# Adding cetuximab to chemotherapy doubles response rate in hard-to-treat breast cancer

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European researchers have proven for the first time that targeting the epidermal growth factor receptor can provide substantial clinical benefit for women with hard-to-treat triple-negative breast cancer.

At the 35th Congress of the European Society for Medical Oncology (ESMO) in Milan, Italy, the researchers presented results from a Phase-II randomized trial showing that adding the anti-EGFR antibody cetuximab to cisplatin chemotherapy doubled the response rate and time to progression when compared to cisplatin chemotherapy given alone in a study of 173 heavily pre-treated women.

"We are very excited by these results," said lead researcher Professor Jose Baselga, until recently chief of the division of Hematology/Oncology at Vall d'Hebron Hospitals in Barcelona, Spain, and currently Associate Director of the Massachusetts General Hospital Cancer Center in Boston, USA. "Although epidermal growth factor receptor (EGFR) had been considered as a potential target for therapy in breast cancer, this is the first proof that this is the case."

Women in the study had so-called triple negative tumors --meaning they did not express estrogen receptors, progesterone receptors or HER2. These tumors are associated with a poor prognosis, partly because they tend to grow and spread through the body very rapidly, and partly because they do not respond well to other therapies.

Prof Baselga led a team that included researchers from Spain, Belgium,

Austria, Portugal, the UK and Israel.

Their study included 173 women with metastatic cancer who were randomized to receive either cetuximab (400 mg/m3 initial dose and then 250 mg/m3 weekly) plus up to six 3-weekly cycles of cisplatin, or cisplatin alone. Patients also had the option to switch to the combination, or cetuximab alone if their disease progressed.

The best overall response rate, of 20%, was seen with the cetuximab/cisplatin combination, the researchers report. This was twice as high as the overall response rate with cisplatin alone (10.3%). Adding cetuximab to cisplatin also more than doubled the median length of progression-free survival, from 1.5 to 3.7 months.

"These two months are very valuable because they more than double the progression-free survival compared to the cisplatin-alone arm," Prof Baselga said. "In this advanced-disease population, this type of improvement is rarely seen and it is highly significant."

"The results of this trial are extremely important and convincing given their magnitude," commented Dr Fabrice André from Institut Gustave Roussy in Villejuif, France. "They need now to be confirmed in the context of a large randomized trial."

"In addition to open new avenues in the field of cancer treatment, these results also have implications in the field of cancer biology". Dr André said. "They suggest that EGFR could play a role in the progression of triple-negative breast cancer."

Prof Baselga noted that triple-negative breast cancer probably represents a number of poorly understood sub-groups of breast cancer. "If we work hard at identifying the different subtypes and identify the appropriate targets, we should be able to change the natural history of this disease."

Dr André agreed, saying: "The results of this trial and others are showing that new and different treatments may provide benefit in subsets of patients with the disease, suggesting that this form of breast cancer might be further re-segmented according to molecular subtypes."

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