Sorafenib significantly improves the length of time before breast cancer worsens

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Berlin, Germany: One of the first of a series of trials to investigate the use of sorafenib - a targeted anti-cancer drug - for the treatment of advanced breast cancer has found that if it is combined with the chemotherapy drug, capecitabine, it makes a significant difference to the time women live without their disease worsening.

Principal investigator of the study, Professor José Baselga told Europe's largest cancer congress, ECCO 15 - ESMO 34, in Berlin today: "This is the first, large, randomised study that demonstrates significant clinical activity of sorafenib in breast cancer when given in combination with chemotherapy. Our results showed that patients who received sorafenib plus capecitabine had a 74% percent improvement in the time they lived without their disease worsening compared to those who received the chemotherapy alone. This is a very positive study and the magnitude of the benefit is such that it suggests that this agent will be an important addition to our therapeutic armoury in breast cancer."

Sorafenib (Nexavar®) is a potent multi-kinase inhibitor, which works by interfering with the growth of cancer cells and slowing the growth of new blood vessels within the tumour. Until now, it has only been used in the treatment of kidney and liver cancer.

Prof Baselga, who is head of the oncology department at Vall d'Hebron University Hospital (Barcelona, Spain), president of ESMO (European Society for Medical Oncology) and a member of the ECCO (European CanCer Organisation) executive committee, and his colleagues in Spain,

France and Brazil enrolled 229 patients with locally advanced or metastatic breast cancer in the double-blind, randomised phase II clinical trial between June 2007 and December 2008. They randomised the patients to receive capecitabine (1000 mg/m2 pill taken twice daily for 14 of every 21 days) and a placebo (114 women), or capecitabine and sorafenib (400 mg pill taken twice daily continuously) for 115 women.

The very first results from the trial only became available in time for the ECCO 15 - ESMO 34 congress, and they show that the average progression free survival (the time that elapses without the cancer getting worse) was 6.4 months for women on capecitabine and sorafenib compared to 4.1 months for women taking the placebo. It is too early for data on overall survival to be available. The only death that occurred was in the placebo arm of the trial, attributed to the effect of capecitabine. The number of patients discontinuing treatment due to adverse side-effects was nine (8%) in the placebo arm and 15 (13.4%) in the sorafenib arm of the trial.

Prof Baselga said: "The regimen was tolerable and the side-effects were mostly manageable. No new or unexpected side effects were observed with this combination. The fact that this treatment could be taken orally may represent a unique and convenient treatment option for patients with breast cancer.

"This trial is an example of good academia and industry partnership. It was designed and conducted by the Spanish breast cooperative group SOLTI with the participation also of Brazilian and French groups. The trial was fully supported by Onyx and Bayer. Based on the encouraging data from this trial so far, Onyx and Bayer are evaluating various strategies for sorafenib in breast cancer.

"This trial is the first of a series of randomised phase II studies with sorafenib that are currently underway in breast cancer. Based on our

results, we believe that the drug shows considerable promise for the treatment of the disease."

Source: ECCO-the European CanCer Organisation