OSE Immunotherapeutics Announces Completion of Enrollment in Phase 2 Clinical Trial Evaluating Lusvertikimab in Patients with Ulcerative Colitis

Nantes, France – March 18, 2024, 7:30 am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) announced today the completion of patient enrollment in the Phase 2b clinical trial evaluating anti-IL-7 receptor monoclonal antibody Lusvertikimab (OSE-127) in patients with moderate to severe active Ulcerative Colitis (UC). The study, (CoTikiS trial: NCT04882007), is sponsored and conducted by OSE Immunotherapeutics.

The purpose of the randomized, double-blind Phase 2 clinical trial CoTikiS is to evaluate the efficacy and safety of Lusvertikimab (OSE-127) versus placebo in patients with moderate to severe active UC who are naïve of treatment or who previously failed, lost response, or were intolerant to previous treatment(s). An interim futility analysis was successfully conducted in the prespecified first 50 patients (i.e. 33% of the total patient enrollment in the study), who completed the induction phase. Top-line efficacy results after the induction phase (primary endpoint at week 10) and the first early assessment after six months of therapy in open-label extension are expected in the next months (mid-2024).

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, commented: *"We are very pleased to complete the enrollment for the Phase 2 evaluation of Lusvertikimab in ulcerative colitis, a major milestone for the Company and the product's development. We are grateful to the investigators and patients for their commitment to this study. We now look forward to the Phase 2 top-line readouts expected in the next six months to confirm the potential of Lusvertikimab as an innovative first-in-class novel therapeutic option for a disabling chronic inflammatory bowel disease. The recent announcement of our global partnership with AbbVie for a preclinical program illustrates the quality of our research in the field of inflammation. Potential positive clinical efficacy results of Lusvertikimab in ulcerative colitis by mid-2024 could also generate a strong catalyst in the coming months and enhance OSE's presence in this growing field of chronic inflammation."*

UC is a debilitating and chronic inflammatory bowel disease that affects 3.3 million patients in the US, Europe, and Japan [(1)], which represents 12.2 per 100,000 people every year [(2)]. The global inflammatory bowel disease market is expected to grow to $27 billion in 2028, with $10 billion designated for UC [(1)]. Despite broad options, remission rates are only 25-30% [(3)], leaving most patients without satisfactory treatments. The preclinical and translational research conducted by OSE and collaborators illustrated that the IL-7 receptor pathway is highly upregulated in the gut mucosa of patients suffering from moderate to severe UC or Crohn's disease and that Lusvertikimab could control colon inflammation in humanized colitis preclinical models or inflamed colon biopsies from UC patients grown ex-vivo [(4)].

(1) *EvaluatePharma*

(2) *Updated Incidence and Prevalence of Crohn's Disease and Ulcerative Colitis in Olmsted County, Minnesota (1970-2011). Loftus EV et al. October 2014.*

(3) *Drugs Context. 2019; 8: 212572 –doi: 10.7573/dic.212572*

(4) *Belarif et al.; Journal of Clinical Investigation 2019*

ABOUT LUSVERTIKIMAB (OSE-127)

Lusvertikimab* is a monoclonal immunomodulatory antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R) that induces a powerful antagonist effect on effector T lymphocytes. Interleukin-7 is a cytokine that specifically regulates the tissue migration of human effector T lymphocytes. The blockage of IL-7R prevents the migration of pathogenic T lymphocytes while preserving regulator T lymphocytes which have a positive impact on autoimmune diseases. This is a novel and differentiated mechanism of action of the only full-antagonist of IL-7R for the treatment of chronic autoimmune diseases. Lusvertikimab is the only compound targeting IL-7R under clinical development in UC.

** IL-7 receptor blockade blunts antigen-specific memory T cell responses and chronic inflammation in primates; Belarif L et al. ; Nature Communications 2018*
IL-7 receptor influences anti-TNF responsiveness and T cell gut homing in inflammatory bowel disease; Belarif L et al.; J Clin Invest. 2019
First-in-Human Study in Healthy Subjects with the Noncytotoxic Monoclonal Antibody OSE-127, a Strict Antagonist of IL-7Rα Poirier N. et al.; The Journal of Immunology 2023

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); ongoing Phase 2 in Ulcerative Colitis (sponsor OSE Immunotherapeutics); ongoing preclinical research in leukemia (OSE Immunotherapeutics).
- **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 765063** and **BI 770371** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; international Phase 1b ongoing clinical trial in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).
- **OSE-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. **OSE-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.
- **Cytokine platform** focused on leveraging the Cis-Delivery of cytokine in IO and I&I. BiCKI® is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new

immunotherapy target to increase anti-tumor efficacy. **BiCKI®-IL-7v** is the most advanced BiCKI® candidate targeting anti-PD1xIL-7. Ongoing additional discovery programs on Cis-Demasking technologies.

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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 May 2, 2023, including the annual financial report for the fiscal year 2022, 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.