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CLINICAL TRIALS  

Roche reports new T-DM1 results

30.09.2013 - New results with Roche's antibody drug conjugate T-DM1 suggest the drug is a more effective breast cancer therapy than trastuzumab and lapatinib.

Interim results from the TH3RESA Phase III study were presented at the European Cancer Congress in Amsterdam. In HER2-positive breast cancer patients whose cancer was inoperable, had recurred or metastasised after several treatments including trastuzumab and lapatinib, progression-free survival (PFS) increased by nearly three months.

In 602 patients randomised to receive 3.6 mg/kg intravenous infusion of the antibody-drug conjugate (ADC) every three weeks compared to a treatment of their physician's choice, a PFS of 3.3 months was observed for the TPC patients compared to 6.2 months for patients receiving T-DM1. Among the T-DM1 patients, 31.3% showed a response to the drug, compared to 8.6% of the TPC patients. An interim analysis of overall patient survival showed a similar trend, but it did not reach the level at which a statistically significant benefit for T-DM1 treatment could be confirmed. Generally, there were fewer serious adverse side-effects in the T-DM1 patients than in the TPC group.

Lead investigator Hans Wildiers said: "This study shows that even in heavily pre-treated women, 75% of whom had cancer that has spread to the internal organs, T-DM1 nearly doubles progression-free survival. Few drugs have been able to achieve both improved progression-free survival and a better toxicity profile."

T-DM1 links Roche's Her2-specific antibody trastuzumab with the tubulin blocker emtansine (DM1) to target and kill breast cancer cells that overexpress the HER2 protein on their cell surfaces. The ADC has already been approved as a treatment for metastatic and recurrent breast cancer-patient in which herceptin + taxane therapy failed under the brand name Kadcyla.

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