Lineage Cell Therapeutics Reports Second Quarter 2022 Financial Results and Provides Business Update

August 11, 2022

- **Advanced RG6501 (OpRegen®) Development in Partnership with Roche and Genentech**
- **Published OPC1 Phase 1/2a Clinical Study Results in *Journal of Neurosurgery: Spine***
- **Completed Key Activities to Support Planned Regulatory Interactions for OPC1 and VAC2**
- **Expanded Collaboration with Advanced BioMatrix for HyStem® Cell Drug Delivery Technology**
- **Cash, Cash Equivalents, and Marketable Securities of $72.0 Million as of June 30, 2022 Expected to Provide Capital Through Q2 2024**

CARLSBAD, Calif.--(BUSINESS WIRE)--Aug. 11, 2022-- 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 second quarter of 2022. Lineage management will host a conference call and webcast today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its second quarter 2022 financial and operating results and to provide a business update.

“We are pleased with the progress on RG6501 (OpRegen) product development under our collaboration with Roche and Genentech. During the second quarter this year, we have made progress across multiple functional areas, including clinical, regulatory, and technology transfer activities,” stated Brian M. Culley, Lineage CEO. “As we continue to position Lineage as a leader in regenerative medicine through the transplant of specific cell types, our focus is on completing the necessary clinical, regulatory and related activities which can create value and reduce risk across our portfolio of five cell transplant assets. In particular, our efforts have been focused on preparing for OPC1 and VAC2 regulatory interactions to enable their next phases of clinical testing in spinal cord injury and oncology, respectively. In parallel, we are advancing our auditory neuron and photoreceptor programs through preclinical development activities which are necessary to support initial clinical testing. We believe our disciplined use of capital and our increased strategic business development activities can support multiple years of growth and the achievement of important milestones in the months and years to come."

Second quarter milestones and activities included:

- **RG6501 (OpRegen)**

  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including:
    - Conducting additional OpRegen manufacturing runs and supporting Chemistry Manufacturing and Controls (CMC) activities.
    - Continuing technology transfer activities.
    - Actively participating in both Joint Advisory and Joint Manufacturing Committees, forums for discussion and planning with respect to next steps in clinical development and related activities.
  - Continuing long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen:
    - Enrolled patients have continued to do well, supporting multi-year durability of a treatment effect with RG6501 (OpRegen).

- **OPC1**

  - Results from a Phase 1/2a clinical study in subacute cervical spinal cord injury were published in the ***Journal of Neurosurgery: Spine***;
    - OPC1 has demonstrated an excellent safety profile, and at one-year post-treatment, 96% of patients had recovered one or more levels of neurological function on at least one side of their body, and 32% of patients had recovered two or more levels of neurological function on at least one side of their body.
  - Preclinical testing of a new thaw and inject formulation of OPC1, manufactured via an improved and larger-scale process, has demonstrated functional recovery, improvement in gait coordination and motor performance with a reduction of the area of cavitation.
  - A majority of the verification and validation activities for the novel parenchymal spinal delivery (PSD) system, and its preclinical testing in support of a regulatory submission have been completed.
  - Preclinical activities to support upcoming regulatory interactions are near completion.
  - Engagement with the California Institute of Regenerative Medicine (CIRM), as well as various patient advocacy organizations and patient advocates, is underway.

- **VAC2**

  - Following technology transfer of the program from Cancer Research UK (CRUK) to Lineage and improvement of

manufacturing processes, production scale was increased and accordingly the cost of goods has been reduced significantly, along with marked improvements in the purity and functionality of the manufactured material.
- CRUK continues to follow patients on the Phase 1 NSCLC clinical study; Lineage has received all necessary clinical information from CRUK required to support U.S., or other, regulatory interactions.

- **ANP1 & PNC1**

- Preclinical activities are continuing, including thought leader engagement to support future preclinical testing.

- **Business Development**

- Broadened collaboration with Advanced BioMatrix, a division of BICO Group AB (STO: BICO), for the HyStem delivery technology to include clinical/commercial GMP (Good Manufacturing Practice) material, increasing the milestone payments and royalty percentages due to Lineage upon ABM reaching certain development milestones and/or product sales.
- Continued work under our collaboration with our strategic partner, Immunomic Therapeutics ("ITI"); currently awaiting decision on next steps for ITI's allogeneic cell-based cancer immunotherapy for the treatment of glioblastoma based on the VAC platform.

Some of the key upcoming milestones and activities anticipated by Lineage include:

- Planned interaction with FDA in Q4 2022 to discuss an OPC1 IND amendment submission to enable clinical performance and safety testing of a novel PSD system.

- A pre-IND regulatory interaction in Q4 2022 to seek feedback on a VAC2 CMC, nonclinical, and clinical package to support U.S. clinical development; pre-IND briefing package submission in Q3 2022.

- Submission of a grant application to the California Institute for Regenerative Medicine (CIRM) for the continued support of the clinical development of OPC1.

- Clinical data update from the ongoing VAC2 Phase 1 non-small cell lung cancer (NSCLC) study, pending release from CRUK.

- Preclinical activities for both the ANP1 and PNC1 programs.

- Additional OPC1 publications, including preclinical study results utilizing a new thaw and inject formulation of OPC1, manufactured via an improved and larger-scale process.

- An additional OPC1 manuscript from a Phase 1/2a clinical study in subacute cervical spinal cord injury, focused on MRI data.

- 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 and accomplishments.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $72 million as of June 30, 2022, which is expected to support operations through Q2 2024.

Second 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 June 30, 2022 were approximately $4.6 million, a net increase of $4.0 million as compared to $0.5 million for the same period in 2021. The increase was primarily related to licensing fees recognized from deferred revenues in connection with the $50.0 million upfront licensing payment received in the first quarter of 2022 from Roche.

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 June 30, 2022 were $8.6 million, an increase of $1.1 million as compared to $7.5 million for the same period in 2021.

R&D Expenses: R&D expenses for the three months ended June 30, 2022 were $3.3 million, a net increase of $0.4 million as compared to $2.9 million for the same period in 2021. The net increase was driven by $0.1 million in higher OpRegen related expenses to support the Roche Collaboration. Another $0.2 million and $0.1 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 June 30, 2022 were $5.3 million, a net increase of approximately $0.7 million as compared to $4.5 million for the same period in 2021. The increase was primarily attributable to $0.4 million in payroll and related benefits expense, and $0.5 million in share-based compensation, partially offset by $0.2 million in lower investor relations expense.

Loss from Operations: Loss from operations for the three months ended June 30, 2022 was $4.2 million, a decrease of $2.9 million as compared to $7.1 million for the same period in 2021.

Other Income/(Expenses), Net: Other income (expenses), net for the three months ended June 30, 2022 reflected other expense, net of ($2.5) million, compared to other income, net of $2.1 million for the same period in 2021. The net change was primarily driven by exchange rate fluctuations related to Lineage's international subsidiaries, as well as a decrease in the value of marketable equity securities, and partially offset by the gain on extinguishment of debt from Lineage's Paycheck Protection Program loan forgiveness recognized in the prior year's quarter.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended June 30, 2022 was $6.8 million, or $0.04 per share (basic and diluted), compared to a net loss attributable to Lineage of $4.8 million, or $0.03 per share (basic and diluted), for the same period in 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 (646) 307-1952 from elsewhere outside the U.S. and Canada and should request the "Lineage Cell Therapeutics Call" or provide conference ID number 6448886. 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 August 18, 2022, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 6448886.

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 five allogeneic ("off-the-shelf") product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in 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 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: our ability to support our operations for at least two years with our existing cash, cash equivalents and marketable securities; our ability to create value and reduce risk across our portfolio; our ability to support multiple years of progress and achieve important milestones; our collaboration and license agreement with Roche and Genentech and the potential to receive milestone and other consideration thereunder; the potential benefits of treatment with OpRegen; the potential future achievements of our clinical and preclinical programs; the timing of anticipated FDA interactions, preclinical activities, clinical trials, and clinical data updates related to our programs, and the submission of a grant application to the CIRM; plans and expectations regarding publications relating to our programs; plans and expectations regarding potential new partnership opportunities and existing collaborations; our ability to broaden awareness of our mission and accomplishments; plans and expectations regarding our products in development. 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 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 we may not establish new partnerships or expand existing collaborations; that we do not successfully broaden awareness of our mission or accomplishments; 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 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.

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

	June 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 70,857	$ 55,742
Marketable equity securities	1,173	2,616
Accounts and grants receivable, net	707	50,840
Prepaid expenses and other current assets	1,289	2,351

Total current assets	74,026	111,549
NONCURRENT ASSETS		
Property and equipment, net	3,869	4,872
Deposits and other long-term assets	598	630
Goodwill	10,672	10,672
Intangible assets, net	46,757	46,822
TOTAL ASSETS	$ 135,922	$ 174,545
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 8,684	$ 27,969
Lease liabilities, current portion	593	801
Financing lease, current portion	29	30
Deferred revenues	15,785	18,119
Liability classified warrants, current portion	-	197
Total current liabilities	25,091	47,116
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion	25,774	32,454
Lease liability, net of current portion	1,459	1,941
Financing lease, net of current portion	19	30
Liability classified warrants and other long-term liabilities	4	30
TOTAL LIABILITIES	54,423	83,647
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of June 30, 2022 and December 31, 2021	-	-
Common shares, no par value, 250,000 shares authorized; 169,748 and 169,477 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	437,151	434,529
Accumulated other comprehensive loss	(3,357)	(5,211)
Accumulated deficit	(350,947)	(337,097)
Lineage Cell Therapeutics, Inc. shareholders' equity	82,847	92,221
Noncontrolling (deficit)	(1,348)	(1,323)
Total shareholders' equity	81,499	90,898
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 135,922	$ 174,545

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
REVENUES:				
Collaboration revenues	$ 4,148	$ 213	$ 9,013	$ 213
Royalties	405	228	777	521
Grant revenues	-	71	-	169
Total revenues	4,553	512	9,790	903
Cost of sales	(215)	(125)	(391)	(237)
Gross profit	4,338	387	9,399	666
OPERATING EXPENSES:				
Research and development	3,302	2,931	6,290	6,325
General and administrative	5,270	4,536	13,739	8,471

Total operating expenses	8,572	7,467	20,029	14,796
Loss from operations	(4,234)	(7,080)	(10,630)	(14,130)
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	51	(3)	51	(1)
Gain on sale of marketable securities	-	-	-	6,024
Unrealized (loss) gain on marketable equity securities	(709)	590	(1,444)	1,830
Gain on extinguishment of debt	-	523	-	523
Gain on revaluation of warrant liability	2	35	223	52
Other income (expense), net	(1,892)	970	(2,075)	(711)
Total other income/(expense), net	(2,548)	2,115	(3,245)	7,717
LOSS BEFORE INCOME TAXES	(6,782)	(4,965)	(13,875)	(6,413)
Deferred income tax benefit	-	169	-	169
NET LOSS	(6,782)	(4,796)	(13,875)	(6,244)
Net loss attributable to noncontrolling interest	19	8	25	40
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (6,763)	$ (4,788)	$ (13,850)	$ (6,204)
NET LOSS PER COMMON SHARE:				
BASIC	$ (0.04)	$ (0.03)	$ (0.08)	$ (0.04)
DILUTED	$ (0.04)	$ (0.03)	$ (0.08)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	169,731	162,914	169,689	160,831
DILUTED	169,731	162,914	169,689	160,831

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

	Six Months Ended June 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (13,850)	$ (6,204)
Net loss allocable to noncontrolling interest	(25)	(40)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash provided by (used in) operating activities:		
Gain on sale of marketable securities	-	(6,024)
Unrealized loss (gain) on marketable equity securities	1,444	(1,830)
Gain on extinguishment of debt	-	(523)
Depreciation expense, including amortization of leasehold improvements	296	338
Amortization of right-of-use asset	(7)	20
Amortization of intangible assets	65	145
Stock-based compensation	2,341	1,458
Common stock issued for services	-	202
Gain on revaluation of warrant liability	(223)	(53)
Deferred tax benefit	-	(169)
Foreign currency remeasurement and other gain	2,331	692
Changes in operating assets and liabilities:		
Accounts and grants receivable	50,111	(353)
Prepaid expenses and other current assets	594	34
Accounts payable and accrued liabilities	(19,230)	(955)
Deferred revenue and other liabilities	(9,005)	422
Net cash provided by (used in) operating activities	14,842	(12,840)

CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	-	10,064
Proceeds from the sale of HBL common shares	-	21
Purchase of equipment and other assets, net	(143)	(126)
Net cash (used in) provided by investing activities	(143)	9,959
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	388	5,348
Common shares received and retired for employee taxes paid	(17)	(27)
Proceeds from exercise of subsidiary warrants, net	99	-
Proceeds from sale of common shares	148	27,813
Payments for offering costs	(57)	(877)
Repayment of lease liability	(15)	-
Net cash provided by financing activities	546	32,257
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(161)	(43)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	15,084	29,333
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	56,277	33,183
At end of the period	$ 71,361	$ 62,516

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Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(442) 287-8963

Russo Partners – Media Relations
Nic Johnson or David Schull
Nic.johnson@russopartnersllc.com
David.schull@russopartnersllc.com
(212) 845-4242

Source: Lineage Cell Therapeutics, Inc.