Lineage Cell Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

November 9, 2023

- **Enrollment Continues in Phase 2a Clinical Study of RG6501 (OpRegen®) in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD) Under Management of Genentech, a Member of the Roche Group**
- **Additional RG6501 (OpRegen®) Data Presented at 23rd Annual EURETINA Congress and 2023 Eyecelerator Meetings**
- **U.S. Patent Issued Covering Manufacturing and Differentiation Process for Retinal Pigment Epithelial (RPE) Cells**
- **Company On Track to Submit OPC1 Investigational New Drug Amendment in Q4 2023**
- **Initiated Development Activities for Hypoimmune Pluripotent Cell Line for Neurology Indications Under Partnership with Eterna Therapeutics**

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 9, 2023-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported financial and operating results for the third quarter ended September 30, 2023 and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results and provide a business update.

“The Lineage team has continued to advance our clinical and preclinical pipeline of differentiated cell transplant programs, supporting our alliances and working to establish new collaborations,” stated Brian M. Culley, Lineage CEO. “The most important area of attention for our team remains our partnership with Roche and Genentech and our support for the ongoing Phase 2a clinical study of OpRegen in patients with geographic atrophy secondary to AMD. Through presentations at medical and scientific conferences, we have broadened awareness of OpRegen’s potential to provide durable anatomical and functional improvements in patients with GA. Most recently, additional observations of rapid improvements to outer retinal structure in the initial Phase 1/2a clinical study of OpRegen were reported; improvements were detectable within the first three months following a single administration, suggesting that OpRegen RPE cells may provide support to the patients’ remaining retinal cells within atrophic areas. Looking forward, we are working with our partners, Roche, and Genentech, on additional clinical data updates on the OpRegen program.”

“In addition, our team continued the necessary work to submit our Investigational New Drug amendment for OPC1 to enable us to initiate the DOSED clinical study in subacute and chronic spinal cord injury patients,” Mr. Culley added. “In parallel, we also initiated certain development activities under our partnership with Eterna Therapeutics, reflecting a key step in a corporate strategy to capitalize on our existing process development capabilities by combining them with cutting-edge cell engineering and editing technologies, to create novel and potentially superior product profiles. As always, we intend to advance our business and programs in a responsible and fiscally conservative way, with an overarching focus on providing a meaningful impact for patients through the development of differentiated allogeneic cell transplants.”

Recent milestones and activities included:

- **RG6501 (OpRegen)**
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a multi-center clinical study in patients with GA secondary to AMD. Additional sites expected to come online for the Phase 2a study.
  - Results of imaging analyses demonstrating rapid improvement in outer retinal structure from patients enrolled in the prior Phase 1/2a clinical study, were presented at the 23rd EURETINA Congress:
    - All five patients who had extensive coverage of the GA lesion with the surgical bleb containing OpRegen in suspension demonstrated evidence of improvement in outer retinal structure as assessed by optical coherence tomography (OCT) within the first three months after treatment.
      - Retinal structural improvements were initially observed on day 1 (n=1), day 14 (n=1), month 1 (n=2), and month 3 (n=1).
      - Structural improvement on OCT was qualitatively defined as meeting all pre-specified criteria on at least two non-adjacent B scans including: 1) reduction in outer plexiform layer (OPL) and/or inner nuclear layer (INL) subsidence; 2) reappearance of external limiting membrane (ELM); and 3) increased hyperreflectivity and/or thickness of RPE and/or Bruch’s membrane or reduction of hypertransmission on at least two non-adjacent B scans.
      - Structural improvement was only observed within GA lesions with extensive coverage with the surgical bleb, suggesting that OpRegen RPE cells provide support to the remaining retinal cells within atrophic areas.
      - These five patients had an average of 4.4 letter best corrected visual acuity (BCVA) gain by 3 months and 12.8 letter BCVA gain by 1 year compared to baseline.

- U.S. Patent No.11,746,324 entitled “Large Scale Production of Retinal Pigment Epithelial Cells,” issued.

- **Investigational New Drug (IND) amendment preparation for clinical testing of novel OPC1 spinal cord delivery system continues**
  - Company remains on track to submit IND amendment to FDA in Q4 2023 to enable initiation of the DOSED clinical study in subacute and chronic spinal cord injury patients.
- **Initiated Development Activities for Hypoimmune Pluripotent Cell Line for Neurology Indications Under Partnership with Eterna Therapeutics**
  - Lineage evaluated its development strategy with a group of leading neurology experts in the U.S. and abroad and following an assessment of the competitive landscape, finalized its selection of specific gene edits for the initial cell lines to be developed by Eterna.
    - The edits include: the targeted deletion of the B2M gene, designed to reduce the immunogenicity of product candidates derived from the lines by inhibiting rejection by CD8+ T cells; the targeted insertion of the HLA-E gene, designed to overexpress HLA-E and prevent the allogeneic NK cell response; and a third undisclosed edit intended to confer clinical differentiation and a competitive advantage in the applicable indications.
- **Positive ANP1 initial proof of concept results from collaboration with the University of Michigan**
  - Initial results demonstrated delivery, engraftment, and survival of ANP1 cells into specific target areas.
  - Results support advancement of the ANP1 program into functional preclinical testing.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $41.3 million as of September 30, 2023, which is expected to support planned operations into Q1 2025.

Third Quarter Operating Results

Revenues: Lineage’s revenue is generated primarily from licensing fees, royalties, collaboration revenues, and research grants. Total revenues for the three months ended September 30, 2023 were $1.2 million, a net decrease of $1.8 million as compared to approximately $3.0 million for the same period in 2022. The decrease was primarily driven by lower collaboration and licensing revenue recognized from deferred revenues from the Collaboration and License Agreement among Lineage and Roche and Genentech entered into in December 2021.

Operating Expenses: Operating expenses are comprised of research and development (“R&D”) expenses and general and administrative (“G&A”) expenses. Total operating expenses for the three months ended September 30, 2023 were $7.8 million, a decrease of $0.2 million as compared to $8.0 million for the same period in 2022.

R&D Expenses: R&D expenses for the three months ended September 30, 2023 were $3.7 million, a net increase of $0.1 million as compared to $3.6 million for the same period in 2022. The net increase was primarily driven by $0.2 million in higher OPC1 program-related expenses, and $0.5 million in expenses to support preclinical and other research and development programs. These increases were partially offset by a $0.5 million decrease in our VAC program, primarily related to reduced manufacturing activities.

G&A Expenses: G&A expenses for the three months ended September 30, 2023 were $4.0 million, a net decrease of approximately $0.4 million as compared to $4.4 million for the same period in 2022. The decrease was primarily attributable to an overall reduction in costs incurred for services by third parties, consulting costs, and recruiting related expenses.

Loss from Operations: Loss from operations for the three months ended September 30, 2023 was $6.7 million, an increase of $1.5 million as compared to a loss of $5.2 million for the same period in 2022.

Other Income/(Expenses), Net: Other income (expenses), net for the three months ended September 30, 2023 reflected other expense, net of approximately ($0.4) million, compared to other expense, net of ($0.3) million for the same period in 2022. The net change was primarily driven by exchange rate fluctuations related to Lineage’s international subsidiaries and fair market value changes in marketable equity securities, partially offset by interest income from our marketable debt securities.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended September 30, 2023 was $7.1 million, or $0.04 per share (basic and diluted), compared to a net loss attributable to Lineage of $6.1 million, or $0.04 per share (basic and diluted), for the same period in 2022.

Conference Call and Webcast

Interested parties may access today’s conference call and webcast, by dialing (800) 715-9871 from the U.S. and Canada and should request the “Lineage Cell Therapeutics Call”. A live webcast of the conference call will be available online in the Investors section of Lineage’s website. A replay of the webcast will be available on Lineage’s website for 30 days and a telephone replay will be available through November 16, 2023, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 2323932.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage’s programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage’s clinical and preclinical programs are in markets with billion dollar opportunities and include five allogeneic (“off-the-shelf”) product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development for the treatment of geographic atrophy secondary to age-related macular degeneration, is being

developed under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage. For more information, please visit www.lineagecell.com or follow the company on Twitter @LineageCell.

Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "aim," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to: the potential benefits of OpRegen and the expansion of the Phase 2a clinical study of OpRegen to additional clinical sites; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the first quarter of 2025; the timing of anticipated regulatory submissions to the FDA related to our programs, the potential future achievements of our clinical, preclinical and development programs, the initiation of clinical trials and the timing and availability of clinical data updates related to our programs; plans and expectations regarding existing collaborations; and the potential of our cell therapy platform and our ability to provide an meaningful impact for patients. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, but not limited to, the following risks: that we may need to allocate our cash to unexpected events and expenses causing us to use our cash, cash equivalents and marketable securities more quickly than expected; that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; that OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients, that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not successfully advance OpRegen or be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that the feedback received from the FDA for OPC1 may not enable further clinical development; that the ongoing Israel-Hamas war may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those risks and uncertainties inherent in Lineage's business and other risks discussed in Lineage's filings with the Securities and Exchange Commission (SEC). Lineage's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports with the SEC, including Lineage's most recent Annual Report on Form 10-K filed with the SEC and its other reports, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 31,474	$ 11,355
Marketable securities	9,858	46,520
Accounts receivable, net	432	297
Prepaid expenses and other current assets	1,717	1,828
Total current assets	43,481	60,000
NONCURRENT ASSETS		
Property and equipment, net	4,854	5,673
Deposits and other long-term assets	552	627
Goodwill	10,672	10,672
Intangible assets, net	46,594	46,692
TOTAL ASSETS	$ 106,153	$ 123,664
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 5,030	$ 8,608
Lease liabilities, current portion	881	916
Financing lease, current portion	55	36
Deferred revenues	9,915	9,421
Total current liabilities	15,881	18,981

LONG-TERM LIABILITIES		
Deferred tax liability	273	2,076
Deferred revenues, net of current portion	21,195	27,725
Lease liability, net of current portion	2,047	2,860
Financing lease, net of current portion	97	84
Other long-term liabilities	-	2
TOTAL LIABILITIES	39,493	51,728
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common shares, no par value, 450,000 and 250,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 174,987 and 170,093 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	450,282	440,280
Accumulated other comprehensive loss	(2,084)	(3,571)
Accumulated deficit	(380,081)	(363,370)
Lineage Cell Therapeutics, Inc. shareholders' equity	68,117	73,339
Noncontrolling deficit	(1,457)	(1,403)
Total shareholders' equity	66,660	71,936
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 106,153	$ 123,664

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(UNAUDITED)

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	**2022**	**2023**	**2022**
REVENUES:				
Collaboration revenues	$ 957	$ 2,592	$ 5,949	$ 11,605
Royalties and license fees	289	406	908	1,183
Total revenues	1,246	2,998	6,857	12,788
Cost of sales	(169)	(235)	(415)	(626)
Gross profit	1,077	2,763	6,442	12,162
OPERATING EXPENSES:				
Research and development	3,741	3,592	11,799	9,883
General and administrative	4,041	4,422	13,014	18,160
Total operating expenses	7,782	8,014	24,813	28,043
Loss from operations	(6,705)	(5,251)	(18,371)	(15,881)
OTHER INCOME (EXPENSES):				
Interest income, net	433	384	1,225	435
Loss on marketable equity securities, net	(60)	(233)	(170)	(1,677)
Gain on revaluation of warrant liability	-	-	1	223
Other expenses, net	(826)	(475)	(1,253)	(2,550)
Total other income (expenses), net	(453)	(324)	(197)	(3,569)
LOSS BEFORE INCOME TAXES	(7,158)	(5,575)	(18,568)	(19,450)
Provision for income tax benefit (expense)	-	(541)	1,803	(541)
NET LOSS	(7,158)	(6,116)	(16,765)	(19,991)
Net loss attributable to noncontrolling interest	48	47	54	72
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (7,110)	$ (6,069)	$ (16,711)	$ (19,919)
NET LOSS PER COMMON SHARE:				

Basic and Diluted	$ (0.04)	$ (0.04)	$ (0.10)	$ (0.12)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic and Diluted	174,868	169,786	171,880	169,722

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Nine Months ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (16,711)	$ (19,919)
Net loss allocable to noncontrolling interest	(54)	(72)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash (used in) provided by operating activities:		
Loss on marketable equity securities, net	170	1,677
Accretion of income on marketable debt securities	(647)	(186)
Depreciation expense, including amortization of leasehold improvements	419	441
Change in right-of-use assets and liabilities	86	(24)
Amortization of intangible assets	98	113
Stock-based compensation	3,580	3,328
Gain on revaluation of warrant liability	(1)	(223)
Deferred income tax benefit	(1,803)	-
Foreign currency remeasurement and other loss	1,893	2,668
Changes in operating assets and liabilities:		
Accounts receivable, net	(141)	50,206
Prepaid expenses and other current assets	56	517
Accounts payable and accrued liabilities	(3,456)	(17,573)
Deferred revenue and other liabilities	(6,036)	(11,591)
Net cash (used in) provided by operating activities	(22,547)	9,362
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	196	-
Purchases of marketable debt securities	(16,403)	(40,628)
Maturities of marketable debt securities	53,497	-
Purchase of equipment	(583)	(429)
Net cash provided by (used in) investing activities	36,707	(41,057)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	88	506
Common shares received and retired for employee taxes paid	(37)	(17)
Proceeds from exercise of subsidiary warrants, net	-	991
Proceeds from sale of common shares	6,625	148
Payments for offering costs	(199)	(95)
Repayment of financing lease liability	(41)	(23)
Net cash provided by financing activities	6,436	1,510
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(532)	(795)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	20,064	(30,980)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	11,936	56,277
At end of the period	$ 32,000	$ 25,297

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