



Notice to patients with SOD1-ALS regarding access to Biogen Tofersen via Compassionate Use – Early Access Program

Biopharmaceutical company Biogen currently runs the global Phase 3 placebo-controlled clinical trial VALOR, evaluating the safety and efficacy of the antisense oligonucleotide (ASO) Tofersen in SOD1-ALS.

The trial became fully enrolled in december 2020. Completion is expected in the third quarter of 2021.

In response to the need of all SOD1 pALS to obtain Tofersen as soon as possible, Biogen is setting up a Compassionate Use – Early Access Program.

The program **takes effect mid-july 2021**, at the moment the last SOD1 pALS receiving placebo in the VALOR study got the opportunity to proceed with Tofersen in the Open Label Extension phase of the trial. The program will cover a subset of the SOD1-ALS population with the most rapidly progressive disease.

If you are an SOD1 pALS that is not enrolled in the VALOR study but has interest in receiving Tofersen under the Compassionate Use – Early Access Program, please **contact your treating physician who can submit your request at Biogen**.

If the Phase 3 study data are positive and if no further controlled clinical studies are required the company has stated it will immediately open an *Early Access Program* for the broad SOD1-ALS population in countries where this is permitted by local regulations and future access. This program will start before submitting filing for market registration.

All details and eligibility criteria of the Biogen Compassionate Use – Early Access Program can be found at https://www.biogen.com/en_us/als-community-update.html

Do not hesitate to contact EUpALS at info@als.eu for all additional questions.

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