OSE Immunotherapeutics and ARCAGY - GINECO Announce Initiation of a Randomized Phase 2 Clinical Trial Evaluating Tedopi® in Combination with Pembrolizumab in Ovarian Cancer

- **This clinical trial will be sponsored and conducted by the French oncology cooperative group ARCAGY-GINECO and supported by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, and OSE Immunotherapeutics.**
- **The study will explore Tedopi®'s potential in an additional oncology indication with significant unmet medical need.**

Nantes, March 15, 2021, 7:30AM CET - OSE Immunotherapeutics (FR0012127173) and the French cooperative group ARCAGY-GINECO today announced that the French National Agency for Medicines and Health Products Safety (ANSM) and the French Central Ethic Committee (CPP) approved the initiation of a new Phase 2 clinical trial evaluating Tedopi® in patients with recurrent ovarian cancer (the TEDOVA trial). Tedopi® will be evaluated alone and in combination with Merck's Keytruda® (pembrolizumab), an immune checkpoint inhibitor, as maintenance treatment in ovarian cancer patients after chemotherapy.

The three arm TEDOVA study will evaluate neo-epitope-based vaccine Tedopi® as a maintenance treatment, alone or in combination with anti-PD-1 Keytruda®, versus the best supportive care in platinum-sensitive recurrent ovarian cancer patients with controlled disease after platinum-based chemotherapy.

The clinical trial is sponsored by the "**A**ssociation de **R**echerche sur les **CA**ncers dont **GY**nécologiques (ARCAGY-GINECO)" on behalf of GINECO, lead group for the TEDOVA trial of the European Network for Gynaecological Trial Groups (ENGOT). It will be supported in part by a research grant from the Investigator-Initiated Studies Program of MSD (Merck Sharp & Dohme Corp), a subsidiary of Merck & Co., Inc.", which will provide Keytruda® (pembrolizumab), and by OSE Immunotherapeutics which will provide Tedopi® for the study as well as partial financial support.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *"This new clinical development program for Tedopi® in ovarian cancer demonstrates the interest in exploring the potential of a PD-1-targeted checkpoint inhibitor combination strategy for combating oncology indications with significant unmet medical needs. We are very pleased to collaborate with the oncology group ARCAGY – GINECO to advance a new therapeutic pathway for patients suffering from a particularly aggressive cancer."*

Dr Alexandra Leary, Chief Investigator of TEDOVA study from Gustave Roussy cancer center, adds: *"Our patients with ovarian cancer do not respond to checkpoint inhibitors (ICI) alone because these tumors are 'immune cold'. The objective of TEDOVA is to turn ovarian cancer into an 'immune hot' tumor using a combination of tumor associated neo-epitopes that have been optimized to break immunological self-tolerance. TEDOVA is the first trial evaluating such an innovative approach in ovarian cancer and has received enthusiastic support from the international gynecological oncology community."*

ABOUT OVARIAN CANCER

Worldwide, ovarian cancer is the seventh most common cancer and the eighth leading cause of cancer death in women. The five-year survival rate for ovarian cancer worldwide is 30-40%. In 2018, there were nearly 300,000 new cases diagnosed. Once the first relapse has occurred, ovarian cancer is managed as a chronic disease, requiring iterative lines of platinum-based chemotherapy. After 6 cycles, chemotherapy is stopped and one of the major priorities is to extend "chemotherapy-free" intervals for the patients by proposing maintenance strategies with targeted therapies (PARP inhibitors or bevacizumab). By the time patients with ovarian cancer present with first or second relapse, they will have received BOTH a PARP inhibitor and bevacizumab, thus patients progressing post-PARP inhibitors and bevacizumab represent an area of unmet medical need, they are offered chemotherapy alone with no maintenance strategy. The TEDOVA trial focuses on these women.

ABOUT GINECO

GINECO (Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein) is the French Cooperative Group in Oncology labelled by INCa (Institut National du Cancer or French NCI) developing and conducting gynecological and metastatic breast cancer clinical trials at the national and international level. The GINECO group was founded in 1993 and is member of international consortia such as ENGOT and GCIG (Gynecologic Cancer InterGroup).

ABOUT ENGOT

ENGOT (European Network for Gynecological Oncological Trial groups) is a research network of the European Society of Gynecological Oncology (ESGO) and was founded in 2007. ENGOT is a platform that guarantees that the European spirit and culture is incorporated into the medical progress in gynaecological oncology, and that all European patients and countries can participate in an active way in clinical research and progress. The ultimate goal is to bring the best treatment to gynecological cancer patients through the best science and enabling every patient in every European country to access a clinical trial. Currently, ENGOT includes 21 cooperative groups from 25 European countries.

ABOUT MSD

Today's MSD is a global healthcare leader working to help the world be well. MSD is a tradename of Merck & Co., Inc., Kenilworth, N.J., U.S.A. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.msd.com**

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 combination.
  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, clinical trial expected to start in Q1 2021.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim; myeloid checkpoint inhibitor in Phase 1 in advanced solid tumors.
- **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): positive Phase 1 results; ongoing Phase 1/2 in renal transplant, 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 2 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 2020, including the annual financial report for the fiscal year 2019, 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.