OSE Immunotherapeutics to Present New Data on Tedopi® from Phase 3 Clinical Trial in Patients with Advanced Non-Small Cell Lung Cancer after Failure to Immune Checkpoint Inhibitors at ESMO Congress 2022

Nantes, France – September 5, 2022, 7:30am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) announces the presentation of two new analyses from the Phase 3 Atalante-1 study of immunotherapy Tedopi®, in patients with advanced non-small cell lung cancer (NSCLC) in secondary resistance after failure of previous checkpoint inhibitor treatments, at the 2022 European Society for Medical Oncology (ESMO) Congress, being held September 9-13, in Paris.

Alexis Vandier, Chief Executive Officer of OSE Immunotherapeutics, commented: *"In patients with no treatment option after failure of two therapeutic classes, in particular post-checkpoint inhibitors, Tedopi® has shown an overall clinical benefit in this phase 3 study, integrating both efficacy and tolerance compared to chemotherapy treatments. This new specific immunotherapy offers prospects for therapeutic management, both in monotherapy and in combination, and we will do our best to make this treatment available as soon as possible for these patients."*

The first analysis compared Tedopi® to the Standard of Care (SoC) in patients with advanced NSCLC after secondary resistance to sequential use of chemotherapy followed by immunotherapy (CT-IO).

The results have shown that in advanced HLA-A2+ NSCLC patients with IO secondary resistance after sequential CT-IO (n=118), overall survival (OS) was longer with Tedopi® versus SoC regardless of the use (or not) of post progression anticancer treatment (with 13.5 months versus 10.6, HR=0.71; without 6.3 months versus 4.5, HR=0.76).

This analysis will be presented by Dr Maria Rosario Garcia Campelo (Head of Medical Oncology Department, Thoracic Tumors Unit, Investigator of Atalante-1 study, University Hospital A Coruña, Spain).

Dr Garcia Campelo said: *"There is a strong medical need for a new therapeutic alternative in these heavily pretreated NSCLC patients, aiming not only at a prolonged survival but desiring a maintained global health status."*

The second analysis assessed the overall benefit/risk of Tedopi® versus SoC chemotherapy in patients with NSCLC who failed therapy with immune checkpoint inhibitors. The Net Treatment Benefit (NTB)*, a new statistical method combining efficacy, safety and quality of life, was assessed in the overall population (n=219). NTB of Tedopi® was of 19% and reached statistical significance (p=0.035).

This analysis will be presented by Dr Marc Buyse, (Founder and Chief Scientific Officer, International Drug Development Institute (IDDI), Brussels, Belgium).

**The Net Benefit of a treatment should take the correlation between benefits and harms into account Marc Buyse et al.; Journal of Clinical Epidemiology, 2021.*

Poster presentation details:

Title: *Pattern of clinical activity of anticancer vaccine OSE2101 in HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO) in Phase 3 Atalante-1 randomized trial*
Presentation Number: 1019P
Speaker: Maria Rosario Garcia Campelo (A Coruña, Spain)
Date: Monday, September 12th, 2022

Title: *Net Treatment Benefit of OSE2101 in HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO) in Phase 3 Atalante-1 randomized trial*
Presentation Number: 1024P
Speaker: Marc E. Buyse (Louvain-la-Neuve, Ottignies, Belgium)
Date: Monday, September 12th, 2022

The abstracts accepted for presentation are available on the ESMO website:
https://www.esmo.org/meetings/esmo-congress-2022/abstracts

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 Immuno-Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Immuno-Oncology first-in-class products

- **Tedopi®** (innovative neoepitope combination): the Company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure.
  Other ongoing combination trials sponsored by cooperative clinical research groups in oncology:
  Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **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 and in combination with ezabenlimab (PD-1 antagonist); ongoing expansion Phase 1; BI sponsored international phase 1b clinical trial ongoing in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) or hepatocellular carcinoma (HCC).
- **OSE-279**, anti-PD1 – advanced preclinical stage.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target (for example: BiCKI®-IL7, preclinical stage) to increase anti-tumor efficacy.

Immuno-Inflammation first-in-class products

- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; ongoing Phase 2 in ulcerative colitis (sponsor OSE) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **FR104** (anti-CD28 monoclonal antibody): licensing partnership agreement with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 1 ongoing in the US (VEL-101, sponsor Veloxis Pharmaceuticals, Inc.); Phase 2 planned in an autoimmune disease indication.
- **OSE-230** (ChemR23 agonist mAb): preclinical stage therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

CoVepiT: a prophylactic second-generation vaccine activating cytotoxic T lymphocytes against COVID-19, developed using optimized epitopes from SARS-CoV2 viral proteins, epitopes non impacted by multi-variants. Shows good tolerance and very good level of T cell immune response. In clinical testing, a long-term memory response was confirmed at 6 months.
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Forward-looking statements

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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 2022, including the annual financial report for the fiscal year 2021, 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.