EDISON

OSE Immunotherapeutics

Regulatory update

FDA support received for Tedopi Phase III trial

Pharma and biotech

OSE has announced that it has received positive recommendations from its 'type C' meeting with the FDA for the planned confirmatory Phase III trial design for Tedopi (neoepitope cancer vaccine), as a second-line treatment in advanced or metastatic non-small cell lung cancer (NSCLC) after checkpoint inhibitor failure. This follows similar advice from the European Medicines Agency (EMA). The company will now undertake the pivotal trial as monotherapy (against standard of care) under this protocol, for patients with HLA-A2+ tumours (c 45% of total population). As a reminder, OSE reported positive data from the previous Phase III ATALANTE-1 trial as second/third-line treatment, although enrolment had to be terminated prematurely due to the COVID-19 pandemic.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	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.

Following endorsement by the FDA and EMA on the proposed trial design, OSE will work on protocol development for the new Phase III trial, which should support the regulatory registration of Tedopi. The confirmatory trial is aimed at HLA-A2+ patients with secondary resistance to immunotherapy (IO)/checkpoint inhibitors after a first line of chemo-IO, followed by failure to maintain IO of at least 12 weeks (the threshold for secondary/acquired resistance). This new development comes after positive data were reported from the truncated Phase III ATALANTE-1 trial in H122, which demonstrated a 44.4% one-year overall survival rate versus 27.5% with chemotherapy along with a superior safety profile.

The Phase III ATALANTE-1 trial evaluated Tedopi as second- or third-line treatment following checkpoint inhibitor failure in HLA-A2+ patients (with locally advanced (stage IIIB), or metastatic (stage IV) NSCLC. The comparator to Tedopi treatment was docetaxel or pemetrexed chemotherapy. Overall survival was the primary endpoint of the trial. Patients who have failed immune checkpoint inhibitor treatment represent an unmet space where no novel treatment has been approved yet, presenting a sizeable market opportunity.

In addition to the above, OSE has three ongoing Phase II trials for Tedopi, led by clinical oncology groups, aiming to expand the clinical utility of Tedopi in combination with Opdivo (NSCLC), Keytruda (ovarian cancer) and chemotherapy (pancreatic cancer). If Tedopi can demonstrate similar or increased survival as a combination regimen compared to the monotherapy in these indications, we expect it could significantly increase the commercial impact of the neoepitope cancer vaccine.

Tedopi is currently available through compassionate use programmes in third or further lines of treatment (post chemotherapy and immunotherapy) in France, Italy and Spain.

16 February 2023

Price	**€6.1**
Market cap	**€114m**

Estimated net debt (€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 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.

Analysts

Jyoti Prakash, CFA +44 (0)20 3077 5700

Nidhi Singh +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

OSE Immunotherapeutics is a research client of Edison Investment Research Limited

General disclaimer and copyright

This report has been commissioned by OSE Immunotherapeutics and prepared and issued by Edison, in consideration of a fee payable by OSE Immunotherapeutics. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia