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University Of São Paulo: Pilot Project For The Treatment Of Leukemia And Lymphomas In Ribeirão Preto Is Approved By Anvisa

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OHemocenter of Ribeirão Preto, linked to the Faculty of Medicine of USP in Ribeirão Preto, together with the Butantan Institute, was chosen by the National Health Surveillance Agency (Anvisa) for a pilot project aimed at developing cell therapy products for the treatment of leukemia and lymphomas and that it is made available to the population through the Unified Health System (SUS).

The professor and scientific director of the Blood Center, Rodrigo do Tocantins Calado de Saloma Rodrigues, from the Faculty of Medicine of Ribeirão Preto (FMRP) at USP, explains that the technology uses the patient's own cells. He explains that the procedure is similar to a blood donation, however, defense cells are isolated – specifically T lymphocytes, which is a type of white blood cell – and taken to the laboratory to be genetically modified with a new genetic code that “teaches” the body to recognize cancer cells in order to kill them.

The project

The partnership between Hemocentro RP and Instituto Butantan, according to Professor Calado, was formed by the expertise of Hemocentro RP in the production of cells and their manipulation, as well as the vector of the disease, adding the expertise of Instituto Butantan to offer biological products for human use and its very important manufacturing experience.

With the partnership formed, registration was carried out in Anvisa's public notice for the pilot project for the development of cell therapy products with a view to use in the SUS. “The reason for the choice, obviously that was a decision by Anvisa, but I imagine it was due to the quality, the robustness of the proposal and the data that we have

The stages of the study

The initial stage, explains Calado, is to submit the project and respond to Anvisa’s steps. Subsequently, carrying out the entire pre-clinical part – which consists of studies prior to testing in humans – to then achieve approval by Anvisa, by the Research Ethics Committee (CEP) of the Hospital das Clínicas, Faculdade de Medicina de Ribeirão Preto (HC - FMRP) and the National Research Ethics Committee (Conep).

Calado indicates that, as soon as the national bodies approve the study, 75 patients will be selected to undergo treatment with CAR-T cells in four different centers. In this phase, patients will be evaluated for about a year, according to the director of the Blood Center. Finally, after this period, patients will be followed up for another year to investigate the effect of the treatment and possible side effects. Only after evaluating the effects will the data be submitted for analysis by Anvisa for the decision to grant, or not, the registration of the product.

“In view of the high value of commercial products available today, which exceed R\$ 2 million, the objective is for us to establish these partnerships with the aim of offering SUS patients this type of treatment. In addition, it is a development of a highly sophisticated national technology, with employment in biotechnology, training people in the area and that may expand in the near future to other diseases, other situations and other types of cells, creating a cutting-edge biotechnology industry in the Country”, concludes Calado.