



Subject: Voluntary withdrawal of ZINBRYTA® (daclizumab) in United States

March 12, 2018

Dear Colleague,

Biogen, in collaboration with our partner AbbVie, has made a decision to voluntarily withdraw the marketing application for ZINBRYTA globally.

Biogen and AbbVie believe it is in the best interest of patients to voluntarily withdraw ZINBRYTA in the United States. Cases of encephalitis and meningoencephalitis have been reported in patients treated with ZINBRYTA. All adverse event reports, including encephalitis and meningoencephalitis, continue to be evaluated. Given the nature and complexity of adverse events being reported with ZINBRYTA, characterizing the evolving benefit/risk profile of ZINBRYTA will not be possible going forward, given the limited number of patients being treated.

Biogen is working closely with the Food and Drug Administration (FDA) and with regulatory authorities around the world on the withdrawal timelines for ZINBRYTA. In the United States, the supply of ZINBRYTA will be phased out by April 30, 2018. No patients naïve to ZINBRYTA will be able to receive ZINBRYTA, including patients already in the process of starting ZINBRYTA who have not yet received their first dose. Patients currently taking ZINBRYTA can receive a maximum of one additional dose, to be dispensed between now and April 30, 2018.

Considering the need to provide patients with time to transition from ZINBRYTA to an appropriate alternative treatment, Biogen and AbbVie are advising all treating HCPs to contact their patients. Biogen and AbbVie are also contacting patients receiving Zinbryta to inform them about the product withdrawal and advising them to contact their health care provider to discuss an appropriate alternative treatment. All patients transitioning from ZINBRYTA should undergo safety assessments in accordance with the Risk Evaluation and Mitigation Strategy (REMS) program and the approved US Prescribing Information. To report SUSPECTED ADVERSE REACTIONS, contact Biogen at 1- 800-456-2255 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please contact Biogen Medical Information at 1-866-633-4636 if you have any questions regarding this withdrawal.

Sincerely,

A handwritten signature in black ink that reads "Alfred Sandrock".

Alfred Sandrock, M.D., Ph.D.
Executive Vice President and Chief Medical Officer