

Newron Pharmaceuticals

Corporate news

Xadago receives FDA approval in PD

Pharma & biotech

Newron and its partners Zambon and US WorldMeds have announced that the FDA has approved Xadago (safinamide) for Parkinson's disease (PD) patients as an add-on therapy to levodopa/carbidopa. While we had expected approval (following the revised PDUFA date of 21 March), the certainty of approval removes a major overhang on the stock, and as such we expect a positive share price reaction. We expect launch in the US market in H217 by sub licensee US WorldMeds. Our valuation of Newron remains unchanged at CHF530m.

22 March 2017

Price CHF26.6

Market cap CHF420m

CHF1.1/€

Net cash (€m) at 31 December 2016 46.2

Shares in issue 15.8m

Free float 77%

Code NWRN

Primary exchange SIX

Secondary exchange N/A

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	2.4	(18.3)	(1.17)	0.0	N/A	N/A
12/16	6.7	(15.2)	(1.04)	0.0	N/A	N/A
12/17e	15.3	(7.2)	(0.46)	0.0	N/A	N/A
12/18e	15.6	(3.9)	(0.24)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles.

Share price performance



Business description

Newron Pharmaceuticals is an Italian CNS-focused biotechnology company. Xadago (safinamide) for Parkinson's disease has been launched in Europe;. Xadago is partnered with Zambon (EU), Meiji Seika (Japan), US WorldMeds (US) and Seqirus (Australia, NZ).

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Commercial partner Zambon has sub licensed its US commercialisation rights to US WorldMeds and we expect US launch in H217; the US approval will trigger a €9m milestone payment to Newron. US WorldMeds is a Kentucky-based pharmaceutical company that markets a number of specialty products including a treatment for PD (APOKYN for the acute treatment of intermittent 'off' episodes). Xadago is a neat fit into its portfolio given its indication for use as add on to levodopa/carbidopa in PD. US WorldMeds plans to focus more than 60 sales representatives on launching Xadago in the US.

Our forecasts and valuation assume Xadago is priced broadly in line with Azilect, leading to peak global sales of c €450m (the US represents c 65% of our peak sales estimate) based on a 10% penetration of the PD patient market. If Xadago can achieve premium pricing to Azilect across Europe and the US, as it has in Germany so far, then all else being equal our peak sales forecast would be closer to €660m. This would contribute a further CHF160m to our valuation, or CHF12/share. Until further pricing is agreed, particularly in the US, we make no changes to our forecasts or valuation at this stage.

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