



# **MEDIA RELEASE**

# Sheba Medical Center Treats First Patient with CAR-T Cell Immunotherapy Manufactured Using the Lonza Cocoon® Platform

- First cancer patient dosed at Sheba Medical Center, Isreal with autologous CAR-T therapy manufactured using Lonza's Cocoon® Platform
- Israeli Ministry of Health (MOH) approved use of the Cocoon Platform to manufacture a CD19 CAR-T cell immunotherapy for an ongoing Phase II clinical trial for B-cell malignancies
- MOH approval follows an extensive study that showed comparability of the therapy whether manufactured using the manual, open process or the automated, functionally closed Cocoon Platform

## Quote from Eytan Abraham, Head of Personalized Medicine, Lonza Pharma & Biotech:

"Treatment of the first patient is a significant milestone for Lonza and demonstrates the Cocoon's capability to manufacture patient-scale cellular immunotherapies in a cGMP setting for clinical use. Moreover, this project has demonstrated the feasibility and attractiveness of moving open processes into the automated and functionally closed Cocoon Platform, and the ability to enable decentralized manufacturing at point-of-care.

Ahead of treating the first patient, the full qualification and CE<sup>1</sup> marking of the Cocoon Platform was also a key achievement. We continue to work with multiple partners on extending the use of the Cocoon Platform for clinical manufacturing of additional cell therapies. Lonza's goal is to provide the flexibility to efficiently manufacture patient-scale cell therapies in a centralized or decentralized model, with a lower cost, and a scalable approach. Ultimately, we believe that this approach will make these lifesaving therapies available to many more patients in need."

## Quote from Professor Dror Harats, VP for Research & Development, Sheba Medical Center:

"Sheba Medical Center is proud to work with Lonza on this unique, cutting-edge Cocoon Platform. This groundbreaking technology will take us one step closer to mass manufacture of CD-19 CAR-T cells in order to save the lives of many critically ill cancer patients."

**Basel, Switzerland and Tel Aviv, Israel, 8 September 2020** – Lonza and Sheba Medical Center announced the first patient has been treated at Sheba Medical Center with a CD19 CAR-T cell immunotherapy manufactured using Lonza's Cocoon® Platform. The Cocoon Platform is an automated and functionally closed system for patient-scale cell therapy manufacturing, designed to overcome some of the manufacturing challenges of manually producing personalized medicines, including autologous CAR-T cell therapies.

With the goal of increasing access to innovative cell therapies, Sheba Medical Center and Lonza have collaborated to translate Sheba's open, manual manufacturing process into the Cocoon Platform since mid-2019. In less than a year, teams from Lonza Personalized Medicine and Collaborative Innovation Center (CIC) in Haifa, IL worked closely with Sheba Medical Center to complete process development, tech transfer, training and a full clinical comparability study requiring regulatory approval before the first patient could be treated. The successful approval of the Cocoon Platform clinical comparability study illustrates the platform's flexibility and ability to manufacture a final cell immunotherapy which is comparable to the original manual process while meeting the extensive patient safety criteria.

The current Phase II clinical trial<sup>2</sup> at Sheba has successfully dosed over 100 patients over the last two years with positive clinical results. Sheba and Lonza plan to treat additional patients under the same CD19 CAR-T cell immunotherapy protocol using the Cocoon Platform. The Cocoon Platform will enable Sheba to reduce immunotherapy manufacturing costs by lowering manpower, time, and space requirements. It is hoped that this will ultimately allow Sheba to deliver potentially curative cellular immunotherapies to more patients.

<sup>&</sup>lt;sup>1</sup> CE marking is a designation ensuring that products meet EU standards for health, safety, and environmental protection

<sup>&</sup>lt;sup>2</sup> https://clinicaltrials.gov/ct2/show/NCT02772198?term=NCT02772198&draw=2&rank=1

#### **About Lonza**

At Lonza, we combine technological innovation with world class manufacturing and process excellence. Together, these enable our customers to deliver their discoveries in the healthcare, preservation and protection sectors.

We are a preferred global partner to the pharmaceutical, biotech and specialty ingredients markets. We work to prevent illness and promote a healthier world by enabling our customers to deliver innovative medicines that help treat or even cure a wide range of diseases. We also offer a broad range of microbial control solutions, which help to create and maintain a healthy environment.

Founded in 1897 in the Swiss Alps, Lonza today operates in 120 sites and offices in more than 35 countries. With approximately 15,500 full-time employees, we are built from high-performing teams and of individual employees who make a meaningful difference to our own business, as well as the communities in which we operate. The company generated sales of CHF 5.9 billion in 2019 with a CORE EBITDA of CHF 1.6 billion. Find out more at www.lonza.com and follow us on Twitter @LonzaGroup or Facebook @LonzaGroupAG.

#### **About Sheba Medical Center**

Sheba Medical Center, Tel HaShomer is the largest and most comprehensive medical center in Israel and the Middle East. Sheba is the only medical center in the region that combines an acute care hospital and a rehabilitation hospital on one campus, and it is at the forefront of medical treatments, patient care, clinical trials, research and education. As a university teaching hospital affiliated with the Sackler School of Medicine at Tel-Aviv University, it welcomes people from all over the world indiscriminately. For the past two years (2019 and 2020), Newsweek Magazine has named Sheba one of the top ten hospitals in the world. For more information, visit: eng.sheba.co.il

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