EDISON

OSE Immunotherapeutics

Regulatory update

US patent to bolster Tedopi's product portfolio

Pharma and biotech

OSE Immunotherapeutics has announced that Tedopi, the company's lead cancer vaccine candidate, has been granted a new patent by the United States Patent and Trademark Office. The patent provides further protection of Tedopi as a potential second-line treatment in non-small cell lung cancer (NSCLC) patients post PD-1/PD-L1 immune checkpoint inhibitor (ICI) failure. We note that Tedopi is already being developed for HLA-A2+ patients with advanced or metastatic NSCLC. OSE is preparing for a follow-on Phase III confirmatory and potentially pivotal trial by end-FY23 or early FY24, and the additional patent protection represents a key milestone in the clinical development of Tedopi, in our view. Additionally, we note that the company already has similar patent approval in Japan, with multiple patent applications pending in other international markets.

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.

The US patent has been granted for the use of Tedopi as a treatment in HLA-A2+ patients after secondary resistance to PD-1/PD-L1 ICI treatment. OSE is targeting the HLA-A2 genotype for Tedopi treatment in the upcoming Phase III clinical trial for NSCLC patients. We note that HLA-A2+ patients account for c 45% of all NSCLC patients and anti-PD1/PD-L1 immunotherapy has emerged as a gold-standard treatment for first- or second-line treatment of stage four NSCLC, but less than 20% of NSCLC patients benefit from this ICI monotherapy treatment. The failure rate provides an opportunity for Tedopi, in our view. According to management estimates, the target population in second-line treatment after PD-1/PD-L1 ICI failure is up to 100,000 patients per year across seven major markets in the United States, Europe, China and Japan.

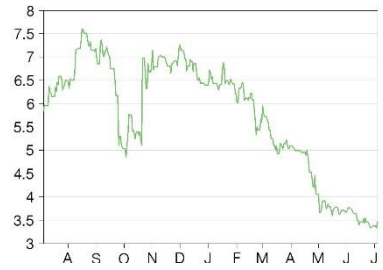
As a reminder, Tedopi reported positive top-line data from the Phase III ATALANTE-1 trial, demonstrating the efficacy of Tedopi in NSCLC patients (increase in overall survival and reduced risk of death by 41% versus chemotherapy). Further, compared to chemotherapy, a superior safety profile was reported (associated with an improved quality of life, based on patient-reported outcomes). However, the data were not sufficient to satisfy the requirements for Tedopi's approval, as the study did not achieve its full patient enrolment due to disruption during the COVID-19 pandemic. Following discussions with regulators (the FDA and EMA), a follow-on Phase III confirmatory and potentially pivotal trial is now planned in second-line NSCLC patients post ICI failure. We expect the new study to start by end-FY23 or early FY24, with readouts in FY25–26, and estimate a launch date for Tedopi in 2028. (Further details can be found in our recently published re-initiation note).

With a FY22 gross cash position of €25.6m, and assuming OSE fully exercises its debt and equity committed financing, management has guided a cash runway into Q224.

5 July 2023

Price	**€3.5**
Market cap	**€65m**
	€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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