Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

May 7, 2021

Subject: Unfavorable benefit-risk of the addition of atezolizumab to neoadjuvant chemotherapy for the treatment of patients with HER2+ early breast cancer

Dear Health Care Provider:

Roche/Genentech would like to inform you of the decision to discontinue the randomized treatment administration for IMpassion050 (BO40747) based upon the unfavorable benefit-risk of the addition of atezolizumab to neoadjuvant anthracycline (doxorubicin) + cyclophosphamide followed by paclitaxel + trastuzumab + pertuzumab (ddAC-PacHP) in this study due to the lack of pathological complete response (pCR) benefit (primary objective of IMpassion050) and the added toxicity compared to placebo. IMpassion050 aimed to investigate the addition of atezolizumab/placebo to a standard of care with ddAC-PacHP for the neoadjuvant treatment (i.e. prior surgery) in patients with HER2-positive early breast cancer (HER2+ BC). Patients were planned to complete a year of atezolizumab in combination with anti-HER2 therapy in the adjuvant phase of treatment.

Of note, atezolizumab is not an approved therapy for treatment of HER2+ BC, in either the early or metastatic setting and is not recommended for use outside of clinical trials for HER2+ BC.

In particular, from a safety perspective there was an imbalance in Grade 5 adverse events (deaths due to adverse events) between the treatment arms (5 in the atezolizumab arm vs 0 in the placebo arm). Three of the five events were sepsis, alveolitis & septic shock and the remaining two were COVID-19 infections. Of note, four of the events were in the neoadjuvant phase and one in the adjuvant phase. Assessment of these adverse events with fatal outcome by Roche/Genentech revealed that the events were confounded with co-morbidities and concurrent events, but a contributory role of atezolizumab cannot be excluded. Incidence of serious and severe adverse events was higher in the atezolizumab arm compared with the placebo arm.

Roche/Genentech will continue to analyze the IMpassion050 data and the study topline results are being submitted to an upcoming international congress.

Reporting Adverse Events

Health care providers should report any adverse events suspected to be associated with the use of Tecentriq (atezolizumab) to Genentech at 1-888-835-2555.

You are encouraged to report negative side effects of prescription drugs to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

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 (atezolizumab).

This letter is not intended as a complete description of the benefits and risks related to the use of Tecentriq (atezolizumab). Please refer to the enclosed full prescribing information and medication guide.

Sincerely,

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