Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

November 2022

Subject: Tecentriq® (atezolizumab) indication in patients with locally advanced or metastatic urothelial carcinoma (mUC) that are cisplatin-ineligible (PD-L1 ≥5%) or platinum-ineligible (irrespective of PD-L1 status) is being voluntarily withdrawn in the United States (U.S.)

Dear Health Care Provider:

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

Indications

Genentech, a member of the Roche Group, announced the voluntary withdrawal of the U.S. indication of Tecentriq for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC, bladder cancer) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1–stained tumor-infiltrating immune cells covering ≥5% of the tumor area) or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

Genentech made this decision following consultation with the FDA and in accordance with the requirements of the Accelerated Approval Program.

This change does not impact other approved Tecentriq indications in the U.S.

Background

Tecentriq was granted accelerated approval in 2017 for the treatment of adults with locally advanced or mUC who are not eligible for cisplatin-containing chemotherapy based on the positive overall response rate and duration of response results from the IMvigor210 study. The confirmatory Phase III trial, IMvigor130, is the designated postmarketing requirement (PMR) for the first-line mUC accelerated approval indication. Although the trial met its co-primary endpoint of progression-free survival, the improvement was modest and because IMvigor130 did not later meet the co-primary endpoint of overall survival (OS) at the final analysis, Genentech made the difficult decision to voluntarily withdraw the U.S. mUC indication.

Prescriber Action

A Dear Patient Letter is enclosed. Please share this letter with your patients who are currently receiving Tecentriq for the treatment of locally advanced or metastatic bladder cancer and are cisplatin-ineligible (PD-L1 ≥5%) or platinum-ineligible (irrespective of PD-L1 status) 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 enclosed current full prescribing information and medication guide. The revised Tecentriq prescribing information is not yet available when this letter is released, and will be posted on gene.com and Tecentriq.com as soon as possible.

Sincerely,

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