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

- **This clinical trial will be sponsored and conducted by the Italian Oncology Foundation FoRT and supported by Bristol Myers Squibb and OSE Immunotherapeutics.**
- **The study will explore the strategy of combining 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 - Rome, Italy – May 27, 2021, 6:00PM CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) and the **FoRT Foundation** (Fondazione Ricerca Traslazionale) today announced that the Italian Medicines Agency (AIFA) and the Italian Ethics Committee approved the initiation of a new 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 HLA-A2 positive patients with metastatic NSCLC after first-line chemo-immunotherapy.

The clinical trial will be sponsored by the Italian oncology Foundation FoRT. It will be supported by Bristol Myers Squibb, which will provide Opdivo®, and by OSE Immunotherapeutics, which will provide Tedopi® for the study as well as a partial financial support.

Federico Cappuzzo, M.D., Ph.D., Director Medical Oncology at Cancer Institute Regina Elena, Roma, Italy, and Chief Investigator of the study, comments: *"Checkpoint inhibitors are now often used in first-line settings in combination with chemotherapy. For patients who have disease progression after checkpoint inhibitors, the standard second-line option remains chemotherapy. In particular for NSCLC patients with disease progression, we need additional second-line combinations of immuno-therapeutic agents to provide these patients with new options. The trial will evaluate 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."*

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We are very pleased to collaborate with Dr Federico Cappuzzo and FoRT to evaluate Tedopi® in combination with Opdivo® in second-line treatment of NSCLC patients after chemo-immunotherapy. This additional development program of Tedopi® in NSCLC will expand the product's clinical data in this indication for a patient population who needs innovative treatment options. Tedopi® was evaluated as monotherapy post-checkpoint failure in NSCLC and already demonstrated positive results for the Step-1 of its Phase 3 Atalante trial, as presented at the 2020 ESMO congress*."*

* OSE Immunotherapeutics presented positive results of Step-1 of its Phase 3 Atalante 1 clinical trial, including a significant increase in overall survival in NSCLC patients after failure with checkpoint inhibitor (survival rate at 12 months in the patients treated with Tedopi® versus standard of care). Today, OSE Immunotherapeutics intends to discuss with the regulatory health authorities, the U.S. Food and Drug Administration and the European Medicines Agency, to determine the best options to continue development of Tedopi® and to maximize the data obtained in terms of risk / benefit ratio.

ABOUT FoRT

The Foundation for Translational Research (FoRT), founded by Dr. Federico Cappuzzo, is an Italian foundation developing and conducting clinical and translational research activities in the field of oncology. By promoting clinical and preclinical trials, FoRT aims at contributing to the development of innovative and personalized cancer treatments to improve the lives of patients.

ABOUT BRISTOL MYERS SQUIBB

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

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 Step-1 of the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure.
  In Phase 2 in pancreatic cancer (TEDOPaM, sponsor GERCOR)
  In Phase 2 in ovary cancer (TEDOVA, sponsor ARCAGY-GINECO)
  Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.
- **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 in August 2020. In clinical Phase 1.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 results in monotherapy and BI 765063 dose escalation study ongoing in combination with Ezabenlimab (PD-1 antagonist).
- **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 transplantation market; ongoing Phase 1/2 in renal transplant (sponsored the Nantes University Hospital); Phase 2-ready asset in a niche indication in autoimmune diseases.
- **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 planned 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:
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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.