Zinbryta® (daclizumab) – Drug withdrawal

- On March 2, 2018, Biogen and AbbVie announced the voluntary worldwide withdrawal of marketing authorizations for Zinbryta (daclizumab) due to the nature and complexity of adverse events being reported with Zinbryta use.
    - Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.
- Biogen and AbbVie have determined that the evolving benefit/risk profile of Zinbryta will not be possible going forward given the limited number of patients being treated.
    - The European Medicines Agency has received reports of inflammatory encephalitis and meningoencephalitis associated with Zinbryta use.
    - In the U.S., a Risk Evaluation and Mitigation Strategy (REMS) program is in place for Zinbryta due to the risks of severe and fatal hepatic injury including autoimmune hepatitis, and other immune-mediated disorders.
- Biogen will continue to work collaboratively with regulatory authorities and with healthcare providers in their management of Zinbryta patients.
- Patients currently treated with Zinbryta should contact their healthcare provider if they have any questions or concerns regarding their Zinbryta therapy.
- Biogen and AbbVie notified healthcare providers of the drug withdrawal of Zinbryta and advised them to transition patients currently taking Zinbryta to another alternative therapy.