OSE Immunotherapeutics Announces Positive Efficacy Results for Lusvertikimab in the Phase 2 trial for the treatment of Ulcerative Colitis

- **Lusvertikimab demonstrates significant efficacy during the 10 week-induction phase of treatment, in the randomized double-blind CotiKis phase 2 study**
- **Favorable safety and tolerability profile in the whole patient population across the two doses tested and during the open label phase of treatment**
- **First anti-IL7R mAb positive efficacy study enabling pathway of future development to potential First-in-Class Interleukin-7 antagonist**

NANTES, France, July 24th, 2024 – 7:30 am CET- OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today reported first positive results from its CoTikiS randomized, double-blind, placebo-controlled, Proof of Concept phase 2 study of Lusvertikimab, a pure antagonist of IL-7 receptor, demonstrating significant efficacy results measured by the improvement of the Modified Mayo Score** (at week 10 primary endpoint of the treatment induction phase). A favorable safety profile was observed during both the induction phase and during the 6 months of open-label extension phase trial.

Nicolas Poirier, Chief Executive Office of OSE Immunotherapeutics, comments: *"We are very excited to share these first positive Phase 2 efficacy results for Lusvertikimab in ulcerative colitis, a disabling chronic relapsing inflammatory bowel disease with a patient population in regular need of alternative new therapies. This clinical proof of concept study establishes Lusvertikimab as a potential first-in-class with novel therapeutic options, based on its differentiated mechanism of action as a pure interleukin-7 antagonist. We are optimistic about the potential for patients, these* positive *clinical efficacy and safety results represent a strong catalyst for future opportunities and enhances OSE presence in this growing field of chronic Immune inflammation.*

Frédérique Corallo, CMO Immuno-Inflammation commented:" *We are very grateful to the patients who participated in this trial, study investigators, and the global team involved for their strong commitment to achieve this important clinical milestone*". She added "*Lusvertikimab has shown very interesting efficacy results with the two doses tested at week-10, in particular on endoscopic improvement, and reinforced efficacy signal for 34 weeks in the open-label extension. A good safety profile was observed in the whole patient population. The full data set will be completed in a specific communication and presented at future medical congresses.*

Lusvertikimab (OSE127) phase 2 Proof of Concept study vs Placebo in Patients with Moderate to Severe Active Ulcerative Colitis (NCT04882007-CoTikiS):

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, lost response, or were intolerant to previous treatment(s)*. Primary endpoint was the efficacy assessment of Lusvertikimab versus placebo on the reduction of the Modified Mayo score** at week 10.

Primary endpoint**: a significant decrease of the Modified Mayo Score (MMS) is achieved versus placebo at week 10:

The 850 mg group (n=50, Placebo n=49) in the principal analysis obtained significant results at week 10 versus Placebo on the improvement of the MMS with a -0.82 (95%CI: -1.63. -0.01) difference$^{\mu}$ in treatment effect between lusvertikimab and placebo (p=0.047).

The 450 mg group (n=35, Placebo n=49) obtained significant results versus placebo (the 450 mg group was considered as exploratory as prematurely interrupted***) with a difference$^{\mu}$ of -1.17 (95%CI: -2.18; -0.16) between lusvertikimab and placebo (p=0.023).

The global treatment effect is significant considering the 450+850mg groups together versus placebo showing a difference$^{\mu}$ of -0.88 (95%CI: -1.64; -0.12) between lusvertikimab and placebo (p= 0.024).

Safety results: no safety signal was reported by the Data Safety Monitoring Board during the trial**.** Both doses of lusvertikimab show favorable safety profile in comparison with placebo, with similar rates of adverse events across the 3 treatment groups.

* *Previous corticosteroids, Immunosuppressive agents or previous biological treatments*

** *Ulcerative Colitis is a chronic inflammatory disease of the rectum and colon characterised by mucosal inflammation, abdominal pain associated with symptoms and frequency of diarrhoea 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.*

$^{\mu}$ *Least Square Mean Difference between lusvertikimab and placebo=difference between groups of the Mean change in MMS between baseline and W10 (Analysis of Covariance model)*

*** *An interim Futility analysis performed early (33% of patients) by the IDMC proposed interruption of the 450 mg group for risk of futility but not confirmed at final analysis. The 850 mg group was hence considered as primary analysis.*

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): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 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 .
- **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.).
- **BI 770371** (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 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 770371** (licensed to Boehringer Ingelheim) is 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.
- **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

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 in light of 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, 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.