EDISON

OSE Immunotherapeutics

Regulatory update

Lusvertikimab progressing on multiple fronts

Pharma and biotech

OSE has announced that Lusvertikimab (or OSE-127), the company's most advanced asset in the immuno-inflammation space, has received a positive review from the independent drug safety monitoring board (DSMB). The review is for the ongoing Phase II clinical trial, which is assessing Lusvertikimab as a potential treatment for ulcerative colitis (UC), and the DSMB has recommended that the study continues to completion. We view this as an encouraging sign that the trial is progressing as anticipated, with no significant adverse events. With the announcement that this asset will no longer be investigated in partnership with Servier as a potential treatment for Sjögren's syndrome, top-line results from the UC trial, expected in December 2023, may represent the next most significant catalyst for this asset, in our view.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	26.3	(17.2)	(0.95)	0.0	N/A	N/A
12/22	18.3	(18.0)	(0.97)	0.0	N/A	N/A
12/23e	15.0	(17.8)	(0.96)	0.0	N/A	N/A
12/24e	15.0	(21.9)	(1.18)	0.0	N/A	N/A

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

As a reminder, Lusvertikimab is an antibody therapy acting as an IL-7R antagonist, more specifically targeting CD127, a cytokine modulating the proliferation, apoptosis and activation of CD4 and CD8 T-cells. OSE is investigating the drug as a potential treatment for UC, a chronic inflammatory bowel disease affecting c 160–290 people per 100,000 each year worldwide, current treatment options for which are associated with having a significant burden on patients' lives. The ongoing Phase II trial is evaluating the efficacy and safety of Lusvertikimab versus placebo in patients with moderate to severe active UC who have failed, lost response or been intolerant to prior treatments.

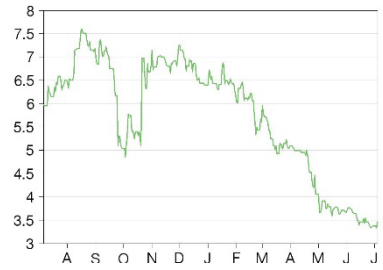
OSE has announced that the independent DSMB has provided a positive recommendation for the continuation of the Phase II trial without any modifications to the trial design. We view this as a positive indicator that the study is progressing as planned, with no significant safety events triggering the safety board to halt the trial. The study is expected to be fully enrolled (expected n=150) by end Q323. Top-line results after induction (primary endpoint at week 10) are anticipated in December 2023, and this update may represent a significant inflexion point, in our view. Additional data will be reported in H124 assessing Lusvertikimab as a potential maintenance treatment after six months of therapy.

Additionally, OSE has reported that the European Medicines Agency has provided a positive opinion on orphan drug designation for Lusvertikimab in acute lymphoblastic leukaemia (ALL). In collaboration with the University Medical Center Schleswig-Holstein in Kiel (Germany), preclinical research has demonstrated the activity of Lusvertikimab in ALL models using leukaemic samples from refractory and relapsed patients. We view the positive opinion from the EMA as encouraging regarding a clinical programme for Lusvertikimab in this indication, provided the preclinical research continues to be supportive.

6 July 2023

Price	**€3.7**
Market cap	**€70m**
	€0.92/US$
Net debt (€m) at 31 December 2022 (excluding lease liabilities)	14.7
Shares in issue	18.5m
Free float	65%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



Business description

OSE Immunotherapeutics is an immunotherapy company based in Nantes and Paris, France, and listed on the Euronext Paris exchange. It is developing immunotherapies for the treatment of solid tumours and autoimmune diseases and has established several partnerships with large pharma companies.

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