

OSE Immunotherapeutics Announces Award for OSE-127's Upcoming Oral Presentation in Acute Lymphoblastic Leukemia At the 2022 American Society of Hematology (ASH) Annual Meeting

Nantes, France – November 3, 2022, 6:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) is pleased to announce that its leukemia research program on OSE-127 has been selected for an oral presentation at the [American Society of Hematology \(ASH\) annual meeting](#) (New Orleans, Louisiana; December 10 - 13, 2022). This upcoming presentation has received the merit-based “Abstract Achievement Award” from the peer-review committee.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: *“We are honored by the recognition and the interest in the quality of our research in Leukemia from the prestigious American Society of Hematology. This award is the result of our fruitful collaboration with the University of Kiel evaluating, in patient-derived xenograft models, the therapeutic potential of OSE-127 in targeting and blocking the high and dysregulated **IL-7 receptor-expression observed in more than 80% of B- or T-Acute Lymphoblastic Leukemia (ALL) patients**”.*

Pr. Denis Schewe (Head of the Pediatrics Department, Otto-von-Guericke-University, Magdeburg and formerly from the University Medical Center Schleswig-Holstein of Kiel) and Dr. Lennart Lenk (Department of Pediatrics I, Christian-Albrechts University Kiel and University Medical Center Schleswig-Holstein, Kiel), leading the research program in collaboration with OSE Immunotherapeutics, say: *“Acute lymphoblastic leukemia is a very aggressive tumor arising from B or T cells precursors (B- and T-ALL, respectively). **Relapse remains a clinical challenge in B-ALL in high-risk patients and treatment options for T-ALL remain very limited.** Novel targeted immunotherapy approaches are urgently needed to prevent relapse and to treat refractory diseases in ALL patients”.*

The global intellectual property for OSE-127 has been further strengthened, based on a unique and innovative dual anti-leukemic mechanism of action. This antibody both blocks oncogenic interleukin-7 fuel pathway and simultaneously triggers macrophage-driven phagocytosis of leukemic cells. Additional patent applications were filed in 2021 and 2022 covering the use of anti-IL-7 receptor antagonist antibodies with macrophage-redirected phagocytic activity for the targeted treatment of IL-7 receptor-positive cancers.

Furthermore, OSE-127 is currently being developed in clinical stage in partnership with Servier. Two clinical studies are ongoing in inflammatory diseases: a phase 2a study conducted in primary Sjögren’s syndrome by Servier and a phase 2 study conducted in ulcerative colitis by OSE Immunotherapeutics.

About Acute Lymphoblastic Leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is a heterogeneous group of lymphoid disorders resulting from clonal proliferation of immature lymphocytes of B-cell (85%) or T-cell (15%) lineages⁽¹⁾ in the blood, bone marrow, and other lymphoid organs.

Although it is one of the most common cancers in children, accounting for approximately 25% of all childhood cancer diagnoses among children under 15 years of age⁽²⁾, adults can also develop ALL. About 40% cases of ALL diagnosed are in adults and among them about 50% present refractory disease or undergo relapse under current conventional therapies⁽²⁾.

The American Cancer Society estimates that almost 6,660 new cases of ALL will be diagnosed in the United States in 2022⁽³⁾. In Europe, 7,000 cases of ALL are diagnosed each year⁽⁴⁾. The number of patients in Japan was reported to be about 5,000 in a survey by the Japanese MHLW in 2017. The number of diagnosed incident cases of acute lymphocytic leukemia (ALL) in Europe, US, Japan and China is estimated to achieve 26,482 cases in 2029⁽⁵⁾.

(1) DeVita, Jr. VT, Hellman S, Rosenberg SA, eds.; *Cancer: Principles and Practice of Oncology*, 10th ed.; Lippincott-Raven, Philadelphia, PA; 2014.

(2) *Childhood Acute Lymphoblastic Leukemia Treatment (PDQ®)—Health Professional Version*, accessed October 2022

(3) American Cancer Society. *Key 2022 Statistics for Acute Lymphocytic Leukemia (ALL)*. Available at:

<https://www.cancer.org/cancer/acute-lymphocytic-leukemia/about/key-statistics.html#references>, accessed October 2022

(4) 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.

(5) *Global Data*

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 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): advanced preclinical stage.
- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor) developed in partnership with Servier; ongoing Phase 2 in ulcerative colitis (sponsor OSE Immunotherapeutics) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier); ongoing pre-clinical research in leukemia.
- **VEL-101/FR104** (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.).
- **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 of BI 765063 in monotherapy and in combination, in particular with anti-PD-1 antibody ezabemlimab; BI sponsored international Phase 1b ongoing clinical trial in combination with ezabemlimab 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. The most advanced BiCKI® candidate is 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

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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 15 April 2022, including the annual financial report for the fiscal year 2021, 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.