

Newron Pharmaceuticals

Phase III ENIGMA-TRS 2 trial underway

Newron Pharmaceuticals has announced the launch of its Phase III ENIGMA-TRS 2 trial in the US, marking an important step for the registrational programme for lead candidate evenamide in treatment-resistant schizophrenia (TRS). ENIGMA-TRS 2 is a global, randomised, double-blind, placebo-controlled, 12-week pivotal study designed to enrol c 400 TRS patients. Topline results are anticipated by Q426, at a similar time to the ENIGMA-TRS 1 trial, representing a highly important inflection point for Newron. Additional US sites for ENIGMA-TRS 2 are due to initiate shortly and regulatory submissions are being made to other countries expected to participate in this trial.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	9.1	(16.0)	(0.90)	0.00	N/A	N/A
12/24	51.4	21.7	0.87	0.00	22.5	N/A
12/25e	15.2	(20.6)	(1.03)	0.00	N/A	N/A
12/26e	7.8	(44.7)	(2.24)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

As per the [announcement](#), Newron's ENIGMA-TRS 2 trial has commenced in the US. The objective of the ENIGMA-TRS programme is to establish evenamide as an add-on therapy for patients with TRS, a patient population with limited treatment options at present, associated with high morbidity and mortality. Following the launch of the ENIGMA-TRS 1 (expected n=600) trial in [August 2025](#), ENIGMA-TRS 2 has been designed as a Phase III, global, 12-week, randomised, double-blind, placebo-controlled study. It is assessing the efficacy, safety and tolerability of evenamide at a twice-daily dose of 15mg as an add-on medication to current antipsychotics (including clozapine, the only approved drug for TRS) compared to placebo in TRS patients.

The trial design was cleared by the US FDA, and will aim to enrol c 400 patients across sites in the US, Europe, Asia and Latin America. Before patients are randomised, they undergo a 42-day screening period and review by the Independent Eligibility Committee (consisting of leaders in the field of schizophrenia). The primary efficacy (Positive and Negative Syndrome Scale, the gold standard for assessing the efficacy of antipsychotic treatments and the endpoint measure used in prior clinical studies) and safety outcomes will be assessed 12 weeks after randomisation to treatment. Topline results for both ENIGMA-TRS 1 and ENIGMA-TRS 2 are anticipated in Q426, potentially representing significant catalysts for investor attention.

Evenamide, with its novel dual mechanism of action as a voltage-gated sodium channel blocker and modulator of post-synaptic glutamate release, has already shown [promise](#) in TRS in the previous Phase II trial (study 014/015). The data showed that over 70% of patients achieved a clinically meaningful reduction in condition severity, c 50% of patients no longer met the protocol severity criteria for a diagnosis of TRS, and 25% of patients were described as achieving clinical remission (a phenomenon that, to our knowledge, has not yet been reported in the TRS patient population). In our view, these outcomes laid a robust foundation for evenamide as it enters the Phase III ENIGMA-TRS programme and, should the encouraging results translate, we believe there could be a sizeable commercial opportunity for Newron.

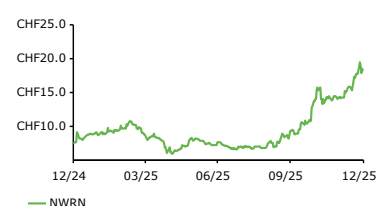
Clinical update

Healthcare

8 December 2025

Price	CHF18.28
Market cap	CHF325m
	€1.07/CHF
Net cash/(debt) at 30 June 2025	€(8.6)m
Shares in issue	17.8m
Free float	95.0%
Code	NWRN
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is involved in a Phase III trial programme targeting treatment-resistant schizophrenia.

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