

# Phase 1 results point to larger trial of enzalutamide and fulvestrant in breast cancer

December 7 2015, by Garth Sundem

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Results of a multicenter phase 1 clinical trial presented today at the 2015 San Antonio Breast Cancer Symposium show that the anti-androgen agent enzalutamide is active and well-tolerated alone and with fulvestrant in patients with advanced breast cancer. The study takes another important step toward larger clinical trials targeting androgen receptors in breast cancer.

"We've known for years that prostate cancer is driven by androgens and now it's increasingly clear that androgens and [androgen receptors](#) can influence many breast cancers as well. AR is actually even more prevalent in breast cancer than estrogen or progesterone receptors. Targeting androgen receptors in breast cancer gives us a new way to attack the disease," says Jennifer Richer, PhD, investigator at the University of Colorado Cancer Center. Results represent collaboration with CU Cancer Center clinical collaborator Anthony Elias, MD, Memorial Sloan Kettering, Medivation, Inc. and Astellas Pharma Global Development.

The goal of the current study was to explore the bioavailability and safety of the anti-androgen agent enzalutamide alone and in combination with the existing agent fulvestrant (FDA approved for use in metastatic hormone-receptor positive breast cancer). The small, phase 1 trial enrolled 11 patients and found that side-effects were similar in this population as previously reported in larger [trials](#) of enzalutamide against

prostate cancer. There were no unexpected interactions between enzalutamide and fulvestrant. Concentrations of both drugs reached target levels in tumor tissues.

This human data follows [extremely promising preclinical data](#) (much of which was reported at the previous year's San Antonio Breast Cancer Symposium) supporting the androgen receptor as a target in [breast cancer](#). Enzalutamide is also being evaluated in a phase 2 clinical trial in combination with the aromatase inhibitor exemestane ([NCT02007512](#)) and demonstrated promising results in another phase 2 trial against estrogen-receptor-negative advanced disease ([NCT01889238](#)).

"It's exciting to see our preclinical work moving into the clinic," Richer says. "These data support moving forward with a larger trial of the enzalutamide plus fulvestrant combination."

**More information:** Conference abstract:  
[www.abstracts2view.com/sabcs15 ... SABCS15L\\_1219&terms=](http://www.abstracts2view.com/sabcs15...SABCS15L_1219&terms=)

Provided by University of Colorado Denver

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