October 17, 2021

Dear members of the ALS community,

In response to your request for information, we are writing to let you know that today, at the American Neurological Association 2021 Annual Meeting, Biogen shared topline results from its pivotal Phase 3 VALOR study of tofersen (BIIB067), an investigational drug being evaluated in people with *SOD1*-ALS.

Data indicate that while VALOR study did not meet the primary endpoint of change from baseline to week 28 in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), trends favoring tofersen were seen across multiple secondary and exploratory measures of biologic activity and clinical function. Most adverse events in both VALOR and the OLE were mild to moderate in severity, including pain related to lumbar puncture procedure, headache, pain in limbs, falls, and back pain.

Biogen is actively engaging with regulators, the medical community, patient advocacy groups and other key stakeholders around the world to determine potential next steps.

In light of the critical unmet need, Biogen will broaden its ongoing early access program (EAP) to all people with SOD1-ALS, in countries where such programs are permitted by local regulations and future access may be secured. If a path forward for tofersen is not established, or if another controlled trial is required by regulators, Biogen may revise or discontinue the EAP.

We will provide additional updates on the tofersen program as we are able.

At Biogen, we understand the dire need for ALS treatments to combat this devastating disease. We extend our deepest and most sincere gratitude to each of the study participants and their families, clinical site staff, physicians and broader ALS advocacy community who contributed to the VALOR study.

Sincerely,
Biogen