Lineage Cell Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 7, 2024

- **Advanced OpRegen® For Dry AMD in Phase 2a Study in Collaboration with Roche and Genentech**
- **Closed $14 Million Registered Direct Offering**
- **OPC1 Investigational New Drug Amendment Cleared; New Clinical Trial Planned**
- **Initiated Development of Hypoimmune iPSC Cell Line for Neurology Indications Under Gene Editing Collaboration with Eterna Therapeutics**
- **Added to Russell 3000® Index**
- **Established 1st Annual Spinal Cord Injury Investor Symposium**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 7, 2024-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported its fourth quarter and full year 2023 financial and operating results and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results and provide a business update.

"Throughout 2023, our team has continued to advance our clinical and preclinical pipeline of differentiated cell transplant programs," stated Brian M. Culley, Lineage CEO. "The most important area of attention has remained our partnership with Roche and Genentech and the support we provide to the ongoing Phase 2a clinical study of OpRegen in patients with geographic atrophy secondary to AMD. With the recent clearance of our IND amendment for OPC1, we are excited for the opportunity to return this program back into the clinic in both subacute and, for the first time, chronic spinal cord injury patients. Following the closing of our recent financing, a transaction conducted without a discount or warrants, our balance sheet has been strengthened, which will help us advance our programs and reach important milestones this year that can help provide a meaningful impact for patients."

2023 Select Development Highlights

- **RG6501 (OpRegen)**
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a clinical study in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
  - Long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen:
    - Positive clinical data presented at 2023 Eyecelerator, 23rd EU RETINA Congress, and 2023 ARVO Annual Meetings.
  - U.S. Patent No.11,746,324 entitled "Large Scale Production of Retinal Pigment Epithelial Cells," issued.
- **OPC1**
  - Submitted an Investigational New Drug Amendment (INDa) for OPC1 for the treatment of chronic and subacute spinal cord injury to enable initiation of DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study in subacute and chronic spinal cord patients. INDa clearance from the U.S. Food and Drug Administration announced in February 2024.
  - Received CIRM grant to support the 1st Annual Spinal Cord Injury Investor Symposium, hosted in partnership with the Christopher & Dana Reeve Foundation.
- **Preclinical Programs**
  - Reported 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, supporting advancement of program into functional preclinical testing.
  - Initiated development activities for hypoimmune pluripotent cell line for neurology indications under collaboration with Eterna Therapeutics.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities of $35.5 million as of December 31, 2023, together with the approximate $13.8 million in net proceeds from the registered direct offering of our common shares completed in February 2024, is expected to support planned operations into Q3 2025.

Fourth Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from collaboration revenues and royalties. Total revenues for the three months ended December 31, 2023 were approximately $2.1 million, a net increase of $0.2 million as compared to $1.9 million for the same period in 2022.

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 December 31, 2023 were $8.2 million, a decrease of $0.3 million as compared to $8.5 million for the same period in 2022.

R&D Expenses: R&D expenses for the three months ended December 31, 2023 were $3.9 million, a decrease of $0.2 million as compared to $4.1 million for the same period in 2022. The net decrease was primarily driven by $0.2 million in OpRegen program expenses and $0.4 million for other research and development expense programs, partially offset by $0.2 million in OPC1 program expenses and $0.2 million for preclinical programs.

G&A Expenses: G&A expenses for the three months ended December 31, 2023 of $4.3 million were in line with expenses for the same period in 2022.

Loss from Operations: Loss from operations for the three months ended December 31, 2023 was $6.4 million, a decrease of $0.2 million as compared to $6.6 million for the same period in 2022.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended December 31, 2023 reflected other income of $1.6 million, compared to other income 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.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended December 31, 2023 was $4.8 million, or $0.03 per share (basic and diluted), compared to a net loss of $6.4 million, or $0.03 per share (basic and diluted), for the same period in 2022.

Full Year Operating Results

Revenues: Lineage's revenue is generated primarily from licensing fees, collaboration revenues, royalties, and research grants. Total revenues for the year ended December 31, 2023 were $8.9 million, a decrease of $5.8 million as compared to $14.7 million for the same period in 2022. The decrease was primarily driven by lower collaboration and licensing revenue recognized from deferred revenues under the collaboration and license agreement with Roche.

Operating Expenses: Operating expenses are comprised of R&D expenses and G&A expenses. Total operating expenses for the year ended December 31, 2023 were $33.0 million, a decrease of $3.5 million as compared to $36.5 million for the same period in 2022.

R&D Expenses: R&D expenses for the year ended December 31, 2023 were $15.7 million, an increase of $1.7 million as compared to $14.0 million for the same period in 2022. The increase was primarily driven by $0.4 million in OpRegen program expenses, $1.2 million in OPC1 program expenses, and $2.0 million in preclinical programs. These increases were partially offset by $1.9 million in other research and development programs, primarily related to reduced manufacturing activities.

G&A Expenses: G&A expenses for the year ended December 31, 2023 were $17.3 million, a decrease of approximately $5.2 million as compared to $22.5 million for the same period in 2022. The decrease was primarily attributable to $4.2 million in lower litigation and legal expenses, as well as an overall reduction in costs incurred for services provided by third parties, consulting costs, and rent-related expenses.

Loss from Operations: Loss from operations for the year ended December 31, 2023 was $24.7 million, an increase of $2.2 million as compared to $22.5 million for the same period in 2022.

Other Income/(Expenses), Net: Other income (expenses), net for the year ended December 31, 2023 reflected other income of $1.5 million, compared to other expense of ($3.3) million for the same period in 2022. The net change was primarily attributable to fluctuations in intercompany balances and related exchange rates applicable to Lineage's international subsidiaries, as well as fair market value changes in marketable equity securities.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the year ended December 31, 2023 was $21.5 million, or $0.12 per share (basic and diluted), compared to a net loss of $26.3 million, or $0.15 per share (basic and diluted), for 2022.

Conference Call and Webcast

Interested parties may access the conference call on March 7th, 2024, 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 March 14, 2024, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 8345585.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel or "off-the-shelf," cell therapies to address unmet medical needs. Lineage's programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient's functional activity. Lineage's neuroscience focused pipeline currently includes: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed in collaboration with Eterna Therapeutics Inc. For more information, please visit www.lineagecell.com or follow the company on X/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. Lineage’s forward-looking statements are based upon its current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. Such statements include, but are not limited to, statements relating to: the timing and availability of clinical data updates on the OpRegen program; the commencement of the DOSED clinical study for OPC1; that we will be able to continue to advance our business and programs in a responsible and fiscally conservative way; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the third quarter of 2025; 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 clinical trials of our product candidates may not commence, progress or be completed as expected due to many factors within and outside of our control; 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 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). 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. All forward-looking statements are expressly qualified in their entirety by these cautionary statements.

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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 35,442	$ 11,355
Marketable securities	50	46,520
Accounts receivable, net	745	297
Prepaid expenses and other current assets	2,204	1,828
Total current assets	38,441	60,000
NONCURRENT ASSETS		
Property and equipment, net	4,767	5,673
Deposits and other long-term assets	577	627
Goodwill	10,672	10,672
Intangible assets, net	46,562	46,692
TOTAL ASSETS	$ 101,019	$ 123,664
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 6,270	$ 8,608
Operating lease liabilities, current portion	830	916
Finance lease liabilities, current portion	52	36
Deferred revenues, current portion	10,808	9,421
Total current liabilities	17,960	18,981
LONG-TERM LIABILITIES		
Deferred tax liability	273	2,076
Deferred revenues, net of current portion	18,693	27,725
Operating lease liabilities, net of current portion	1,979	2,860
Finance lease liabilities, net of current portion	91	84
Other long-term liabilities	—	2
TOTAL LIABILITIES	38,996	51,728

SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of December 31, 2023 and 2022	—	—
Common shares, no par value, 450,000 and 250,000 shares authorized as of December 31, 2023 and 2022, respectively; 174,987 and 170,093 shares issued and outstanding as of December 31, 2023 and 2022, respectively	451,343	440,280
Accumulated other comprehensive loss	(3,068)	(3,571)
Accumulated deficit	(384,856)	(363,370)
Lineage's shareholders' equity	63,419	73,339
Noncontrolling deficit	(1,396)	(1,403)
Total shareholders' equity	62,023	71,936
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 101,019	$ 123,664

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

	Year Ended December 31,	
	2023	**2022**
REVENUES:		
Collaboration revenues	$ 7,588	$ 13,367
Royalties, license and other revenues	1,357	1,336
Total revenues	8,945	14,703
Cost of sales	(671)	(728)
Gross profit	8,274	13,975
OPERATING EXPENSES:		
Research and development	15,705	13,987
General and administrative	17,302	22,508
Total operating expenses	33,007	36,495
Loss from operations	(24,733)	(22,520)
OTHER INCOME (EXPENSES):		
Interest income, net	1,629	829
Loss on marketable equity securities, net	(176)	(2,194)
Gain on revaluation of warrant liability	2	225
Other expenses, net	(4)	(2,152)
Total other income (expenses), net	1,451	(3,292)
LOSS BEFORE INCOME TAXES	(23,282)	(25,812)
Provision for income tax benefit (expense)	1,803	(541)
NET LOSS	(21,479)	(26,353)
Net (income) loss attributable to noncontrolling interest	(7)	80
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (21,486)	$ (26,273)
NET LOSS PER COMMON SHARE ATTRIBUTABLE TO LINEAGE		
Basic and Diluted	$ (0.12)	$ (0.15)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		

Basic and Diluted	172,663	169,792

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

	Year Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (21,486)	$ (26,273)
Net income (loss) allocable to noncontrolling interest	7	(80)
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	176	2,194
Accretion of income on marketable debt securities	(679)	(501)
Depreciation expense, including amortization of leasehold improvements	562	582
Change in right-of-use assets and liabilities	91	(35)
Amortization of intangible assets	130	145
Stock-based compensation	4,640	4,287
Gain on revaluation of warrant liability	(2)	(225)
Deferred income tax benefit	(1,803)	—
Foreign currency remeasurement and other loss	602	2,272
Gain on sale of assets		(11)
Changes in operating assets and liabilities:		
Accounts receivable, net	(446)	50,314
Prepaid expenses and other current assets	(418)	446
Accounts payable and accrued liabilities	(2,295)	(18,702)
Deferred revenue	(7,645)	(13,354)
Net cash (used in) provided by operating activities	(28,566)	1,059
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	196	—
Purchases of marketable debt securities	(16,403)	(53,412)
Maturities of marketable debt securities	63,330	7,666
Purchase of equipment	(674)	(413)
Net cash provided by (used in) investing activities	46,449	(46,159)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	88	648
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)	(106)
Repayment of finance lease liabilities	(54)	(32)
Net cash provided by financing activities	6,423	1,632
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(250)	(873)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	24,056	(44,341)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	11,936	56,277
At end of the period	$ 35,992	$ 11,936

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