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NEZGLYAL Receives Positive CHMP Opinion for Cerebral Adrenoleukodystrophy

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The recommendation is based on NEXUS data, with Minoryx and Neuraxpharm expecting European Commission approval by the end of September 2026.

Minoryx Therapeutics and Neuraxpharm Group have announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting marketing authorisation approval under exceptional circumstances for NEZGLYAL (leriglitazone) as a treatment for male cALD patients, aged 2-12 years with Gadolinium (Gd) negative brain lesions. European Commission approval is expected by the end of September 2026.

The opinion is based on results from the Phase 2/3 NEXUS1 study and additional real-world evidence from compassionate use programmes. Cerebral adrenoleukodystrophy (cALD) is a debilitating disease characterised by demyelinating brain lesions that can progress rapidly, leading to acute neurological decline and death in three to four years. There are currently no approved pharmacological treatments for cALD in the EU.

"The positive CHMP opinion is a regulatory validation, and we are very pleased that we will soon be able to provide a new therapeutic option to boys suffering from cALD. I would like to take the opportunity to thank physicians, patients, their families and the wider ALD community, we are enormously grateful for the support we received throughout these years," said Marc Martinell, CEO, Minoryx. "The journey continues towards US approval and future European label-expansion, as we generate new data in adult male cALD patients with Gadolinium enhancing lesions from the ongoing CALYX 2 trial."

"cALD is a severe neurodegenerative disease and we look forward to bringing NEZGLYAL, a long-awaited treatment, to European patients following EC approval later this year. This reflects Neuraxpharm's enduring commitment to delivering innovative solutions to CNS patients with significant unmet medical needs. Collaborations between Neuraxpharm and strategic partners like Minoryx throughout the clinical and regulatory process can deliver real-world impact for the CNS community. We remain committed to supporting Minoryx as we look ahead to obtaining European label-expansion in the future," said Dr. Jörg Thomas Dierks, CEO, Neuraxpharm.

Minoryx and Neuraxpharm entered into a license agreement under which Neuraxpharm will commercialise the product in Europe following marketing authorisation.

The development program continues, including the ongoing CALYX Phase 3 trial in adult male cALD patients with Gadolinium enhancing lesions and the TREE3 Phase 2a trial in pediatric patients with Rett syndrome, with read-outs

expected by early 2028 and end of 2026 respectively.