Biogen Shares Update on FDA Advisory Committee Meeting for Tofersen

January 23, 2023

On January 23, 2023, the Federal Register published a notice that the U.S. Food and Drug Administration (FDA) will convene a virtual meeting of the Peripheral and Central Nervous System Drugs Advisory Committee for the New Drug Application (NDA) for tofersen, an investigational product for the treatment of superoxide dismutase 1 (SOD1) amyotrophic lateral sclerosis (ALS). The advisory committee meeting is scheduled for March 22, 2023 and will be available for live streaming.

The FDA intends to make the advisory committee meeting's background materials available to the public no later than two business days before the meeting, according to the notice. The FDA said if they are unable to post the background materials on its website prior to the advisory committee meeting, the background material will be made publicly available on the FDA's website at the time of the advisory committee meeting.

SOD1-ALS is an ultra-rare genetic form of ALS that affects approximately 330 people in the U.S.[1], it is progressive, leads to the loss of everyday functions and is uniformly fatal. Biogen's NDA for tofersen was accepted for priority review by the FDA under the accelerated approval pathway and has a Prescription Drug User Fee Act action date of April 25, 2023.

Biogen Safe Harbor

This statement includes forward-looking statements based on Biogen's current expectations and beliefs that are subject to risks and uncertainties. Biogen's actual results may differ materially. Please consult the risk factors section of Biogen's SEC filings.

References:

1. Brown CA, Lally C, Kupelian V, Flanders WD. Estimated Prevalence and Incidence of Amyotrophic Lateral Sclerosis and SOD1 and C9orf72 Genetic Variants. Neuroepidemiology. 2021