HER2 AS A GENOMIC PREDICTOR IN HER2+ BREAST CANCER

DESCRIPTION OF THE TECHNOLOGY

Knowing the genetics of a tumour provides fundamental clues to address its treatment. In breast cancer, the different rates of survival and response to treatments are partly explained by molecular differences within this disease. This molecular variability makes it evident that there is a need to better label each patient's type of breast cancer in order to refine the prognosis and response to treatment.

By analysing a defined number of these genes, the new genomic tests allow tumours to be classified into different groups. This makes it possible to predict the risk of relapse more accurately, and to define the benefits of the different treatments available to prevent it.

One of these groups of breast cancer is determined by the activation of a number of proteins - genes linked to the HER2 pathway -. The activation of this pathway, known as HER2-positive (HER2+), increases the proliferation, aggressiveness and resistance of tumour cells. However, the presence of this protein has become in recent years a key piece in the therapy of this group of tumours. The combination of chemotherapy with therapies specifically aimed at blocking this pathway has transformed this disease to become the one with the best prognosis.

The present invention allows predicting the degree of efficacy of different therapies in HER2+ breast cancer patients. The method uses an *in vitro* marker that helps the oncologist decide the most appropriate therapy, and particularly in the possibility of avoiding chemotherapy in the early stages of this disease.

MARKET APPLICATION SECTORS

Equipment and tool development companies focused on genomic studies, especially in the field of Oncology, with application in basic and applied research, translational medicine and molecular diagnosis.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

Given the genetic heterogeneity in HER2 + breast cancer, this invention has the following advantages:

- It allows directing and optimizing the treatment according to the genomic profile of the tumour.
- It allows predicting the benefit that will be obtained according to the treatment, and the evolution of the disease.
- Helps identify patients who obtain a high efficacy to the treatments targeted against HER2, thereby avoiding the chemotherapy.

This method brings us closer to the personalized medicine. Bearing in mind that HER2+ patients represent about 20% of all women diagnosed with breast cancer, and that 40% of them, which present the determined genomic profile, will have a complete response to targeted therapies directed against HER2 protein, approximately 10.000 women diagnosed each year in Europe could retain maximum cure options without the need for chemotherapy.

CURRENT STATE OF DEVELOPMENT

The method has been clinically validated in patients with HER2+, stage I - IIIA, phase 2 breast cancer. The study is on-going, in follow-up status (ClinicalTrials.gov Identifier: NCT01973660).

The next step is to demonstrate that patients with HER2+ tumors who have not received chemotherapy, based on this method, have a high survival rate.

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INTELLECTUAL PROPERTY RIGHTS

The technology has been filed under patent application to the European Patent Office, with priority date 07/12/2016, and in co-ownership with the Vall d'Hebron Institute of Oncology Private Foundation, SOLTI Foundation and Hospital Clínic de Barcelona.

COLABORATION SOUGHT

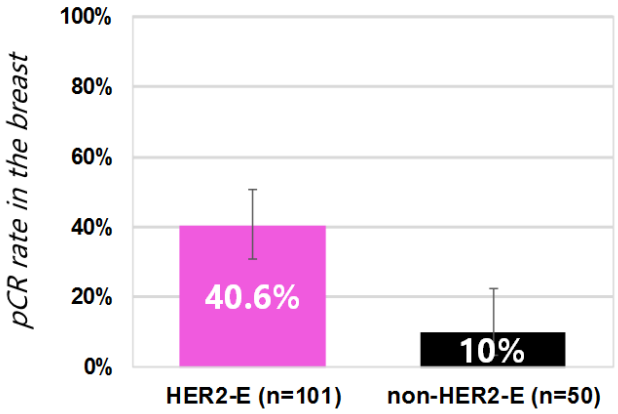
Patent license agreement to develop technology as a prognostic tool for breast cancer treatment.

RELATED IMAGES

Baseline samples (N=151)

	Number of patients with molecular subtype at baseline	Number of patients achieving pathological complete response	Pathological complete response (95% CI)
Total	151	46	30% (23–39)
Luminal A	22	0	0%
Luminal B	16	2	13% (4–36)
HER2-enriched	101	41	41% (31–51)
Basal-like	9	1	11% (2–44)
Normal-like	3	2	67% (21–94)

Table 2: Pathological complete response at the time of surgery, by intrinsic molecular subtype assessed at baseline



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