Lineage Cell Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 9, 2023

- **Phase 2a Clinical Study of RG6501 (OpRegen®) in Patients with GA Secondary to AMD Initiated by Genentech, a Member of the Roche Group**
- **Submitted RMAT and Pre-IND Materials to Support OPC1 and VAC2 Programs in Spinal Cord Injury and Oncology, Respectively**
- **Launched Two New Cell Therapy Programs for the Treatment of Hearing and Vision Loss**
- **Established New R&D Facility and Expanded Existing cGMP Manufacturing Facility**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 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 fourth quarter and full year ended December 31, 2022 and will host a conference call today at 4:30 p.m. Eastern Time to discuss these results.

“2022 marked a year of clinical and regulatory execution for the Lineage team, as we worked alongside our partners and internally to advance our clinical and preclinical programs,” stated Brian M. Culley, Lineage CEO. “A significant area of focus last year was our alliance with Roche and Genentech, including supporting the initiation of a Phase 2a clinical study of OpRegen in patients with GA secondary to AMD. We believe we have selected the most capable partner to advance OpRegen and we anticipate that the findings from the Phase 2a study will be highly informative to the OpRegen development program in any future larger, comparative trials. We also made considerable progress expanding and diversifying our pipeline, primarily through the addition of two new cell transplant programs. We believe the learnings from our dry AMD program may prove valuable to our newer product opportunities, which are similarly based on our differentiated cell transplant technology.

“We also completed key regulatory activities for our OPC1 and VAC2 programs, which help provide insights into their continued development,” Mr. Culley added. “Our corporate objectives for 2023 will be to emphasize the further progression of our allogeneic cell therapy programs, making responsible investments in the expansion of our novel approach to cell transplant medicine in disease settings where we believe we can make a meaningful impact, and the continued support of both our newly established and existing collaborations, all in support of our overarching vision of building Lineage into a leading cell therapy company.”

Other significant milestones achieved in 2022 include:

- **RG6501 (OpRegen)**
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for 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 2022 Association for Research in Vision and Ophthalmology Annual Meeting.
- **OPC1**
  - Completed verification and validation and preclinical testing activities for a novel parenchymal spinal delivery (PSD) system to support planned regulatory submissions.
  - Key data from OPC1, a Phase 1 clinical study in acute thoracic spinal cord injury and a Phase 1/2a clinical study in subacute cervical spinal cord injury, were published in the *Journal of Neurosurgery: Spine.*
  - Preclinical testing of a new thaw and inject formulation of OPC1, manufactured via an improved and larger-scale process, demonstrated functional recovery, improvement in gait coordination and motor performance with a reduction of the area of cavitation.
  - Engagement with the California Institute of Regenerative Medicine (CIRM), as well as various patient advocacy organizations and patient advocates continued.
- **VAC2**
  - Pre-Investigational New Drug (IND) application briefing package submitted to the FDA to support U.S. clinical development for immuno-oncology.
  - Reported completion of enrollment in VAC2 Phase 1 non-small cell lung cancer (NSCLC) Study by Cancer Research UK.
  - Following technology transfer of the program from Cancer Research UK to Lineage and improvement of manufacturing processes, production scale increased and accordingly the cost of goods was reduced significantly, along with marked improvements in the purity and functionality of the manufactured material.
- Launched two new cell therapy programs for the treatment of hearing and vision loss.
  - Process development and related activities were ongoing in support of planned preclinical testing.

- Established new U.S. R&D facility and expanded current GMP manufacturing facility in Israel.
- Strengthened intellectual property portfolio with Notice of Allowance for various patent applications including but not limited to covering oligodendrocyte progenitor cells.
- Announced appointment of Jill Howe as Chief Financial Officer.

Some of the events and milestones anticipated by Lineage in 2023 include:

- Results from imaging analyses of structural changes in addition to visual data from a Phase 1/2a clinical study of RG6501 (OpRegen), to be presented at the 2023 Association for Research in Vision and Ophthalmology Annual Meeting.
- Type B Meeting with FDA to discuss our proposed amendment to the Investigational New Drug Application (IND) for OPC1 to enable clinical testing of a novel spinal cord delivery system, anticipated in the second quarter.
- Clinical data update from the ongoing VAC2 Phase 1 NSCLC study, pending release from Cancer Research UK, anticipated in the second quarter.
- Amendment of an IND for OPC1 to enable clinical testing of a novel spinal cord delivery system.
- Initiation of DOSED (**D**elivery of **O**ligodendrocyte Progenitor Cells for **S**pinal Cord Injury: **E**valuation of a Novel **D**evice) clinical study of OPC1.
- Submission of an additional OPC1 manuscript describing magnetic resonance imaging (MRI) findings from the subacute studies in both thoracic and cervical spinal cord injury.
- Submission of a grant application to CIRM for the continued support of the clinical development of OPC1.
- Development update on hypo immune induced pluripotent stem cell (iPSC) lines for neurology indications, under collaboration with Eterna Therapeutics.
- Updates from ongoing ANP1 preclinical testing at the University of Michigan Kresge Hearing Research Institute under a collaboration with the University of Michigan.
- Evaluation of new partnership opportunities and/or expansion of existing collaborations.
- Continued participation in investor and partnering meetings and medical and industry conferences to broaden awareness of our mission, programs, and accomplishments.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $57.9 million as of December 31, 2022, which is expected to support planned operations into Q3 2024.

Fourth Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from licensing fees, collaboration revenues, royalties, and research grants. Total revenues for the three months ended December 31, 2022 were approximately $1.9 million, a net increase of $0.7 million as compared to $1.2 million for the same period in 2021. The increase was related to the recognition of deferred collaboration revenues in connection with a Collaboration and License Agreement (the "Roche Agreement") we entered into with F. Hoffmann-La Roche Ltd. and Genentech, Inc., a member of the Roche Group (collectively or individually, "Roche" or "Genentech"), in 2021, partially offset by lower royalty and grant revenues.

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, 2022 were $8.5 million, a decrease of $20.7 million as compared to $29.2 million for the same period in 2021. The overall decrease was almost entirely driven by a decrease in R&D expenses under the Roche Agreement.

R&D Expenses: R&D expenses for the three months ended December 31, 2022 were $4.1 million, a decrease of $20.7 million as compared to $24.8 million for the same period in 2021. The decrease was substantially driven by the prior year $21.0 million accrual for financial obligations payable to the Israel Innovation Authority ("IIA") and Hadasit Medical Research Services and Development Ltd ("Hadasit"), in connection with the $50.0 million upfront payment received under the Roche Agreement. This decrease was partially offset by $0.1 million and $0.2 million in higher expenses to support the development of the new photoreceptor and auditory neuron cell therapy program, respectively.

G&A Expenses: G&A expenses for the three months ended December 31, 2022 were $4.3 million, a decrease of $0.1 million as compared to $4.4 million for the same period in 2021. The decrease was primarily attributable to a decrease of $0.4 million in legal and litigation expenses, partially offset by approximately $0.1 million in higher salaries and related benefit fees, and $0.1 million in higher share-based compensation expense.

Loss from Operations: Loss from operations for the three months ended December 31, 2022 was $6.6 million, a decrease of $21.6 million as compared to $28.2 million for the same period in 2021, principally owing to collaboration-related expense accruals of $21.0 million under the Roche Agreement.

Other Income, Net: Other income, net for the three months ended December 31, 2022 was $0.3 million, compared to other income, net of $0.2 million for the same period in 2021. The net variance was primarily related to offsetting variances between the changes in the value of marketable equity securities, as well as exchange rate fluctuations related to Lineage's international subsidiaries for the applicable periods.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended December 31, 2022 was $6.4 million, or $0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of $29.0 million, or $0.17 per share (basic and diluted), for the same period in 2021.

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, 2022 were $14.7 million, an increase of $10.4 million as compared to $4.3 million for the same period in 2021. The increase was primarily related to a $12.2 million increase in collaboration revenues recognized from deferred revenues stemming from the $50.0 million upfront payment under the Roche Agreement, partially offset by lower royalty and grant revenues.

Operating Expenses: Operating expenses are comprised of R&D expenses and G&A expenses. Total operating expenses for the year ended December 31, 2022 were $36.5 million, a decrease of $15.6 million as compared to $52.1 million for the same period in 2021.

R&D Expenses: R&D expenses for the year ended December 31, 2022 were $14.0 million, a decrease of $19.9 million as compared to $33.9 million for the same period in 2021. The decrease was substantially driven by the prior year $21.0 million accrual for financial obligations payable to the IIA and Hadasit. This decrease was partially offset by $0.7 million and $0.5 million in R&D spending on the new auditory neuron and photoreceptor cell therapy programs, respectively.

G&A Expenses: G&A expenses for the year ended December 31, 2022 were $22.5 million, an increase of approximately $4.3 million as compared to $18.2 million for the same period in 2021. The increase was primarily attributable to increases of $2.1 million in litigation and legal expenses, $1.3 million in salaries and related benefit fees, $0.9 million in share-based compensation expenses, and $0.4 million in audit and tax services, partially offset by $0.5 million in lower investor relations expense.

Loss from Operations: Loss from operations for the year ended December 31, 2022 was $22.5 million, a decrease of $26.7 million as compared to $49.2 million for the same period in 2021.

Other Income/(Expenses), Net: Other income (expenses), net for the year ended December 31, 2022 reflected other expense, net of ($3.3) million, compared to other income, net of $5.9 million for the same period in 2021. The net variance was primarily related to a prior year gain on sale of marketable equity securities, as well exchange rate fluctuations related to Lineage's international subsidiaries for the applicable periods.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the year ended December 31, 2022 was $26.3 million, or $0.15 per share (basic and diluted), compared to a net loss attributable to Lineage of $43.0 million, or $0.26 per share (basic and diluted), for 2021.

Conference Call and Webcast

Interested parties may access today's conference call 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 16, 2023, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 5707771.

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, including the potential that it will be informative and increase the probability of success in future larger, comparative trials; 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 timing of the anticipated submission of a grant application to CIRM, the initiation of clinical trials and the availability of clinical data updates related to our programs, plans and expectations regarding potential new partnership opportunities and existing collaborations, and our ability to broaden awareness of our mission, programs and accomplishments; the potential of our cell therapy platform and our ability to become a leading cell therapy company. 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 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 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
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 11,355	$ 55,742
Marketable securities	46,520	2,616
Accounts and grants receivable, net	297	50,840
Prepaid expenses and other current assets	1,828	2,351
Total current assets	60,000	111,549
NONCURRENT ASSETS		
Property and equipment, net	5,673	4,872
Deposits and other long-term assets	627	630
Goodwill	10,672	10,672
Intangible assets, net	46,692	46,822
TOTAL ASSETS	$ 123,664	$ 174,545
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 8,608	$ 27,969
Lease liabilities, current portion	916	801
Financing lease, current portion	36	30
Deferred revenues	9,421	18,119
Liability classified warrants, current portion	-	197
Total current liabilities	18,981	47,116
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion	27,725	32,454
Lease liability, net of current portion	2,860	1,941
Financing lease, net of current portion	84	30
Other long-term liabilities	2	30
TOTAL LIABILITIES	51,728	83,647
SHAREHOLDERS’ EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2022 and 2021, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 170,093 and 169,477 shares issued and outstanding as of December 31, 2022 and 2021, respectively	440,280	434,529
Accumulated other comprehensive loss	(3,571)	(5,211)
Accumulated deficit	(363,370)	(337,097)
Lineage Cell Therapeutics, Inc. shareholders’ equity	73,339	92,221
Noncontrolling deficit	(1,403)	(1,323)
Total shareholders’ equity	71,936	90,898
TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY	$ 123,664	$ 174,545

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

	Year Ended December 31,	
	2022	2021

REVENUES:		
Collaboration revenues	$ 13,367	$ 1,120
Royalties	1,336	2,776
Grant revenues	-	445
Total revenues	14,703	4,341
Cost of sales	728	1,426
Gross profit	13,975	2,915
OPERATING EXPENSES:		
Research and development	13,987	33,914
General and administrative	22,508	18,212
Total operating expenses	36,495	52,126
Loss from operations	(22,520)	(49,211)
OTHER INCOME (EXPENSES):		
Interest income, net	829	2
Gain on sale of marketable securities	-	6,024
Unrealized loss on marketable equity securities	(2,194)	(2,299)
Gain on extinguishment of debt	-	523
Gain on revaluation of warrant liability	225	205
Other income (expense), net	(2,152)	1,486
Total other income/(expense)	(3,292)	5,941
LOSS BEFORE INCOME TAXES	(25,812)	(43,270)
Income tax expense	(541)	-
NET LOSS	(26,353)	(43,270)
Net loss attributable to noncontrolling interest	80	251
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (26,273)	$ (43,019)
NET LOSS PER COMMON SHARE:		
BASIC AND DILUTED	$ (0.15)	$ (0.26)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC AND DILUTED	169,792	164,502

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

	Year Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (26,273)	$ (43,019)
Net loss attributable to noncontrolling interest	(80)	(251)
Adjustments to reconcile net loss attributable to Lineage to net cash used in operating activities:		
Gain on sale of marketable equity securities	-	(6,024)
Unrealized loss on marketable equity securities	2,194	2,299
Accretion of income on marketable debt securities	(501)	-
Depreciation expense, including amortization of leasehold improvements	582	663
Change in right-of-use assets and liabilities	(35)	14
Amortization of intangible assets	145	210
Stock-based compensation	4,287	3,519
Common stock issued for services	-	202
Gain on revaluation of warrant liability	(225)	(205)
Foreign currency remeasurement and other loss/(gain)	2,272	(1,566)
Loss/(gain) on sale of assets	(11)	24

Gain on extinguishment of debt	-	(523)
Changes in operating assets and liabilities:		
Accounts and grants receivable (Note 3)	50,314	(857)
Prepaid expenses and other current assets	446	(72)
Accounts payable and accrued liabilities	(18,702)	21,645
Deferred revenue and other liabilities	(13,354)	380
Net cash provided by (used in) operating activities	1,059	(23,561)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable debt securities	(53,412)	-
Maturities of marketable debt securities	7,666	-
Purchases of property and equipment, net	(413)	(340)
Proceeds from sale of OncoCyte common shares	-	10,064
Proceeds from the sale of HBL common shares	-	21
Net cash (used in) provided by investing activities	(46,159)	9,745
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	648	7,240
Common shares received and retired for employee taxes paid	(17)	(54)
Proceeds from sale of common shares	148	30,865
Proceeds from exercise of subsidiary warrants, net	991	-
Repayments of financing lease liabilities	(32)	(20)
Payments for offering costs	(106)	(1,101)
Net cash provided by financing activities	1,632	36,930
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(873)	(20)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(44,341)	23,094
At beginning of year	56,277	33,183
At end of year	$ 11,936	$ 56,277
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during year for interest	$ 13	$ 13
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Receivable from sale of common shares in at the market offering	$ -	$ 147
Receivable from exercise of stock options	$ 32	$ 189

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