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Pertuzumab adds 16 months survival benefit to trastuzumab and chemo treatment for HER2-positive breast cancer

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Patients with HER2-positive breast cancer that has spread to other parts of their body live around 16 months longer if treated with a combination of pertuzumab, trastuzumab and chemotherapy compared to those treated with trastuzumab and chemotherapy alone, updated results from the CLEOPATRA study reveal.

CLEOPATRA was a pivotal phase III study where researchers evaluated the safety and efficacy of pertuzumab, trastuzumb and chemotherapy in 808 patients with previously untreated HER2-positive metastatic breast cancer. HER2-positive metastatic breast cancer has historically been one of the most aggressive forms of the disease.

"In CLEOPATRA we evaluated whether dual HER2 blockade by combining the antibody pertuzumab with trastuzumab and chemotherapy would help people live longer (overall survival, OS) or live longer without their disease worsening (progression-free survival, PFS)," explains lead author Dr Sandra Swain from Washington Hospital Center, Washington, USA.

New results presented at ESMO 2014 in Madrid showed that people treated with the combination lived 15.7 months longer than those who received trastuzumab and chemotherapy alone, with a median overall survival of 56.5 vs. 40.8 months.

"The survival improvement of nearly 16 months observed in CLEOPATRA is unprecedented among studies of metastatic breast cancer," said Swain.

The study authors had previously reported that the pertuzumab regimen significantly extended progression-free survival and overall survival. The new data reports the results of the final analysis of survival in CLEOPATRA after a median of 50 months follow-up of patients.

In the current analysis, overall survival was analysed using all randomised patients, with no adjustments for cross-over once the study treatments were unblinded. Patients who crossed over from the placebo arm to the pertuzumab arm were analysed as part of the placebo arm, Swain explains. "As such, this is a very conservative final analysis of survival."

The overall survival benefit observed with the pertuzumab regimen in CLEOPATRA was consistent across patient subgroups, the researchers say, and the previously observed benefit in progression-free survival was maintained after long-term follow-up. The long-term safety profile of the pertuzumab regimen also was unchanged from previous analyses and the long-term cardiac safety profile was maintained.

"This is the kind of survival improvement for which we have worked, and this data will be incredibly meaningful to patients and their families," Swain said.

Javier Cortes, Director of the Breast Cancer Program at Vall D'Hebron Institute of Oncology in Barcelona, Spain, another author on the study, said: "The median overall survival data presented by Sandra Swain at ESMO 2014 with pertuzumab and trastuzumab-based therapy in patients with HER2-positive metastatic breast cancer is remarkable. This is one of the biggest steps toward making this disease a chronic condition in the

near future."

"What is more surprising is that the improvement in median overall survival exceeds the improvement in progression-free survival; maybe because of the different mechanisms of action that monoclonal antibodies have," Cortes said.

"We should consider this combination as the standard of care for our patients," Cortes added. "I can see no reason to justify the use of trastuzumab without pertuzumab. The impressive overall survival data we have observed at ESMO 2014 will help us, as physicians, to continue working; it will help patients, to fight against their disease; and it will help society to understand that people will not die of cancer in the future."

Looking to the future, researchers need to study the mechanisms of resistance to this combination, to improve its therapeutic activity and to try to identify which patients will not need chemotherapy, Cortes concluded.

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