

July 2017

**IMPORTANT
DRUG
WARNING**

**Subject: Severe Cases of Myocarditis Reported with TECENTRIQ®
(atezolizumab)**

Dear Healthcare Provider:

The purpose of this letter is to inform you of important new safety information for TECENTRIQ 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 the Use of TECENTRIQ

- Cases of myocarditis have been reported in cancer patients receiving TECENTRIQ treatment in clinical trials. A cumulative analysis of the company safety database, which includes data from clinical trials and post-marketing setting (data cut-off date 20 February 2017), identified two non-fatal cases of myocarditis, including one case with biopsy confirmation. Approximately 8,000 clinical trial patients and 5,000 post-marketing patients have been exposed to TECENTRIQ to date.
- The mechanism of action of TECENTRIQ permits the possibility of developing myocarditis. Moreover, immune-mediated myocarditis is listed on the labels of similar-in-class drugs.

Prescriber Action

- It is recommended that TECENTRIQ should be permanently discontinued for all grades of myocarditis. Corticosteroids and/or additional immunosuppressive agents should be administered as clinically indicated.

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events in patients taking TECENTRIQ to Genentech at 1-888-835-2555. You are also



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encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Company Contact

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 indications, benefits and risks related to the use of TECENTRIQ. Please refer to the full prescribing information, including Medication Guide. These can be found online at https://www.gene.com/download/pdf/tecentriq_prescribing.pdf

This letter is being sent in agreement with the FDA pursuant to requirement set forth in 21 CFR 200.5.

Sincerely,

A handwritten signature in blue ink that reads "Edith J. Perez".

Edith Perez, M.D.

VP, Head of BioOncology, US Medical Affairs