Lineage Cell Therapeutics Receives CE Mark Approval for Renevia®

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Comparative clinical trial met its primary endpoint of change in hemifacial volume at six months (p<.001)

CARLSBAD, Calif.--(BUSINESS WIRE)--Sep. 19, 2019-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, announced today 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.

"Obtaining CE Mark approval for Renevia is an important corporate accomplishment that demonstrates Lineage's ability to generate positive data from clinical trials and direct a regulatory application through a successful review and registration process. I wish to congratulate our clinical/regulatory and technical operations teams on achieving this milestone," stated Brian M. Culley, Chief Executive Officer. "As a next step, our Board of Directors has authorized us to engage a European business development representative to evaluate and negotiate partnership opportunities for Renevia. In light of our focus on advancing our three clinical-stage cell therapy programs, we believe it is in the best interests of our shareholders to seek an external partner with the commercial capabilities and know-how to launch Renevia in the European market and in return, provide Lineage with non-dilutive capital to support our novel cell therapy programs. We also will continue to invite and explore development and partnership opportunities for Renevia's underlying hydrogel technology, HyStem®, which may hold potential as a supportive scaffold for cell therapy, including patient-derived organoid culture and bioprinting of new organs."

"Renevia, in combination with autologous adipose tissue, offers a new small-volume treatment for facial lipoatrophy," Mr. Culley continued. "In Renevia's pivotal trial in Europe, Lineage studied patients with human immunodeficiency virus (HIV) treatment-associated lipoatrophy, a severe form of lipoatrophy characterized by the pathological loss of body fat from under the skin. Renevia is designed to mimic the naturally occurring extracellular matrix in the body and provide a 3-D scaffold, which we believe supports effective adipose tissue transplant, retention, engraftment, and metabolic support. Renevia and Lineage's other HyStem-associated hydrogel injectable matrices are designed to facilitate the survival and growth of transplanted cells. Data from the pivotal trial suggest that Renevia may be a stable long-term solution not only for people with HIV-associated lipoatrophy, but also for people with other forms of facial fat loss, such as those caused by pharmaceuticals or aging. Additionally, Renevia may be able to serve as a premium alternative to currently available dermal fillers, which we believe account for more than a million procedures each year in the European facial aesthetics market. Use of Renevia and autologous adipose tissue may have the potential to create a better, longer-lasting, and more natural outcome than other fillers used alone."

As Lineage proceeds with its efforts to evaluate and negotiate partnership opportunities for Renevia, it expects to provide investors with additional information regarding commercial plans for the program.

About Renevia Pivotal Trial

In 2017, the Company announced that the Renevia® pivotal trial in Europe had met its primary endpoint. The primary endpoint was the change in hemifacial volume at six months in the treated patients compared to patients in the delayed treatment arm as measured by 3D photographic volumetric assessment. Treated patients received approximately 5cc of Renevia in each side of the face (hemifacial). On average, treated patients retained approximately 100% of transplanted volume at six months. Untreated patients had no incremental hemifacial volume after six months. Comparison of the two trial arms had a statistical p value <.001. All Renevia transplants were well tolerated and there were no device-related serious adverse events noted in this pivotal trial. As well as meeting the primary endpoint, treated patients retained an average of 70% of transplanted volume at 12 months and 64% at 18 months.

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/IIa 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/IIa 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. 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 Lineage's marketing, distribution and commercial plans for Renevia and Hystem. 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

described 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 filed 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 occur or circumstances that exist after the date on which they were made, except as required by law.

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