OSE Immunotherapeutics Receives New Approval for an Early Access Program for Tedopi® in Spain in Non-Small Cell Lung Cancer After Failure to Immunotherapies

Nantes, France – March 1st, 2023, 7:30 a.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that the Spanish Drug Agency (Agencia Espanola de Medicamentos y Productos Sanitarios, AEMPS) has made a new early access program available that will allow access to Tedopi® through a Special Situation Authorization(1) in the treatment of advanced or metastatic non-small cell lung cancer (NSCLC) after immune checkpoint inhibitor (ICI) failure. This Special Situation Authorization is based on the positive clinical data from the initial phase 3 trial of Tedopi® (ATALANTE-1) in third line treatment and the high unmet need for these patients.

Tedopi® is the first cancer vaccine to show positive and clinically meaningful efficacy results with significant gain in survival associated with a better safety and quality of life profile in advanced NSCLC patients, administered in monotherapy versus active comparator (chemotherapy-based standard of care), in third line with secondary resistance to immune checkpoint inhibitor (ICI).

OSE Immunotherapeutics is committed to provide Tedopi® through early access and compassionate use programs across European countries to address patients' needs alongside physicians' engagement. Patients can benefit from Tedopi® through compassionate use programs in third or further lines of treatment (post chemotherapy and immunotherapy) currently approved in France and Italy.

In Spain, following the earlier nominative compassionate use program for patients that were included in the phase 3 ATALANTE-1 trial, the Health Authorities are now expecting applications for the early access to Tedopi® through an unlimited Special Situation program, confirming thereby the significant medical need for new therapeutic alternatives in this patient population.

Dr. Santiago Viteri, investigator in the ATALANTE-1 study and Medical Director of UOMI Cancer Center, Clinica Mi Tres Torres, Barcelona, comments:

"The decision of the Spanish Health Agency to approve Tedopi® under a Special Situation Authorization for use will facilitate early access to treatment until Marketing Authorization and represent a significant benefit for patients in third line in secondary resistance post-sequential chemotherapy and immunotherapy. Indeed, there is a high unmet need for these patients as there are no therapeutic options yet approved after failure to immunotherapies and last resort chemotherapies are associated with multiple side effects and a poor quality of life."

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: "*Following the positive recommendations from the US Food and Drug Administration (FDA) "Type C" meeting and the European Medicines Agency (EMA) scientific advice, OSE Immunotherapeutics is continuing the clinical development for Tedopi® in second line treatment to support its regulatory registration in secondary resistance to immunotherapy. We are preparing a new confirmatory phase 3 clinical trial versus standard of care for HLA-A2+ patients in advanced in non-small cell lung cancer (NSCLC).*"

[1] *The Special Situation Authorization (Real Decreto 1015/2009) is intended to provide early access to medicines for patients with a severe or rare disease with high unmet need and for which no authorized therapeutic alternatives are available.*

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): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127/S95011** - *lusvertikimab* (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 (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
Click and follow us on Twitter and LinkedIn

Contacts

OSE Immunotherapeutics
Sylvie Détry
sylvie.detry@ose-immuno.com
+33 1 53 198 757

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

International Media: **MEDiSTRAVA Consulting**
Sylvie Berrebi
OSEImmuno@medistrava.com
+44 203 928 6900

Investor Relations
Thomas Guillot
thomas.guillot@ose-immuno.com
+33 6 07 380 431

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 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.