Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

August 2021

Subject: Voluntary withdrawal of Tecentriq® (atezolizumab) in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumors express PD-L1

Dear Health Care Provider:

This letter is to inform you about an important change to the Tecentriq® (atezolizumab) label in the United States (U.S.).

Indications

Genentech, a member of the Roche Group, announced on Aug 27, 2021 the decision to voluntarily withdraw the U.S. accelerated approval for Tecentriq in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1. This decision was made following consultation with the U.S. Food and Drug Administration (FDA) based on the Agency's assessment of the current mTNBC landscape, and in accordance with Agency's requirements for accelerated approvals with confirmatory trials that did not meet their primary endpoint(s) and have yet to attain regular approval. Genentech will work with FDA over the coming weeks to complete the withdrawal process.

No new data on safety or efficacy of Tecentriq informed this decision.

This change does NOT impact other approved Tecentriq indications in the US.

Prescriber Action

A Dear Patient Letter is enclosed that addresses concerns about insurance coverage. Please share this letter with your patients who are currently receiving Tecentriq in combination with paclitaxel protein-bound for the treatment of unresectable locally advanced or metastatic TNBC whose tumors express PD-L1, and discuss the impact of the withdrawal of this indication on their treatment plans.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events or side effects related to the use of these products to Genentech at 1-888-835-2555.

Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

You may also contact the Genentech Medical Communications department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of Tecentriq.

This letter is not intended as a complete description of the benefits and risks related to the use of Tecentriq. Please refer to the current full prescribing information and medication guide. The Tecentriq prescribing information will be revised in consultation with the FDA.

Sincerely,

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs