OSE Immunotherapeutics Receives First Notice of Allowance of a Patent for Use of Tedopi® after Failure with PD-1 or PD-L1 Immune Checkpoint Inhibitor Treatment in HLA-A2 Positive Cancer Patients

Issued by the Japanese Patent Office
A New Protection Covering Tedopi® Until 2037

Nantes, France – January 25, 2022, 6:30pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announced that the Japanese Patent Office has issued the notice of allowance for a new patent covering Tedopi®, a combination of neoepitopes, for use after failure with PD-1 or PD-L1 immune checkpoint inhibitor treatment in HLA-A2 positive cancer patients. This patent, which will further strengthen Tedopi®'s global intellectual property portfolio in immuno-oncology, will provide the product with a new protection until 2037.

This new patent recognises the innovation of a multiepitope composition (all peptides included in Tedopi®) administered after immune checkpoint inhibitor (progression of the cancer), in particular in secondary resistance situation.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, comments:

"This first notice of allowance for a Japanese patent for Tedopi® after failure with immune checkpoint inhibitors, issued in a significant territory, is of major interest and is the first step to the corresponding patent family that has been filed internationally in many other territories.

In addition, it further supports the product's clinical development focus and the positive results of the Atalante 1 Phase 3 trial of Tedopi® in patients with advanced non-small cell lung cancer (NSCLC) with secondary resistance to PD-1/PD-L1 immune checkpoint inhibitor, a hard-to-treat patient population with high unmet medical need. Based on the finalized positive results of Atalante 1, we are preparing discussions with regulatory agencies on optimal paths for potential approval of Tedopi® in patients with NSCLC in secondary resistance after immune checkpoint inhibitor treatment."

The Atalante 1 clinical trial evaluated the benefit of Tedopi® in an HLA-A2 positive patient population with NSCLC at invasive stage IIIB or metastatic stage IV, in 2nd or 3rd line treatment following checkpoint inhibitor failure. The Tedopi® treatment was compared to docetaxel or pemetrexed chemotherapy (CT) treatments in this patient population, with overall survival as the primary endpoint of the trial.

Tedopi® demonstrated a favourable benefit/risk ratio versus standard of care (SoC) docetaxel or pemetrexed in advanced HLA-A2 positive NSCLC patients with secondary resistance to PD-1 or PD-L1 immune checkpoint inhibitors.

ABOUT LUNG CANCER

Lung cancer is the leading cause of cancer death (18.0% of the total cancer deaths) with an estimated 2.2 million new cancer cases per year and with 1.8 million deaths [(1)]. About 85% of lung cancers are Non-Small Cell Lung Cancers (NSCLC) and for metastatic NSCLC, the 5-year survival rate is 7% [(2)].

Treatment regimens including immune checkpoint inhibitors (ICIs) have become the new standard of care for the majority of patients with NSCLC. However, with the increasing use of ICIs in clinical practice, disease progression can be observed in several patients. This therapeutic escape is described as a secondary resistance [(3)] when it occurs after initial clinical benefit under ICI treatment. Over half of the patients will eventually develop secondary resistance to ICIs [(4)].

1 - Sung H et al , CA Cancer J Clin 2021 (GLOBOCAN 2020 – Lung Cancer : Estimated cancer incidence, mortality and prevalence worldwide): https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf

2 - American Cancer Society: What Is Lung Cancer? https://www.cancer.org/cancer/lung-cancer/about/what-is.html

3 - Zhou B et al. Front Immunol 2021 Acquired Resistance to Immune Checkpoint Blockades: The Underlying Mechanisms and Potential Strategies.

4 - Schoenfeld AJ, Hellmann MD. Acquired Resistance to Immune Checkpoint Inhibitors. Cancer Cell. 2020 Apr 13.

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. Clinical data (Nov. 2021) validating the multi-target vaccine show good tolerance and promising efficacy signals. Results from 6-month memory T cell responses expected Q1 2022.

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.

Autoimmunity 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.