

EORTC study opens for elderly patients with HER-2 positive metastatic breast cancer

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Despite the fact that the incidence of cancer is many fold higher in persons over 65 years of age, we still have an inadequate understanding on how best to treat these older cancer patients. Furthermore, even though elderly patients are occasionally included in clinical trials, those elderly patients who are eventually included are mostly 'healthy' (fit) elderly patients. Thus, the broader elderly patient population is not well represented in clinical trials. The EORTC Cancer in the Elderly Task Force is now starting a new phase 2 trial in precisely this group of patients: EORTC 75111 – 10114 for non-fit elderly patients with HER-2 positive metastatic breast cancer.

Overall survival for patients with HER-2 positive breast cancer is improved with a combination of chemotherapy and agents that specifically target the HER-2 (human <u>epidermal growth factor receptor</u> 2) gene. Chemotherapy, however, is often accompanied with side effects that can adversely affect health related quality of life in elderly patients. EORTC trial 75111-10114 attempts to find out if HER-2 targeted regimens with minimal toxicity for the <u>elderly population</u> might delay, or even completely obviate, the use of conventional chemotherapy. New HER-2 targeted strategies have created an opportunity to try this strategy.

Patients who progress under pertuzumab and trastuzumab will be allowed to switch to Trastuzumab-DM1 conjugate (T-DM1), another recently available targeted therapy. The binding of trastuzumab to the cell allows intracellular delivery of the cytotoxic agent DM1. The



trastuzumab-DM1 conjugate has been shown to have a favorable toxicity profile.

The main objectives of EORTC trial 75111 – 10114 are to evaluate the efficacy as measured by progression free survival at six months following treatment with pertuzumab combined with trastuzumab or pertuzumab combined with trastuzumab plus metronomic chemotherapy in elderly metastatic breast cancer patients and to select attractive treatments for further development in Phase III. Metronomic chemotherapy uses low doses of chemotherapy drugs so as to minimize toxicity. This EORTC trial will include elderly patients with histologically proven HER-2 positive invasive breast cancer, but might also be suitable for fit (category 1) elderly patients who are wary of the side effects associated with conventional chemotherapy.

Prof. Hans P.M.W. Wildiers, Universitair Ziekenhuis Leuven - Campus Gasthuisberg, Chair of the EORTC Cancer in the Elderly Task Force, and Coordinator of this study says "With these very well tolerated new targeted therapies, we hope to control tumor growth sufficiently long so that toxic chemotherapy would not be needed, and many older patients would more likely die from ageing than cancer."

Provided by European Organisation for Research and Treatment of Cancer

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