

Team successfully completes first clinical trial on HER-2-negative breast cancer with nintedanib

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The experimental drug nintedanib, combined with standard chemotherapy with paclitaxel, causes a total remission of tumours in 50% of patients suffering from early HER-2- negative breast cancer, the most common type of breast cancer. These are the conclusions of the Phase I Clinical Trial, sponsored by the Spanish National Cancer Research Centre (CNIO) and carried out by CNIO's Breast Cancer Clinical Research Unit. The study has been published today in *British Journal of Cancer*.

According to Miguel Ángel Quintela, head of the Unit: "The drug combination of paclitaxel and nintedanib has turned out to be a complete success, given that it is proved to be safe and that the pathologic complete response [rate of complete recovery] was 50%, which doubles the response compared to patients treated with standard therapy with [paclitaxel](#)." The trial has also included 10 HER-2-negative [breast cancer](#) patients, all of them in early stages of the disease.

In light of the results, the CNIO Breast Cancer Clinical Research Unit has already launched a large-scale Phase II Clinical Trial to validate the results in a large group of patients. These results, including biomarker studies that will facilitate advances in personalised medicine, will be released by early 2015.

In parallel, the Unit has just completed a second Phase I Clinical Trial

with a drug of the same family named dovitinib. The study has been tested in metastatic patients with different primary tumours such as breast, colon and lung cancer. The results, still in a preliminary stage, show that patients with a specific variant in the RET gene -a proto-oncogene or cancer driver gene; variant G2071A- could be more sensitive to this drug. This work has been published by Molecular Oncology.

As Quintela says, if these data are confirmed, this genetic variant -present in 15% of Caucasian people- could be used as a reliable biomarker in personalised medicine to select the best suited candidates to receive this drug.

Recent theories suggest that a possible solution to cancer might be to 'suffocate the tumour' by blocking the formation of new blood vessels that surround it.

The mechanism of action of the experimental drugs nintedanib (Boehringer Ingelheim) and dovitinib (Novartis) precisely consists on blocking the formation of new blood vessels, so-called angiogenesis, which can lead to retardation in tumour growth rates and limit its viability.

"Nintedanib [a drug that there is more experimental data on] is an improved antiangiogenic drug compared to previous angiogenesis inhibitors, given that it prevents angiogenesis in a more efficient way and with lower toxicity than its predecessors", explains Quintela.

Nintedanib, in addition to blocking vascular endothelial [growth factor](#) receptors (VEGFR) and platelet derived growth factor receptors (PDGFR), also acts on fibroblast growth factor receptors (FGFR), which makes it different to classical angiogenesis inhibitors.

FGFRs work in an aberrant manner in 10-15% of HER-2 negative breast cancers, which could explain a greater the compound's greater anti-[tumour](#) activity compared to other compounds.

After becoming one of the world's leading cancer research centres, one of CNIO's aims is to undertake developing a comprehensive project for excellence in oncology research, where the pathology can be looked at from different basic and translational viewpoints to facilitate the conversion of scientific knowledge into advances that benefit the care of patients.

An effective way to achieve that is by conducting clinical trials for cancer patients launched by the Clinical Research Programme, directed by oncologist Manuel Hidalgo.

"The clinical trials we are presenting are the first organised by CNIO, to whom several pharmaceutical companies have entrusted complete development of the previously mentioned experimental drugs", says Quintela. As the researcher explains, this "wouldn't have been possible without the fluid collaboration of hospitals from the Spanish National Health System, and the Spanish Breast Cancer Research Group".

Hidalgo says: "doing this type of study is critical to be able to test hypotheses formulated in the laboratory on patients without commercial pressures", adding that: "these studies show that it is possible to create a network of research centres and hospitals to carry out [clinical trials](#) with a strong scientific component".

Provided by Centro Nacional de Investigaciones Oncologicas

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