

OSE Immunotherapeutics strengthens Growth Strategy: Accelerates key pillars of Inflammation and Immuno-Oncology

- **Ignites strong momentum in immunology & inflammation pipeline** through lusvertikimab development, leveraging a new predictive biomarker.
- **Leads a new era in cancer vaccines** with Tedopi® on track for registration.
- **Drives company transformation through responsible governance:** international development, rigorous financial planning and clinical execution.

NANTES, France – June 4th, 2025, 8:00 am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), a biotech company dedicated to developing first-in-class therapies in immuno-oncology and immuno-inflammation, today outlined the company’s ambition for long-term growth and sustainable shareholder and societal value.

Nicolas Poirier, CEO of OSE Immunotherapeutics notes: *"OSE's grounding in solid science, our collaborative approach and a skilled workforce have resulted in a transformative two years, progressing our mission to bring breakthrough immunotherapies to the clinic. We are proud of our accomplishments, particularly delivering positive results for our lead assets, lusvertikimab and Tedopi®, which hold the potential to redefine standards of care across multiple diseases in I&I and I/O. We also secured new partnerships for our preclinical programs and significantly strengthened our financial position with over €90 million in new non-dilutive funding. OSE is positioned among Europe's leading biotechs. Now, it's time to build a more ambitious international company and unlock greater long-term value for all stakeholders."*

OSE Immunotherapeutics' **Board of Directors**, led by Chairman, **Didier Hoch**, commented: *"Under the joint leadership of the Board and Executive Team, OSE has shown resilience and growth in a competitive biotech landscape. The company is entering a decisive phase. Our strategy is built on three pillars: maintaining scientific leadership, expanding strategic alliances, and ensuring disciplined financial management for sustainable growth. To achieve this, the company will explore various options, including business development, strategic alliances, international investments, and a potential Nasdaq listing. We are shaping the future by building an ambitious international biotech, driven by innovation creating lasting value for patients, employees, and shareholders."*

New predictive biomarker with potential to revolutionize UC treatment, an emerging value lever for lusvertikimab

Despite intensive therapeutic research in IBD, only 25–30% of UC patients currently achieve clinical remission, and this limitation—commonly referred to as the therapeutic ceiling (*Vieujean S. Nature Reviews Gastroenterology, 2025*)—persists across all approved therapies and drug classes in late-stage development.

OSE research and translational teams, in collaboration with foundational model specialists, have identified a predictive biomarker that can isolate a subpopulation of patients (~30%) and offer significantly enhanced treatment outcomes, potentially achieving clinical remission rates exceeding 50%. This biomarker-driven approach was developed using advanced AI and transfer learning. The model was trained on multimodal data from millions of chronic inflammatory disease patients and refined with data from CoTikiS Phase 2 study.

Importantly, biomarker-negative patients showed 0% clinical remission in this dataset, indicating no loss of treatment opportunity when prioritizing treatment based on biomarker status. This precision medicine approach could position lusvertikimab as a first-line therapy for the biomarker-positive population; a potential addressable market opportunity exceeding \$3 billion across seven major markets. Next steps include prospective validation of this predictive biomarker through stratification in future clinical trials.

Nicolas Poirier details: *“Our comprehensive dataset for lusvertikimab, with its novel upstream mechanism demonstrating clinical efficacy and good safety supports development in UC and other autoimmune diseases. The identification of a predictive biomarker is a breakthrough, suggesting that around 30% of UC patients could achieve remission rates over 50%. This reinforces lusvertikimab’s potential as a monotherapy in UC and acts as an additional catalyst to accelerate development. We are designing a Phase 2b program to demonstrate efficacy by 2027, establish the dose for registrational studies, explore a subcutaneous formulation, and validate the predictive biomarker.”*

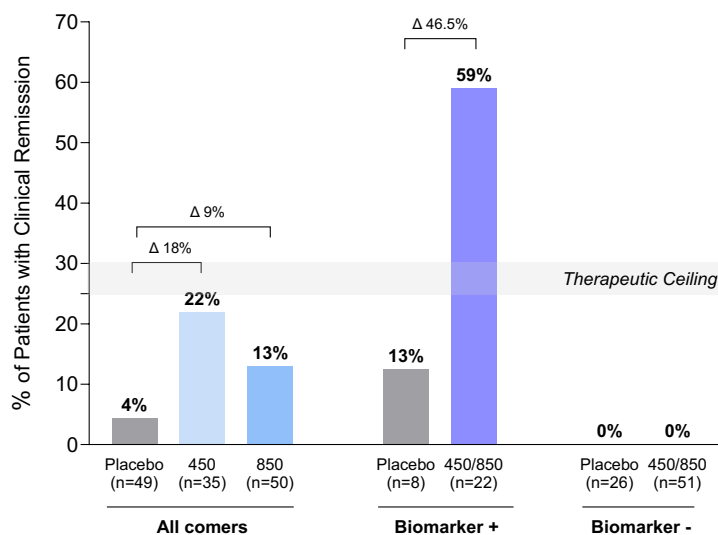


Figure 1: Clinical Remission rate observed in all-comers population and sub-population according to composite IL7R axis biomarker in CoTikiS phase 2 study.

Commenting on OSE’s progress in Tedopi, **Nicolas Poirier** adds: *“Earlier this week, we shared our progress with Tedopi® ([link to press release](#)). To summarize, our pivotal Phase 3 program in NSCLC with Tedopi® is progressing well, keeping us in the race to register the first therapeutic cancer vaccine. Enrolment is advancing across 144 clinical sites in Europe and North America and is on track to complete in the second half of 2026. The data readout is expected in 2027. The recent positive results in pancreatic cancer highlight the growing momentum behind therapeutic cancer vaccines. We are looking forward to additional Phase 2 readouts in combination with anti-PD1 from our ovarian and lung cancer trials in 2026.”*

Nicolas Poirier concludes: *“OSE is at the forefront of transformative scientific breakthroughs in areas of critical unmet medical need. I am convinced that the company is at a turning-point, with a clear international trajectory toward value creation and long-term impact. With strong science, strategic focus, and a robust diversified pipeline, OSE is uniquely positioned to deliver meaningful returns for shareholders—while transforming outcomes for patients worldwide.”*

DOCUMENTS MADE AVAILABLE TO SHAREHOLDERS

The convening brochure for the combined shareholders' meeting of June 25, 2025, now available on the Company's website (<https://www.ose-immuno.com/en/general-shareholders-meetings>), is an essential tool for understanding the strategy pursued by the Board of Directors, informing shareholders and facilitating their voting decision. The related press release, presenting the context of the combined shareholders' meeting and the Board's position on all resolutions, is also available here: <https://www.ose-immuno.com/en/press-releases/>

ABOUT COTIKIS

The CoTikiS study, a 50-week randomized, double-blind, placebo-controlled trial, included a 10-week induction period evaluating two doses (450 mg or 850 mg) of lusvertikimab versus placebo; followed by a 24-week open label extension (OLE) with 850 mg infusions every four weeks; and a 16-week safety follow-up. Findings from the induction phase, presented at the 2025 ECCO congress, showed both doses met the primary efficacy endpoint (improvement in Modified Mayo Score at Week 10) and demonstrated significant results on secondary endpoints. The study highlights lusvertikimab's potential as a first-in-class monotherapy with a novel mechanism of action in the treatment of chronic and inflammatory diseases. Clinical and preclinical data were presented at ECCO 2025 and Digestive Disease Week (DDW) in May 2025, showing high rates of clinical and endoscopic remission, histological improvement and Histo-Endoscopic Mucosal Improvement (HEMI) with a favorable safety profile. Early efficacy signals in both biologic-naïve and experienced populations suggest rapid onset of effect, indicating potential as a first-line biologic or for patients resistant to anti-TNF and anti-IL-12/23 therapies. OLE data shows over 90% of UC patients who achieved a clinical response after 10 weeks maintained symptomatic remission for an additional 24 weeks, with 61% of those not in remission after 10 weeks achieving it after a further 24 weeks on the 850 mg dose. Lusvertikimab was well tolerated over the extended treatment period.

ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology (IO) and immuno-inflammation (I&I) that address the unmet patient needs of today and tomorrow. We partner with leading academic institutions and biopharmaceutical companies in our efforts to develop and bring to the market transformative medicines for people with serious diseases. OSE Immunotherapeutics is based between Nantes and Paris and is quoted on Euronext.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com. Click and follow us on LinkedIn.



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Forward-looking statements

This press release contains express or implied information and statements that might be deemed forward-looking information and statements in respect of OSE Immunotherapeutics. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE Immunotherapeutics' management considering its experience and its perception of historical trends, current economic and industry conditions, expected future developments and other factors they believe to be appropriate.

These forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import. Although the OSE Immunotherapeutics management believes that the forward-looking statements and information are reasonable, the OSE Immunotherapeutics' shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE Immunotherapeutics. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or identified in the public filings made by OSE Immunotherapeutics with the AMF. Such forward-looking statements are not guarantees of future performance. This press release includes only summary information and should be read with the OSE Immunotherapeutics Universal Registration Document filed with the AMF on April 30, 2025, including the



annual financial report for the fiscal year 2024, available on the OSE Immunotherapeutics' website. Other than as required by applicable law, OSE Immunotherapeutics issues this press release at the date hereof and does not undertake any obligation to update or revise the forward-looking information or statements.