EDISON

OSE Immunotherapeutics

Clinical update

Tedopi registrational study commences

Pharma and biotech

OSE Immunotherapeutics has announced the initiation of its Phase III registrational study (Artemia) for lead cancer vaccine Tedopi, with the trial launching in the US, Canada, Europe and the UK. Artemia is a confirmatory pivotal trial designed to assess the efficacy and safety of Tedopi as a monotherapy versus the standard of care (SoC) in HLA-A2-positive patients with metastatic non-small cell lung cancer (NSCLC) and secondary (acquired) resistance to immune checkpoint inhibitors (ICIs). The primary endpoint is overall survival (OS) and we expect top-line results in 2027. If the data are positive, this should support a regulatory registration in the second-line setting in Europe and North America.

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	103.7	72.1	3.32	0.0	2.4	N/A
12/25e	82.7	51.1	2.35	0.0	3.4	N/A

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

The initiation of Artemia is an important milestone for OSE as it takes the company a step closer to the regulatory approval of Tedopi, an off-the-shelf cancer vaccine comprising a unique combination of neoepitopes and, to our knowledge, the most advanced neoepitope-based vaccine in the clinic. This registrational trial begins in the US, Canada, Europe and the UK, following regulatory clearance by international health agencies across 14 countries. The target population is metastatic NSCLC patients, with secondary resistance to ICIs (initial response to ICIs but with disease progression after 12 weeks of treatment). From this broader cohort, the Artemia trial will recruit HLA-A2-positive patients (c 45% of NSCLC patients) based on Tedopi's underlying mechanism of action, which activates tumour-specific T-cells that then bind tumour-associated antigens presented on the surface of cancer cells by the HLA-A2 receptor. The trial is being facilitated by a companion diagnostic screening test to help identify HLA-A2-positive patients, which we believe should support accelerated enrolment. Eligible patients will be randomised (2:1) to either Tedopi or SoC docetaxel treatment and the primary endpoint will be OS, with secondary objectives relating to patient-reported outcomes, quality of life and safety.

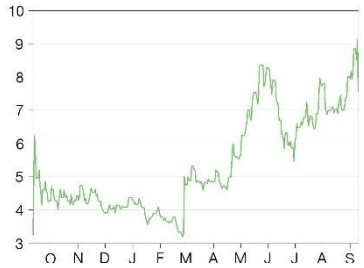
We expect investors will be paying close attention to whether Artemia will confirm the encouraging findings of ATALANTE-1, the prior Phase III trial for Tedopi (covered in our FY23 update note). We note that ATALANTE-1 was assessing Tedopi as monotherapy in the second- or third-line setting and, while the patient population included patients with both primary and secondary resistance to ICIs, a post-hoc analysis identified the cohort with secondary resistance to benefit the most. We expect Artemia to build on ATALANTE-1 by assessing data from a larger population of interest (expected n=363 vs 139 evaluable patients in ATALANTE-1, of which 118 had secondary resistant to ICIs).

We expect OSE to present interim data starting in 2025, with top-line results in 2027 and possible commercial launch in 2028, should the data be supportive. OSE's funding position remains comfortable (cash runway into 2027) following recent capital injections from AbbVie and Boehringer Ingelheim, as well as public grants.

11 September 2024

Price	**€9.12**
Market cap	**€199m**
	€0.92/US$
Pro-forma net cash (€m) at 31 May 2024 (including the upfront payments from AbbVie and Boehringer Ingelheim)	68
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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