# OSE Immunotherapeutics Announces Statistically Significant and Clinically Meaningful Results from the Phase 2 Study of Anti-IL7R mAb Lusvertikimab for the Treatment of Ulcerative Colitis

- **Lusvertikimab met the primary endpoint (modified Mayo Score improvement) at each dose tested during the 10 week-induction period of treatment in the randomized double-blind CoTikiS Phase 2 study.**
- **Highly favorable positive results on the key secondary endpoints demonstrating significantly high rate of clinical and endoscopic remission.**
- **Across all doses and patient groups, Lusvertikimab demonstrated favorable safety and tolerability profile during the induction period and 24-week additional open label extension treatment (total of 34 weeks) with no specific safety signal identified.**
- **First anti-IL7R mAb positive efficacy study enabling pathway of future development to potential First-in-Class Interleukin-7 antagonist in autoimmune and inflammatory diseases.**

**NANTES, France, November 4th, 2024 – 7:30am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE)**, today reported positive results from the induction period of the CoTikiS randomized, double-blind, placebo-controlled, Phase 2 study of Lusvertikimab (OSE-127) demonstrating a strong efficacy and favorable safety profile in moderate to severe active ulcerative colitis (UC).

**Topline results from the CoTikiS Phase 2 Study**

The randomized, double-blind Phase 2 clinical trial CoTikiS has evaluated the efficacy and the safety of Lusvertikimab versus placebo in 136 patients with moderate to severe active UC who failed or lost response to previous treatment(s)*. CoTikiS is a 50-week study, with a 10-week induction period evaluating two doses (450mg or 850mg) of Lusvertikimab against placebo, a 24-week additional open label treatment extension period (OLE) during which all subjects received Lusvertikimab 850mg infusions every 4 weeks and a 16-week safety follow-up period free of treatment.

Lusvertikimab (Lusv) met the primary efficacy endpoint defined by the improvement of the Modified Mayo Score (MMS)** at week 10 (W10) at the two doses tested and demonstrated statistically significant and clinically meaningful results on key secondary endpoints. A favorable safety profile was observed during both the induction period and during the 6 months of open-label extension period trial. 134 patients were analyzed in the W0-W10 period [group 850mg (50 patients); group 450mg (35 patients); drug group pooled 850mg + 450mg (85 patients); group placebo (49 patients)]. A total of 120 patients treated with Lusvertikimab participated to the additional 24-week OLE treatment period.

Final analysis of the primary endpoint at W10***

**Improvement of the global Disease Activity Index of UC (MMS)**

- Lusv 850mg group: difference of -0.9 point versus placebo (p=0.036)
- Lusv 450mg group: difference of -1.16 point versus placebo (p= 0.019)
- 450 + 850mg pooled group: difference of -1.00 point versus placebo (p= 0.010)

Key secondary endpoint results at W10

**Clinical remission****

- 13% Lusv 850mg group, adjusted difference versus placebo of 8.6% (Odds Ratio [OR] 3.26)
- 22% Lusv 450mg group, adjusted difference versus placebo of 17.6% (OR 6.19)
- 4% in the placebo group

**Endoscopic remission (endoscopic score at 0)**

- 19.4% Lusv 850mg group, adjusted difference versus placebo of 6.8% (OR 1.68)
- 34.7% Lusv 450mg group, adjusted difference versus placebo of 22% (OR 3.71)
- 12.6% in the placebo group

**Endoscopic improvement (endoscopic score ≤ 1 point)**

- 24.3% Lusv 850mg group, adjusted difference versus placebo of 11.7% (OR 2.25)
- 44.5% group Lusv 450mg group, adjusted difference versus placebo of 31.9% (OR 5.62)
- 12.6% in the placebo group

**Ulcerative Colitis Endoscopic index of Severity***** (UCEIS score decreases at week 10)**

- Lusv 850mg group: difference of -0.82 (SD: 0.415) versus placebo (p=0.05)
- Lusv 450mg group: difference of -1.35 (SD: 0.478) versus placebo (p=0.006)
- 450+850mg pooled group: difference of -1.038 (SD: 0.379) versus placebo (p=0.007)

Safety Profile

Lusvertikimab displayed a good safety profile and was well tolerated, with no difference between both dose groups and placebo in the incidence of drug related serious adverse events (SAEs), adverse events (AEs) leading to discontinuation, severe drug-related AEs, opportunistic infections or infusion reactions during the induction period. In addition, no safety signal was observed in the patient population who received 850mg of Lusvertikimab for an additional 24-week period in the OLE, regardless of the initial randomization groups.

**Pr. Arnaud Bourreille,** Associate professor in Gastroenterology, Institut des Maladies de l'Appareil Digestif, Nantes University Hospital, **Principal/ Scientific coordination of the CoTikiS study**, said:

*"We are very excited to share these positive topline efficacy results which could establish Lusvertikimab as a potential new breakthrough therapeutic option for UC patients. We are beyond enthusiastic with the very high endoscopy efficacy and what it could mean for patients suffering from chronic ulcerative colitis. This promising drug-candidate with a differentiated mode of action and very good safety profile needs to be further actively explored in ulcerative colitis and in other indications. We are grateful to all*

*the investigators and patients for their participation in this study and we are eager to present a more complete clinical and biomarkers data set in future medical congresses."*

**Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics**, adds:

*"These impressive efficacy and safety results represent a major milestone in the clinical development of Lusvertikimab and a strong catalyst for the subsequent steps. Lusvertikimab has clearly demonstrated meaningful clinical proof-of-efficacy in UC and we are now looking forward to further evaluating it in additional studies with the ultimate goal of making this innovative therapy accessible to millions of patients in need of more efficacious and safe treatments. Lusvertikimab is a pure interleukin-7 receptor antagonist mAb and we believe it has a broad first-in-class potential in various chronic inflammatory and autoimmune diseases. We look forward to making progress on this strategy and to go ahead with the most relevant partners."*

** Previous corticosteroids, immunosuppressive agents or previous biological treatments.*

*** Ulcerative Colitis is a chronic inflammatory disease of the rectum and colon characterized by mucosal inflammation, abdominal pain associated with symptoms and frequency of diarrhea and rectal bleeding. The moderate to severe UC is measured by a Modified Mayo Score (MMS) between 4 and 9, inclusive. The primary endpoint is the mean change at Week 10 from baseline in the Modified Mayo Score, a Disease Activity Index for UC defined by the addition of the stool frequency and the rectal bleeding sub-scores (two patient's clinical elements as Patient Reported Outcomes) and the endoscopic sub-score (mucosal endoscopy activity), assessed by an endoscopist through a central reading platform.*

**** An interim Futility analysis performed early (about 30% of patients) by the IDMC proposed interruption of the 450 mg group for risk of futility. The 850 mg group was initially considered as primary analysis, in the final analysis the futility of the 450mg was not confirmed. SAP (Statistical Analysis Plan) Addendum: Results of 450mg group reconsidered with all patients already included in this group. In addition, the two groups have been pooled for the drugs cohort to a global treatment effect.*

***** Clinical remission at Week 10, a modified Mayo score of ≤ 2 points with no individual sub-score of > 1 point and a rectal bleeding at 0, therefore a stool frequency score of 0 or 1 and an endoscopic score of 0 or 1.*

****** Ulcerative Colitis Endoscopic Index of Severity, UCEIS, is a validated endoscopic scoring tool with lower interobserver variability, score change at Week 10 from baseline measuring specific subscores: vascular pattern/ presence of bleeding/ erosions and ulcerations (Pabla B S et al Gastroenterol Clin North Am. 2020).*

## 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).
The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): most advanced therapeutic cancer vaccine in development; positive results from a randomized Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in third-line secondary resistance after checkpoint inhibitor failure. Ongoing randomized registration Phase 3 study (Artemia) in second-line NSCLC in HLA-A2+ patients with secondary resistance. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.

- **OSE-127** - *Lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); Positive Phase 2 (CoTikiS) study in Ulcerative Colitis; ongoing preclinical research in leukemia.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 in solid tumors.
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); successful Phase 1 in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **Anti-SIRPα monoclonal antibody** developed in partnership with Boehringer Ingelheim in advanced solid tumors and cardiovascular-renal-metabolic diseases (CRM); positive Phase 1 dose escalation results in monotherapy and in combination; Phase 2 in CRM diseases planned to be initiated end of 2024.
- **ABBV-230** (ChemR23 agonist mAb) developed in partnership with AbbVie in chronic inflammation.

OSE Immunotherapeutics expects to generate further significant value from its three proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapies:

- **Pro-resolutive mAb platform** focused on targeting and advancing inflammation resolution and optimizing the therapeutic potential of targeting Neutrophils and Macrophages in I&I. **ABBV-230** (licensed to AbbVie) is the first candidate generated by the platform, additional discovery programs ongoing on new pro-resolutive GPCRs.
- **Myeloid Checkpoint platform** focused on optimizing the therapeutic potential of myeloid cells in IO by targeting immune regulatory receptors expressed by Macrophages and Dendritic cells. **BI 765063** and **BI 770371** (licensed to Boehringer Ingelheim) are the most advanced candidates generated by the platform. Ongoing additional discovery programs, in particular with positive preclinical results obtained in monotherapy with new anti-**CLEC-1** mAbs.
- **BiCKI® Platform** is a bifunctional fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy by "cis-potentiating" tumor-specific T cells. A first program has been acquired by Boehringer Ingelheim. **OSE-CYTOMASK** is an innovative technology to create cytokine therapeutics with improved therapeutic index.
- **mRNA Therapeutic platform** allows local delivery into the inflammatory site of innovative immunotherapies encoded by RNA to locally controls and/or suppress immune responses and inflammation.

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

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**Forward-looking statements**

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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, 2024, including the annual financial report for the fiscal year 2023, 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