



Lineage Cell Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

March 11, 2021

- **Completed Enrollment in Phase 1/2a Clinical Trial of OpRegen for the Treatment of Dry Age-Related Macular Degeneration**
- **Announced First Known Report of Human Retinal Tissue Restoration; Persisted to 23 Months with Improved Vision**
- **Made Significant Improvements to OPC1 Manufacturing, Including to Process, Purity, and Scale**
- **Reacquired the VAC Immuno-Oncology Platform and Reported Initial Data in Ongoing Phase 1 Clinical Trial in Non-Small Cell Lung Cancer**
- **Received \$24.6 Million Installment Payment from Juvenescence Ltd. Related to Sale of AgeX Therapeutics**
- **Current Cash Position Expected to Support Operations Well Into 2023**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 11, 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 fourth quarter and full year 2020. 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 fourth quarter and full year 2020 financial and operating results and to provide a business update.

"Our goal is to build Lineage into the preeminent allogeneic cell transplant company, and we hit our stride in 2020, reaching significant clinical, manufacturing, and business milestones and creating substantial value for our shareholders. We also positioned ourselves for success in 2021 and beyond," stated Brian M. Culley, Lineage CEO. "We know of no other company that possesses a comparable combination of cell therapy patent breadth, in-house manufacturing capabilities, and encouraging clinical evidence in three distinct disease areas, each with large unmet needs and billion-dollar commercial opportunities. We believe the field of cell therapy is poised for explosive growth in the months and years ahead. Our objective is to be positioned for that growth by continuing to provide evidence that allogeneic approaches can generate safety and efficacy data which leads to commercial and clinical advantages over alternate approaches. Importantly, Lineage also recently added \$35.9 million in new capital through the timely sales of our equity and marketable securities. We believe this new capital will ensure we are funded to deliver additional significant milestones from our novel cell therapy pipeline and provide us with optionality in ongoing partnership discussions."

Some of the significant milestones we achieved during 2020 include:

- [Completion](#) of enrollment in a 24 patient Phase 1/2a clinical study of [OpRegen®](#) for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA) with encouraging preliminary signs of tolerability and efficacy;
- [Announcing](#) the first known finding of retinal tissue restoration in a patient who received a retinal pigment epithelium (RPE) cell transplant which had persisted to 23 months with further improvements to visual acuity;
- Making major [manufacturing improvements](#) to our [OPC1](#) acute spinal cord injury (SCI) program, including to the process, purity, and scale, and to the development of a "ready-to-inject" formulation, enabling use at a much larger number of treatment centers;
- The [early exercise](#) of our option with [Cancer Research UK](#) to bring the VAC immuno-oncology platform in-house;
- [Reporting](#) encouraging preliminary Phase 1 clinical study results with [VAC2](#) for the treatment of non-small cell lung cancer with evidence of high levels of antigen-specific immunogenicity observed in all patients treated to date;
- [Receiving](#) a new research & development grant from the Israel Innovation Authority under their bio-convergence initiative, for the development of a novel bio-retinal patch for the treatment of retinal diseases in partnership with Precise Bio Ltd.;
- [Announcing](#) the extension of an OpRegen development grant from the Israel Innovation Authority;
- [Receiving](#) a \$24.6 million payment from Juvenescence Ltd. for principal and interest due under a convertible promissory note issued as partial payment for the sale of common stock of AgeX Therapeutics, Inc.; and
- Successfully monetizing portions of Lineage's non-core patent portfolio.

Some of the events and milestones that our shareholders can look forward to in 2021 include:

- Present new and accumulated OpRegen data from the ongoing Phase 1/2a clinical study on two occasions during the first and second quarters of 2021;
- Plan to meet with the FDA to discuss further clinical development of the OpRegen program, anticipated in the third quarter of 2021;
- Complete VAC2 patient enrollment in the ongoing Phase 1 clinical study for the treatment of non-small cell lung cancer, anticipated in the second quarter of 2021;
- Evaluate the Neurgain Parenchymal Spinal Delivery (PSD) system for OPC1, currently ongoing and throughout 2021;

- Plan to meet with the FDA to discuss plans to evaluate the Neurgain Parenchymal Spinal Delivery (PSD) system for OPC1, anticipated in the second quarter of 2021;
- Complete OPC1 process development to support a late-stage clinical trial, currently ongoing and throughout 2021;
- Introduce manufacturing enhancements to the VAC2 program, anticipated throughout 2021;
- Report results from the ongoing Phase 1 clinical study of VAC2 for the treatment of non-small cell lung cancer, anticipated in the fourth quarter of 2021;
- Plan to meet with the FDA to discuss further development of the OPC1 program and manufacturing improvements, including a late-stage clinical study, anticipated in the fourth quarter of 2021;
- Evaluate opportunities for new VAC product candidates based on newly discovered tumor antigens/neoantigens, throughout 2021; and
- Evaluate partnership opportunities and expansion of existing external collaborations and identification of new collaborations for OpRegen, OPC1 and VAC2, currently ongoing and throughout 2021.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled \$41.6 million as of December 31, 2020. Marketable securities as of December 31, 2020 include our remaining ownership of unrestricted securities in OncoCyte, and Hadasit Bio-Holdings Ltd (Hadasit).

During 2020, we funded our operations primarily by receiving payment in full for a total of \$24.6 million on the Juvenescence promissory note, and by selling a portion of our marketable securities, resulting in net proceeds of approximately \$13.1 million.

Additionally, during 2020, we selectively sold 3,094,322 of our common shares under the ATM offering for gross proceeds of approximately \$5.1 million (which excludes \$0.3 million of cash in transit related to 2020 sales that settled in 2021).

2021 fundraising activities

From January 1, 2021 through March 5, 2021, we sold an additional portion of our marketable securities, resulting in net proceeds of approximately \$10.1 million and an additional \$19.9 million in gross proceeds through sales of 7,941,122 of our common shares under the ATM offering (which includes \$0.3 million in cash in transit related to 2020 sales that settled in 2021). As of March 5, 2021, the value of the Company's cash and cash equivalents were in excess of \$57 million.

As of March 5, 2021, we hold 1,122,401 shares of OncoCyte stock valued at approximately \$4.2 million and 169,167 shares of Hadasit stock valued at approximately \$330,000, in each case based on the closing prices of those shares on March 5, 2021.

The Company anticipates that net operational spend for 2021 will be approximately \$20.0 to \$22.0 million, which is similar to 2020 spending levels. The Company believes that it is well funded into 2023 as a result of sustained cost savings initiatives in 2020 and recent fundraising activities.

Fourth Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the three months ended December 31, 2020 were approximately \$0.4 million, a decrease of \$0.8 million as compared to \$1.2 million for the same period in 2019. The decrease was primarily related to an approximate \$0.6 million decrease in royalties and licensing fees, which was primarily driven by the absence of a \$0.6 million upfront payment from a new license agreement in 2019, and a \$0.2 million decrease in grant revenues due to 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 December 31, 2020 were \$6.1 million, a decrease of \$1.9 million as compared to \$8.0 million for the same period in 2019.

R&D Expenses: R&D expenses for the three months ended December 31, 2020 were \$2.6 million, a decrease of \$0.9 million as compared to \$3.5 million for the same period in 2019. The overall decrease was primarily related to decreases of \$1.5 million in OpRegen and other ophthalmic application expenses, attributable primarily to a decrease in manufacturing activities in 2020 as compared to 2019, and \$0.1 million in Renevia and HyStem related expenses, offset by an increase of \$0.5 million in OPC1 expenses, attributable primarily to an increase in manufacturing activities, and a \$0.3 million increase in VAC program expenses.

G&A Expenses: G&A expenses for the three months ended December 31, 2020 were \$3.5 million, a decrease of \$1.0 million as compared to \$4.5 million for the same period in 2019. The decrease was primarily attributable to decreases of \$0.4 million in legal and patent expenses, \$0.3 million in rent expense, \$0.3 million in expenses related to our merger with Asterias Biotherapeutics, Inc. (Asterias Merger) and \$0.2 million in accounting and consulting expenses, offset by a \$0.2 million increase related to the cessation of shared services reimbursements.

Loss from Operations: Loss from operations for the three months ended December 31, 2020 was \$5.9 million, a decrease of \$1.0 million as compared to \$6.9 million for the same period in 2019.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended December 31, 2020 reflected other income, net of \$6.9 million, compared to other income, net of \$1.5 million for the same period in 2019. The variance was primarily related to the gain on sale of marketable securities and changes in the value of marketable equity securities for the applicable periods, as well as foreign currency translation adjustments related to Lineage's international subsidiaries.

Net Income/(Loss) attributable to Lineage: The net income attributable to Lineage for the three months ended December 31, 2020 was \$2.0 million, or \$0.01 per share (basic and diluted), compared to a net loss attributable to Lineage of (\$4.5) million, or (\$0.03) per share (basic and diluted), for the same period in 2019.

Full Year Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the year ended December 31, 2020 were \$1.8 million, a decrease of \$1.7 million as compared to \$3.5 million for the same period in 2019. The decrease was primarily related to a \$1.0 million decrease in grant revenue due to less grant-related activities, \$0.4 million decrease in royalties from product sales and license fees, and a \$0.3 million decrease in the sale of research products and services due to the cessation of such sales.

Operating Expenses: Operating expenses are comprised of R&D expenses and G&A expenses. Total operating expenses for the year ended December 31, 2020 were \$27.9 million, a decrease of \$14.1 million as compared to \$42.0 million for the same period in 2019.

R&D Expenses: R&D expenses for the year ended December 31, 2020 were \$12.3 million, a decrease of \$5.6 million as compared to \$17.9 million for the same period in 2019. The overall decrease was primarily related to a decrease of \$6.5 million in OpRegen and other ophthalmic application expenses, attributable primarily to a decrease in manufacturing activities in 2020 as compared to 2019, a decrease of \$0.8 million in Renevia and other related expense as we are spending less and actively looking for a commercialization partner, and a \$0.5 million decrease in OPC1-related expenses, primarily driven by a return of unspent project funds of approximately \$0.8 million from a former Asterias service provider, offset by a \$2.2 million increase in VAC program expenses, primarily related to the accrual of the signature fee of £1.25 million (\$1.6 million) to Cancer Research UK.

G&A Expenses: G&A expenses for the year ended December 31, 2020 were \$15.6 million, a decrease of approximately \$8.4 million as compared to \$24.0 million for the same period in 2019. The decrease was primarily attributable to a \$5.5 million decrease in Asterias Merger related expenses, a \$2.1 million reduction in compensation costs as a result of headcount reductions in 2019, a \$0.9 million reduction in accounting expenses, a \$0.5 million reduction in rent and utilities, a \$0.3 million reduction in travel expenses, a \$0.3 million reduction in office and information technology related expenses and a \$0.2 million reduction in consulting expenses, offset by a \$0.9 million increase related to the cessation of shared services reimbursements and a \$0.5 million increase in legal and patent expenses.

Loss from Operations: Loss from operations for the year ended December 31, 2020 was \$26.4 million, a decrease of \$12.5 million as compared to \$38.9 million for the same period in 2019.

Other Income, Net: Other income, net for the year ended December 31, 2020 reflected other income, net of \$4.5 million, compared to other income, net of \$19.6 million for the same period in 2019. The variance was primarily related to the changes in the value of equity method investments and marketable equity securities for the applicable periods, gain on sale of marketable securities for the applicable periods, as well as foreign currency translation adjustments related to Lineage's international subsidiaries.

Net loss attributable to Lineage: The net loss attributable to Lineage for the year ended December 31, 2020 was \$20.6 million, or \$0.14 per share (basic and diluted), compared to a net loss attributable to Lineage of \$11.7 million, or \$0.08 per share (basic and diluted), for 2019.

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 fourth quarter and full year 2020 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 March 19, 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 4176568.

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) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, currently in 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," "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 anticipated net operational spend for 2021, data presentations, clinical trial advancement, planned meetings with the FDA and partnership evaluations. 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 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)

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 32,585	\$ 9,497
Marketable equity securities	8,977	21,219
Promissory note from Juvenescence	-	23,616
Trade accounts and grants receivable, net	4	317
Receivables from affiliates, net	-	7
Prepaid expenses and other current assets	2,433	2,863
Total current assets	<u>43,999</u>	<u>57,519</u>
NONCURRENT ASSETS		
Property and equipment, net	5,630	8,175
Deposits and other long-term assets	616	864
Goodwill	10,672	10,672
Intangible assets, net	47,032	48,248
TOTAL ASSETS	<u>\$ 107,949</u>	<u>\$ 125,478</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 6,813	\$ 5,226
Financing lease and right-of-use liabilities, current portion	762	1,223
Deferred revenues	193	45
Liability classified warrants, current portion	1	-
Total current liabilities	<u>7,769</u>	<u>6,494</u>
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	3,315
Deferred revenues, net of current portion	-	200
Right-of-use lease liability, net of current portion	2,514	3,868
Financing lease, net of current portion	26	77
Liability classified warrants and other long-term liabilities	437	277
TOTAL LIABILITIES	<u>12,822</u>	<u>14,231</u>
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2020 and 2019, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 153,096 and 149,804 shares issued and outstanding as of December 31, 2020 and 2019, respectively	393,944	387,062
Accumulated other comprehensive loss	(3,667)	(681)
Accumulated deficit	(294,078)	(273,422)
Lineage Cell Therapeutics, Inc. shareholders' equity	<u>96,199</u>	<u>112,959</u>
Noncontrolling interest (deficit)	(1,072)	(1,712)
Total shareholders' equity	<u>95,127</u>	<u>111,247</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 107,949</u>	<u>\$ 125,478</u>

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

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
REVENUES:		
Grant revenue	\$ 1,053	\$ 2,037
Royalties from product sales and license fees	773	1,221

Sale of research products and services	-	257
Total revenues	1,826	3,515
Cost of sales	(385)	(412)
Gross profit	1,441	3,103
OPERATING EXPENSES:		
Research and development	12,317	17,948
General and administrative	15,571	24,031
Total operating expenses	27,888	41,979
Loss from operations	(26,447)	(38,876)
OTHER INCOME, NET:		
Interest income, net	1,039	1,685
Gain on sale of marketable securities	4,560	2,421
Gain on sale of equity method investment in OncoCyte	-	546
Unrealized loss on marketable equity securities	(3,782)	(2,898)
Unrealized gain on equity method investment in OncoCyte at fair value	-	8,001
Unrealized gain on equity method investment in Asterias at fair value	-	6,744
Unrealized (loss) gain on warrant liability	(174)	611
Other income, net	2,880	2,532
Total other income, net	4,523	19,642
LOSS BEFORE INCOME TAXES	(21,924)	(19,234)
Income tax benefit	1,239	7,407
NET LOSS	(20,685)	(11,827)
Net loss attributable to noncontrolling interest	36	118
NET LOSS ATTRIBUTABLE TO LINEAGE	<u>\$ (20,649)</u>	<u>\$ (11,709)</u>
NET LOSS PER COMMON SHARE:		
BASIC AND DILUTED	<u>\$ (0.14)</u>	<u>\$ (0.08)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC AND DILUTED	<u>150,044</u>	<u>145,533</u>

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

	Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (20,649)	\$ (11,709)
Net loss attributable to noncontrolling interest	(36)	(118)
Adjustments to reconcile net loss attributable to Lineage to net cash used in operating activities:		
Unrealized gain on equity method investment in OncoCyte at fair value	-	(8,001)
Unrealized gain on equity method investment in Asterias at fair value	-	(6,744)
Gain on sale of marketable equity securities	(4,560)	(2,967)
Unrealized loss on marketable equity securities	3,782	2,898
Income tax benefit	(1,239)	(7,407)
Depreciation expense, including amortization of leasehold improvements	823	1,002
Amortization of right-of-use assets	72	129
Amortization of intangible assets	1,216	1,998
Stock-based compensation	2,227	3,580
Common stock issued for services	119	-
Change in unrealized loss (gain) on warrant liability	174	(611)
Write-off of security deposit	150	-
Amortization of deferred license fee	(200)	-
Foreign currency remeasurement and other (gain) loss	(2,957)	(2,367)

(Gain) loss on sale of assets	(20)	273
Realized loss on warrant exercise	44	-
Dividend received	-	182
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	287	467
Accrued interest receivable	(1,008)	(1,512)
Receivables from affiliates, net of payables	7	2,105
Prepaid expenses and other current assets	1,575	(260)
Accounts payable and accrued liabilities	308	(2,885)
Deferred revenue and other liabilities	132	-
Net cash used in operating activities	(19,753)	(31,947)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of OncoCyte common shares	10,941	10,738
Proceeds from the sale of AgeX common shares	1,290	1,734
Proceeds from the sale of Hadasit common shares	830	1,743
Cash and cash equivalents acquired in the Asterias Merger	-	3,117
Purchase of property and equipment	(64)	(440)
Proceeds from sale of assets	23	82
Security deposit paid and other	18	(17)
Net cash provided by investing activities	13,038	16,957
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from payment of Juvenescence promissory note	24,624	-
Common shares received and retired for employee taxes paid	(27)	(110)
Proceeds from sale of subsidiary warrants	-	(40)
Proceeds from sale of common shares	5,127	103
Payments for offering costs	(356)	-
Repayment of financing lease liabilities	(26)	(30)
Proceeds from Paycheck Protection Program ("PPP") Loan (Note 8)	523	-
Reimbursement from landlord on tenant improvements	-	764
Repayment of principal portion of promissory notes	-	(70)
Net cash provided by financing activities	29,865	617
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(63)	70
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	23,087	(14,303)
At beginning of year	10,096	24,399
At end of year	\$ 33,183	\$ 10,096

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