OSE Immunotherapeutics and the FoRT Foundation Announce First Patient Randomized in Phase 2 Clinical Trial Evaluating Tedopi® in Combination with Opdivo® (nivolumab) in Non-Small Cell Lung Cancer

- **Clinical trial sponsored and conducted by the Italian Oncology Foundation FoRT and supported by Bristol Myers Squibb and OSE Immunotherapeutics.**
- **A strategy of combining Opdivo®, a PD-1 targeted checkpoint inhibitor, with Tedopi® as a second-line treatment in patients with metastatic non-small cell lung cancer after first-line chemo-immunotherapy.**

Nantes, France – November 17, 2021, 7:30 a.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) and the **FoRT Foundation** (Fondazione Ricerca Traslazionale) announced today that the first patient has been randomized in the Phase 2 clinical trial evaluating Tedopi® in combination with Opdivo® or chemotherapy as second-line treatment in patients with metastatic non-small cell lung cancer (NSCLC).

This three-arm Phase 2 study will evaluate neo-epitope-based vaccine Tedopi® in combination with Bristol Myers Squibb's Opdivo® (nivolumab), an immune checkpoint inhibitor, or Tedopi® plus chemotherapy or chemotherapy alone as second-line treatment in patients with HLA-A2 positive metastatic NSCLC after first-line chemo-immunotherapy.

Federico Cappuzzo, M.D., Ph.D., Director Medical Oncology at Cancer Institute Regina Elena, Roma, Italy, and Chief Investigator of the study, comments: *"We are very pleased to announce enrollment of the first patient in this Phase 2 trial evaluating a new treatment strategy with the combination of therapeutic vaccine Tedopi® which, by activating T lymphocytes, might efficiently optimize a checkpoint inhibitor or chemotherapy treatment in patients with acquired resistance to immunotherapy. We look forward to evaluating this second-line combination of immuno-therapeutic agents in NSCLC patients with disease progression, a population who needs new treatment options."*

The clinical trial, sponsored and conducted by the Italian oncology foundation FoRT, is designed to enroll 105 patients.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, adds: *"Having the first patient enrolled in an additional oncology indication marks a key milestone in broadening the scope of Tedopi®'s development. On the heels of the positive final results from the Phase 3 trial in NSCLC patients in secondary resistance to ICIs*, including promising clinical benefit and good safety profile, this Phase 2 development of Tedopi® in NSCLC will expand and enhance the product's clinical data. We are expecting first results of Tedopi® as a potential second-line treatment of NSCLC patients after chemo-immunotherapy in 2024."*

** Results presented at the 2021 ESMO (European Society for Medical Oncology) conference: "Activity of OSE-2101 in HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO): Final results of Phase 3 Atalante-1 randomised trial"*

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. Positive preclinical and human ex vivo results. Voluntary and temporary Phase 1 enrollment suspension on-going (July 2021).

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 increase 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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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.