Ad hoc announcement pursuant to Art. 53 LR

Newron Provides Update on Phase 3 ENIGMA-TRS 2 Study

U.S. clinical hold remains in place; study continues in all other countries

Company initiates expansion of clinical sites and enrollment in Europe, Asia and Latin America

Topline data from ENIGMA-TRS 1 expected in Q1 2027

Milan, Italy, and Morristown, NJ, USA – September 25, 2026, 05:45 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, today announced that it has been informed by the U.S. Food and Drug Administration (FDA) that the hold on the enrollment of new patients will remain in place at U.S. sites in the Phase 3 ENIGMA-TRS 2 study with evenamide. Enrollment in the study continues outside the U.S. Newron anticipates receiving a written communication from the FDA with additional information regarding its decision and any further potential protocol changes that may be required to lift the hold.

Evenamide targets the modulation of excessive release of glutamate in patients suffering from treatment-resistant schizophrenia (TRS).

Newron is initiating the expansion of clinical sites and enrollment for ENIGMA-TRS 2 in Europe, Asia and Latin America. To date, approximately 80 patients have entered screening. The study is expected to enroll at least 400 patients following successful completion of the 42-day screening period.

The ENIGMA-TRS 1 study is currently ongoing in 20 countries, with ENIGMA-TRS 2 ongoing in four countries.

"Newron is highly confident in the significant body of clinical and preclinical safety data for evenamide, and we will continue to work constructively with the FDA to address the clinical hold," said Ravi Anand, Chief Medical Officer of Newron.

About ENIGMA-TRS

ENIGMA-TRS 1 is an ongoing, international, 52-week, randomized, double-blind, placebo-controlled Phase 3 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 is expected to have enrolled at least 600 patients in the study by mid-October 2026, at study centers in 20 countries in Europe, Asia, Latin America, and Canada.

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 to be 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 Q1 2027.

ENIGMA-TRS 2 is taking place at centers in the U.S. 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 3 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 U.S., following approvals from the U.S, 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. On April 29, 2026, Newron reported a hold by the FDA on the enrollment of new patients in the U.S. sites of the study, following Newron's notification to the agency of the sudden unexpected death 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. While U.S. patients entered screening, no U.S. patients have been dosed with evenamide, in 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 3 development program. Clinical trial results to date demonstrate the benefits of this drug candidate in 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: https://www.newron.com and connect with us on LinkedIn.

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