EDISON

OSE Immunotherapeutics

KOL event highlights lusvertikimab's potential

Company update

Healthcare

7 March 2025

OSE Immunotherapeutics and Edison held a key opinion leader (KOL) event on 5 March 2025, providing up-to-date insights into OSE's lead immuno-inflammation candidate, lusvertikimab, following the European Crohn's and Colitis Organisation (ECCO) 2025 Congress in late-February. Lusvertikimab is an anti-IL-7 receptor antibody therapy that, to our knowledge, has a unique mechanism of action for the target indication of ulcerative colitis (UC). It completed a Phase II trial last year, and with the additional data presented at ECCO, the KOLs were encouraged by both the safety and efficacy of the candidate. Following the latest update for the programme, we believe the data to date provide a robust foundation for further clinical development efforts, and lusvertikimab has the potential to address key unmet needs in the space.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/22	18.3	(18.0)	(0.96)	0.00	N/A	N/A
12/23	2.2	(23.2)	(1.18)	0.00	N/A	N/A
12/24e	98.5	64.5	2.80	0.00	2.3	N/A
12/25e	86.3	50.9	2.33	0.00	2.7	N/A

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

ECCO update bolsters the lusvertikimab data package

The data presented at ECCO recapped the CoTIKiS results, whereby lusvertikimab achieved statistical significance on the primary and secondary endpoints. The results also showed high rates of clinical and endoscopic remission, with meaningful histological improvement and histo-endoscopic mucosal improvement (HEMI) rates. Further, the latest data demonstrated that lusvertikimab treatment was associated with significant decreases in fecal calprotein (FCP), a recognised biomarker of mucosal inflammation in UC patients, serving as an early predictor of endoscopic and histological responses. As such, statistically significant efficacy was observed in clinical and endoscopic remission in the subgroup characterised by high FCP levels at baseline (considered the 'active UC' population) , highlighting the benefit of lusvertikimab in this population. The Phase II results for lusvertikimab also confirmed its desirable safety and tolerability, which, with the favourable efficacy data, provide a robust foundation for subsequent development efforts, in our view.

Combination approach promising, but not a priority

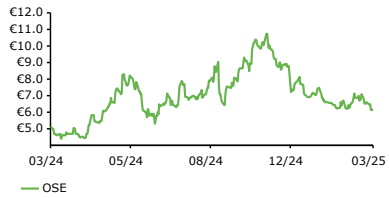
At ECCO, OSE also presented some preclinical data on the combination of lusvertikimab with anti-IL-12/23 antibody therapies in chronic colitis. The reported data showed that while IL-12/23 antagonists can be effective, monotherapy is insufficient to achieve complete remission. However, when combined with an IL-7 receptor antagonist such as lusvertikimab, the synergy can lead to a reduction of all colitis symptoms. While encouraging, we note that this is early-stage research, and highlight that the main focus for OSE remains the lead post-Phase II programme.

Valuation: €541.2m or €24.8 per share

For now, we keep our valuation for OSE unchanged at €541.2m or €24.8 per share. This was last upgraded following the release of the more detailed Phase II results in November 2024.

Price	**€6.32**
Market cap	**€137m**
	€0.89/US$
Gross cash and cash equivalents at 30 June 2024	€80.8m
Shares in issue	21.9m
Free float	65.0%
Code	OSE
Primary exchange	NXT PA
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(2.3)	(15.5)	28.1
52-week high/low		€11.6	€4.4

Business description

OSE Immunotherapeutics (OSE) 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.

Next events

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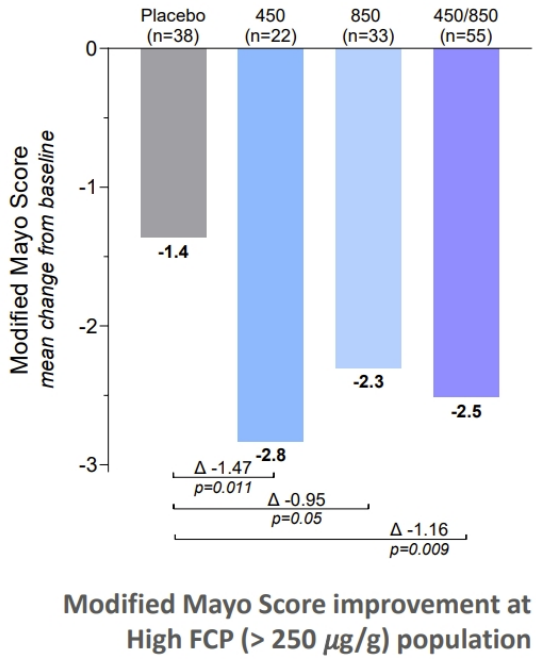
Lusvertikimab: A promising candidate for UC

Latest data presented at ECCO

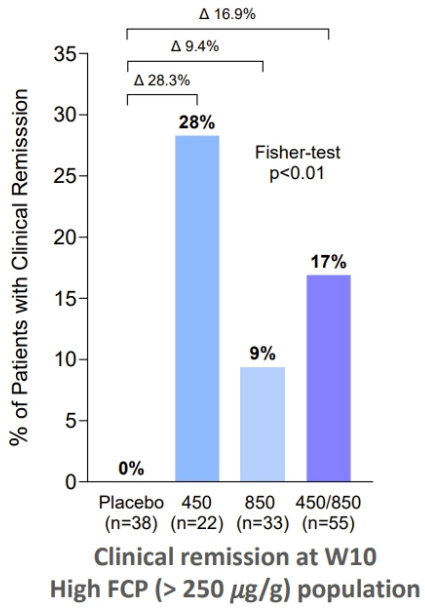
The data from the Phase II CoTikiS trial were initially reported in November 2024; for a detailed discussion we direct readers to our prior update note. The new data presented at ECCO focused on outcomes in relation to the FCP biomarker. As mentioned above, CoTikiS met its primary endpoint, which was based on Modified Mayo Score (MMS) improvements, an FDA-recognised outcome measure. An important takeaway from the ECCO update was the focus on the active disease sub-population, defined by FCP levels at baseline exceeding a threshold of 250µg/g. For this subgroup, there were statistically significant differences between the pooled cohort, the 450mg group and the 850 mg group, compared to the placebo group (Exhibit 1). The greatest response was observed in the 450mg group, which showed a 2.8-point improvement (p=0.011). We understand that the greatest response in the 450mg group, as seen in the detailed data reported for CoTikIS in November 2024, may be due to a number of factors, such as individual patient differences and whether they were treatment naive, for example. A similar trend was seen in the clinical remission data, a key secondary efficacy measure from the study (defined by an MMS of ≤2 points with no individual sub-score of >1 point; rectal bleeding at 0; stool frequency score of 0 or 1; endoscopic score of 0 or 1). The results showed that, compared to 0% in the placebo group that had active disease at baseline, 28% of patients with active disease in the 450mg group achieved clinical remission (Exhibit 2).

Exhibit 1: MMS improvement (primary endpoint measure) for the active UC population



Source: Company resources

Exhibit 2: Clinical remission data (key secondary endpoint measure) for the active UC population

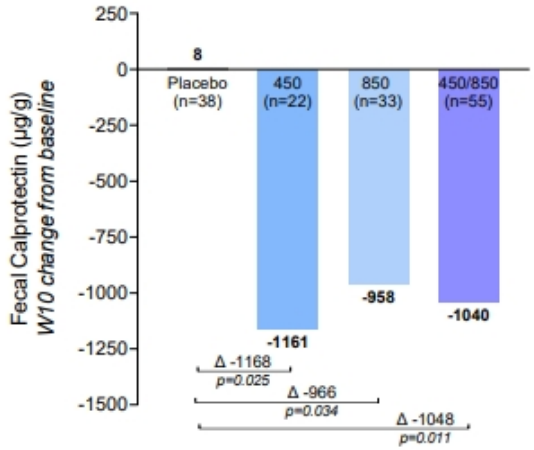


Source: Company resources

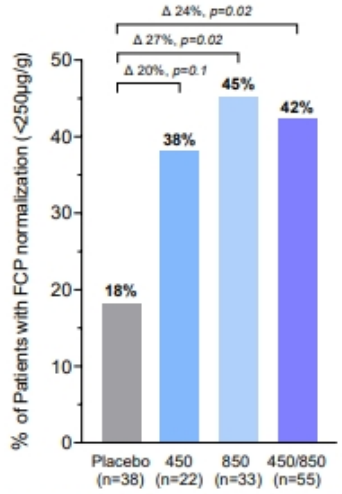
Further to this, lusvertikimab treatment was also shown to significantly decrease or normalise FCP after 10 weeks of treatment in UC patients with active disease (Exhibit 3). In terms of FCP change from baseline, the result was again most pronounced for the 450mg group, which showed a improvement of 1,169µg/g compared to placebo (p=0.025). For the measures of normalisation (to FCP levels below 250µg/g), the greatest effect was observed in the 850mg group, whereby 45% of patients with active disease at baseline achieved normalisation at week 10, a 27% improvement compared to placebo.

Collectively, we view these additional data as favourable for the potential of lusvertikimab to address moderate to severe UC, particularly in patients characterised as having active disease at baseline.

Exhibit 3: Additional CoTikiS data presented at ECCO showed that lusvertikimab significantly decreased/ normalised FCP after 10 weeks of treatment in patients with active disease



Fecal calprotectin (FCP) change at W10
High FCP (> 250 µg/g) population



Fecal calprotectin (FCP) normalization at W10
High FCP (> 250 µg/g) population

Source: Company resources

A brief overview of ulcerative colitis and the current treatment landscape

UC is a form of inflammatory bowel disease (IBD) characterised by inflammation around the lining of the large intestines (colon) and rectum. As summarised during the KOL event, the condition presents burdens related to disease outcomes, including: hospitalisations, abdominal pain, diarrhoea, anaemia, bowel damage and surgery; as well as burdens related to patient-reported outcomes, including: impaired quality of life, colonoscopy/imaging, blood/faecal test monitoring, fatigue, side effects from medications and fear of cancer risk.

The condition most commonly affects people between the ages of 15 and 30, and can range from mild to severe. In 2023, the global prevalence of UC was estimated at five million cases, with 600–900k cases in the US alone. According to a report by Market Research Future, the global UC treatment market was estimated to be worth c US$7.2bn in 2022, and projected to reach c US$10.8bn by 2032, reflecting an expected increase in prevalence, and corresponding to a compound annual growth rate of 5.1%.

In the first-line setting, typical UC treatment involves aminosalicylates (5-ASA drugs), though these are often more effective in mild to moderate cases of the condition. For patients who do not respond to 5-ASA drugs, alternative treatment options include corticosteroids (such as prednisone) and immunomodulators (such as methotrexate and azathioprine), and more recently JAK inhibitors (such as upadacitinib) and biologics. Biologic treatments often work by blocking the proteins that cause inflammation, and they have recently emerged as the standard of care in moderate to severe cases of UC. Broadly, there are three distinct categories of biologics:

- Anti-tumour necrosis factor (anti-TNF) inhibitors: Humira (adalimumab), Remicade (infliximab) and Simponi (golimumab).
- Integrin receptor antagonists: Entyvio (vedolizumab).
- Interleukin-12 and interleukin-23 antagonists: Stelara (Ustekinumab) and Skyrizi (risankizumab).

While anti-TNFs were the first biologics to receive the regulatory green light in UC, second-generation biologics, such as interleukin (IL) antagonists, are gaining prominence. The most recently approved biologic for UC is Skyrizi (an IL-23 antagonist), which was granted FDA approval in June 2024 in moderate to severe UC. While biologics provide an effective treatment option for a portion of UC patients, some remain either unresponsive or eventually develop resistance to biologic treatments. Research has also demonstrated that the efficacy of UC treatments can plateau over time, meaning that less than 50% of patients achieve remission over one year. We therefore believe that there is ample opportunity in the space for effective new treatment options with novel mechanisms of action.

OSE's lusvertikimab (formerly OSE-127) targets the IL-7 receptor, which is implicated in UC and other forms of IBD. To our knowledge, it is the most clinically advanced IL-7 receptor antagonist in clinical development. More specifically, it

targets CD127, a cytokine that modulates the proliferation, apoptosis and activation of CD4 and CD8 T-cells. Given that reported scientific data have shown that high IL-7 receptor expression is associated with poorer responses to alternative biological treatments (such as anti-TNF treatments), lusvertikimab may be a potentially more effective treatment option compared to currently available biologics.

Key opinion leader (KOL) event (5 March 2025)

Please see below for a recording of the KOL event, which:

- provides an overview of the candidate's mechanism of action, presented by Nicolas Poirier, CEO of OSE Immunotherapeutics,
- showcased the key clinical results from CoTikiS, presented by Professor Arnaud Bourreille, Institut des Maladies de l'Appareil Digestif,
- discusses the additional data that was shared at ECCO, which showed that lusvertikimab significantly decreased FCP after 10 weeks of treatment in UC patients with active disease, presented by Professor Vipul Jairath, Schulich School of Medicine and Dentistry, and
- discusses the current treatment landscape in UC and IBD, presented by Professor Laurent Peyrin-Biroulet, Nancy University Hospital.

KOL insights post-ECCO webinar recording

Source: OSE Immunotherapeutics, Edison Investment Research

Financials and valuation

As mentioned above, our valuation for OSE stands at €541.2m or €24.8 per share. This was upgraded (from €541.2m or €24.8/share, previously) following the release of the more detailed Phase II results in November 2024, whereby we increased our assigned probability of success for the programme to 35% (from 17%). For details, please see our prior update note.

Our valuation is based on a sum-of-the-parts risk-adjusted net present value (rNPV) approach for the company's proprietary and partnered clinical-stage programmes. A breakdown of our valuation can be found in Exhibit 4.

Exhibit 4: OSE rNPV valuation

Product	Launch	Peak Sales (EURm)	NPV (EURm)	NPV/share (EUR)	Probability	rNPV (EURm)	rNPV/Share (EUR)
Tedopi - NSCLC	2028	541	421.1	19.3	67%	274.3	12.6
OSE-127 - ulcerative colitis	2028	819	318.4	14.6	35%	125.9	5.8
BI 765063 - multiple cancer indications (MSS CRC)	2029	513	202.2	9.3	14%	40.5	1.9
FR104 - Veloxis deal milestones (kidney transplantation)	2029	92	149.7	6.9	17%	27.7	1.3
OSE-279 solid tumours (SCLC)	2029	416	206.0	9.4	14%	35.9	1.6
Net Cash/(Debt) at 30 June 2024 (including lease liabilities)			36.9	1.7	100%	36.9	1.7
Valuation			**1,334.2**	**61.1**		**541.2**	**24.8**

Source: Edison Investment Research

Based on our cash burn projection, we estimate the current cash reserves to be sufficient for the company to fund operations into 2027, in line with management guidance. We note that this does not consider further licensing or milestone-related inflows from partners, which should lengthen the runway further.

OSE is due to present its financial results for FY24 on 26 March 2025, after which we will update our estimates.

Exhibit 5: Financial summary

€000s Year end 31 December	2022 IFRS	2023 IFRS	2024e IFRS	2025e IFRS
PROFIT & LOSS				
Revenue	18,302	2,227	98,480	86,271
Cost of Sales	0	0	0	0
Gross Profit	18,302	2,227	98,480	86,271
Research and development	(26,893)	(17,158)	(23,575)	(26,696)
Overhead expenses	(6,673)	(6,015)	(7,218)	(7,435)
EBITDA	(14,992)	(19,566)	66,673	53,348
Operating Profit (before amort. and excepts.)	(18,478)	(22,986)	65,523	52,140
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(18,478)	(22,986)	65,523	52,140
Net Interest	455	(235)	(1,070)	(1,231)
Profit Before Tax (norm)	(18,023)	(23,221)	64,453	50,910
Profit Before Tax (reported)	(18,023)	(23,221)	64,453	50,910
Tax	263	219	(3,540)	0
Profit After Tax (norm)	(17,760)	(23,002)	60,913	50,910
Profit After Tax (reported)	(17,760)	(23,002)	60,913	50,910
Average Number of Shares Outstanding (m)	19	20	22	22
EPS - normalised (c)	(96)	(118)	280	233
EPS - reported (€)	(1)	(1)	3	2
Gross Margin (%)	100	100	100	100
EBITDA Margin (%)	N/A	N/A	68	62
Operating Margin (before GW and except.) (%)	N/A	N/A	67	60
BALANCE SHEET				
Fixed Assets	54,580	51,576	55,950	49,108
Intangible Assets	48,784	46,401	45,594	44,787
Tangible Assets	743	464	471	520
Investments	5,053	4,711	9,885	3,801
Current Assets	37,200	30,478	85,599	139,027
Stocks	0	0	0	0
Debtors	403	982	1,031	1,083
Cash and cash equivalents	25,620	18,672	73,744	127,121
Other	11,177	10,824	10,824	10,824
Current Liabilities	16,268	18,799	17,108	24,520
Creditors	8,539	9,299	9,764	10,252
Short term borrowings	3,093	6,403	4,247	11,171
Other	4,636	3,097	3,097	3,097
Long Term Liabilities	42,855	40,280	38,175	26,439
Long term borrowings	37,231	35,508	34,261	23,090
Deferred tax liabilities	1,514	1,311	1,311	1,311
Other long term liabilities	4,110	3,461	2,603	2,038
Net Assets	32,657	22,975	86,267	137,177
CASH FLOW				
Operating Cash Flow	(17,760)	(23,002)	60,913	50,910
Movements in working capital	(3,142)	(835)	416	437
Depreciation and other	3,486	3,420	1,150	1,208
Net Interest	(3,066)	(657)	0	0
Tax	(499)	(435)	0	0
Others	2,728	1,746	2,164	0
Net Cash Flows from Operations	(18,253)	(19,763)	64,642	52,554
Capex	(274)	(232)	(350)	(450)
Acquisitions/disposals	0	0	0	0
Others	300	(275)	0	0
Net Cash Flow from Investing Activities	26	(507)	(54,330)	54,440
Equity Financing	6	11,357	215	0
Debt financing	11,046	2,304	(3,403)	(4,247)
Other	(785)	(337)	(858)	(565)
Net Cash Flow from Financing Activities	10,267	13,324	(4,046)	(4,812)
Effect of FX	0	0	0	0
Net Cash Flow	(7,960)	(6,946)	6,266	102,182
Opening net debt/(cash)	(1,167)	14,704	23,239	(35,236)
Change in debt	7,912	1,587	(3,403)	(4,247)
Change in cash	7,960	6,946	(6,266)	(102,182)
Closing net debt/(cash)	14,704	23,239	(35,236)	(92,860)

Source: Company reports, Edison Investment Research

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