OSE Immunotherapeutics Selects Chronic Pouchitis and Hidradenitis Suppurativa as New Key Indications for Lusvertikimab

- Development built on strong IL-7R biological rationale
- Chronic Pouchitis offers a capital-efficient rare-disease path with fast route to market
- Hidradenitis Suppurativa enables rapid proof-of-concept in a large dermatology market
- First Phase 2 clinical trial expected to start in H2 2026, subject to financing
- Ulcerative Colitis remains a key indication to be partnered

Nantes, France, January 29, 2026 – 7:30am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today announced the selection of two new clinical indications for lusvertikimab (OSE-127): chronic pouchitis and hidradenitis suppurativa (HS). These indications were chosen based on strong, IL-7R-driven biology and are fully aligned with the Company's 2026–2028 strategic plan to expand lusvertikimab into targeted, high value immune-mediated diseases. Development of one or both indications will proceed subject to financing, with the first Phase 2 clinical trial planned to initiate in H2 2026.

A Science-Led Selection of Two High-Value Indications with Significant Unmet Medical Need

Chronic pouchitis and HS both exhibit robust translational alignment with IL-7R biology, including T cell-driven inflammation and dysregulation of IL-7/IL-7R pathway and overexpression in diseased tissues.

This mechanism mirrors ulcerative colitis, where lusvertikimab has demonstrated statistically significant Phase 2 efficacy and favorable safety profile. Together, the data support lusvertikimab's potential as a differentiated immunology platform across multiple immune-driven diseases.

Marc Le Bozec, Chief Executive Officer of OSE Immunotherapeutics commented: *"We selected pouchitis and hidradenitis suppurativa because both indications present compelling scientific rationale for lusvertikimab, which could become the first-in-class IL-7R antagonist to reach the market. Pouchitis is a natural extension of our ulcerative colitis work and, due to its well-defined population, represents a rare-disease opportunity we can advance independently at a reasonable cost. HS, by contrast, is a much larger dermatology indication where we can move quickly toward a proof-of-concept readout with a highly differentiated asset. Our goal is to initiate a first Phase 2 study in the second half of 2026, subject to financing. Together, these indications reinforce our strategy and strengthen the long-term potential of lusvertikimab as a differentiated immunology platform with multi-billion peak sales potential."*

Chronic Pouchitis: Rare, High-Need and Capital-Efficient

Approximately 30% of patients with ulcerative colitis are refractory to available therapies and require proctocolectomy with ileal pouch-anal anastomosis (IPAA), an artificial rectum surgically created[1]. Approximately 70% of these patients undergoing surgery will develop pouchitis.[3] Pouchitis is an

[1] Sriranganathan D, Kilic Y, Nabil Quraishi M, et al. Colorectal Dis 2022;24:27–39

inflammatory condition of the ileal pouch. Symptoms include increased stool frequency, urgency, and abdominal discomfort, significantly affecting patients' quality of life. Traditionally the mainstay treatment of acute pouchitis involves the use of antibiotics, but approximately 15% of patients, or an estimated 45,000 patients across the European Union, North America and Japan [2,3], develop chronic pouchitis, which poses significant challenges in terms of management and is an area of significant unmet medical need (only one EMA-approved therapy to date and no FDA-approved options). With a clearly identifiable population, pathogenetic continuity with ulcerative colitis, and limited competition, chronic pouchitis is a high-value, capital-efficient opportunity for OSE to pursue independently.

Hidradenitis Suppurativa: Large Dermatological Indication with Fast Proof-of-Concept Potential

HS is an inflammatory disorder characterized by recurrent suppurative and painful nodules, abscesses and draining sinus tracts primarily in intertriginous areas of the skin. While not a rare disease, affecting approximately 1% of the general population[4] or an estimated 9.5M individuals across Europe, North America and Japan[2], HS is a condition rarely talked about, with patients waiting an average of up to 10 years to receive a proper diagnosis. HS is associated with tremendous impact on quality of life: visible skin lesions associated with intense pain, an unpleasant smell and scarring can cause patients to experience social stigma and depression. An estimated 0.5-0.6M moderate-to-severe patients may be eligible for biologic therapy.[2,5]

Despite several approved biologics, many patients remain inadequately controlled over the long term. HS shows intense Th1/Th17 activation and increased IL-7R expression, offering a strong biological rationale for IL-7R blockade. The indication enables rapid clinical readouts, supporting a fast, data-driven proof-of-concept strategy in a large, high-value immune-dermatology market.

Next Steps and Timelines:

- **First Phase 2 study initiation:** H2 2026 (either Chronic pouchitis or HS), subject to financing.
- **Second Phase 2 study initiation:** H1 2027, contingent on financing.

These studies complement the subcutaneous Ulcerative Colitis program, support a balanced late-stage diversification strategy across near-term rare disease and mid-term dermatology, and enhance partnering optionality by demonstrating the breadth and therapeutic relevance of IL-7R biology. Both studies are designed to be capital-efficient and to deliver clear evidence of differentiated clinical efficacy and safety.

In parallel of developing these two new indications, OSE will advance the Ulcerative Colitis indication through developing a subcutaneous formulation of lusvertikimab and aims to partner this asset once bioequivalence data have been generated. Additional scientific evidence will be generated to further validate the biomarker signature potentially predictive of a strong clinical response identified in the Lusvertikimab Phase 2 CoTikiS study. Confirming these early findings with a subcutaneous formulation

[2] Company estimates based on available literature and third-party sources
[3] Inflammatory Bowel Diseases, Volume 31, Issue 2, February 2025, Pages 597–600
[4] JAMA Dermatol. 2025 Aug 27;161(10):1022-1028. doi: 10.1001/jamadermatol.2025.2373.
[5] https://www.pasteur.fr/en/medical-center/disease-sheets/hidradenitis-suppurativa

would position Lusvertikimab in Ulcerative Colitis as a game changer in the treatment of this disease, and significantly enhance the attractiveness of this asset for potential partners.

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

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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.