

OSE Immunotherapeutics Announces for Lusvertikimab, its Anti-IL-7 Receptor Antagonist:

- **Positive Review from the Drug Safety Monitoring Board (DSMB) on the Ongoing Phase 2 Clinical Trial in Ulcerative Colitis.**
- **Positive Opinion for Orphan Drug Designation from the European Medicines Agency in the Treatment of Acute Lymphoblastic Leukemia.**

Nantes, France – July 6, 2023, 7:30am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that the trial’s Independent Drug Safety Monitoring Board (DSMB) provided a positive recommendation on the continuation until its completion of the Phase 2 clinical trial of IL-7 Receptor (IL-7R) antagonist Lusvertikimab (OSE-127) in ulcerative colitis.

In parallel, the European Medicines Agency (EMA) provided a positive opinion on Orphan Drug Designation for Lusvertikimab for the treatment of Acute Lymphoblastic Leukemia (ALL).

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: *“After the planned DSMB review recommendation to continue the study until its completion, the Company’s primary and strategic focus remains clinical evaluation of Lusvertikimab in this ongoing ulcerative colitis Phase 2 study with end of accrual expected in the following months. In parallel, based on strong preclinical activity demonstrated by Lusvertikimab using patient’s leukemic samples, we are happy to have received a positive opinion on Orphan Drug Designation from the European Medicines Agency. Lusvertikimab orphan status for the treatment of Acute Lymphoblastic Leukemia from B or T cell precursors is opening future potential new indications in ALL, rare diseases with limited treatment options. We warmly thank our academic and clinician partners in Kiel, involved with us in this innovative research program.”*

ABOUT LUSVERTIKIMAB CLINICAL EVALUATION IN ULCERATIVE COLITIS (UC)

The ongoing Phase 2 clinical trial sponsored by OSE Immunotherapeutics is evaluating the efficacy and safety of Lusvertikimab (OSE-127) versus placebo in patients with moderate to severe active UC who failed or lost response or were intolerant to previous treatment(s) (*CoTikiS trial: NCT04882007*). A positive interim futility analysis was observed in the prespecified first 50 patients (i.e., 33% of the total patient enrollment in the study) having completed the induction phase. The upcoming major milestone for this Phase 2 clinical trial is expected in the following months with the top-line results after the induction phase (primary endpoint at week 10) and in H1 2024 for the first early assessment in maintenance after 6 months of therapy. UC is a debilitating and chronic inflammatory bowel disease which affects 3.3 million patients in US, Europe and Japan ⁽¹⁾, representing 12.2 per 100,000 people by year ⁽²⁾. Despite broad available options, remission rates remain only 25-30% ⁽³⁾, leaving most patients without satisfactory treatments.

⁽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

ABOUT THE LUSVERTIKIMAB RESEARCH PROGRAM IN ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

This collaborative research program between OSE Immunotherapeutics and the University Medical Center Schleswig-Holstein in Kiel (Germany) evaluated the therapeutic potential of Lusvertikimab in targeting and blocking the high and dysregulated

IL-7R expression observed in 84% of B- or T-Cell ALL (B- and T-ALL) patients. In particular, significant preclinical activity of Lusvertikimab has been demonstrated in models using leukemic samples from refractory and relapsed patients. The latest preclinical data on the use of Lusvertikimab for the treatment of B- and T-ALL and its dual anti-leukemic efficacy were presented and awarded at the American Society of Hematology (ASH) annual meeting in December 2022.

In Europe, 7,000 cases of ALL are diagnosed each year ⁽¹⁾. The condition is estimated to be affecting approximately 1.7 in 10,000 persons in the European Union ⁽²⁾. More globally, the number of diagnosed incident cases of ALL in Europe, US, Japan and China is estimated to achieve 26,482 cases in 2029⁽³⁾.

⁽¹⁾ Gatta G, van der Zwan JM, Casali P, et al. Rare cancers are not so rare: The rare cancer burden in Europe. *Eur. J. Cancer.* 2011; 47: 2493-2511.

⁽²⁾ Using epidemiological information from the European Cancer Information System (ECIS)⁽¹⁾

⁽³⁾ Global Data

ABOUT ORPHAN MEDICINAL PRODUCT DESIGNATION

Orphan designation in the European Union (EU) is granted by the European Commission after the opinion is issued by the EMA's Committee for Orphan Medicinal Products (COMP). The EMA's orphan designation is available to companies developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention or treatment are authorized, or, if such exists, the medicine being developed must provide significant benefit. Medicines that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives that include protocol assistance from the EMA at reduced fees during the product development phase and access to centralized authorization procedure and a 10-year period of marketing exclusivity in the EU after product approval.

ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation. 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 first 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): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI[®] platform.
- **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); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **OSE-172/BI 765063** (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 Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI[®] platform** focused on immuno-oncology (IO) 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-7 is the most advanced BiCKI[®] candidate targeting anti-PD1xIL-7.
- **Myeloid platform** focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

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

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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.