EDISON

OSE Immunotherapeutics

Clinical update

Encouraging safety data for OSE-127

Pharma and biotech

OSE Immunotherapeutics has announced that the data from its earlier Phase I study for OSE-127/S95011, initially released in 2019, has been published in the Journal of Immunology. The study, involving 63 healthy volunteers, was a first-in-human, randomised, double-blind, placebo-controlled trial that demonstrated a promising safety and tolerability profile for OSE-127. This candidate is a monoclonal antibody therapy being assessed as a treatment for primary Sjögren's syndrome (pSS) and ulcerative colitis (UC) in two ongoing Phase IIa studies (NCT04605978 and NCT04882007). Patient enrolment for the pSS trial was completed in Q422, with updates expected in H123; readouts for UC are expected in FY23. While we caution read-across between studies, we believe the high target occupancy observed in the Phase I study, along with a favourable safety profile, support the ongoing clinical programmes involving OSE-127.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	DPS (%)	Yield (%)
12/20	10.4	(18.5)	(1.02)	0.0	N/A	N/A
12/21	26.3	(16.5)	(0.89)	0.0	N/A	N/A

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

OSE-127 is a monoclonal antibody therapy that acts as an antagonist of the interleukin-7 receptor (IL-7R), a cytokine on the surface of certain immune system T cells; targeting IL-7R is expected to cause a downregulation in the inflammatory immune response. The Phase I data showed promising safety and tolerability for OSE-127 in 63 healthy volunteers. Subjects were monitored for up to 146 days and the results revealed high and sustained levels of target occupancy. There was also no evidence of cytokine-release syndrome or lymphopenia (potential adverse events that may be associated with antibody therapies targeting cytokines/T cells, or with CAR-T cell therapies and haploidentical transplantations), meaning OSE-127 may be further assessed for clinical benefit in IL-7R-implicated diseases.

OSE is continuing its clinical development of OSE-127 with two ongoing Phase IIa studies. These are both international, randomised, double-blind, placebo-controlled studies assessing the efficacy and tolerance of the antibody therapy. For the pSS study (conducted in partnership with Servier), patient enrolment (n=48) was completed in Q422, with updates expected in H123. For the UC study (conducted by OSE), readouts are expected in FY23, which we view as the next catalyst for the share price.

To date, existing approved treatments for pSS only address the symptoms. OSE-127 is being developed with the goal of being the first disease-modifying therapy, which, in our view, potentially offers significant market differentiation. To our knowledge, OSE-127 is the only therapeutic targeting IL-7R under clinical development for pSS and UC. However, IL-7R antagonists have been the subject of some notable recent deal activity. These include the recent licensing agreement between Horizon Therapeutics and Q32 in a deal worth up to US$700m and the acquisition of Zura Bio by SPAC JATT for Zura Bio's IL-7R asset for a pro-forma enterprise value of US$215m. We believe such transactions highlight the interest of IL-7R antagonists in the market.

1 March 2023

Price	**€5.57**
Market cap	**€99m**
Estimated net cash (€m) at 31 December 2022 (including €10m EIB payment)	17.8
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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