Lineage Reports Third Quarter 2021 Financial Results and Highlights Progress From Clinical Cell Therapy Programs

November 10, 2021

- **OpRegen® Continues to Demonstrate Functional and Anatomical Improvements in Patients with Dry AMD**
- **Performance Testing Underway to Support New Delivery Device for OPC1 Clinical Trials**
- **Cash, Cash Equivalents, and Marketable Securities of $65.1 Million**

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 10, 2021-- 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 2021. Lineage will host a conference call today at 4:30 p.m. Eastern Time to discuss its third quarter 2021 financial results and to provide a business update.

“Lineage’s approach is to produce specific types of human cells and stably transplant those cells as a treatment for serious medical conditions. We believe our approach, in certain settings, can generate clinical outcomes beyond the reach of traditional methods, as evidenced by the restoration of retinal tissue in patients in our dry AMD trial and the restoration of a tissue matrix in patients in our spinal cord injury trial,” stated Brian M. Culley, Lineage CEO. “During the third quarter, we reported positive interim outcomes in patients with dry AMD with geographic atrophy, initiated performance testing of our OPC1 delivery device for spinal cord injury, and we expanded our executive team with the appointment of a new General Counsel. Looking ahead, we are preparing for engagement with FDA for our OpRegen program to discuss aspects of product designation, manufacturing plans, and later-stage clinical development. In parallel, we look forward to the initiation of our OPC1 and novel delivery device clinical safety study early next year. We believe our technology platform has broad potential beyond even the indications we currently are pursuing and while we continue to advance our three clinical-stage programs, we also are evaluating new applications of our technology, either on our own or through strategic alliances.”

Some of the milestones achieved in the third quarter include:

- Presented OpRegen clinical data at the 54th Annual Scientific Meeting of the American Retina Society from the ongoing Phase 1/2a study of OpRegen for the treatment of dry-AMD with GA; statistically significant evidence of a treatment effect with OpRegen was observed in Cohort 4 better vision patients.

- Reported continued positive interim clinical data with OpRegen: 8/12 (67%) of the Cohort 4 patients’ treated eyes were at or above baseline visual acuity at their last assessment, based on per protocol scheduled visits ranging from 9 months to over 3 years post-transplant, while visual acuity predictably declined in the majority of untreated eyes; notably, three patients with evidence of retinal restoration and confirmed history of GA growth continued to demonstrate areas of retinal restoration as of their last per protocol assessments, ranging from 9 months to 33 months following treatment.

- Announced the appointment of George A. Samuel III as General Counsel and Corporate Secretary. Mr. Samuel brings extensive corporate, transactional, intellectual property and commercial expertise which spans nearly 15 years across the life sciences and technology sectors as well as in private practice.

- Featured in the B. Riley Securities Fall 2021 “Growth Biotech Best Idea” Virtual Series, as well as the 2021 Cantor Fitzgerald Virtual Global Healthcare Conference.

Some of the events and milestones anticipated by Lineage include:

- OpRegen Program

  - Additional interim data from the Phase 1/2a clinical study to be featured at the 2021 American Academy of Ophthalmology Annual Meeting in a presentation on November 13, 2021, as part of the Gene and Cell-Based Therapies Session, by Michael S. Ip, M.D., Professor, Department of Ophthalmology at the David Geffen School of Medicine at the University of California, Los Angeles.
  - Multiple interactions with the U.S. Food and Drug Administration (FDA) planned to discuss product designation, manufacturing plans, and later-stage clinical development, anticipated to begin in Q4 2021 and continue in Q1 2022.

- OPC1 Program

  - Complete evaluation of a novel Parenchymal Spinal Delivery (PSD) system in non-clinical testing; anticipated in Q4 2021.
  - Complete GMP production of OPC1 via an improved and larger-scale manufacturing process and a new thaw-and-inject formulation; anticipated in Q1 2022.
  - FDA interaction to discuss recent manufacturing improvements made to OPC1; anticipated in Q1 2022.
  - Initiation of clinical performance and safety testing of the novel PSD device for OPC1; anticipated Investigational New Drug (IND) amendment submission in Q1 2022.

- VAC Programs

- Completion of enrollment by Cancer Research UK in the ongoing VAC2 Phase 1 non-small cell lung cancer study; anticipated in Q1 2022.
- Continued development of a dendritic cell-based therapeutic for glioblastoma with our strategic partner; ongoing throughout 2022.
- Evaluation of opportunities for new VAC product candidates based on internally identified or partnered tumor antigens; ongoing throughout 2022.

- Business Development

- Evaluation of partnership opportunities and expansion of existing collaborations; ongoing throughout 2022.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $65.1 million as of September 30, 2021. Marketable securities of $4.3 million as of September 30, 2021 include the Company's remaining ownership in OncoCyte Corporation ("OncoCyte") and Hadasit Bio-Holdings Ltd.

Third Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the three months ended September 30, 2021 were approximately $2.3 million, an increase of $1.7 million as compared to $0.6 million for the same period in 2020. The increase was primarily related to a $1.6 million increase in royalty revenues, and a $0.3 million increase in licensing revenues in connection with a collaboration agreement, partially offset by a $0.2 million decrease in 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 September 30, 2021 were $8.1 million, an increase of $0.9 million as compared to $7.2 million for the same period in 2020.

R&D Expenses: R&D expenses for the three months ended September 30, 2021 were $2.8 million, a decrease of approximately $0.8 million as compared to $3.6 million for the same period in 2020. The decrease was primarily driven by lower VAC program expenses, related to a non-recurring prior year accrual of a $1.6 million signature fee to Cancer Research UK, partially offset by an increase in OPC1 expenses resulting from a return of unspent project funds of approximately $0.8 million in the prior year period from a former Asterias BioTherapeutics, Inc. ("Asterias") service provider.

G&A Expenses: G&A expenses for the three months ended September 30, 2021 were $5.3 million, an increase of approximately $1.7 million as compared to $3.6 million for the same period in 2020. The increase was primarily attributable to increases of $0.8 million in litigation and other expenses related to Lineage's merger with Asterias, and $0.5 million in share-based compensation.

Loss from Operations: Loss from operations for the three months ended September 30, 2021 was approximately $6.8 million, an increase of $0.1 million as compared to $6.7 million for the same period in 2020.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended September 30, 2021 reflected other expense, net of ($2.0) million, compared to other expense, net of ($1.2) million for the same period in 2020. The variance was primarily related to a decrease in the value of Lineage's OncoCyte shares, a decrease in interest income following settlement of the Juvenescence Limited note receivable in the prior year, and no sales of marketable equity securities as compared to the prior year's quarter.

Net loss attributable to Lineage: The net loss attributable to Lineage for the three months ended September 30, 2021 was $7.8 million, or $0.05 per share (basic and diluted), compared to a net loss attributable to Lineage of $7.8 million, or $0.05 per share (basic and diluted), for the same period in 2020.

Conference Call and Webcast

Lineage will host a conference call and webcast today, at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its third quarter 2021 financial results and to provide a business update. Interested parties may access the conference call by dialing (866) 888-8633 from the U.S. and Canada and (636) 812-6629 from elsewhere outside 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 18, 2021, by dialing (855) 859-2056 from the U.S. and Canada and (404) 537-3406 from elsewhere outside the U.S. and Canada and entering conference ID number 9352189.

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 programs are in markets with billion dollar opportunities and include three allogeneic ("off-the-shelf") product candidates: (i) OpRegen ®, a retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic 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. 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,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “can,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” ‘suggest,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, the ability of Lineage’s approach to generate clinical outcomes beyond the reach of traditional methods, the broad potential for Lineage’s technology platform, the projected timing of milestones of future studies, including their initiation and completion, the projected timing of interactions with the FDA to discuss product designation, manufacturing plans and improvements, and later-stage clinical development, the continued development of its product candidates, the potential opportunities for the establishment or expansion of strategic partnerships and collaborations and the timing thereof, and the potential for Lineage’s investigational allogeneic cell therapies to provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 risks and uncertainties inherent in Lineage’s business and other risks 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 and Quarterly Report on Form 10-Q 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.

Tables to follow

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

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 60,809	$ 32,585
Marketable equity securities	4,295	8,977
Trade accounts receivable, net	79	4
Prepaid expenses and other current assets	3,161	2,433
Total current assets	68,344	43,999
NONCURRENT ASSETS		
Property and equipment, net	4,728	5,630
Deposits and other long-term assets	614	616
Goodwill	10,672	10,672
Intangible assets, net	46,854	47,032
TOTAL ASSETS	$ 131,212	$ 107,949
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 6,705	$ 6,813
Lease liabilities, current portion	801	746
Financing lease, current portion	17	16
Deferred revenues	975	193
Liability classified warrants, current portion	293	1
Total current liabilities	8,791	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	894	2,076
Lease liability, net of current portion	1,887	2,514
Financing lease, net of current portion	12	26
Liability classified warrants, net of current portion	39	437
TOTAL LIABILITIES	11,623	12,822
	-	-
SHAREHOLDERS’ EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of September 30, 2021 and December 31, 2020	-	-

Common shares, no par value, 250,000 shares authorized; 168,465 and 153,096 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	432,250	393,944
Accumulated other comprehensive loss	(3,433)	(3,667)
Accumulated deficit	(308,105)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	120,712	96,199
Noncontrolling deficit	(1,123)	(1,072)
Total shareholders' equity	119,589	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 131,212	$ 107,949

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,	
	2021	**2020**	**2021**	**2020**
REVENUES:				
Royalties	$ 1,909	$ 342	$ 2,430	$ 607
Grant revenues	68	229	237	864
Collaboration revenues	293	-	506	-
Total revenues	2,270	571	3,173	1,471
Cost of sales	(985)	(102)	(1,222)	(271)
Gross profit	1,285	469	1,951	1,200
OPERATING EXPENSES:				
Research and development	2,811	3,566	9,136	9,710
General and administrative	5,317	3,628	13,788	12,055
Total operating expenses	8,128	7,194	22,924	21,765
Loss from operations	(6,843)	(6,725)	(20,973)	(20,565)
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	1	252	(1)	1,037
Gain on sale of marketable securities	-	120	6,024	3,848
Unrealized loss on marketable equity securities	(2,450)	(2,003)	(621)	(7,487)
Gain on extinguishment of debt	-	-	523	-
Unrealized gain on warrant liability	53	55	105	84
Other income (expense), net	393	351	(318)	175
Total other income/(expense), net	(2,003)	(1,225)	5,712	(2,343)
LOSS BEFORE INCOME TAXES	(8,846)	(7,950)	(15,261)	(22,908)
Deferred income tax benefit	1,012	178	1,181	178
NET LOSS	(7,834)	(7,772)	(14,080)	(22,730)
Net loss attributable to noncontrolling interest	11	12	51	49
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (7,823)	$ (7,760)	$ (14,029)	$ (22,681)
NET LOSS PER COMMON SHARE:				
BASIC	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.15)
DILUTED	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.15)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	167,624	149,973	163,120	149,868
DILUTED	167,624	149,973	163,120	149,868

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (14,029)	$ (22,681)
Net loss allocable to noncontrolling interest	(51)	(49)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Gain on sale of marketable securities	(6,024)	(3,848)
Unrealized loss on marketable equity securities	621	7,487
Gain on extinguishment of debt	(523)	-
Depreciation expense, including amortization of leasehold improvements	504	623
Amortization of right-of-use asset	19	47
Amortization of intangible assets	178	1,080
Stock-based compensation	2,601	1,733
Common stock issued for services	202	59
Change in unrealized gain on warrant liability	(105)	(84)
Write-off of security deposit	-	150
Deferred tax benefit	(1,181)	(178)
Foreign currency remeasurement and other gain	300	(116)
Gain on write-off and sales of assets	(5)	(154)
Amortization of deferred license fee	-	(200)
Changes in operating assets and liabilities:		
Accounts and grants receivable	(104)	51
Accrued interest receivable	-	(1,008)
Prepaid expenses and other current assets	(1,229)	1,634
Accounts payable and accrued liabilities	354	1,342
Deferred revenue and other liabilities	784	-
Net cash used in operating activities	(17,688)	(14,112)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	10,064	10,941
Proceeds from the sale of AgeX common shares	-	1,196
Proceeds from the sale of HBL common shares	21	3
Purchase of equipment	(208)	(40)
Proceeds from the sale of equipment	14	18
Other deposits	-	18
Net cash provided by investing activities	9,891	12,136
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	6,269	24,624
Common shares received and retired for employee taxes paid	(41)	(19)
Repayment of financing lease liabilities	(13)	(24)
Proceeds from Paycheck Protection Program (“PPP”) Loan	-	523
Proceeds from sale of common shares	30,741	-
Payments for offering costs	(980)	(53)
Net cash provided by financing activities	35,976	25,051
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(34)	(36)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	28,145	23,039
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	33,183	10,096
At end of the period	$ 61,328	$ 33,135

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