EDISON

Newron Pharmaceuticals

Clinical data update

Evenamide efficacy still going strong after 52 weeks

Pharma and biotech

Newron Pharmaceuticals has announced positive interim results from the first 100 randomised patients completing one year of treatment (77 out of 100) in the Phase II 014/015 clinical trial (international, open label, rater-blinded study), in which evenamide is an add-on therapy to antipsychotics in moderate to severe treatment-resistant schizophrenia (TRS). The data are consistent with a gradual and sustained pattern of improvement in key efficacy measures compared with results after six weeks and six months of treatment, with the proportion of patients achieving meaningful improvements increasing over time. We view these updated results as particularly encouraging for evenamide as an effective treatment for TRS, and continued justification of Newron's strategy to expand into this schizophrenia patient population.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	5.26	(18.16)	(1.09)	0.00	N/A	N/A
12/21	5.76	(14.12)	(0.79)	0.00	N/A	N/A
12/22e	6.60	(15.51)	(0.87)	0.00	N/A	N/A
12/23e	7.89	(16.41)	(0.92)	0.00	N/A	N/A

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

It is estimated that 30–60% of schizophrenia patients are diagnosed with TRS, resulting in increased morbidity, mortality and suicide, and TRS continues to represent an unmet medical need. Clozapine is a typical choice for the management of TRS but, unfortunately, over half of patients are unresponsive to clozapine, highlighting the opportunity for improved therapies.

The Phase II study is an international, randomised, open label, rater-blinded study of evenamide (study 014 – six weeks and study 015 – extension study) as an add-on to an antipsychotic (excluding clozapine) in patients with moderate to severe TRS not responding to current medication. Of the first 100 patients randomised, 77 completed the 52-week endpoint in the extension study. Encouragingly, the efficacy data continued to show sustained improvements across the duration of the trial. After 52 weeks of treatment, the proportion of patients demonstrating a clinically meaningful improvement on the Positive and Negative Syndrome Scale was 3x greater than that observed at week six (16.5%). The scale also showed an increase of more than 50% over the statistically significant benefit noted at six weeks. Comparable benefit at the six-month mark was >30%. Patients experiencing meaningful improvement as measured by the Clinical Global Impression of Change (CGI-C) and Severity of Illness (CGI-S) scales also increased: CGI – another 10% increase from 27% at week 6 and CGI-S – doubling over the 10% figure at week six. We note that these data mostly relate to patients receiving the 7.5mg and 15mg doses and see potentially greater benefit from the 30mg dose arm once the study is completed (014 March 2023, 015 Q124).

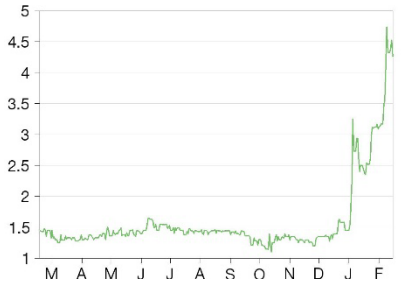
We view the results in this update are particularly positive for the outlook of evenamide as an effective treatment for TRS, representing a significant catalyst in our opinion. Based on these encouraging results, Newron plans to initiate a potentially pivotal, placebo-controlled Phase III trial in patients with TRS (study 003) in 2023.

16 February 2023

Price	**CHF4.26**
Market cap	**CHF81m**

Net debt (€m) at end June 2022	15.5
Shares in issue	17.8m
Free float	99%
Code	NWRN
Primary exchange	SIX Swiss Exchange
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 II/III trial programme targeting schizophrenia patients experiencing inadequate responses to current antipsychotic medications.

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