OSE Immunotherapeutics Presents First Preclinical Efficacy Data on Anti-IL-7 Receptor Antagonist OSE-127 in Acute Lymphoblastic Leukemia

At the 2021 American Society of Hematology (ASH) Annual Meeting

Nantes, France – December 13, 2021, 7:30 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) presented the first preclinical data on anti-leukemic efficacy of anti-IL-7 receptor antagonist OSE-127 in patient-derived xenograft (PDX) models of B-Cell Precursor Acute Lymphoblastic Leukemia (BCP-ALL) at the American Society of Hematology (ASH) annual meeting held in person (Atlanta) and virtually on December 11 – 14, 2021.

The results from a collaborative research program conducted by OSE Immunotherapeutics and the University Medical Center Schleswig-Holstein in Kiel, Germany, investigating the anti-leukemic efficacy of OSE-127 immunotherapy in PDX models of BCP-ALL, were presented in a poster, entitled*: "IL7R targeting using OSE-127 Shows Robust Anti-Leukemic Activity in B-cell Precursor Acute Lymphoblastic Leukemia Xenografts"*,* by Dr. Lennart Lenk (Department of Pediatrics, ALL-BFM Study Group, Christian-Albrechts University Kiel and University Medical Center Schleswig-Holstein, Kiel, Germany).

Pr. Denis Schewe, Head of the Department of Pediatrics, Otto-von-Guericke-University, Magdeburg (formerly from the Department of Pediatrics, ALL-BFM Study Group, Christian-Albrechts University Kiel and University Medical Center Schleswig-Holstein, Kiel), comments: "*Our research is based on solid preclinical and clinical data as well as on a rationale supporting the development of a CD127 targeting immunotherapy in the treatment of B- and, potentially also T-cell acute lymphoblastic leukemia. Novel targeted immunotherapy options are urgently needed for relapsing patients, and we are happy to collaborate with the OSE's R&D team to face this clinical challenge."*

OSE-127 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. Targeting IL-7R CD127 is a promising novel strategy in BCP-ALL and T-ALL, since CD127 signalling is important for B- and T-cell development, and recent reports promote the view that CD127 is important for the development of BCP-ALL and T-ALL (T-cell lymphoblastic leukemia) **. Despite the favourable prognosis of BCP-ALL, relapse remains a clinical challenge and novel targeted immunotherapy options are urgently needed. T-ALL is an aggressive haematological cancer for which treatment options are limited at relapse.

OSE Immunotherapeutics and the University of Kiel's research teams demonstrated that using OSE-127 to target IL-7R is an efficient approach for BCP-ALL immunotherapy and may be particularly beneficial for patients with high IL-7R-expression and/or relapsed/refractory disease after escape to CD19 antigen therapy.

OSE-127/S95011 is being developed in partnership with Servier as part of a collaboration agreement with license option upon completion of two independent Phase 2 clinical studies currently underway:

in ulcerative colitis (sponsor OSE Immunotherapeutics) and in the Sjögren's syndrome (sponsor Servier). The product had already demonstrated Phase 1 positive results with a good safety and tolerability profile showing no signs of lymphopenia, cytokine release syndrome, or T-cell compartment alterations.

* Presentation details:
"*IL7R targeting using OSE-127 Shows Robust Anti-Leukemic Activity in B-cell Precursor Acute Lymphoblastic Leukemia Xenografts"*
Program: Oral and Poster Abstracts
Session: 618. Acute Lymphoblastic Leukemias: Biomarkers, Molecular Markers and Minimal Residual Disease in Diagnosis and Prognosis: Poster I
Hematology Disease Topics & Pathways:
Biological, Antibody Therapy, Translational Research, Clinically Relevant, Therapies
Saturday, December 11, 2021, 5:30 PM-7:30 PM

** Thomas et al. Leukemia 2021: "*Activated interleukin-7 receptor signaling drives B-cell acute lymphoblastic leukemia in mice"*

Silva et al. 2021: "*Overexpression of wild-type IL-7Rα promotes T-cell acute lymphoblastic leukemia/lymphoma"*

ABOUT OSE-127/S95011

OSE-127/S95011 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 which specifically regulates the tissue migration of human effector T lymphocytes, especially in the gut. The blockage of IL-7R prevents the migration of pathogenic T lymphocytes while preserving regulator T lymphocytes which have a positive impact in autoimmune diseases.

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Vaccine platform

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients after secondary resistance to checkpoint inhibitors.
  In Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  In Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **CoVepiT**: a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Clinical data (Nov. 2021) have shown good tolerance and promising efficacy signals. Results from 6-month memory T cell responses expected Q1 2022.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb 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 or in combination with ezabenlimab (PD-1 antagonist); Expansion Phase 1 open for screening.

- **CLEC-1** (novel myeloid checkpoint target): identification of mAb antagonists of CLEC-1 blocking the "Don't Eat Me" signal that increases both tumor cell phagocytosis by macrophages and antigen capture by dendritic cells.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2nd generation of PD-(L)1 inhibitors to increase antitumor efficacity.

Auto-immunity and inflammation platform

- **FR104** (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplant market; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 2-ready asset in an autoimmune disease indication.
- **OSE-127/S95011** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2a ongoing in Sjögren's syndrome (Servier sponsor).
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

For more information: https://ose-immuno.com/en/
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Contacts

OSE Immunotherapeutics
Sylvie Détry
sylvie.detry@ose-immuno.com
+33 153 198 757

Investor Relations
Thomas Guillot
thomas.guillot@ose-immuno.com
+33 607 380 431

Media

U.S. Media: LifeSci Communications
Darren Opland, Ph.D.
darren@lifescicomms.com
+1 646 627 8387

Guillaume van Renterghem – LifeSci Advisors
gvanrenterghem@lifesciadvisors.com
+41 76 735 01 31

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

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 15 April 2021, including the annual financial report for the fiscal year 2020, 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.