IRLAB Therapeutics

EMA alignment on mesdopetam Phase III plans

Regulatory update

Healthcare

20 February 2025

IRLAB has bolstered the value of its lead programme, mesdopetam in levodopa-induced dyskinesias (PD-LIDs), following confirmation that the European Medicines Agency (EMA) is aligned with the company on its proposed plans for Phase III. The EMA has agreed on the primary endpoint for the Phase III programme being the Unified Dyskinesia Rating Scale (UDysRS), on which mesdopetam demonstrated a statistically significant improvement (p=0.026) in the prior Phase IIb trial (where it was a secondary endpoint). Importantly, IRLAB is now aligned with the US Food and Drug Administration (FDA) and the EMA and, hence, is in a position to proceed with preparations for the registrational studies of the candidate while meeting regulatory requirements in both the US and Europe. With this latest update, we anticipate partnering discussions to pick up pace in the coming weeks.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/23	5.7	(177.8)	(3.43)	0.00	N/A	N/A
12/24	114.1	(83.1)	(1.60)	0.00	N/A	N/A
12/25e	20.9	(145.0)	(2.80)	0.00	N/A	N/A
12/26e	32.6	(144.0)	(2.78)	0.00	N/A	N/A

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

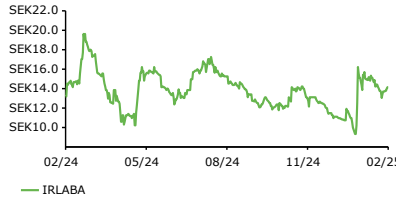
In our view, the positive feedback from the EMA on the IRLAB's plans for a Phase III programme for mesdopetam in PD-LIDs is an encouraging sign, and aligns the company with both the European and US regulators. According to the announcement, the EMA has accepted the following components of IRLAB's plans for Phase III: the patient population will be the same as in prior studies for the mesdopetam programme; the primary endpoint will be improvement on UDysRS (part 1, 3, and 4 of the scale); secondary endpoints will be based on elements of UDysRS, the MDS-Unified Parkinson's Disease Rating Scale and 24-hour diaries; the estimated number of participants will be 250–270, distributed across two parallel studies (both with a 1:1 randomisation between treatment and placebo) with a three-month treatment duration; mesdopetam will be evaluated at a dose of 7.5mg bid; and the required safety documentation will include a population of at least 100 patients treated with a clinically relevant dose of mesdopetam during one year in the safety extension portion of the programme.

We highlight that in the prior Phase IIb trial for mesdopetam, the results showed that mesdopetam demonstrated a nominally significant and clinically meaningful anti-dyskinetic effect compared to placebo, as measured by UDysRS, at the 7.5mg bid dose, and in a dose-dependent manner with the other tested doses. We note that the UDysRS measurements formed the basis of Adamas' Gocovri approval, the only FDA-approved treatment for PD-LIDs, exemplifying the clinical relevance of the scale.

With new financing in place to provide operational headroom potentially into Q425, and with this latest boost to the value proposition of the mesdopetam programme, we believe IRLAB is in a robust position to negotiate deal terms with potential partners. Assuming a suitable partnership is secured, management aims to initiate the Phase III programme within 2025.

Price	**SEK14.10**
Market cap	**SEK731m**
	SEK10.70/US$
Net cash at 31 December 2024 (including lease liabilities)	SEK6.5m
Shares in issue	51.9m
Free float	61.5%
Code	IRLABA
Primary exchange	OMX
Secondary exchange	N/A

Share price performance



Business description

Based in Sweden, IRLAB Therapeutics is focused on developing novel drugs for the treatment of neurodegenerative diseases utilising its ISP technology platform. Its two lead assets are in late-stage clinical trials for the symptomatic treatment of Parkinson's disease: mesdopetam (D3 antagonist) and pirepemat (PFC enhancer).

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