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

- **Clinical trial sponsored and conducted by the French oncology cooperative group ARCAGY-GINECO and supported by Merck Sharp & Dohme Corp. (MSD), a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, known as MSD outside of the US and Canada, and OSE Immunotherapeutics.**
- **Innovative approach in ovarian cancer, an oncology indication with high unmet medical need.**
- **First Results expected beginning of 2025.**

Nantes, France, August 26, 2021, 6:00 PM CET – OSE Immunotherapeutics (ISIN: FR0012127173) and the French cooperative group ARCAGY-GINECO announced today that the first patient has been randomized in the Phase 2 clinical trial evaluating Tedopi® alone and in combination with MSD's Keytruda® (pembrolizumab) as maintenance treatment in patients with recurrent ovarian cancer after chemotherapy (the TEDOVA trial).

The three arm TEDOVA study aims at evaluating the neo-epitope-based vaccine Tedopi® as a maintenance treatment, alone or in combination with anti-PD-1 immune checkpoint inhibitor Keytruda®, versus best supportive care in patients with first or second platinum-sensitive recurrent ovarian cancer with controlled disease after platinum-based chemotherapy and who have already received both bevacizumab and a PARP (Poly ADP-Ribose Polymerase) inhibitor.

Dr Alexandra Leary, Chief Investigator of TEDOVA study from Gustave Roussy cancer center, comments: *"We are very pleased to announce enrolment of the first patient in TEDOVA, the first trial evaluating an innovative maintenance strategy for patients in first or second platinum sensitive relapse post-PARP inhibitor and bevacizumab. We look forward to evaluating this therapeutic option for women with ovarian cancer and a strong unmet medical need "*.

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.

This Phase 2 trial, sponsored by the "**A**ssociation de **R**echerche sur les **CA**ncers dont **GY**nécologiques (ARCAGY-GINECO)" on behalf of GINECO, is designed to enroll 180 patients and will be conducted at approximately 30 sites in France and around 12 sites in Germany and Belgium.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, adds: *"Having the first patient enrolled by our oncology group partner marks a significant milestone in Tedopi®'s development by exploring its impact in an additional oncology indication. We are expecting first results on the potential of such an innovative PD-1 targeted checkpoint combination strategy at the beginning of 2025".*

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

Established in France since 1961, MSD France, a research-based pharmaceutical company, is a subsidiary of the American company Merck & Co., Inc., Kenilworth, NJ, USA. MSD France aims to deliver patients and healthcare professionals with a global innovative health offer including prescription medicines (mainly in four major therapeutic areas: cardio-metabolism, oncology, infectious diseases, vaccines), solutions and services, especially in the digital field. 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 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 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 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 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: 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

ARCAGY-GINECO
www.arcagy.org
www.twitter.com/ArcagyGineco
Bénédicte Votan
bvotan@arcagy.org

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.