# FDA Issues Alert About Tecentriq Plus Paclitaxel for Breast Cancer

A recent clinical trial found that the combination did not work.

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FDA alerts health care professionals and oncology clinical investigators about efficacy and potential safety concerns with atezolizumab in combination with paclitaxel for treatment of breast cancer

FDA is alerting health care professionals, oncology clinical investigators, and patients that a clinical trial studying the use of atezolizumab (Tecentriq) and paclitaxel in patients with previously untreated inoperable locally advanced or metastatic triple negative breast cancer (mTNBC) showed the drug combination did not work to treat the disease.

Atezolizumab in combination with paclitaxel is not approved for use in breast cancer. However, atezolizumab in combination with paclitaxel protein-bound (Abraxane)—a different combination therapy—is currently approved for the treatment of adult patients with mTNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering ≥1% of the tumor area), as determined by an FDA-approved test. Continued approval of atezolizumab in combination with paclitaxel protein-bound may be contingent on proven benefit of the treatment in additional trials.

Health care professionals should not replace paclitaxel protein-bound (Abraxane) with paclitaxel in clinical practice.

The trial, IMpassion131, was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial of atezolizumab in combination with paclitaxel compared with placebo and paclitaxel for patients with mTNBC.

In this clinical trial, treatment with atezolizumab and paclitaxel did not significantly reduce the risk of cancer progression and death compared with placebo and paclitaxel in the PD-L1-positive population. Additionally, interim overall survival results favored paclitaxel + placebo, over paclitaxel + atezolizumab in both the PD-L1-positive population and total population.

FDA will review the findings of IMpassion131 and will communicate new information regarding the IMpassion131 results and any potential changes to prescribing information. FDA is also evaluating the use of atezolizumab and paclitaxel in ongoing clinical trials for breast cancer and will

recommend additional changes as appropriate.

Patients taking atezolizumab and paclitaxel for other approved uses should continue to take their medication as directed by their health care professional.

Patients should talk to their doctor if they have questions or concerns. Health care professionals and patients should report any adverse events or side effects related to the use of these products and other similar products to FDA's MedWatch Adverse Event Reporting program.

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