FDA OKs second treatment for neuromyelitis optica spectrum disorder

15 June 2020

(HealthDay)—Uplizna (inebilizumab-cdon) injection is now approved to treat neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive, the U.S. Food and Drug Administration announced Thursday.

Uplizna, approved for intravenous use, is the second treatment for NMOSD approved within the past year. There are an estimated 4,000 to 8,000 patients with NMOSD in the United States, the agency noted.

The approval was based on clinical data from 230 adult patients, 213 of whom were anti-AQP4 antibody positive. During the study, which lasted for 197 days, the 161 anti-AQP4 antibody positive patients treated with Uplizna had a 77 percent reduction in NMOSD relapse compared with patients who received placebo. The researchers found no evidence of a benefit in patients who were anti-AQP4 antibody negative.

The most commonly reported adverse reactions included urinary tract infection, headache, arthralgia, nausea, and back pain. The prescribing information for Uplizna includes warnings for infusion reactions, potential hypogammaglobulinemia, and a potential increased risk for infection, including progressive multifocal leukoencephalopathy, reactivation of hepatitis B, and tuberculosis.

Approval was granted to Viela Bio.

More information: More Information