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Minoryx and Neuraxpharm complete enrolment in Phase III CALYX trial of leriglitazone

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The global study has enrolled 41 adult male patients with cerebral adrenoleukodystrophy, with top-line results expected in early 2028 to support EU label expansion and a future US filing.

Minoryx Therapeutics and Neuraxpharm have completed enrolment in the global Phase III CALYX trial evaluating leriglitazone, or NEZGLYAL, in adult male patients with cerebral adrenoleukodystrophy.

The pivotal study has enrolled 41 patients across selected centres of excellence in the United States, Europe, South America and India.

Cerebral adrenoleukodystrophy is a rare neurodegenerative disease for which the companies said there are currently no pharmacological treatment options.

CALYX is a global, double-blind, randomised and placebo-controlled Phase III study designed to evaluate the disease-modifying potential of leriglitazone in adults with cALD.

The primary endpoint evaluates survival, while secondary endpoints include Loes score, major functional disabilities, activities of daily living and major neurocognitive impairment.

Top-line results are expected in early 2028.

Minoryx said completion of enrolment represents an important step towards supporting potential label expansion in Europe and enabling a New Drug Application filing in the United States.

“The full recruitment of CALYX is a major milestone towards confirming the disease-modifying potential of leriglitazone, expanding the label in the EU and obtaining approval for leriglitazone in the US,” said Arun Mistry, Chief Medical Officer at Minoryx.

He added that the enrolment milestone allows the company to begin preliminary planning for US regulatory and commercial infrastructure ahead of the expected read-out.

In Europe, leriglitazone has already received a positive opinion from the Committee for Medicinal Products for Human Use for the treatment of boys aged two to 12 years with cALD and non-gadolinium enhancing lesions.

European Commission approval under exceptional circumstances is expected later in September 2026.

Neuraxpharm, Minoryx’s strategic partner in Europe, is preparing for commercial launch if approval is granted.

“Completion of enrolment in CALYX marks an important milestone in the development of leriglitazone and the generation of clinical evidence in adult patients with cALD,” said Francisco Jurado, Chief Scientific Officer at Neuraxpharm.

He said the programme could support future regulatory applications across different cALD patient populations in Europe.

Minoryx also acknowledged the role of patients, families and advocacy groups in supporting enrolment across the multinational study.

The CALYX programme is intended to broaden the clinical evidence base for leriglitazone beyond paediatric patients and establish whether the therapy can provide disease-modifying benefit in adult cALD.

If the study is successful, the data could support both a broader European label and entry into the US regulatory process.