Ad hoc announcement pursuant to Art. 53 LR

Newron reports a pause in enrollment of new study participants in US centers of ENIGMA-TRS 2 study

Pause of enrollment limited to US sites in ENIGMA-TRS 2; Global ENIGMA-TRS 1 study continues with over 400 patients enrolled

Milan, Italy, and Morristown, NJ, USA – April 29, 2026, 5:50 pm CEST – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN, XETRA: NP5), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system (CNS), today announced that the U.S. Food and Drug Administration (FDA) has placed a hold on the enrollment of new patients in the US sites of its Phase III ENIGMA-TRS 2 study of evenamide, targeting the modulation of excessive release of glutamate in patients suffering from treatment-resistant schizophrenia (TRS).

The FDA action follows Newron's notification to the agency of the sudden death (SUD) of a study participant at a clinical site outside the United States. The investigator assessed the event as unrelated to study treatment. Newron has informed the independent international safety monitoring board for the overall ENIGMA-TRS program, which has reviewed the event and recommended that the studies continue as designed. ENIGMA-TRS 1, performed in 21 countries, continues with over 400 patients having been enrolled. ENIGMA-TRS 2 has received regulatory approval in Argentina and India and is in final stages of receiving approval in Colombia and Malaysia.

Newron is working closely with the FDA and intends to provide the requested information to support resolution of the hold and the resumption of enrollment at U.S. sites for the ENIGMA-TRS 2 study.

"Patient safety remains our highest priority, all patients who enroll in the evenamide program are thoroughly evaluated. The ENIGMA-TRS program with evenamide is monitored by an independent international safety monitoring board. The board has been informed of the event and has concluded that the studies should continue as designed. In the evenamide development program, to date, there is no increase in the risk of mortality between evenamide and placebo-treated patients based on the duration of treatment. Sudden death unfortunately is not uncommon in patients with schizophrenia," said Ravi Anand, Newron's Chief Medical Officer.

Studies show that schizophrenia significantly increases mortality and reduces life expectancy by 10-25 years compared with the general population and sudden unexpected deaths (SUD) are noted in at least 20% of these cases of mortality[1].

[1] see Simpson JC et al., 1996; Correll et al., 2022; Ifteni P et al., 2014

About ENIGMA-TRS

ENIGMA-TRS 1 is an ongoing, international, 52-week, randomized, double-blind, placebo-controlled Phase III study evaluating the efficacy, tolerability, and safety of the 15mg BID and 30mg BID therapeutic doses of evenamide compared to placebo. Patients on second-generation antipsychotics, including clozapine, will meet Treatment Response and Resistance Psychosis international consensus criteria for TRS. The study will enroll at least 600 patients at study centers in Europe, Asia, Latin America and Canada. The first patients were successfully enrolled in August 2025, following the completion of a rigorous 42-day screening period. Patients are currently being enrolled across eight countries on all target continents.

The primary assessment of efficacy and safety of ENIGMA-TRS 1 will be performed 12 weeks after randomization to treatment. Following this initial period, the study will continue double-blind and placebo-controlled until the 26- and 52-week time points. The primary efficacy endpoint of the trial will be the change from baseline in the Positive and Negative Syndrome Scale (PANSS) scores at 12 weeks. Newron expects to announce results from the 12-week primary endpoint assessment in QIV 2026.

ENIGMA-TRS 2 is taking place at centers in the US and selected additional countries with the same screening procedure as the ENIGMA-TRS 1 trial. ENIGMA-TRS 2 will include at least 400 patients in a 12-week, randomized, double-blind, placebo-controlled Phase III study, designed to evaluate the efficacy, tolerability, and safety of the 15mg BID dose of evenamide compared to placebo. In December 2025, ENIGMA-TRS 2 was initiated in the US, following approvals from the US Food and Drug Administration (FDA) and the Institutional Review Board (IRB). The efficacy and safety analysis will be performed at the 12-week point following successful completion of the study.

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on the development of innovative therapies for patients with diseases of the central and peripheral nervous system. Headquartered in Bresso near Milan, Italy, the Company has a strong track record of advancing neuroscience-based treatments from discovery to market. Newron's lead compound, evenamide, is a first-in-class glutamate modulator and has the potential to be the first add-on therapy for treatment-resistant schizophrenia (TRS) and for poorly responding patients with schizophrenia. Evenamide is currently developed in the global pivotal ENIGMA-TRS Phase III development program. Clinical trial results to date demonstrate the benefits of this drug candidate in the TRS as well as poorly responding patient population, with significant improvements across key efficacy measures increasing over time, as well as a favorable safety profile, which is uncommon for available antipsychotic medications. Newron has signed development and commercialization agreements for evenamide with EA Pharma (a subsidiary of Eisai) for Japan and other Asian territories, as well as Myung In Pharm for South Korea. Newron's first marketed product, Xadago®/safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland, the UK, the USA, Australia, Canada, Latin America, Israel, the United Arab Emirates, Japan and South Korea. The product is commercialized by Newron's partner Zambon, with Supernus Pharmaceuticals holding marketing rights in the U.S., and Meiji Seika responsible for development and commercialization in Japan and other key Asian territories. For more information, please visit: www.newron.com

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