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

May 11, 2023

- **Additional RG6501 (OpRegen®) Phase 1/2a Clinical Study Results Presented at ARVO 2023**
- **Enrolling Phase 2a Clinical Study of RG6501 (OpRegen) in Patients with GA Secondary to AMD Under Management of Genentech, a Member of the Roche Group**
- **Awarded CIRM Grant to Support 1st Annual Spinal Cord Injury Investor Symposium**
- **Signed Option and License Agreement with Eterna Therapeutics to Develop Hypoimmune iPSC Lines**
- **Initiated Preclinical Testing of ANP1 for Treatment of Hearing Loss**

CARLSBAD, Calif.--(BUSINESS WIRE)--May 11, 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 first quarter ended March 31, 2023 and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results.

“During the first quarter of this year, the Lineage team executed on multiple fronts, advancing our clinical and preclinical cell transplant programs while continuing support of our existing alliances and establishing new ones,” stated Brian M. Culley, Lineage CEO. “A key area of focus was our partnership with Roche and Genentech and supporting the ongoing Phase 2a clinical study of OpRegen in patients with GA secondary to AMD, which is enrolling and treating patients at multiple sites in the U.S. Through presentations at various medical and scientific conferences, we also broadened our efforts to enhance awareness of OpRegen’s potential to provide durable anatomical and functional improvements in dry AMD patients. In addition, we established new collaborations with CIRM and the Christopher & Dana Reeve Foundation to support a new SCI conference which aims to identify, discuss, and address gaps in the product development process and elevate the patient’s voice in the treatment process. Looking ahead, we will be working on regulatory interactions for OPC1 while continuing to maintain our commitment to disciplined spending and making responsible investments in disease settings where we believe the use of differentiated cell transplants can provide a meaningful impact for patients.”

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 geographic atrophy (GA) secondary to age-related macular degeneration (AMD):
    - Additional sites expected to come online this year.
  - Long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen:
    - Preliminary evidence of durable anatomical and functional improvements following administration of OpRegen cells was presented at 2023 Association for Research in Vision and Ophthalmology Annual Meeting and other medical and scientific meetings.

- **Received CIRM grant to support 1st Annual Spinal Cord Injury Investor Symposium**

  - California Institute for Regenerative Medicine (CIRM) awarded Lineage an educational grant with a total award value of $50,000, recognizing this event as an important mission-specific conference, which will allow for the exchange of scientific information, create opportunities to accelerate the development of stem cell therapies to patients, increase the likelihood of successful treatments reaching patients, addresses an unmet clinical need, and can be impactful to CIRM’s overall mission.

- **Strengthened OPC1 intellectual property portfolio**

  - United States Patent and Trademark Office has granted a patent for the Company’s U.S. patent application No. 16/750,975, now U.S. Patent No. 11,603,518, entitled “Dorsally-Derived Oligodendrocyte Progenitor Cells From Human Pluripotent Stem Cells,” with claims covering proprietary manufacturing processes developed by Lineage for its oligodendrocyte progenitor cell therapy candidate (OPC1) for the treatment of spinal cord injury. The patent has a term that would expire no earlier than 2040.

- **Executed option and license agreement with Eterna Therapeutics**

  - Enables development of novel beta 2 microglobulin (B2M)-deficient iPSC lines, which Lineage will evaluate for development into differentiated cell transplant therapies, specifically for the treatment of certain central nervous system disorders and other neurology indications.

- **Initiated preclinical testing of ANP1**

    - Preclinical testing underway through a collaboration with the University of Michigan and Yehoash Raphael, Ph.D., The R. Jamison and Betty Williams Professor of Otolaryngology, Department of Otolaryngology-Head and Neck Surgery and Lab Director at the University of Michigan Kresge Hearing Research Institute.

Some of the events anticipated by Lineage include:

- Type B Meeting with FDA to discuss a proposed amendment to the Investigational New Drug Application (IND) for OPC1 to enable clinical testing of a novel spinal cord delivery system.

- Amendment of an IND for OPC1 to enable clinical testing of a novel spinal cord delivery system.

- Submission of an additional OPC1 manuscript describing magnetic resonance imaging (MRI) findings from the subacute studies in both thoracic and cervical spinal cord injury.

- Updates from ongoing ANP1 preclinical testing at the University of Michigan Kresge Hearing Research Institute under a collaboration with the University of Michigan.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $46.8 million as of March 31, 2023, which is expected to support planned operations into Q3 2024.

First 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 March 31, 2023 were approximately $2.4 million, a net decrease of $2.8 million as compared to $5.2 million for the same period in 2022. The decrease was driven by less collaboration and licensing revenue recognized from deferred revenues from the Roche Agreement.

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 March 31, 2023 were $8.9 million, a decrease of $2.5 million as compared to $11.4 million for the same period in 2022.

R&D Expenses: R&D expenses for the three months ended March 31, 2023 were $4.2 million, a net increase of $1.2 million as compared to $3.0 million for the same period in 2022. The net increase was primarily driven by $0.5 million for nonclinical-related expenses to support the OPC1 program, and $0.2 million in OpRegen program expenses to support the Roche collaboration. Another $0.4 million and $0.2 million of the increase was related to R&D spending on the new auditory neuron and photoreceptor cell therapy programs, respectively.

G&A Expenses: G&A expenses for the three months ended March 31, 2023 were $4.7 million, a net decrease of $3.7 million as compared to approximately $8.4 million for the same period in 2022. The decrease was primarily driven by $3.5 million in lower litigation and legal expenses, mostly due to the Asterias litigation settlement expense accrued in the prior year, and $0.2 million in lower expense for accounting and tax services.

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

Other Income/(Expenses), Net: Other income (expenses), net for the three months ended March 31, 2023 reflected other income, net of $0.4 million, compared to other expense, net of ($0.7) million for the same period in 2022. The net income was primarily driven by fair market value changes in marketable equity securities, interest income from our marketable debt securities, and other income recorded in the current period related to the employee retention credit program, partially offset by exchange rate fluctuations related to Lineage's international subsidiaries.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2023 was $4.4 million, or $0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of $7.1 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 May 18, 2023, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 8339383.

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 significance of the Phase 2a clinical study of OpRegen; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the third quarter of 2024; the timing and nature of events and milestones anticipated to occur in 2023, including plans and expectations regarding publications and presentations related to our programs, 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 availability of clinical data updates related to our programs; plans and expectations regarding existing collaborations, including our plans to develop new cell lines into differentiated cell transplant therapies and potential product candidates, and the potential indications thereof as a result of the Agreement with Eterna; our ability to broaden awareness of our mission, programs and accomplishments; 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 planned regulatory interaction with FDA for OPC1 may not enable further clinical development; that the SCIIS will not accelerate SCI research, clinical trials or product development; 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)

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 15,451	$ 11,355
Marketable securities	31,363	46,520
Accounts receivable, net	203	297
Prepaid expenses and other current assets	2,638	1,828
Total current assets	49,655	60,000
NONCURRENT ASSETS		
Property and equipment, net	5,584	5,673
Deposits and other long-term assets	635	627
Goodwill	10,672	10,672
Intangible assets, net	46,659	46,692
TOTAL ASSETS	$ 113,205	$ 123,664
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 5,252	$ 8,608
Lease liabilities, current portion	912	916
Financing lease, current portion	51	36
Deferred revenues	11,009	9,421
Other current liabilities	1	-
Total current liabilities	17,225	18,981
LONG-TERM LIABILITIES		
Deferred tax liability	273	2,076
Deferred revenues, net of current portion	24,017	27,725
Lease liability, net of current portion	2,542	2,860
Financing lease, net of current portion	133	84

Other long-term liabilities	-	2
TOTAL LIABILITIES	44,190	51,728
	-	
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Common shares, no par value, 250,000 shares authorized; 170,174 and 170,093 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	441,299	440,280
Accumulated other comprehensive loss	(3,107)	(3,571)
Accumulated deficit	(367,742)	(363,370)
Lineage Cell Therapeutics, Inc. shareholders' equity	70,450	73,339
Noncontrolling deficit	(1,435)	(1,403)
Total shareholders' equity	69,015	71,936
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 113,205	$ 123,664

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

	Three Months Ended March 31,	
	2023	**2022**
REVENUES:		
Collaboration revenues	$ 2,121	$ 4,865
Royalties	265	372
Total revenues	2,386	5,237
Cost of sales	(119)	(176)
Gross profit	2,267	5,061
OPERATING EXPENSES:		
Research and development	4,185	2,988
General and administrative	4,724	8,469
Total operating expenses	8,909	11,457
Loss from operations	(6,642)	(6,396)
OTHER INCOME (EXPENSES):		
Interest income, net	410	1
Unrealized gain (loss) on marketable equity securities	40	(735)
Gain on revaluation of warrant liability	1	221
Other expenses, net	(16)	(184)
Total other income (expenses), net	435	(697)
LOSS BEFORE INCOME TAXES	(6,207)	(7,093)
Deferred income tax benefit	1,803	-
NET LOSS	(4,404)	(7,093)
Net loss attributable to noncontrolling interest	32	6
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (4,372)	$ (7,087)
NET LOSS PER COMMON SHARE:		
BASIC	$ (0.03)	$ (0.04)
DILUTED	$ (0.03)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		

BASIC	170,127	169,647
DILUTED	170,127	169,647

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

	Three Months Ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (4,372)	$ (7,087)
Net loss attributable to noncontrolling interest	(32)	(6)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash (used in) provided by operating activities:		
Accretion of income on marketable debt securities	(326)	-
Unrealized (gain)/loss on marketable equity securities	(40)	735
Depreciation expense, including amortization of leasehold improvements	138	150
Amortization of intangible assets	33	28
Stock-based compensation	1,031	1,106
Deferred income tax benefit	(1,803)	-
Gain on revaluation of warrant liability	(1)	(221)
Foreign currency remeasurement	466	75
Changes in operating assets and liabilities:		
Accounts receivable, net	95	50,321
Prepaid expenses and other current assets	(847)	573
Accounts payable and accrued liabilities	(3,463)	(18,905)
Deferred revenue and other liabilities	(2,121)	(4,865)
Net cash (used in) provided by operating activities	(11,242)	21,904
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable debt securities	(7,718)	-
Maturities of marketable debt securities	23,332	-
Purchase of equipment and other assets, net	(188)	(46)
Net cash provided by (used in) investing activities	15,426	(46)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	51	379
Common shares received and retired for employee taxes paid	(37)	(8)
Proceeds from exercise of subsidiary warrants, net	-	2
Proceeds from sale of common shares	-	148
Repayment of financing lease liability	(13)	(8)
Net cash provided by financing activities	1	513
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(100)	(42)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	4,085	22,329
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	11,936	56,277
At end of the period	$ 16,021	$ 78,606
SUPPLEMENTAL DISCLOSURES		
Cash paid for interest	$ 2	$ 5

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