus -

PHILADELPHIA, December 9, 2023 – 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 the presentation of initial clinical data from a single-patient case study which Century believes support the potential for a multi-dosing strategy for CAR iNK enabled by Allo-Evasion™ edits at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition, being held December 9-12 in San Diego. The poster, titled, "Multiple Doses of CNTY-101, an iPSC-Derived Allogeneic CD19 Targeting CAR-NK Product, are Safe and Result in Tumor Microenvironment Changes Associated with Response: A Case Study", is available on the <u>Scientific Resources</u> page of the Company's website.

"We are thrilled that the initial clinical evidence for CNTY-101 provides support for the potential for Allo-Evasion<sup>TM</sup> to enable a multi-dosing regimen without the need for continued lymphodepletion. This is highly encouraging in advancing our goal to increase persistence of the cells during the treatment period and potentially lead to deeper and more durable responses," said Brent Pfeiffenberger, Pharm.D., Chief Executive Officer of Century Therapeutics. "We look forward to advancing the study at both higher and more frequent doses of CNTY-101, and plan to present additional clinical data in mid-2024."

"As the first cell therapy product candidate engineered with six precision gene edits aimed at providing selectivity and persistence, CNTY-101 is positioned to potentially fill a high unmet need among heavily pretreated non-Hodgkin lymphoma patients," said Krish Patel, M.D., Director of Lymphoma Program, Director of Hematologic Malignancies and Cellular Therapy, Swedish Cancer Institute, Seattle. "The encouraging initial data presented today from this patient who received low doses of CNTY-101 exhibits signals of persistence of CNTY-101 cells out of circulation and supports testing at higher doses. I look forward to the continuation of the study and to further investigating the full therapeutic potential of CNTY-101."



Data featured in a single-patient case study presented at ASH involves a 63-year-old patient with relapsed/refractory (R/R) progressive follicular lymphoma previously treated with four prior lines of therapy who was enrolled at Dose Level 1 (100 million cells). As of a data cutoff date of November 13, 2023, the patient has received seven 28-day cycles of a single infusion of CNTY-101 at Dose Level 1. Cycles one and two included three days of lymphodepletion (LD), whereas cycles three through seven were given with no LD. Interleukin-2 (IL-2) was administered for all cycles except for the first. The patient maintained a complete response with a duration of six months before subsequently progressing.

Data from the single-patient case study indicated that CNTY-101 was generally well tolerated in this patient at Dose level 1 (100 million cells). No dose-limiting toxicities, cytokine release syndrome or immune effector cell—associated neurotoxicity syndrome were observed, and no adverse events related to treatment with CNTY-101 were detected in this patient, to date. Additionally, no concerted changes in inflammatory cytokines and mediators associated with cytokine release syndrome or neurotoxicity have been detected in this patient.

Following administration of two cycles with and three cycles without LD, serum assessments from available data of the first five cycles of CNTY-101 treatment in this patient showed no evidence of functional pre-existing or induced humoral immunogenicity against CNTY-101. Importantly, tumor microenvironment initial analyses demonstrated a vigorous increase in T cells within 8 days of the 1<sup>st</sup> CNTY-101 cell infusion. Increases in proliferating cytotoxic T cells and TNF $\alpha$  and IFP $\gamma$ -secreting cells were observed, suggestive of induction of adaptive immune responses within the tumor. Additionally, ddPCR analysis of CNTY-101 genomic DNA and cell-free DNA from Dose Level 1 patient (n=4) samples suggest that CNTY-101 cells were able to traffic out of circulation shortly after infusion and showed persistence in tissues for at least 3 days.

In addition to the preliminary clinical data presented today, the Company will also present additional results from patients treated at Dose Level 1 (100 million cell dose), as well as preliminary data from three patients treated at Dose Level 2 (300 million cell dose) during a conference call and webcast on Monday, December 11 at 7:30 AM PT/10:30 AM ET. In addition, the Company will discuss its planned Phase 1 trial, including supporting preclinical data, for CNTY-101 in systemic lupus erythematosus, the Company's first autoimmune and inflammatory disease indication.

#### Conference Call and Webcast

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website. Alternatively, the conference call may be accessed through the following:

- · Conference ID: century2023
- · Domestic Dial-in Number: (800) 590-8290
- International Dial-in Number: (240) 690-8800
- · Live webcast: https://century-therapeutics-initial-clinical-data-call.open-exchange.net/

For those unable to participate in the conference call or webcast, a replay will be available on the Investors section of the Company's website at <a href="https://www.centurytx.com">www.centurytx.com</a> approximately 24 hours after the conference call and will be available for 90 days following the call.



#### About Allo-Evasion<sup>TM</sup>

Century's proprietary Allo-Evasion<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> technology may allow the implementation of more flexible and effective repeat dosing protocols for off-the-shelf product candidates.

#### About EL IDSE

The Phase 1 ELiPSE-1 trial (NCT05336409) is intended to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of CNTY-101 in adult 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.

#### A b --- CNITS/ 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<sup>TM</sup> 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 moderate to severe systemic lupus erythematosus.

#### **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 <a href="https://www.centurytx.com">www.centurytx.com</a>.



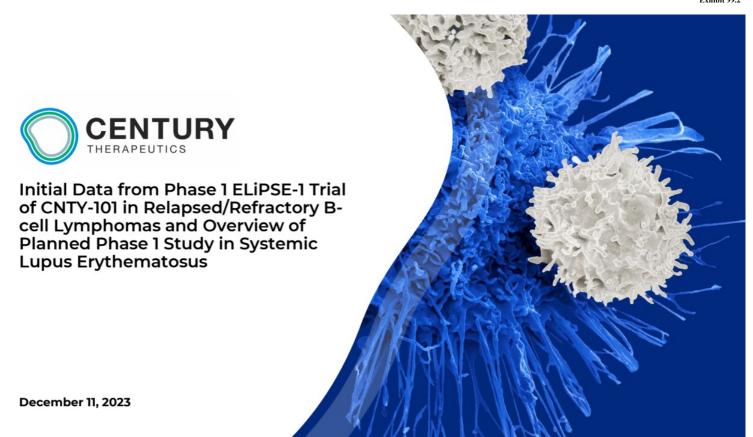
#### Century Therapeutics Forward-Looking Statement

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 is 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 earlier-stage clinical trials, which may not be predictive of final results or the results of later-stage clinical trials, which may not be predictive of final results or the results of expendictive or final results or the results of expendic



### For More Information:

 $Investors/Media: Melissa\ Forst/Maghan\ Meyers - \underline{century@argotpartners.com}$ 



## Forward-looking statements

This presentation contains forward-looking statements within the meaning of, and made pursuant to the safe harbour provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this document, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding possible or assumed future results of operations, business strategies, research and development plans, regulatory activities, market opportunity, competitive position and potential growth opportunities 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 I 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 ar projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-look statements speak only as of the date of this presentation 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 produc 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 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 commer and complete clinical trials on expected timelines, or at all; our reliance on the maintenance on 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 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 suppli and manufacturers; our ability to successfully commercialize our product candidates and develop sales and marketing capabilities, if our product candidates approved; and our ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are describe 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 achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic indus 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.



## Today's agenda

Introduction
Brent Pfeiffenberger, Pharm.D., Chief Executive Officer

Overview of Foundational Platform Technologies
Hy Levitsky, M.D., President of Research and Development

Review of Initial ELIPSE-1 Data for CNTY-101
Nick Trede, M.D., Ph.D., SVP, Head of Clinical Development

CNTY-101 in Systemic Lupus Erythematosus
Adrienne Farid, Ph.D., Chief Operations Officer and Head of Early Development

Closing
Brent Pfeiffenberger, Pharm.D., Chief Executive Officer

Also Joining for Q&A
Michael Diem, M.D., Chief Financial Officer
Greg Russotti, Ph.D., Chief Technology and Manufacturing Officer



## Century Therapeutics: Building an industry-leading, nextgeneration allogeneic iPSC-derived cell therapy platform

LIMITLESS POTENTIAL...

PRECISION DESIGN...

**ENDURING IMPACT...** 

Foundational investments in iPSC technolog genetic editing, and manufacturing

Progressing multiple clinical programs in oncology and autoimmune and inflammator diseases

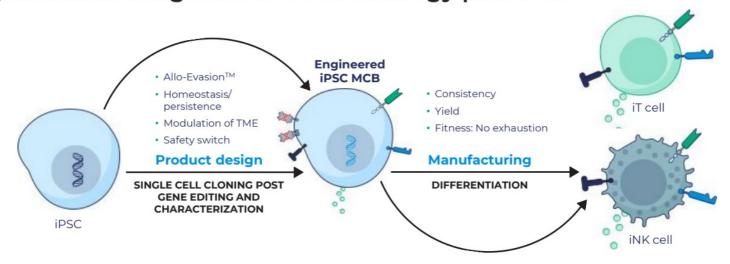
Well-capitalized into 2026 to enable delivery on key milestones and clinical data





Overview of Foundational Platform Technologies: iPSCs, Allo-Evasion™ and the Creation of CNTY-101

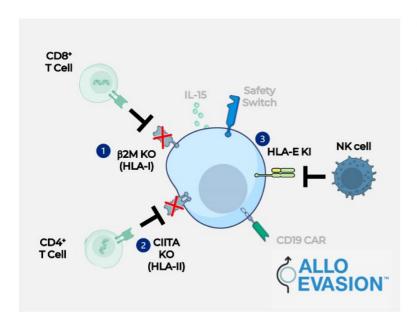
Versatility and unprecedented control: Century's nextgeneration allogeneic iPSC technology platform



Iterative optimization of product functionality and manufacturability



## Allo-Evasion $^{\text{TM}}$ 1.0 designed to overcome 3 major pathways c host vs. graft rejection

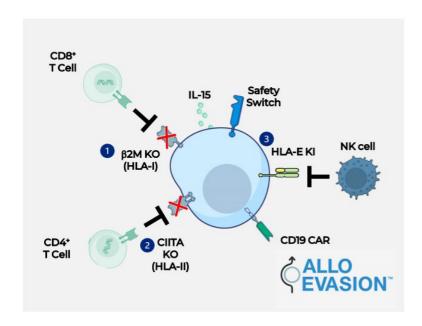


## Three core edits disarm host cells from eliminating therapy

- 1. Deletion of  $\beta$ 2M, a protein required to express HLA-1 on the cell surface prevents recognition by CD8 T cells
- 2. Knock out of CIITA eliminates HLA-II expression to escape elimination by CD4 T cells
- 3. Knock-in of HLA-E prevents killing by NK cells



## CNTY-101: Differentiated next-gen CD19 targeted product



## Delivering on our vision to change the cell therapy treatment paradigm

- Goal to improve durability, tolerability and ease of outpatient administration
- Potential to eliminate need for lymphodepletion with subsequent cycles of therapy
- First CD19-targeted agent to test durability benefit of repeat dosing enabled by Allo-Evasion™ edits



# CNTY-101: Extending drug exposure in R/R B-cell NHL via repeat dosing and changing the treatment paradigm with Allo-Evasion $^{\text{TM}}$

Aim: extending the period of pharmacologic pressure on tumor cells



#### **Unmet need:**

- Autologous CD19 CAR-T curative in only a subset of patients
- Autologous CD19 CAR-T access is limited and/or can fail in manufacturing as quality is dependent on patientderived starting material
- Limited options and poor prognosis for patients who fail autologous CAR-T



### Potential solution from Century's platform:

- Off-the-shelf product offers immediate access and consistency
- Multiple doses to increase pharmacological pressul increase durability
- Host rejection addressed by Allo-Evasion<sup>™</sup> edits



 $\textit{R/R: relapsed or refractory, NHL: non-Hodgkin lymphoma, CAR-T: chimeric antigen receptor T cell the rapy and the results of the relation of the results of the results$ 



## Review of Initial ELiPSE-1 Data for CNTY-101

## CNTY-101: ELiPSE-1 (NCT05336409) Phase 1 BOIN design

### Inclusion:

- R/R CD19+ NHL
- Aggressive B cell lymphoma (DLBCL, tFL, high-grade B cell lymphoma, PMBCL, MCL, FL3B)
- High-risk indolent lymphoma

### **Endpoints:**

- Primary: MTD based on DLTs; RP2R
- Key Secondary: Safety, tolerability, Efficacy (ORR, CF
- Exploratory: feasibility of additional cycles, Allo-Evasion™

## **Patient** enrollment N=15 dose esc

N=20 expansion

LYMPHO-DEPLETION

## **Initial Dose**

## Additional Cycles<sup>2</sup>

First additional cycle: lymphodepletion at investigator's discretion

No lymphodepletion for following cycles

### Schedule A

- Dose level 1: 100e6
- Dose level 2: 300e6
- Dose level 3: 1000e6



IL-2 x 8 days

















- Dose level 2: 300e6
- Dose level 3: 1000e6

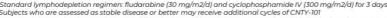








IL-2 x 22 days



<sup>1</sup> Standard lymphodepletion regimen: fludarabine (30 mg/m2/d) and cyclophosphamide IV (300 mg/m2/d) for 3 days <sup>2</sup> Subjects who are assessed as stable disease or better may receive additional cycles of CNTV-101 BOIN: Bayesian Optimal Interval, DLBCL: diffuse large B cell lymphoma, tFL: transformed follicular lymphoma, PMBCL: primary mediastinal B-cell lymphoma, MCL: mantle cell lymphoma, FL3B: follicular lymphoma grade 3B, DLT: dose-limiting toxicity, RP2R: recommended Phase 2 regimen, ORR: objective response rate, CRR: complete response rate, DoR: duration of response, PK: pharmacokinetics, IL-2: interleukin-2



## ELiPSE-1 initial data: Key takeaways

- · Heavily pretreated and refractory patient population treated in first-in-human dose escalation t
- · Favorable safety profile; can be delivered in an outpatient setting
- Encouraging early efficacy signals at lowest dose levels
  - o 2 patients achieving CR, including 1 patient with 6-month durable CR
- · No evidence of allo-rejection
- Initial data for CNTY-101 supports the potential for Allo-Evasion™ to enable a multidosing regimen without the need for continued lymphodepletion

CR: Complete response



## **ELiPSE-1** enrolled heavily pretreated patients

BASELINE CHARACTERISTICS	
Patients treated	7
Median age (range)	68 (60-72)
PRIOR THERAPY	
Median # of prior therapies (range)	4 (2-6)
Prior CD-19-targeted CAR T-cell therapy	3a (43%)
DISEASE CHARACTERISTICS	
Aggressive histology	5 (71%)
Refractory to last line of therapy	6 (86%)
Elevated LDH at screening	5 (71%)
Stage 4 (Dx   Screening)	5 (71%)   7 (100%)
Median baseline target lesion SPD (mm²) (range)	2044 (641-29716)

Data cutoff date of November 13, 2023, represents data verified post data cut a. One additional subject had CAR T-cell manufacturing failure LDH: Lactate dehydrogenase, SPD: sum of the products of diameters



## **ELiPSE-1: Overview of patients**

сонокт			DISEA	TREATMENT			
	PATIENT	Indication	Prior Lines Therapy	Prior CAR T?	Relapse or Refractory to Last Line	Dose	Cycles Completed
	1	iFL	4	N	Refractory	100 x 10 <sup>6</sup>	7
DOSE LEVEL 1	2	DLBCL/tFL	4	Υ	Refractory	100 x 10 <sup>6</sup>	1
DOSE LEVEL I	3	DLBCL	2	Na	Refractory	100 x 10 <sup>6</sup>	1
	4	DLBCL/tMZL	4	N	Refractory	100 x 10 <sup>6</sup>	1
	5	MZL	4	N	Refractory	300 x 10 <sup>6</sup>	2
DOSE LEVEL 2	6	DLBCL	4	Υ	Refractory	300 x 10 <sup>6</sup>	1
	7	DLBCL/tFL	6	Υ	Relapsed	300 x 10 <sup>6</sup>	1*

Data cutoff date of November 13, 2023; represents data verified post data cut

<sup>a.</sup> CAR T manufacturing failure

CRS: cytokine release syndrome, ICANS: immune effector cell-associated neurotoxicity syndrome, AE: adverse event, SAE: serious adverse event



## ELiPSE-1: Favorable initial safety profile

сонокт	PATIENT		DISEASE HI	TREAT	MENT	SAFETY					
		Indication	Prior Lines Therapy	Prior CAR T?	Relapse or Refractory to Last Line	Dose	Cycles Completed	DLTs	CRS (Grade)	ICANS	CNT Relate AE/
	1	iFL	4	N	Refractory	100 x 10 <sup>6</sup>	7	N	N	N	
DOSE LEVEL 1	2	DLBCL/ tFL	4	Υ	Refractory	100 x 10 <sup>6</sup>	1	N	N	N	
	3	DLBCL	2	Na	Refractory	100 x 10 <sup>6</sup>	1	N	N	N	
	4	DLBCL/ tMZL	4	N	Refractory	100 x 10 <sup>6</sup>	1	N	Y (1)	N	87
	5	MZL	4	N	Refractory	300 x 10 <sup>6</sup>	2	N	Y (2)	N	
DOSE LEVEL 2	6	DLBCL	4	Υ	Refractory	300 x 10 <sup>6</sup>	1	N	N	N	
	7	DLBCL/ tFL	6	Υ	Relapsed	300 x 10 <sup>6</sup>	]*	N*	N*	N*	h

\*Data cutoff date of November 13, 2023; represents data verified post data cut a. CAR T manufacturing failure



# ELiPSE-1: Early evidence of anti-lymphoma activity at lowest dose levels

сонокт	PATIENT	DISEASE HISTORY				TREATMENT		SAFETY				RESP
		Indication	Prior Lines The rapy	Prior CAR T?	Relapse or Refractory to Last Line	Dose	Cycles Completed	DLTs	CRS	ICANS	CNTY-101 Related Gr3+ AE/SAE	Best Res
	1	iFL	4	N	Refractory	100 x 10 <sup>6</sup>	7	N	N	N	N	C
DOSE LEVEL 1	2	DLBCL/tFL	4	Υ	Refractory	100 x 10 <sup>6</sup>	1	N	N	N	N	F
	3	DLBCL	2	Nª	Refractory	100 x 10 <sup>6</sup>	1	N	N	N	N	Ŀ
	4	DLBCL/tMZL	4	N	Refractory	100 x 10 <sup>6</sup>	1	N	Υ	N	Υ	F
	5	MZL	4	N	Refractory	300 x 10 <sup>6</sup>	2	N	Υ	N	Υ	t
DOSE LEVEL 2	6	DLBCL	4	Υ	Refractory	300 x 10 <sup>6</sup>	1	N	N	N	N	F
	7	DLBCL/tFL	6	Υ	Relapsed	300 x 10 <sup>6</sup>	1*	N*	N*	N*	N*	C

\*Data cutoff date of November 13, 2023; represents data verified post data cut  $^{\rm a.}$  CAR T manufacturing failure



## ASH case study: Dose level 1 patient with 6-month durable complete response<sup>^</sup>

Multiple Doses of CNTY-101, an iPSC-Derived Allogeneic CD19 Targeting CAR-NK Product, are Safe and Result in Tumor Microenvironment Changes
Associated with Response: A Case Study

Indu Ramachandran¹, Sarah Rothman¹, Mariano Clausi¹, Kile McFadden¹, Brenda Salantes¹, Gloria Jih¹, Thomas Brigman¹, Sam Kelly¹, Matthew S. Hall¹, Stephanie Yee Iphigenia Koumenis¹, Poulomee Das¹, Jordan Briggs², Tori Braun², Ying Yuan³, Elizabeth Devlin¹, Adrienne Farid¹, Nikolaus Trede¹, Tamara K. Moyo⁵, Tahir Latif⁴, Krish Patel²

<sup>1</sup>Century Therapeutics, Philadelphia, PA <sup>2</sup>Swedish Cancer Institute, Seattle, WA <sup>3</sup>MD Anderson Cancer Center, Houston, TX <sup>4</sup>Atrium Health Levine Cancer Institute, Charlotte NC <sup>5</sup>University of Cincinnati Medical Center, Cincinnati, OH



Sex/Age: Female/63 Tumor Subtype: Follicular Lymphoma Dose/Schedule: 100e6 cells x 1 per cycle (Dose Level 1; Schedule A)

#### **Prior Therapy:**

- 4 prior lines of therapy including anti-CD20, bispecific, and investigational therapy
- High-risk R/R Relapsed within 12 months of starting R-CHOP

Additional Initial Additional Additional Additional Additional Additional Dose Cycle 1 Cycle 2 Cycle 3 Cycle 4 Cycle 5 Cycle 6 lympholymphodepletion depletion No IL-2 IL-2 IL-2 IL-2 IL-2 IL-2 No lymphodepletion

IL-2: subcutaneous 3e6 IU for 8 days, except for initial cycle

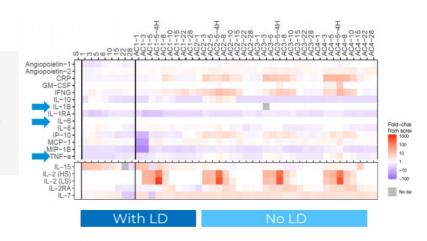
\*Data cutoff date of November 13, 2023; represents data verified post data cut ^Patient subsequently progressed Ramachandran, et al. 2023 ASH Annual Conference



## ASH case study: Favorable initial safety profile

## Safety profile in first 7 subjects:

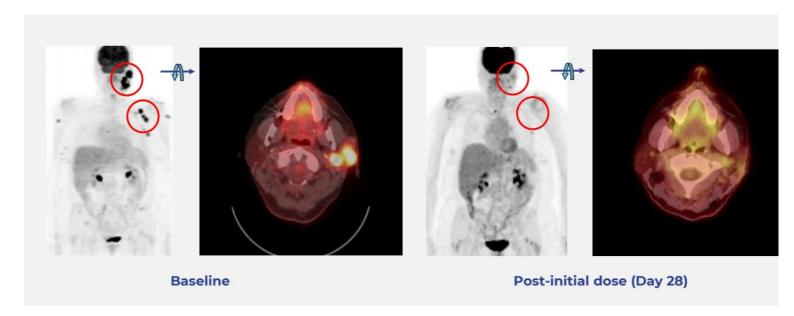
- No DLTs, no CRS, no ICANS
- No AEs related to CNTY-101
- Factors associated with CRS and neurotoxicity were not significantly elevated
- Elevation in peripheral IL-2 is observed, coinciding with IL-2 administration



\*Data cutoff date of November 13, 2023; represents data verified post data cut AC: Additional Cycle Ramachandran, et al. 2023 ASH Annual Conference



## ASH case study: Early evidence of anti-lymphoma activity with durable 6-month complete response<sup>^</sup>



^Patient subsequently progressed Ramachandran, et al. 2023 ASH Annual Conference



## ASH case study: CNTY-101 persists outside of circulation and humoral immunogenicity is not detected

PK shows CNTY-101 cells traffic out of circulation shortly after infusion; consistent levels at 1 hour post-infusion are observed with and without LD

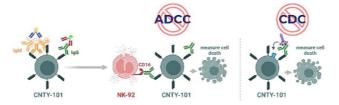
CNTY-101 cells persist in tissues for at least three days as measured cfDNA; consistent CNTY-101 cfDNA levels are observed with and without LD at Day 3





Detectable signal [+] was determined to be significantly above negative controls using sample Poisson test, p < 0.05; transgene copies detected in 1 mL of plasma is indicate

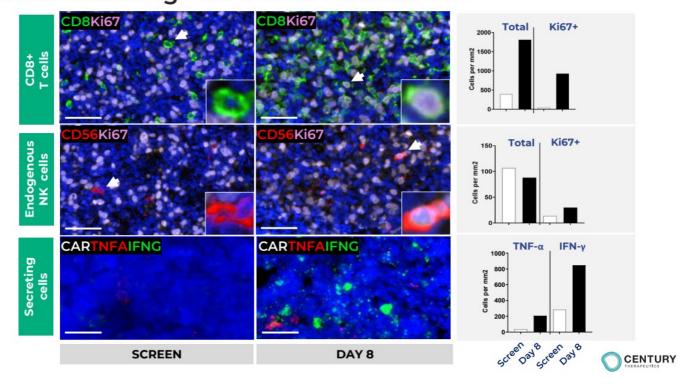
Anti-drug antibodies and functional humoral immune response against CNTY-101 are not detected (five cycles evaluated)



cfDNA: cell-free DNA, LD: lymphodepletion Romachandran, et al. 2023 ASH Annual Conference



## ASH case study: Intra-tumoral adaptive immune response observed following initial dose without IL-2



## Summary of ELiPSE-1 data

- · Heavily pretreated and refractory patient population treated in first-in-human dose escalation t
- · Favorable safety profile; can be delivered in an outpatient setting
- · Encouraging early efficacy signals at lowest dose levels
  - o 2 patients achieving CR, including 1 patient with 6-month durable CR
- No evidence of allo-rejection
- Initial data for CNTY-101 supports the potential for Allo-Evasion™ to enable a multidosing regimen without the need for continued lymphodepletion
- We believe CNTY-101's manageable initial safety profile, initial response data, and PK/PD supports advancing to higher doses to potentially deepen and prolong clinical response

Cohorts of 1 billion cells/1 monthly dose and 300 million/weekly x 3 doses are open;
Additional clinical data expected in mid-2024





## CNTY-101 in Systemic Lupus Erythematosus

## Opportunity in systemic lupus erythematosus to improve long-term disease control

### Estimated global prevalence of 3.4 million patients1

- Abnormal B cell function and autoantibody production are central to disease pathogenesis
- Major causes of morbidity and mortality involve multiple systems
  - o Renal, CNS and cardiovascular involvement are major causes of morbidity and mortality

### Despite approved treatments, significant unmet need remain

- Chronic treatment with broad-acting anti-inflammatory and immunosuppressives
- Current treatments fail to significantly impact morbidity in the moderate to severe population
- Treatment toxicity and disease flares remain common

### Autologous anti-CD19 CAR T cell therapies have established a promising efficacy proof of concept in SLE<sup>2</sup>

 Challenges remain due to potential exposure to CRS and ICANS, produ availability, and long-term risks including B-cell aplasia

Tian J, et al. Ann Rheum Dis 2023;82:351-356 http://dx.doi.org/10.1136/ard-2022-223035
 Mackensen A, et al. Nature Medicine 2022 28:10 (2124-2132) https://doi.org/10.1038/s41591-022-02017-5
 CNS: central nervous system, SLE: systemic lupus erythematosus



## CNTY-101 aims to eliminate pathogenic B-cells in SLE leading to remission via repeat dosing facilitated by Allo-Evasion<sup>TM</sup>

Aim: Safely provide immune reset with an immediately available therapy



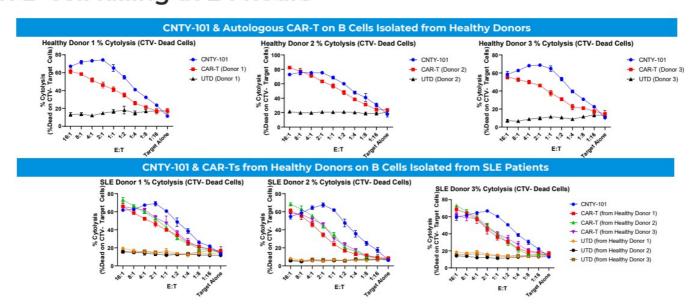
### CNTY-101 has the potential to improve on current SLE treatments

- Anti-CD19 CAR-iNK cells derived from an HDR precision-edited iPSC clone, including IL-15 cytokine support, a safety switch, and Allo-Evasion™ edits
- · Clonal, consistent, well-characterized product
- · Available off-the-shelf, without requiring patient apheresis, no manufacturing wait time
- · Favorable initial safety profile, allowing for outpatient treatment
- · Ability to be redosed without lymphodepletion, while avoiding allo-rejection based on initial data
- · Potential to enable B cell depletion and a reduction in auto-antibodies without prolonged B-cell aplasia

HDR: homology-directed repair



## CNTY-101 initial clinical data comparable to primary CAR-T cel at B-cell killing at 24 hours



CNTY-101 cells show similar potency to primary CAR-T cells in preclinical comparison

Isolated B cells or CD19+ target cells were co-cultured with CNTY-101 or primary CAR-T at several E:Ts in 96-well U bottom plates in NKCM with assay harvested at 24h



## CNTY-101: Systemic lupus erythematosus Phase 1 study

#### Inclusion:

Patients with moderate to severe SLE after
 2+ standard immunosuppressive therapies

#### **Endpoints:**

- Key endpoints: safety, SLE manifestations per SLEDAI, LLDAS, De
- Translational Endpoints: B-cell depletion, auto-antibody decline



LYMPHO-DEPLETION

**Initial Dose** 

Additional Cycle
No lymphodepletion

DAY 1
DAY 8
DAY 15

RESPONS ASSESSMEN Months 2-

#### **Schedule**

- Dose level 1: 300e6
- Dose level 2: 1000e6











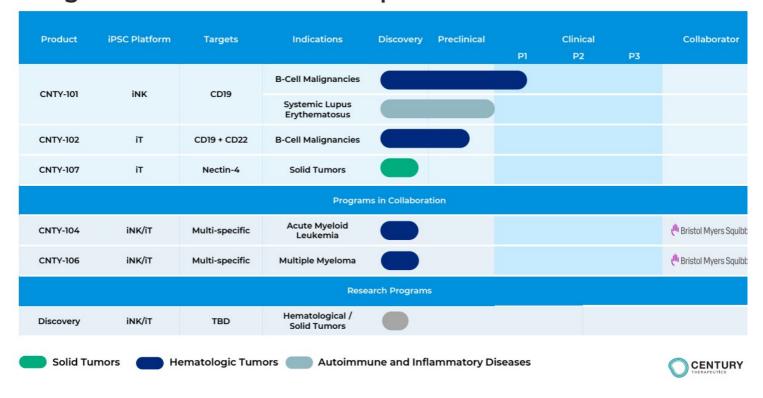


Trial planned to initiate in the first half of 2024; initial data expected by year-end 2024

 $^1$  Standard lymphodepletion regimen: fludarabine (30 mg/m2/d) and cyclophosphamide IV (300 mg/m2/d) for 3 days



## Century Therapeutics pipeline of iPSC-derived allogeneic NK and T cell therapies





Closing

## Century Therapeutics: Building an industry-leading, nextgeneration allogeneic iPSC-derived cell therapy platform

LIMITLESS POTENTIAL...

PRECISION DESIGN...

**ENDURING IMPACT...** 

Foundational investments in iPSC technolog genetic editing, and manufacturing

Progressing multiple clinical programs in oncology and autoimmune and inflammator diseases

Well-capitalized into 2026 to enable delivery on key milestones and clinical data



## **Q&A** participants

Brent Pfeiffenberger, Pharm.D., Chief Executive Officer
Hy Levitsky, M.D., President of Research and Development
Nick Trede, M.D., Ph.D., SVP, Head of Clinical Development
Adrienne Farid, Ph.D., Chief Operations Officer and Head of Early Development
Michael Diem, M.D., Chief Financial Officer
Greg Russotti, Ph.D., Chief Technology and Manufacturing Officer



