

Two Cell and Gene Therapies Manufactured at Lonza Houston Reach US FDA Approval in Q3 2022

- The two recent FDA approvals of ZYNTEGLO® (betibeglogene autotemcel) and SKYSONA® (elivaldogene autotemcel), both developed by bluebird bio, mean that Lonza's Houston (US) site now supports three commercial cell and gene therapy (CGT) products with manufacturing services, including cell therapy manufacturing and viral vector manufacturing
 - Approval milestones reflect the effectiveness of Lonza's New Product Introduction (NPI) process, which provides customers with a systematic approach to tech transfers, cGMP manufacturing and pre-approval inspection readiness
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Basel, Switzerland, Thursday 6 October 2022 – Lonza, a global manufacturing partner to the pharmaceutical, biotech and nutrition industries, today announced that two additional cell and gene therapies manufactured at its Houston (US) site have reached commercial approval in Q3 2022. ZYNTEGLO®, for the treatment of transfusion-dependent beta-thalassemia; and SKYSONA®, for the treatment of early, active cerebral adrenoleukodystrophy, are both manufactured by bluebird bio of Somerville, Massachusetts and were approved in August and September, respectively. These regulatory approvals represent the second and third cell and gene therapy commercial approvals supported by Lonza's Houston (US) facility.

Lonza Houston (US) is dedicated to contract cell and gene therapy development and manufacturing. The facility successfully passed Food and Drug Administration (FDA) pre-Licensing inspections for the viral vector manufacturing or for the cell therapy manufacturing of three commercial cell and gene therapy products that were subsequently approved by the FDA for commercial use in 2021 and 2022.

Lonza's Cell & Gene Technologies (CGT) business, the contract development and manufacturing business unit of its Cell & Gene division, has developed an NPI process to support customers on their journey from early-stage development to commercialization. It provides a roadmap and a systematic approach to development and manufacturing, ensuring necessary quality standards are met for tech transfers, cGMP manufacturing and pre-approval inspection readiness. This NPI process has been designed to support more CGT customers in reaching commercialization with their new and innovative products.

Alberto Santagostino, SVP, Head of Cell and Gene Technologies at Lonza, commented: "The two new approvals represent an important milestone for bluebird bio and the patients who can now benefit from these therapies. The successful approvals reflect our colleagues' dedication to

supporting our customers in bringing these cell and gene therapies to market. Opened less than five years ago, our Houston site is now manufacturing three commercial cell and gene therapies. We look forward to supporting more customers on their path to commercialization as we continue on our journey towards wider cell and gene therapy adoption."

Lonza is committed to continuous improvement of quality and operations in collaboration with regulatory authorities. It also remains committed to playing an active role in establishing quality standards for commercial manufacturing as the cell and gene therapy field continues to evolve.

To learn more about Lonza's Cell and Gene Division offerings, visit: <https://www.lonza.com/cell-and-gene>

About Lonza

Lonza is a preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare industry.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With more than 17,000 full-time employees, we comprise high-performing teams and individual talent who make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 3 billion with a CORE EBITDA of CHF 987 million in H1 2022. Find out more at www.lonza.com.

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