Genentech
A Member of the Roche Group

IMPORTANT DRUG WARNING

August 2018

Subject: Severe Cases of Immune-Mediated Nephritis Reported with TECENTRIQ® (atezolizumab) and Recommended Dose Modifications for Adverse Reactions

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information and recommended dose modifications for specific adverse reactions for TECENTRIQ® which is indicated for the treatment of locally advanced or metastatic urothelial carcinoma, or metastatic non-small cell lung cancer (for detailed information about indications, please see the US package insert).

Serious Risk with Use of TECENTRIQ®

- Cases of immune-mediated nephritis including biopsy-confirmed cases were identified in a cumulative analysis of the safety and clinical databases. Approximately 17,215 clinical trial patients and 20,783 post-marketing patients have been exposed to TECENTRIQ® to date. Based on the assessment of the available data, immune-related nephritis is now considered an important adverse reaction for TECENTRIQ® (atezolizumab).

Recommended Prescriber Actions

- Continue counseling patients about the risks and benefits of TECENTRIQ®, including the important adverse reaction of immune-mediated nephritis.
- For patients with immune-mediated nephritis, it is recommended that TECENTRIQ® (atezolizumab) be withheld for moderate (Grade 2) cases and permanently discontinued for severe (Grade 3 and 4) cases. Tecentriq® may be resumed after the event resolved or improved to Grade 1. Refer patients to a renal specialist and consider renal biopsy and supportive measures as indicated. Corticosteroids and/or additional immunosuppressive agents should be administered as clinically indicated.

Tell your patients to contact their doctor immediately to report any changes in urine color and amount of urine.

Reporting Adverse Events

Health Care Providers should report any adverse events suspected to be associated with the use of TECENTRIQ® 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

If you have any questions or concerns about the information contained in this letter or the safe and effective use of TECENTRIQ®, you may contact the Genentech Medical Communications Department at 1-800-821-8590.

This letter is not intended as a complete description of the indications, benefits, and risks associated with the use of TECENTRIQ®. Please refer to the enclosed full prescribing information, including the Medication Guide. These can be found only at https://www.gene.com/download/pdf/tecentriq_prescribing.pdf.

Sincerely,

Lance Baldo, M.D.
Head of U.S. Medical Affairs