

OSE Immunotherapeutics Unveils 2026–2028 Strategic Plan With Four Opportunities for Value Creation

- Completion of Tedopi's phase 3 in Non-Small Cell Lung Cancer
- One or two new rare/specialty indications for Lusvertikimab
- Subcutaneous formulation and combination strategies for Lusvertikimab in UC
- Management webcast on Wednesday, December 10th at 6pm CET

Nantes, France, December 9, 2025 – 7:30am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today announced its new three-year strategic plan designed to accelerate development of its most promising programs while maintaining financial discipline. This plan creates multiple near-term catalysts and reinforces OSE Immunotherapeutics' commitment to immunology innovation.

Four Value Creating Opportunities

1. **Complete Tedopi's Artemia Phase 3 Trial at Limited Cost:** The Tedopi® Pivotal Phase 3 in Non-Small Cell Lung Cancer (NSCLC) is progressing as planned with a futility analysis expected in the Q3 2026 and a full read-out in Q1 2028. The completion of this clinical trial will require limited additional financial resources from OSE and ongoing investigator-led Phase 2 studies could also add additional proof-of-concept data at minimal cost.
2. **Develop Lusvertikimab Intravenous (IV) in One or Two New Rare/Specialty Indications:** Use existing intravenous (IV) formulation to target one or two new rare or specialty diseases with high unmet medical needs, and with a precision medicine approach. These clinical developments will require more modest financial investment than further development in Ulcerative Colitis (UC) and will expand the asset's potential to treat multiple immune-mediated conditions, with a faster route to market. Indications and clinical development plans are being refined and will be disclosed in early 2026.
3. **Lusvertikimab Subcutaneous (SC) in Ulcerative Colitis (UC):** While great Phase 2 clinical data were generated with Lusvertikimab intravenous formulation, the overall UC market is almost entirely focused on more convenient oral and sub-cutaneous formulations. OSE has therefore decided to pivot the UC indication to a subcutaneous formulation of Lusvertikimab and aims to partner this asset once bioequivalence data have been generated. Additional scientific evidence will be generated on the biomarker that seems predictive of a strong clinical response in approximately 25% of patients tested in the Lusvertikimab IV Phase 2 CoTikiS study. Confirming these early findings would position Lusvertikimab SC in Ulcerative Colitis as a game changer in the treatment of this disease, allowing well over 30% of treated patients to achieve clinical remission, and significantly enhance the attractiveness of this asset for potential partners.
4. **Maintain Scientific Leadership:** Leverage OSE Immunotherapeutics' differentiated research engine to fuel innovation for rare and large indications and explore combination strategies for Lusvertikimab. Optimize Intellectual Property management with best-in-class processes for agility, cost efficiency, and maximum value creation.

Advancing one or two specialty indications and a subcutaneous formulation for Lusvertikimab strengthens its value proposition and opens new business opportunities. This strategy is supported by disciplined financial management and scientific leadership — securing financing aligned with strategic goals, optimizing capital structure, and leveraging partnerships and milestone payments, while showcasing OSE Immunotherapeutics' expertise and differentiated mechanisms of action.

Marc Le Bozec, Chief Executive Officer at OSE Immunotherapeutics commented:
"This strategy positions OSE for success by concentrating resources where they can create the most value for all our stakeholders over the next three years. It's ambitious yet realistic for a company our size.

"We've reached an inflection point where we focus on programs with the greatest potential for near-term catalysts and return, while preparing to partner assets that require larger scale once they are Phase 3-ready. Our plan strikes the right balance between clinical risk and financial opportunity, prioritizing late-stage assets and keeping our research engine strong. It reflects our vision and the exceptional dedication of our teams, which is the foundation of OSE's ability to deliver on these goals."

Financial Visibility and Strategy

OSE Immunotherapeutics enters this strategic cycle with an ambition to limit shareholder dilution while securing a reasonable cash runway through a mix of complementary financing options, including equity, new debt and restructuring of existing debt. The Company currently has financial visibility until early Q4 2026, excluding any additional financing or milestone payments from existing partnerships. While the three-year strategic plan requires far less investment than the previously planned Phase 2b for Lusvertikimab IV in ulcerative colitis, additional financial resources will be necessary to complete it.

In parallel, OSE Immunotherapeutics will continue to investigate new strategic partnerships on its proprietary assets and may also be eligible to receive milestones under current agreements, notably a EUR 17.5m payment from Boehringer Ingelheim, related to the 2024 acquisition of a cis-targeting anti-PD-1/cytokine asset, which would significantly reduce financing needs.

Beyond these priorities, other proprietary assets will advance in preclinical development at limited cost to maximize partnership opportunities.

A Webcast will take place on **Wednesday, December 10th, 2025, at 18:00 CET / noon ET** to discuss this Strategic Plan and answer Shareholder questions.
Register [here](#) for the French version and [here](#) for the English version.

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 listed on Euronext. Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com. 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.