

Newron Pharmaceuticals

ENIGMA-TRS 1 commences enrolment

Clinical update

Healthcare

12 August 2025

Newron Pharmaceuticals has confirmed that enrolment has begun for its registrational ENIGMA-TRS Phase III programme for lead candidate evenamide. The first of two trials for the programme is ENIGMA-TRS 1, an international, one-year, double-blinded, placebo-controlled, pivotal Phase III study. It aims to enrol 600 patients with treatment-resistant schizophrenia (TRS), and a 12-week readout is anticipated from Q426. Patient enrolment has commenced in line with prior guided timelines, and marks a key milestone for Newron's lead programme. In parallel, Newron is preparing for the second trial, ENIGMA-TRS 2, which will be a 400-patient international study (including the US). This trial is anticipated to launch by October 2025.

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	9.5	N/A
12/25e	7.3	(37.2)	(1.86)	0.00	N/A	N/A
12/26e	7.8	(40.2)	(2.01)	0.00	N/A	N/A

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

According to the [announcement](#), following completion of the 42-day screening period and review by the Independent Eligibility Committee, the first patients have now been randomised in the ENIGMA-TRS 1 trial. This study is assessing evenamide, in TRS, as an add-on therapy to current antipsychotics (including clozapine, the only approved drug for TRS). It is an international, 52-week, randomised, double-blinded, placebo-controlled study, testing the efficacy, tolerability and safety of evenamide at 15mg BID and 30mg BID doses (compared to placebo). Study centres are based in Europe, Asia, Latin America and Canada. The primary efficacy (Positive and Negative Syndrome Scale, PANSS) and safety outcomes will be measured 12 weeks after randomisation. The trial will continue, double-blinded and placebo-controlled, until the 52-week point. The 12-week results are expected in Q426, representing an important inflection point for Newron.

ENIGMA-TRS 2 will be an international trial, including US sites, expected to launch in October 2025. This trial will assess the efficacy, tolerability and safety of evenamide at 15mg BID only. Collectively, these two studies should meet the regulatory requirements to submit registration applications in major geographies, including Europe and the US.

We believe evenamide has a robust foundation as it enters this registrational Phase III programme. The results of the prior Phase II trial (study 014/015) were highly encouraging, in our view. Notably, 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. For a more detailed discussion, see our prior [outlook note](#).

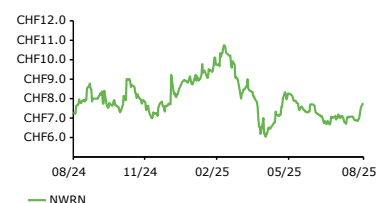
The data to date support evenamide's novel, dual mechanism of action, as a voltage-gated sodium channel blocker and modulator of post-synaptic glutamate release. In a recent separate announcement, Newron reported the [publication](#) of preclinical research in *Neuropsychopharmacology*, showing that evenamide targets the key site of schizophrenia pathology. Should the results of the registrational ENIGMA-TRS programme continue to be supportive, we believe this could translate to a sizeable commercial opportunity for Newron.

Price CHF7.74
Market cap CHF155m

€1.06/CHF

Pro forma net cash at 31 December 2024 (including €44.4m upfront proceeds from EA Pharma) €4.6m
Shares in issue 20.0m
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.

Analysts

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