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News and Articles

Fiocruz installs modular laboratory for the production of CAR-T therapies.



This Saturday (May 23), President Luiz Inácio Lula da Silva visited the **CAR-T Therapy Development and Production Center**, where the first **100% nationally** developed trispecific CAR-T **cell therapy** will be produced. The laboratory is located in a modular unit at the Institute of Technology in Immunobiologicals (**Bio-Manguinhos/Fiocruz**).

The launch of the Center is the first physical milestone of the technology transfer partnership established in November 2023 between Fiocruz, the Ministry of Health, and the US non-profit organization Caring Cross. The initiative represents a landmark in the **Brazilian strategy for cell therapies**, with two key structural differentiators:

Decentralized model (point of care) – The modular laboratory, installed in a container, allows the production of CAR-T therapy to occur close to treatment centers, enabling a decentralized national strategy. This model reduces logistical costs, speeds up care, and can be replicated in different regions of the country, expanding access to highly complex treatments within the SUS (Brazilian Public Health System). The first production unit using this model is already installed in Rio de Janeiro at Bio-Manguinhos/Fiocruz and will soon be operational, supporting the start of clinical studies in the country.

Domestic Production of Lentiviral Vectors – Because they are responsible for transporting the CAR (Chimeric Antigen Receptor) gene to the DNA of the patient's immune cells (T lymphocytes), vectors are the key component of the therapy. The production of high-quality CAR-T cells depends on safe and efficient lentiviral vectors. Bio-Manguinhos will be the first domestic producer of viral vectors, guaranteeing the country complete control of the entire therapy production chain and eliminating dependence on imports.

This initiative is part of the **Fiocruz Strategy for Advanced Therapies** and reinforces the institution's role as a facilitator of structural solutions for the Brazilian Unified Health System (SUS). The project foresees the vertical integration of the main production stages of this treatment within the country, significantly reducing external dependence and expanding the country's capacity to respond to complex health challenges. Through technology transfers, Bio-Manguinhos/Fiocruz becomes a global producer of advanced therapies, locally replicating the manufacturing processes of **viral vectors** and cell processing developed by the technology transfer partners.

The main objective of the technology transfer agreement is to make these therapies available to a larger number of patients who currently lack access due to the high cost. With production by Bio-Manguinhos/Fiocruz, the treatment could be available to the Brazilian population through the **Unified Health System (SUS)**. In the United States, CAR-T cell products approved for commercial use have an average cost of US\$350,000 to US\$400,000 per dose. With production at Bio-Manguinhos/Fiocruz, the cost could be reduced to about 10% of that value.

In practice, this reduction could represent a potential savings of billions of reais for the SUS (Brazilian Public Health System) over the next few years, in addition to allowing for an increase in the number of patients served and the gradual incorporation of these therapies into the public system.

According to Rosane Cuber, director of Bio-Manguinhos, lentiviral vectors are one of the most expensive components in the entire CAR-T therapy production chain and represent one of the main bottlenecks for price reduction and increased access.

“Local production of lentiviral vectors is a central strategy to reduce costs and ensure the sustainability of treatment. Furthermore, with the CAR-T Therapy Development and Production Center, Bio-Manguinhos delivers a decentralized solution that not only serves the Brazilian public system, but also makes us a reference *hub in the production and export of this model of advanced therapies for all of Latin America*,” explains director Rosane Cuber.

Lentivirus production will take place in a plant used for the Covid-19 vaccine.

The production of the lentiviral vector, necessary for the genetic modification of cells, will take place at the Bio-Manguinhos/Fiocruz viral vector plant recently used for the **Covid-19 vaccine**. In other words, the advances in the production of these therapies are the result of investment and technological training carried out during the pandemic.

At the CAR-T Therapy Development and Production Center, a modular laboratory manufactured in the United States, measuring approximately 70 square meters and currently installed at Bio-Manguinhos, the genetic modification of the patient's cells will be carried out. It is in this location that the cells will be "reprogrammed" to acquire therapeutic capacity and generate the cellular product (CAR-T) that will be infused into the patients.

How does CAR-T cell therapy work?



The therapy to be developed by Fiocruz is the trispecific duoCAR-T (technology developed by Caring Cross), whose main advantage is recognizing and simultaneously attacking three different antigens in cancer treatment. This ensures a more robust and comprehensive elimination of the disease, with the expectation of lasting clinical responses.

The project includes a clinical study led by the **National Cancer Institute (INCA)** for adult patients with **diffuse non-Hodgkin lymphoma** and **acute lymphoblastic leukemia** that are difficult to treat. Study participants will

have their cells extracted, the material will be transported to the laboratory where it will be transformed and then taken back to the hospital to be infused into the patients. The first patients are expected to receive the treatment in the second half of this year.

CAR-T cell therapy is an innovative type of treatment that uses the patient's own cells to fight cancer. First, healthcare professionals remove T lymphocytes, which are the patient's own immune cells. In the laboratory, these cells undergo genetic modification to receive a special receptor, called CAR, which allows them to recognize cancerous cells. These cells are multiplied in large quantities in the laboratory and reinfused into the patient, in a process similar to a common blood transfusion.

Once inside the patient's body, CAR-T cells identify and attack tumor cells. CAR-T therapy is considered one of the greatest recent advances in the field of oncology.

Text and art: Ascom/Bio-Manguinhos

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