EDISON

OSE Immunotherapeutics

Funding update

Funding accelerates Tedopi clinical development

Pharma and biotech

Despite the challenging macroeconomic environment, OSE announced an encouraging funding win with the receipt of €8.4m in non-dilutive public funding from Bpifrance (a French public sector financing institution). Proceeds will be directed to support the upcoming registrational Phase III study of lead asset Tedopi, in second-line treatment in HLA-A2 positive non-small cell lung cancer (NSCLC) patients with secondary (acquired) resistance to anti-PD-(L)1 immunotherapy. This announcement follows the company's $713m deal with AbbVie, reported in February, for preclinical asset OSE-230 (in chronic inflammation). Bpifrance in Q223 had granted €1.5m in non-dilutive funding to support the development of a companion diagnostic screening test to help identify HLA-A2 positive NSCLC patients, who have a higher likelihood of responding to Tedopi.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/22	18.3	(18.0)	(0.96)	0.0	N/A	N/A
12/23	2.2	(23.2)	(1.18)	0.0	N/A	N/A
12/24e	56.9	25.3	1.15	0.0	4.0	N/A
12/25e	65.5	33.7	1.49	0.0	3.1	N/A

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

Tedopi is an off-the-shelf cancer vaccine that comprises a unique combination of neoepitopes, and is being developed to treat NSCLC patients with secondary (acquired) resistance to checkpoint inhibitors. It is designed to directly activate tumour-specific T-cells that bind tumour-associated antigens presented on the surface of cancer cells by the HLA-A2 receptor. NSCLC accounts for c 85% of lung cancers, and c 45% of patients express HLA-A2. Tedopi has already demonstrated efficacy and safety in the ATALANTE-1 trial, showing a median overall survival of 11.1 months, and associated with a low rate of severe adverse events at 11% (versus 7.5 months, and 35%, respectively, with standard of care). While positive, the data were not sufficient for regulatory approval as the study did not reach full patient enrolment due to disruption from the COVID-19 pandemic. However, the FDA and EMA supported a follow-on confirmatory pivotal Phase III trial. This will build on the results observed to date by evaluating Tedopi specifically in the second-line setting (ATALANTE-1 targeted the second- or third-line setting), in a larger patient population of c 350 (ATALANTE-1 involved 139 patients in the Tedopi arm). With cancer vaccines garnering increasing recognition, the encouraging data seen to date, and with the NSCLC treatment market estimated by Spherical Insights to reach c $39bn by 2030, we believe there is sizable opportunity for OSE.

The newly announced funding from Bpifrance follows the €1.5m (June 2023) previously granted to support the development of a companion diagnostic screening test to help identify HLA-A2 positive NSCLC patients, who have a higher likelihood of responding to Tedopi. The clinical trial application dossier (including the study protocol and use of the diagnostic companion test, developed in collaboration with GenDx) was accepted by the FDA in mid-January; study initiation is expected in Q224 and will represent an important milestone for OSE. Management plans to submit the dossier to the EMA in the coming weeks; we expect an extension to European trial sites from H224.

12 April 2024

Price	**€4.65**
Market cap	**€101m**
	€0.93/US$
Net debt (€m) at 31 December 2023 (excluding $48m in upfront payment from AbbVie in February 2024)	23.2
Shares in issue	21.8m
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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