LineaBio submits Drug Master File for Linea 1 GMP iPSC line to U.S. Food and Drug Administration

November 20, 2024 (Toronto, Ontario) – LineaBio, a cell line company, today announced it has submitted a Type II Drug Master File (DMF) to the U.S. Food and Drug Administration (FDA) for its flagship unmodified, off-the-shelf, Good Manufacturing Practices (GMP)-compliant induced pluripotent stem cell (iPSC) line, Linea 1.

LineaBio was launched in 2023 by parent companies CCRM, a global leader in iPSC capabilities and platform development, and OmniaBio, a technology-focused cell and gene therapy clinical and commercial contract development and manufacturing organization. The company's off-the-shelf iPSC lines will enable cell therapy developers by accelerating time to GMP by 12 months and reducing cell line development costs by up to 60 per cent.

The DMF provides a comprehensive chemistry, manufacturing and controls (CMC) data package for Linea 1. More broadly, the DMF includes information related to the manufacturers, manufacturing process, control of materials, specifications and analytical procedures used in the manufacturing of Linea 1. Any developer that executes a commercial license with LineaBio to conduct clinical research using the Linea 1 line will be provided a Letter of Authorization (LOA) at the time of its Investigational New Drug (IND) submission to the FDA. The LOA will allow the FDA to refer to the contents of the DMF during review of an IND submission.

"Ultimately, LineaBio's mission is to enable the cell and gene therapy industry. Drug master files are an essential component of high-quality, off-the-shelf iPSC lines, as they standardize the CMC data package," says Mark Curtis, CEO of LineaBio. "LineaBio is committed to ensuring all current and prospective off-the-shelf Linea iPSC lines are covered by a DMF, so drug developers can readily incorporate a comprehensive CMC data package into their regulatory submissions by reference."

LineaBio engaged Dark Horse Consulting (DHC) to author the DMF. DHC's team of technical writers has considerable experience in preparing master files for submission to the FDA and deep technical expertise in the field of iPSCs.

LineaBio is actively working on characterizing the Linea 1 GMP iPSC line. The DMF for Linea 1 will be updated as necessary to support client needs and programs.

About LineaBio

LineaBio's mission is to enable the cell and gene therapy industry by providing access to high-quality, off-the-shelf iPSC lines manufactured under GMP that streamline drug product manufacturing. By allowing therapeutic developers to cut costs and accelerate timelines for GMP reprogramming, LineaBio strives to achieve its vision of making cell therapy universally accessible and affordable. Founded in 2023 by parent companies CCRM and OmniaBio, LineaBio draws on a team of iPSC experts that have been developing an iPSC platform since 2012. Visit www.lineabio.com to learn more.

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