Century Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 5, 2024

– Expansion of Phase 1 CALiPSO-1 trial of CNTY-101 in autoimmune disease to include diffuse cutaneous systemic sclerosis and idiopathic inflammatory myopathy –

– Overall response rate (ORR) of 83% observed at CNTY-101 Dose Level 3B alongside a favorable safety profile in patients with r/r B-cell lymphomas in Phase 1 ELiPSE-1 study –

– CNTY-101 shows persistence upon repeated cell dosing at Dose Level 3B, consistent with the anticipated protective activity of Century's proprietary Allo-Evasion™ technology –

– Ended third quarter 2024 with cash, cash equivalents, and investments of $244.7 million; organizational efficiencies extend expected cash runway into second half of 2026 –

PHILADELPHIA, Nov. 05, 2024 (GLOBE NEWSWIRE) -- Century Therapeutics, Inc. ("Century", NASDAQ: IPSC), an innovative biotechnology company developing induced pluripotent stem cell (iPSC)-derived cell therapies in immuno-oncology and autoimmune disease, today reported financial results and business highlights for the third quarter ended September 30, 2024.

"Broadening our strategic focus in autoimmune indications to include idiopathic inflammatory myopathy and diffuse cutaneous systemic sclerosis will give us greater insight into the potential of CNTY-101 in an underserved therapeutic category that we believe is uniquely suited to allogeneic iNK cell therapies. Our confidence in the application of CNTY-101 in autoimmune diseases continues to be reinforced by the Phase 1 ELiPSE-1 trial in patients with r/r B-cell lymphomas where updated interim data shows increased overall response rates at higher doses and observations of deepening responses with additional cycles, alongside a continued favorable safety profile," said Brent Pfeiffenberger, Pharm.D., Chief Executive Officer of Century Therapeutics. "The advancement of our pre-clinical pipeline across multiple cell types is similarly promising, as highlighted by what we believe to be the industry-first presentation of iPSC-derived CD4+ and CD8+ CAR T cells that demonstrate αβ-like T cell function at the upcoming American Society of Hematology Annual Meeting. Building on this progress, we are conducting a strategic review of Century's pre-clinical pipeline and expect to announce the outcome in the first quarter of 2025. We have recently refined our organizational structure to enhance ongoing efficiencies and program alignment. On behalf of everyone here at Century, I'd like to thank departing colleagues for their important contributions to building the company's programs and technology. Supported by extended cash runway from these changes, we remain focused on execution in the period ahead and look forward to delivering our next set of potential catalysts."

Research & Development Highlights

- Consistent with Century's commitment to expand investigation of autoimmune disease indications during the second half of 2024, the company recently amended the Phase 1 CALiPSO-1 trial of CNTY-101 (NCT06255028) and Investigational New Drug (IND) application to include evaluation of idiopathic inflammatory myopathy (IIM) and diffuse cutaneous systemic sclerosis (dcSSc). This builds upon earlier alignment with the U.S. Food and Drug Administration to expand clinical development to lupus nephritis (LN) in addition to systemic lupus erythematosus (SLE). With the implementation of this amendment, CALiPSO-1 consists of a basket protocol study design, with four arms designed to evaluate the safety and preliminary efficacy of CNTY-101. The study will enroll participants ≥17 years old with refractory B-cell-mediated autoimmune diseases following an inadequate response to at least two lines of prior standard of care immunosuppressive therapies, now including those with moderate to severe IIM and dcSSc with treatment-resistant and active disease alongside those with moderate to severe SLE with or without LN. Century has activated multiple clinical sites in the United States, and expects to activate additional sites in the coming months, with ability to enroll patients across indications. To further facilitate enrollment, the company plans to expand trial sites to select European countries. Century will provide updated timing on initial clinical data from CALiPSO-1 once a clear cadence of patient enrollment has been established across indications.

- Updated interim clinical data from Century's ongoing Phase 1 ELiPSE-1 study evaluating CNTY-101 (NCT05336409) in relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) has shown increased overall response rates at higher doses and observations of deepening responses with additional cycles alongside a favorable safety profile, building on encouraging interim data previously presented at the 2024 American Society of Clinical Oncology Annual Meeting. As of the data snapshot October 15, 2024, eight additional participants have been treated with CNTY-101 for a total of 20 participants evaluable for safety and 19 for preliminary efficacy. Treatment with CNTY-101 continued to be safe and generally well tolerated with no dose-limiting toxicities reported, no additional cases of immune effector cell-associated neurotoxicity syndrome (ICANS), and no Grade 3 or higher cytokine release syndrome (CRS). Consistent with the manageable safety profile observed to date, a majority of participants received CNTY-101 infusions in an outpatient setting. Dose level DL3B (1 billion cells in each of three weekly doses per cycle), which represents the largest single trial cohort

(n=6), has shown an overall response rate (ORR) of 83% and a complete response rate (CRR) of 33%, with all participants receiving additional cycles of treatment.

A dose-dependent increase in CNTY-101 exposure was observed as evaluated by a novel pharmacokinetics cell-free DNA (cfDNA) method for detecting total body presence of CNTY-101. Preliminary cfDNA data from Schedule B (three weekly CNTY-101 infusions per cycle) showed that in cycles starting with lymphodepletion, a similar level of exposure was observed between the first and third infusion when the patients' endogenous T and NK cells had recovered. This supports persistence upon repeated cell dosing, consistent with the anticipated protective activity of Century's proprietary Allo-Evasion™ technology.

Efficient B-cell depletion was observed in all participants treated with CNTY-101 who had measurable circulating B cells at baseline. Evaluable re-emergent B cells (N=4 participants) were enriched for naive subtypes with minimal class-switched memory subsets detected. This profile in re-emergent B cells has been associated with SLE responses after CD19 cell therapy treatment, which we believe further supports application of CNTY-101 in the CALiPSO-1 study. Based on favorable safety and encouraging early efficacy data at DL3B, Century is proceeding with DL4B (3 billion cells in each of three weekly doses per cycle), and recently treated the first participant at this dose. The company expects to provide updated clinical data by mid-2025.

Further details pertaining to the ELiPSE-1 data update can be found in Century's corporate presentation housed on the investor relations section of the website.

- Century separately announced the acceptance of five poster presentations at the upcoming 66th American Society of Hematology Annual Meeting to be held in San Diego, CA from December 7-10, 2024. The presentations include demonstration of pre-clinical function comparable to autologous T cells by allogeneic iPSC-derived CD4+ and CD8+ CAR T cells, alongside additional innovations that highlight the engineerability of the iPSC-derived immune effector cells, a core benefit of the company's platform. These include data from advanced CAR endo-domains that improved cytotoxicity and persistence, enhanced Allo-Evasion™ via a novel CD300a TASR that demonstrated universal protection from NK cells, and differentiation stage specific promoters that allow for selective control of gene expression.

Business Highlights

- Following the integration of Clade Therapeutics, Century is conducting a strategic review of the pre-clinical pipeline to leverage the unique capabilities and technologies at Century towards high-value and differentiated programs. The company expects to conclude and communicate the results of this review in the first quarter of 2025. As part of this review, in October, Century implemented changes to the organization structure including elimination of overlapping technical and research capabilities to enhance ongoing efficiencies and alignment with the company's key programs. With these changes, Century has extended expected cash runway into the second half of 2026.

- In September 2024, Century announced the appointments of Morgan Conn, Ph.D., as Chief Financial Officer and Chad Cowan, Ph.D., as Chief Scientific Officer. The company also announced the transition of Hy Levitsky, M.D., President of Research and Development, from operational duties to serve as an advisor to Century.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $244.7 million as of September 30, 2024, as compared to $261.8 million as of December 31, 2023. Net cash used in operations was $85.9 million for the nine months ended September 30, 2024, compared to net cash used in operations of $62.1 million for the nine months ended September 30, 2023.

- **Collaboration Revenue:** Collaboration revenue generated through the company's collaboration, option, and license agreement with Bristol-Myers Squibb was $0.8 million for the three months ended September 30, 2024, compared to $0.1 million for the same period in 2023.

- **Research and Development (R&D) expenses**: R&D expenses were $27.2 million for the three months ended September 30, 2024, compared to $22.8 million for the same period in 2023. The increase in R&D expenses was primarily due to progression of the ELiPSE-1 trial and start-up costs of the CALiPSO-1 trial, increased manufacturing activity for CNTY-101, and the acquisition of Clade Therapeutics.

- **General and Administrative (G&A) expenses**: G&A expenses were $8.4 million for the three months ended September 30, 2024, compared to $9.0 million for the same period in 2023.

- **Net loss**: Net loss was $31.2 million for the three months ended September 30, 2024, compared to $32.7 million for the three months ended September 30, 2023.

Financial Guidance

- The company expects full year generally accepted accounting principles (GAAP) operating expenses to be between $150 million and $160 million.
- The company estimates its cash, cash equivalents, and investments will support operations into the second half of 2026.

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.

About Idiopathic Inflammatory Myopathy

Idiopathic inflammatory myopathies (IIM) include a heterogenous group of rare disorders including dermatomyositis and polymyositis in which the immune system attacks muscle and frequently the lungs, skin, joints, and gastrointestinal tract. IIM can cause weakness, pain, and lung failure which can lead to chronic disability and potentially mortality. With a prevalence of at least 60,000 people in the US, significant unmet need in IIM stems from the limited efficacy of current therapies, as corticosteroids and immunosuppressants often fail to halt disease progression. Additionally, these treatments carry significant side effects, including increased infection risk and long-term complications. A lack of targeted therapies and reliable biomarkers for early diagnosis complicates disease management and underscores the urgent need for better treatment options and personalized care approaches.

About Systemic Sclerosis

Systemic sclerosis (SSc), a type of scleroderma, is a chronic autoimmune disease characterized by inflammation and hardening with tightening of the skin and internal organs such as the lungs, heart, and gut, leading to life-threatening complications. Over half of people with SSc develop lung fibrosis, a leading cause of death. SSc, which affects at least 80,000 people in the US, typically appears between the ages of 30 and 50. A third of this patient population has diffuse cutaneous systemic sclerosis, the most severe and rapidly progressing disease subtype. There is no cure for SSc, and current therapies focus on managing symptoms and slowing disease progression. Medications like immunosuppressants, vasodilators, and antifibrotic agents may help, but often come with significant side effects. Furthermore, treatment response varies between people, and organ damage may be irreversible by the time of diagnosis, making early detection and intervention crucial.

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 and 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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Century Therapeutics, Inc
Condensed Balance Sheets
(unaudited, in thousands)

Assets	**September 30, 2024**	**December 31, 2023**
Current Assets:	**$**	**$**
Cash and cash equivalents	52,593	47,324
Short-term investments	145,519	125,414
Prepaid expenses and other current assets	7,897	4,256
Total current assets	206,009	176,994
Property and equipment, net	65,284	71,705
Operating lease right-of-use assets, net	28,828	20,376
Long-term investments	46,565	89,096
Goodwill	4,727	-
Intangible assets	33,800	-
Other long-term assets	3,404	2,520
Total assets	$ 388,617	$ 360,691
Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	**$** 2,598	**$** 2,741
Accrued expenses and other liabilities	13,653	10,733
Deferred revenue, current	3,569	4,372
Total current liabilities	19,820	17,846
Operating lease liability, noncurrent	50,837	46,658
Other long-term liabilities	20	56
Deferred revenue	109,768	111,381
Contingent consideration liability	8,983	-
Deferred tax liability	3,503	-
Total liabilities	192,931	175,941
Stockholders' equity		
Common stock	9	6
Additional paid-in capital	941,185	840,407
Accumulated deficit	(746,266)	(655,771)
Accumulated other comprehensive loss	758	108
Total stockholders' equity	195,686	184,750
Total liabilities and stockholders' equity	$ 388,617	$ 360,691

Century Therapeutics, Inc
Condensed consolidated statements of operations
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Collaboration Revenue	$ 791	$ 148	$ 2,416	$ 1,967
Operating Expenses				
Research and development	27,228	22,788	77,869	70,414
General and administrative	8,352	8,986	25,400	26,117
In-process research and development	-	4,000	-	4,000
Impairment on long-lived assets	-	-	-	4,220
Total operating expenses	35,580	35,774	103,269	104,751
Loss from operations	(34,789)	(35,626)	(100,853)	(102,784)
Interest expense	-	-	-	(540)
Interest income	3,305	3,486	10,126	9,167
Other income, net	250	12	248	(368)
Loss before provision for income taxes	(31,234)	(32,128)	(90,479)	(94,525)
Benefit (provision) for income taxes	8	(592)	(14)	(2,750)
Net Loss	$ (31,226)	$ (32,720)	$ (90,493)	$ (97,275)
Unrealized gain (loss) on investments	1,075	(95)	622	1,157
Foreign currency translation adjustment gain (loss)	(8)	(2)	28	(1)
Comprehensive loss	$ (30,159)	$ (32,817)	$ (89,843)	$ (96,119)
Net loss per common share - Basic and Diluted	(0.37)	(0.55)	(1.18)	(1.65)
Weighted average common shares outstanding	84,704,352	59,448,229	76,394,266	59,087,374