EDISON

OSE Immunotherapeutics

Collaboration update

Collaboration bolsters upcoming Tedopi Phase III

Pharma and biotech

OSE Immunotherapeutics (OSE) has announced a collaboration with GenDx for the development and validation of a companion diagnostic screening test to support its upcoming Phase III trial for Tedopi, an oncology vaccine for non-small cell lung cancer (NSCLC) in the second-line setting. The simple blood sample and next-generation sequencing test is intended to identify HLA-A*02 positive NSCLC patients who are more likely to respond to Tedopi epitopes. As GenDx is a leading molecular diagnostics company with experience in the human leukocyte antigen (HLA) field, the development of this companion diagnostic test should accelerate the enrolment of eligible patients. OSE's registrational pivotal clinical trial is to commence in 2024.

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	2.7	(26.2)	(1.34)	0.0	N/A	N/A
12/24e	15.0	(21.8)	(0.98)	0.0	N/A	N/A

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

The announced collaboration for the development of a companion diagnostic test screening for patients with the HLA-A*02 genotype, a predictive biomarker, is expected to assist in enrolling patients who are more likely to respond to Tedopi epitopes for the upcoming Phase III trial. We note that NSCLC accounts for c 85% of lung cancers, and c 45% of these patients show HLA-A*02 expression. The registrational pivotal clinical trial will assess the safety and efficacy of Tedopi for second-line treatment of NSCLC patients who have experienced secondary resistance post checkpoint inhibitor failure. The trial will be conducted in the US and Europe and is anticipated to commence in 2024.

We note that in June 2023, OSE received €1.5m in non-dilutive funding from Bpifrance (a French public sector investment bank) as part of the R&D Innovation Loan programme for the development of this companion diagnostic to support the Phase III trial for Tedopi. Tedopi has already demonstrated encouraging efficacy and safety in the Phase III ATALANTE-1 clinical trial. The results (first presented in September 2021) showed that Tedopi met its primary endpoint with significantly improved overall survival, while also maintaining positive patient-reported outcomes, quality of life and safety. However, the data were not sufficient to satisfy the requirements for Tedopi's approval as the study did not achieve complete patient enrolment due to disruption amid the COVID-19 pandemic. Despite this, in February 2023, OSE received positive recommendations from the FDA and EMA to conduct the subsequent pivotal Phase III trial. This is likely to conclude in 2026, and we believe that the results of the trial could be a significant catalyst for the company.

27 November 2023

Price	**€4.26**
Market cap	**€92m**
	€0.94/US$
Pro-forma net debt (€m) at 30 June 2023 (including September equity raise)	8.2
Shares in issue	21.6m
Free float	65%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

Business description

OSE Immunotherapeutics is based in Nantes and Paris in France and is 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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