

SABCS congress news: Chemotherapy plus sorafenib 'offers breast cancer patients improvement in response rate'

Date: 11/12/2009 11:09:11

Combining chemotherapy with a drug widely used to treat liver and kidney cancer has offered advanced breast cancer patients with HER2-negative tumors significant improvement in overall response rate and time-to-disease progression, according to new results from an international trial presented at the annual CTRC-AACR San Antonio Breast Cancer Symposium, USA.

The combination of sorafenib and paclitaxel also demonstrated a favorable trend in progression-free survival, according to lead investigator Prof. William Gradishar, professor of medicine at the Robert H. Lurie Comprehensive Cancer Center at Northwestern University. Data on overall survival are not yet available. "These data indicate that sorafenib provides added benefit when combined with paclitaxel compared to single agent paclitaxel in the first-line treatment of advanced breast cancer," Gradishar said.

The study, a double-blind, randomized, placebo-controlled phase IIb study, was conducted in the United States (95 patients), India (170 patients) and Brazil (15 patients). It is the second in a series of four worldwide stage IIb clinical trials testing the use of sorafenib in recurrent or metastatic HER2-negative breast cancer in a program called TIES (Trials to Investigate the Effects of Sorafenib in breast cancer).

The first study to be reported demonstrated a significant progression-free survival benefit in patients with advanced breast cancer who were treated with capecitabine chemotherapy and sorafenib, compared to treatment with capecitabine alone. The other two studies are ongoing.

Sorafenib is an oral agent that has been shown to target members of two classes of kinases involved in cell growth and angiogenesis, the growth of blood vessels to feed tumors. It is approved to treat advanced kidney cancer and liver cancer. Paclitaxel is used to treat a number of different cancers, including both early and advanced breast cancer.

Early research suggested sorafenib may be a promising treatment for breast cancer, and initial clinical studies demonstrated it has a modest activity as a single agent in patients with metastatic disease.

To see if benefit improved when sorafenib was paired with chemotherapy, the researchers randomized 119 patients to the combination therapy and 118 patients to a placebo and paclitaxel.

Results showed median progression-free survival was 6.9 months (combination therapy) vs. 5.6 months (placebo/paclitaxel). Median time-to-progression was 8.1 months vs. 5.6 months for patients receiving sorafenib/paclitaxel compared to placebo/paclitaxel. The overall response rate was 67 percent vs. 54 percent, respectively.

Discontinuation of study treatment due to adverse events occurred in 23 patients in the combination arm compared to five patients in the placebo/paclitaxel arm. With the exception of neuropathy, more grade 3 and 4 toxicities occurred in patients who received sorafenib/paclitaxel. Treatment-related deaths occurred in two patients in the combination treatment arm.

"There were no new toxicities observed with the combination and adverse events were manageable," Gradishar said.

Source: www.sabcs.org

Watch a press briefing by Prof. William Gradishar on [ecancertv](#) here.

© 2010 [ecancermedicalscience](#)