

Lineage Cell Therapeutics Reports Third Quarter 2019 Financial Results and Provides Business Update

November 12, 2019

- New Data from Phase I/IIa Clinical Study of OpRegen® Presented at 2019 AAO Meeting; All Cohort 4 Patients Have Better Visual Acuity as of Last Visit
- Implemented Significant Additional Cost-Cutting Measures to Reduce Budget for 2020
- Received CE Mark Approval for Renevia®; Working to Identify European Commercial Partner
- Conducted Sales of 6.25 Million Shares of OncoCyte Corporation for \$10.7 Million in Net Proceeds
- Strengthened Extensive IP Portfolio with the Issuance of 3 New U.S. Patents
- Awarded Additional NIH Grant for Innovative Vision Restoration Program

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 12, 2019-- <u>Lineage Cell Therapeutics</u>. <u>Inc.</u> (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cellular therapies for unmet medical needs, reported financial and operating results for the third quarter ended September 30, 2019. 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 third quarter 2019 financial results and to provide a business update.

"We are excited about our cell therapy programs and how they may benefit patients with serious medical conditions such as dry AMD, spinal cord injury, and cancer," stated Brian M. Culley, CEO of Lineage. "We believe that Lineage has one of the largest and most comprehensive patent estates in cell therapy and that our clinical-stage programs are making important advances. We also recently implemented additional cost-cutting measures that will reduce our planned 2020 net operational spend to \$16 million, \$8 million to \$12 million less than our previous estimate of \$24 million to \$28 million. Under this plan, our primary goal will be to complete enrollment in our Phase I/IIa clinical study of OpRegen early next year and collect the follow-up data to guide our late-stage study design and partnership discussions. We also have completed the transfer of OPC1 to our manufacturing facility and will continue our efforts to introduce manufacturing enhancements to OPC1 in preparation for the initiation of a randomized clinical study in 2021. We believe reducing our cash burn and focusing on OpRegen, our nearest-term high value asset, as well as on finding a strong marketing partner for Renevia, is the best way to create near-term shareholder value. In August 2020, we also are entitled to receive our final payment of \$24.6 million in principal and interest for the 2018 sale of AgeX Therapeutics shares to Juvenescence, an amount which exceeds our anticipated cash needs from now through the end of next year."

"Additionally, we are looking forward to hosting two therapeutic area experts in ophthalmology and spinal cord injury at Solebury Trout's KOL Event for analysts and investors in New York City on November 15, 2019," added Mr. Culley. "Our executive team will be joined by renowned experts Allen C. Ho, M.D. FACS, Wills Eye Hospital Attending Surgeon and Director of Retina Research, and John Steeves, B.Sc., Ph.D., Emeritus Principal Investigator at ICORD and Professor in the Department of Neuroscience at the University of British Columbia. We will be providing an update on our OpRegen and OPC1 clinical programs, as well as an update on the SCiStar Clinical Study for the treatment of spinal cord injury."

Recent Significant Highlights

- Provided an update of our Phase I/IIa clinical study of OpRegen in patients with dry age-related macular degeneration (dry AMD) with geographic atrophy at the 2019 American Academy of Ophthalmology Annual Meeting (AAO 2019) in San Francisco, CA on October 14, 2019. Data from the study demonstrated that treatment with OpRegen continued to be well tolerated and, at the furthest time point collected, all four Cohort 4 patients treated to date had better visual acuity on an Early Treatment Diabetic Retinopathy Scale (ETDRS) in the treated eye (range +8 to +19 letters) than in the untreated eye (range -2 to +7 letters). The largest increase recorded at any single timepoint in a Cohort 4 patient was +22 letters. Cohort 4 patients have better baseline vision and less advanced disease than Cohorts 1-3 patients, who were legally blind at baseline. Previously reported structural improvements in the retina and decreases in drusen density observed in some patients were maintained and there was evidence of the continued presence of transplanted OpRegen cells in patients treated in the first 3 cohorts, some over 3 years following administration. Of note, the first patient successfully dosed using the Orbit Subretinal Delivery System (Orbit SDS) as well as a new Thaw-and-Inject (TAI) formulation of OpRegen was also demonstrating signs of improved visual acuity, having gained 13 letters in the 3 months following administration as assessed by ETDRS. Overall, OpRegen appeared well tolerated with preliminary evidence of improved structural changes and potential improvement in visual acuity following treatment in some patients.
- Announced that Renevia, the Company's facial aesthetics product, has been granted a Conformité Européenne (CE) Mark. Renevia received a Class III classification with an intended use in adults as a resorbable matrix for the delivery of autologous adipose tissue preparations to restore and/or augment facial volume after subcutaneous fat volume loss for the treatment of facial lipoatrophy. The CE Mark provides Lineage, or its authorized agent, the authority to market and distribute Renevia throughout the European Union (EU) and in other countries that recognize the CE Mark. The Company has engaged an EU-based business development agent to identify opportunities to partner this asset and has begun the process of engaging with commercially capable partners for Renevia.

- Completed the launch of our new corporate brand and identity as well as a change in corporate name to Lineage Cell Therapeutics, Inc., reflecting our commitment to becoming an innovative, leading cell therapy company and highlighting our extensive cell therapy platform. In conjunction with the name change, the Company's ticker symbol was changed to "LCTX" on August 12, 2019. The Company also relocated its corporate headquarters to Carlsbad, California, effective August 12, 2019, a move which provides proximity to world-leading academic centers, public and private cell therapy peers, and offers more centralized decision-making, cost-savings, and access to an extensive network of experienced staff. The Company also terminated shared services with OncoCyte Corporation (OncoCyte, NYSE American: OCX) and AgeX Therapeutics, Inc. (AgeX, NYSE American: AGE) on September 30, 2019, an important step in our plan to simplify our business structure.
- <u>Converted</u> approximately 43% of our investment in OncoCyte into cash to support our operations with the sale of 6,250,000 shares of OncoCyte common stock for net proceeds totaling \$10.7 million. Lineage continues to own approximately 16% or 8.4 million shares of OncoCyte's outstanding common stock. Based on the closing price of OncoCyte's common stock on November 8, 2019, the value of our remaining OncoCyte shares is approximately \$14.1 million.

Near Term Milestones for 2019 and 2020

- Complete patient enrollment in the United States with the Orbit SDS in the ongoing Phase I/IIa clinical study of OpRegen for the treatment of dry AMD, expected in Q1 2020.
- Obtain VAC2 immunogenicity data from the initial patients in the ongoing Phase I study in NSCLC (non-small cell lung cancer) run by Cancer Research UK, expected around year end.
- Present new OpRegen data from the ongoing Phase I/IIa clinical study at the Association for Research in Vision and Ophthalmology Meeting (ARVO) in May 2020.
- Advance the OPC1 manufacturing program by introducing enhancements to the manufacturing process in our GMP manufacturing facility, ongoing throughout 2020.
- Meet with the FDA to discuss the manufacturing and clinical development of OPC1, around the middle of 2020.
- Identify an external partner for commercialization of Renevia in Europe, targeted for the first half of 2020.
- Continue engagement with the investment and medical communities with participation at medical and healthcare industry conferences, ongoing throughout 2020.
- Strengthen existing partnerships with the <u>National Institutes of Health</u>, the <u>Israel Innovation Authority</u>, the <u>California Institute</u> for Regenerative Medicine and Cancer Research UK.

Balance Sheet Highlights

Cash, cash equivalents and marketable securities totaled \$35.7 million as of September 30, 2019. Marketable securities include our remaining ownership stakes in OncoCyte, AgeX and Hadasit Bio-Holdings Ltd (Hadasit), which are now all under 20% of their respective total outstanding shares. Lineage sold 6,250,000 shares of OncoCyte's common stock in the third quarter of 2019 for net proceeds of \$10.7 million. Lineage also sold 651,839 shares of AgeX common stock in the third quarter of 2019 for net proceeds of \$1.6 million and 647,397 shares of Hadasit common stock in July 2019 for net proceeds of \$1.2 million.

Lineage's promissory note due from Juvenescence Limited had an outstanding balance (principal plus accrued interest) of \$23.2 million as of September 30, 2019. Unless earlier converted into Juvenescence ordinary shares, the promissory note is payable in cash, plus accrued interest at 7% per year, at maturity in August 2020. If Juvenescence completes an initial public offering (IPO) resulting in gross proceeds of not less than \$50.0 million, the promissory note automatically converts into the Juvenescence securities issued in the IPO based on the per-share price to the public in the IPO, subject to an upward adjustment in the number of shares that would be issued to Lineage upon such conversion if the 20-day volume-weighted average trading price of one share of common stock of AgeX before the IPO is priced above \$3.00. If the promissory note is converted, the Juvenescence ordinary shares will be a marketable security that Lineage may use to supplement its liquidity, as needed and as market conditions allow.

In summary, as of September 30, 2019, the value of the Company's cash, marketable securities, and the balance of a promissory note due to it in August 2020 were in excess of \$58.9 million.

Lineage expects to spend approximately \$6 million in the fourth quarter of 2019. The Company has implemented significant cost savings initiatives and now anticipates that net operational spend for 2020 will be \$16 million. This planned spending level represents a significant reduction from 2019 forecasted spending levels of \$34 million and 2018 spending levels of \$43 million for Lineage and Asterias Biotherapeutics, Inc. (Asterias) combined. Lineage acquired Asterias on March 8, 2019.

Third Quarter Operating Results

Note regarding AgeX: On August 30, 2018, Lineage deconsolidated AgeX from its consolidated financial statements due to the sale by Lineage of 14,400,000 shares of AgeX common stock to Juvenescence and the related decrease of Lineage's ownership position in AgeX from 80.4% to 40.2%. Accordingly, Lineage ceased recognizing revenue and expenses related to AgeX and its programs on such date.

Revenues: Lineage's revenue is generated primarily from research grants, licensing fees and royalties. Total revenues for the three months ended September 30, 2019 were \$0.6 million, a decrease of \$0.4 million as compared to the same period in 2018. The decrease was primarily related to a \$0.4 million decrease in grant revenues, which is primarily based on the timing of grant-related activities.

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, 2019 were \$8.9 million, a decrease of \$2.4 million as compared to the same period in 2018.

R&D Expenses: R&D expenses for the three months ended September 30, 2019 were \$4.3 million, a decrease of \$0.6 million as compared to the same period in 2018. The decrease was primarily related to a \$0.8 million decrease from the AgeX deconsolidation and the absence of AgeX R&D expenses incurred after August 30, 2018, offset by a net increase of \$0.2 million in Lineage programs primarily related to: (1) an increase of \$1.4 million in OPC1 and VAC2 expenses (these programs were acquired in the Asterias merger) offset by (2) decreases of \$1.2 million in Renevia, OpRegen and other research-related expenses.

G&A Expenses: G&A expenses for the three months ended September 30, 2019 were \$4.6 million, a decrease of \$1.8 million as compared to the same period in 2018. The decrease was primarily attributable to a \$0.8 million decrease in AgeX related general and administrative expenses, a \$0.5 million reduction in legal and patent expenses, a \$0.4 million decrease in salaries, benefits and severance costs primarily related to terminated personnel and a \$0.3 million reduction in consulting expenses, offset by a \$0.2 million increase in rent expense, which is primarily related to the implementation of ASC 842 Leases in 2019.

Loss from Operations: Loss from operations for the three months ended September 30, 2019 was \$8.4 million, a decrease of \$2.0 million as compared to the same period in 2018.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended September 30, 2019 reflected other expense, net of (\$9.1) million, compared to other income, net of \$76.9 million for the same period in 2018. The variance was primarily related to the gain on the deconsolidation of AgeX in 2018 and the changes in the value of investments in marketable equity securities for the applicable periods.

Conference Call and Webcast

Lineage will host a conference call and webcast today, at 1:30pm PT/4:30pm ET to discuss its third quarter 2019 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 <u>Investors</u> 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 19, 2019, 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 1473397.

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 proprietary cell-based therapy platform and associated 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 either to 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 assets include (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase I/lla 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 I/lla development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. Lineage is also evaluating potential partnership opportunities for Renevia®, a facial aesthetics product that was recently granted a Conformité Européenne (CE) Mark. 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," "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 Lineage's cost-savings efforts, manufacturing plans, enrollment activities, data presentations, clinical study advancement, drug evaluation, and anticipated net operational spend for the fourth quarter of 2019 and full year 2020. 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 (the 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 Annual Report on Form 10-K filed with the SEC on March 14, 2019 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 o

Tables to follow

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

September 30,	December
2019	31,
(Unaudited)	2018
(Notes 1 and	(Notes 1 and
3)	6)

ASSETS

CUDDENT ACCETS				
Current Assets	¢	14 266	Ф	22 507
Cash and cash equivalents	\$	14,366 21,318	Ф	23,587
Marketable equity securities		•		7,154
Promissory note from Juvenescence (Note 5)		23,238		- 767
Trade accounts and grants receivable, net		157 164		2,112
Receivables from affiliates, net (Note 10)		2,342		2,112
Prepaid expenses and other current assets	_			
Total current assets	_	61,585		36,358
NONCHIDDENT ASSETS				
NONCURRENT ASSETS Property and equipment, net (Notes 7 & 15)		8,844		5,835
Deposits and other long-term assets		826		505
Promissory note from Juvenescence (Note 5)		020		22,104
·		_		20,250
Equity method investment in OncoCyte, at fair value (Note 4) Equity method investment in Asterias, at fair value (Note 3)		-		13,483
Goodwill		12,977		13,403
		48,746		3,125
Intangible assets, net	\$	132,978	<u>_</u>	101,660
TOTAL ASSETS	φ	132,970	φ	101,000
LIABILITIES AND SHAREHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable and accrued liabilities	\$	4,842	\$	6,463
Financing lease and right of use lease liabilities, current portion (Note 15)	Ψ	1,138	Ψ	237
Promissory notes, current portion		-,		70
Deferred grant revenue		182		42
Total current liabilities		6,162		6,812
Total out of the last the second of the seco		-, -		- , -
LONG-TERM LIABILITIES				
Deferred tax liability		6,343		-
Deferred revenues, net of current portion		240		-
Deferred rent liabilities, net of current portion		-		244
Right-of-use lease liability, net of current portion (Note 15)		4,087		1,854
Financing lease, net of current portion		87		104
Liability classified warrants, net of current portion, and other long-term liabilities		540		400
TOTAL LIABILITIES		17,459		9,414
Commitments and contingencies (Note 15)				
SHAREHOLDERS' EQUITY				
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of September 30, 2019 and December 31, 2018		-		-
Common shares, no par value, 250,000 shares authorized; 149,790 shares issued and outstanding as of September 30, 2019 and 127,136 shares issued and outstanding as of December 31, 2018		386,454		354,270
Accumulated other comprehensive income		(357)		1,426
Accumulated deficit		(268,940)		(261,856)
Lineage Cell Therapeutics, Inc. shareholders' equity		117,157		93,840
Noncontrolling interest (deficit)		(1,638)		(1,594)
	_	115,519		92,246
Total shareholders' equity	©	132,978	Φ_	101,660
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	φ	132,310	ψ	101,000

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

(0.0.020.22)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019 2018		2019 2018			
REVENUES:						
Grant revenue	\$	350	\$ 718	\$ 1,628	\$ 2,985	
Royalties from product sales and license fees		164	85	390	312	
Subscription and advertisement revenues		-	119	-	691	

Sale of research products and services	53	60	256	242
Total revenues	567	982	2,274	4,230
Cost of sales	(114)	(35)	(289)	(250)
Gross profit	453	947	1,985	3,980
OPERATING EXPENSES:				
Research and development	4,266	4,882	14,462	17,175
Acquired in-process research and development	4 000	- 0.400	40.507	800
General and administrative	4,609	6,422	19,527	17,585
Total operating expenses	8,875	11,304	33,989	35,560
Loss from operations	(8,422)	(10,357)	(32,004)	(31,580)
OTHER INCOME/(EXPENSES):				
Interest income, net	399	174	1,278	278
Gain on sale of marketable equity securities	2,055	-	2,055	-
Gain on sale of equity method investment in OncoCyte	546	-	546	-
Gain on sale of equity method investment in Ascendance	-	-	-	3,215
Gain on sale of AgeX shares and deconsolidation of AgeX	-	78,511	-	78,511
Unrealized (loss) gain on marketable equity securities	(4,458)	23	(3,134)	635
Unrealized (loss) gain on equity method investment in OncoCyte at fair value	(8,287)	(734)	8,001	(31,550)
Unrealized (loss) gain on equity method investment in Asterias at fair value		(1,087)	6,744	(20,660)
Unrealized gain on warrant liability	79	21	350	372
Other income (expense), net	582	(7)	2,270	(1,021)
Total other (expense) income, net	(9,084)	76,901	18,110	29,780
(LOSS)/INCOME BEFORE INCOME TAXES	(17,506)	66,544	(13,894)	(1,800)
Deferred income tax benefit	991		6,623	
NET (LOSS)/INCOME	(16,515)	66,544	(7,271)	(1,800)
Net loss attributable to noncontrolling interest	10	181	44	762
NET (LOSS)/INCOME ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	\$ (16,505) \$	66,725	\$ (7,227)	\$ (1,038)
NET (LOSS)/INCOME PER COMMON SHARE:				
BASIC	\$ (0.11) \$	0.53	\$ (0.05)	\$ (0.01)
				<u>_</u>
DILUTED	\$ (0.11) \$	0.53	\$ (0.05)	\$ (0.01)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	149,659	126,878	144,097	126,872
	149,659			
DILUTED	149,009	126,973	144,097	126,872

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Lineage Cell Therapeutics, Inc. IR

loana C. Hone (ir@lineagecell.com) (510) 871-4188

Solebury Trout IR Gitanjali Jain Ogawa (Gogawa@troutgroup.com) (646) 378-2949