Phase 3 trial finds no benefit from atrasentan added to chemo for advanced prostate cancer

21 April 2011

A Data and Safety Monitoring Committee (DSMC) has determined that patients in a phase III clinical trial given atrasentan in addition to a standard chemotherapy regimen for advanced prostate cancer did not have longer survival or longer progression-free survival than patients on the same chemotherapy regimen who got a placebo rather than atrasentan.

Almost 1,000 patients who had advanced, hormone-refractory prostate cancer were given up to 36 weeks of chemotherapy with docetaxel and prednisone. These patients were randomized so that one half got an additional pill with a dose of atrasentan while the other half got a placebo pill. Patients who completed their chemotherapy and showed no progression of the disease were given the option of continuing the additional blinded pill (atrasentan or placebo).

The study's DSMC evaluated a planned interim analysis of trial data and determined the evidence indicating no benefit from the drug was strong enough to close the study early rather than waiting another 18 months as was originally planned. The DSMC did not find evidence that the drug was harming patients.

New patient enrollment to the study stopped in April 2010 and few patients continue to take the study pill. Patients still taking study medication should speak to their doctor about stopping safely and what to do with their remaining pills. Treatment assignment is being unblinded, so patients can learn from their study doctor whether they took atrasentan or a placebo.

The study ("S0421: Phase III Study of Docetaxel and Atrasentan Versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer") was supported by the National Cancer Institute (NCI) and was conducted by SWOG (formerly the Southwest Oncology Group) with the participation of several other NCI cooperative groups.

Atrasentan for the trial was provided under an agreement with Abbott Laboratories and was distributed by the Department of Veterans Affairs Cooperative Studies Program Clinical Research Pharmacy Coordinating Center.

Provided by University of Michigan Health System

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