PRESS RELEASE

DEPARTMENT OF MEDICAL AREA – UNIVERSITY OF UDINE

TRIPLE NEGATIVE BREAST CANCER, BREAKTHROUGH IN RESEARCH FOR AUTOLOGUS CELL VACCINE

Department of Medical Area UniUD, VivaBioCell, Celica Biomedical, Veneto and Slovenia together to fight one of the most aggressive breast cancers, with fewer treatment options, poorer prognosis and low survival rate.

The aim is to define by the end of the year a joint protocol for the production of a biological drug, obtained from the same cells as the patient, which has already proved successful in the treatment of prostate cancer.

Autologus cell therapy, i.e. using cells taken from the patient herself, is the promising answer that the Immuno-Cluster cross-border reasearch project intends to put down on paper for the treatment of triple-negative breast cancer (NTBC), one of the most aggressive forms of breast cancer and the most difficult to treat. Its aggressiveness is confirmed by the name of the tumour itself, which accounts for 10-20% of all breast cancer diagnoses, affecting mainly young women, with a high incidence in north-eastern Italy and Slovenia (over 160 and 120 cases per 100,000 women), and for which the possibility of recurrence, even with chemotherapy, is extremely high.

«Triple negative – clarifies **Francesco Curcio, Professor of Clinical Pathology and Scientific Responsible for Department of Medical Area UniUD, together with the Valdotra Orthopaedic Hospital (SLO)** – derives from the fact that, unlike other breast tumors, it is characterized by the absence of estrogenic and progestin receptors and the lack of overexpression of the human epidermal growth factor receptor 2 (HER2), thus making it very difficult to treat the disease with standard approaches. Immunotherapy, which uses the parent's own immune system to fight the disease, and which has been in the experimental phase for decades in combinaton with traditional protocols, has certainly opened the way to promising new treatment possibilities. It is now essential to create a common critical mass of expertise, both clinical and manufacturing, that can work together as a system, also using new cellular and molecular approaches».

This is the starting point for the challenge of the research project, which is being carried out by a network of universities, cutting-edge hospitals, pharmaceutical and biotechnology companies that are already very active in advanced therapies for the treatment of cancer and in immunotherapy. It is up to them to define a shared protocol that will enable them to produce, by the end of the year, an autologus cellular medicine to be tested on patients with TNBC, who will be recruited by **the Institute of Oncology in Ljubliana** on the basis of specific parameters. A promising starting point is the HybriCureR clinical trial developed by the project lead partner, **Celica Biomedical**, and already clinically tested on a small number of patients with hormone-resistant prostate cancer. Safe, non-toxic and able to extend the time to secondary therapy by more than 4 times, as confirmed by **the Director, Robert Zorec**, it has also proven to be an ideal candidate for the treatment of TNBC. A treatment that aims to produce, through a complex process and an integration of different skills, those cells of the immune system, so-called "dendritic", which are specialised in the recognition and capture of antigenic (foreign) proteins and in the stimulation of an immune response by the body. «To obtain them, we have to start from blood samples sent to us by **the Ospedale dell'Angelo, the reference hub in the province of Venice**, and which, at this stage of the research, come from healthy donors. In the future, when the protocol is finalised, blood samples will be taken directly from women with TNBCs – explains **Flavia Mazzarol, Business Development Specialist at VivaBioCell**; At the moment, the Friuli Venezia Giulia facility has the task of experimentig the procedure in a "closed system", using the automatic bioreactor NANT, to significantly reduce the cost of cell therapy products and make it accessible, in the future, to more

and more people. Once these autologus dendritic cells, differentiated from monocytes, have been obtained, we will have to hybridise them, by means of electro-fusion, with the tumour cells surgically removed from the patient. In this way, once re-injected, they will be able to activate the immune system helping it to fight the cancer, having first allowed it to recognise it».

And while there are still a few more steps to be taken on the road to transferring the procedure to the patient's bedside, it is already clear that the expected results will also have a decidedly positive impact of companies and transnational healthcare system, with lower costs for treatment and care, and undoubted advantages for patients, who will benefit from a better quality of life and a better chance of recovery.

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