OSE Immunotherapeutics Announces Publication of Preclinical Efficacy Results with Lusvertikimab in Acute Lymphoblastic Leukemia in the Journal 'Blood'

Nantes, France – July 1st, 2024 – 7:30 am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced the publication of an article on latest preclinical efficacy data on the use of its anti-IL-7 receptor (IL-7R) antagonist Lusvertikimab (OSE-127) for the treatment of B- and T-Cell Acute Lymphoblastic Leukemia (B- and T-ALL) in 'Blood', a peer-reviewed medical journal published by the American Society of Hematology.

The preclinical data on Lusvertikimab published in 'Blood' was generated from a collaborative research program between OSE Immunotherapeutics and the University Medical Center Schleswig-Holstein in Kiel (Germany). This collaboration is using patient-derived samples and *in-vivo* xenograft models to evaluate the therapeutic potential of anti-IL-7R antagonist Lusvertikimab in targeting and blocking the high and dysregulated IL-7R-expression observed in nearly 85% of B- or T-Acute Lymphoblastic Leukemia (ALL) patients.

Pr. Denis Schewe (newly appointed Head of Pediatric Hematology/Oncology, University Hospital Dresden and National Center for Tumor Diseases, Partner Site Dresden, 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, comment: *"Treatment options for T-ALL remain very limited and there is an urgent need for novel immunotherapy approaches to reduce toxicity and to target relapsed or refractory disease in ALL patients. Through its dual mode of action comprising both IL-7R signaling blockade and antibody-dependent cellular phagocytosis induction, Lusvertikimab may represent a promising novel immunotherapy option for CD127 positive ALL patients, particularly in combination with polychemotherapy standard of care. When translated into the clinic, Lusvertikimab could significantly improve ALL-therapy and the outcome of relapsed/refractory disease."*

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, concludes: "*We are very pleased with this publication on Lusvertikimab in 'Blood', a high-level journal within the field of hematology whose manuscripts are reviewed by prominent specialists. Novel targeted immunotherapy options are urgently needed for B-ALL and T-ALL patients and we are happy to collaborate with the research leaders in hematology from the University of Kiel to face this clinical challenge."*

The abstract, titled: *"The IL-7R antagonist Lusvertikimab reduces leukemic burden in xenograft-ALL via antibody-dependent cellular phagocytosis"* reported that IL-7R immunotherapy with Lusvertikimab shows significant *in vivo* efficacy in preclinical models using samples from B-ALL and T-ALL. Mechanistically, Lusvertikimab targeted ALL cells via a dual mode:

- On one hand it blocks IL-7 receptor signaling and hence block proliferative and pro-survival signals induced by Interleukin-7.

- In parallel, it induces leukemic cells elimination by macrophages (antibody-dependent phagocytosis), in particular with strong correlation with the level of IL-7R surface expression on leukemic cells.

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 [(3)] 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 [(4)], 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 [(4)].

The American Cancer Society estimates that almost 6,660 new cases of ALL will be diagnosed in the United States in 2022[(5)]. In Europe, 7,000 cases of ALL are diagnosed each year [(6)]. 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[(7)].

(1) ASH Publication – Blood (2022) 140 (Supplement 1): 1045 - 1047
(2) Lennart Lenk, PhD, Irène Baccelli, PhD, Dorothee Winterberg, PhD, Anna Dietterle, Frédérique Corallo, MD, Julien Taurelle, Emma Narbeburu, Anna Laqua, PhD, Beat Bornhauser, PhD, Jean-Pierre Bourquin, MD, PhD, Fotini Vogiatzi, PhD, Martin Schrappe, MD, Gunnar Cario, Monika Brüggemann, MD, Nicolas Poirier, PhD and Denis Martin Schewe, MD*
(3) DeVita, Jr. VT, Hellman S, Rosenberg SA, eds.; Cancer: Principles and Practice of Oncology, 10th ed.; Lippincott-Raven, Philadelphia, PA; 2014.
(4) Childhood Acute Lymphoblastic Leukemia Treatment (PDQ®)–Health Professional Version, accessed October 2022
(5) 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
(6) 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.
(7) Global Data

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.).
- **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.
- **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
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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.