FDA approves new drug to treat multiple sclerosis

Silver Spring, MD, USA (May 31, 2016) - The U.S. Food and Drug Administration approved Zinbryta (daclizumab) for the treatment of adults with relapsing forms of multiple sclerosis (MS). Zinbryta is a long-acting injection that is self- administered by the patient monthly.

Zinbryta should generally be used only in patients who have had an inadequate response to two or more MS drugs because Zinbryta has serious safety risks, including liver injury and immune conditions. Because of the risks, Zinbryta has a boxed warning and is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy.

The boxed warning tells prescribers that the drug can cause severe liver injury, including life-threatening and fatal events. Health care professionals should perform blood tests to monitor the patient’s liver function prior to starting Zinbryta, monthly before each dose, and for up to six months after the last dose.

The boxed warning also highlights other important risks of Zinbryta treatment including immune conditions, such as inflammation of the colon (non-infectious colitis), skin reactions, and enlargement of lymph nodes (lymphadenopathy).

Additional highlighted warnings include hypersensitivity reactions (anaphylaxis or angioedema), increased risk of infections, and symptoms of depression and/or suicidal ideation.

The most common adverse reactions reported by patients receiving Zinbryta in the clinical trial that compared it to Avonex include cold symptoms (nasopharyngitis), upper respiratory tract infection, rash, influenza, dermatitis, throat (oropharyngeal) pain, eczema, and enlargement of lymph nodes. The most common adverse reactions reported by patients receiving Zinbryta when

compared to placebo are depression, rash, and increased alanine aminotransferase.

- For more information, please visit: Zinbryta:

U.S. Food and Drug Administration, 31.05.2016 (tB).