

OSE Immunotherapeutics

Clinical update

Lusvertikimab shines in Phase II UC trial

Pharma and biotech

26 July 2024

OSE Immunotherapeutics' run of positive news continues with the announcement of encouraging data from the Phase II proof-of-concept CoTikiS study, evaluating Lusvertikimab as a novel treatment for ulcerative colitis (UC). The randomised, double-blind trial (n=136) has reported encouraging, statistically significant benefits, reflected in material improvements on the Modified Mayo Score (MMS). The full data set will be presented in due course, and we expect the next stage of development to be undertaken in partnership, which we estimate will be in place in 2025. Lusvertikimab is a potentially first-in-class IL-7R antagonist, offering a differentiated mechanism of action to other available biologics that currently dominate the UC market. We expect the next major catalyst for OSE to be the initiation of the Phase III trial for lead asset Tedopi, anticipated to commence imminently (previous guided timeline was Q224).

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.

OSE has reported [positive top-line data](#) from the Phase II [CoTikiS](#) study, a double-blind, placebo-controlled trial assessing the anti-IL7R antibody in UC patients. The MMS (a nine-point scale based on a combination of stool frequency, rectal bleeding and endoscopic sub scores) is the standard outcome measure for UC and was used as the primary endpoint. 136 patients with moderate to severe active UC, who failed, lost response or were intolerant to previous treatments, were randomised to one of two dose cohorts (850mg and 450mg). Both dose groups achieved statistically significant benefits, with the principal analysis 850mg group (n=50; placebo=49) reporting a -0.82 difference in treatment effect following the 10-week induction period (95% CI: -1.63; -0.01; p-value=0.047), while the truncated 450mg group (n=35) reported a -1.17 difference (95% CI: -2.18; -0.16; p-value=0.047). Management has indicated that efficacy was maintained over the subsequent 34-week open-label period.

We await the release of the full data set, including details on improvement over baseline scores, which could facilitate comparisons with other available biologics in UC, such as the recently approved [risankizumab](#) (Skyrizi; AbbVie), an IL-23 inhibitor. We understand that OSE plans for subsequent development work to be undertaken as part of a partnership/licensing agreement and note that the recent US\$3.2bn Lilly/Morphic [deal](#) suggests that big pharma continues to hold an interest in this space. We highlight that OSE is also evaluating Lusvertikimab in acute lymphoblastic leukaemia, and recently [published](#) preclinical efficacy results in *Blood*. We await further updates on this programme in H224.

In the nearer term, we expect investor attention to be focused on the upcoming Phase III registrational study for lead cancer vaccine Tedopi in non-small cell lung cancer, which we anticipate will commence imminently. As highlighted previously, the [funding position](#) remains comfortable (cash runway into 2027) following recent capital injections from AbbVie and Boehringer Ingelheim, as well as public grants.

Price €6.91

Market cap €151m

€0.92/US\$

Pro-forma net cash (€m) at 31 May 2024 68
(including the upfront payments from AbbVie and Boehringer Ingelheim)

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.

Analysts

Soo Romanoff +44 (0)20 3077 5700

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

Dr Arron Aatkar +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 of 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.

Copyright: Copyright 2024 Edison Investment Research Limited (Edison).

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.
