

New hope for advanced post-menopausal breast cancer patients resistant to hormonal therapy

September 26 2011

Results from a phase III clinical trial have shown that combining two existing cancer drugs to treat post-menopausal women with advanced breast cancer resistant to hormonal therapy significantly improves outcome. Researchers told the 2011 European Multidisciplinary Cancer Congress that women treated with a combination of everolimus and exemestane had an improved progression-free survival of nearly seven months compared to women who were treated only with exemestane.

Trial leader, Professor José Baselga from the Massachusetts General Hospital and Harvard Medical School, Boston (USA), will tell the meeting: "These results are impressive and, potentially, could represent a new therapeutic option for [women](#) with advanced post-menopausal [breast cancer](#) who have previously been treated with hormonal therapy."

The hormone oestrogen promotes the growth of about two thirds of breast cancers, and hormonal therapies such as exemestane, which block the effect of oestrogen or reduce oestrogen levels, are used to treat these hormone receptor-positive breast cancers. However, many breast cancer patients and nearly all patients with [advanced breast cancer](#) that has spread (metastasised) to other parts of the body become resistant to hormonal therapy. "When patients stop responding to hormonal therapy, the benefits from any secondary therapy are limited," says Prof. Baselga.

Exemestane is currently used to treat women who have metastatic breast

cancer and women whose breast cancer has returned after initial treatment. It is also used to treat women with early breast cancer after they have completed two or three years of treatment with another hormonal therapy, tamoxifen.

Everolimus is an established treatment for recurrent, advanced kidney cancer and researchers are now looking at its use in other cancers. Phase II trials involving patients with advanced cancer driven by oestrogen receptor-positive advanced breast cancer have been promising when everolimus is used on its own or in combination with [hormonal therapy](#). In order to follow this up, the [phase III](#) clinical trial BOLERO 2 was set up to investigate the efficacy of everolimus in patients who have become resistant to aromatase inhibitors – drugs that decrease the amount of oestrogen produced and help to slow or reverse the growth of the cancer.

The multi-national trial was conducted with 724 patients in 24 countries, with an average age of 62. All patients had been treated previously with the aromatase inhibitors letrozole or anastrozole. Earlier treatments also included tamoxifen (48% of patients), fulvestrant (16% of patients) and chemotherapy (68% of patients).

A group of 485 patients was randomised to receive everolimus and exemestane, while 239 received only exemestane until the disease progressed or unacceptable levels of toxicity were recorded. The trial was stopped early after an interim analysis revealed that further tumour growth did not occur for nearly 11 months in patients who received everolimus, whereas patients receiving only [exemestane](#) had progression-free survival for approximately four months.

Prof Baselga says: "This is a highly significant improvement in the time to disease progression in a patient population that is highly resistant to therapy."

Trial sponsor Novartis plans to file worldwide regulatory submissions for everolimus as a treatment for oestrogen receptor-positive, advanced breast cancer by the end of 2011.

Provided by ECCO-the European CanCer Organisation

Citation: New hope for advanced post-menopausal breast cancer patients resistant to hormonal therapy (2011, September 26) retrieved 11 July 2024 from <https://medicalxpress.com/news/2011-09-advanced-post-menopausal-breast-cancer-patients.html>

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