OSE Immunotherapeutics to Resume Accrual in Phase 3 Clinical Trial of Tedopi® in Advanced Non-Small Cell Lung Cancer Patients Following Immune Checkpoint Inhibitor Treatment

- *Independent Data Monitoring Committee recommends future recruitment focused on patients who have previously failed immune checkpoint inhibitor treatment*
- *New strategy adjusts for rapidly-evolving clinical practice with recent PD-1/ PD-L1 immune checkpoint inhibitor approvals in first- and second-line NSCLC*
- *Accrual to resume following approval from competent authorities*

Company to host conference call to further discuss Tedopi® clinical development program on December 7, 2017 at 2:30pm CET*

NANTES, France, 7 Dec. 2017, 7:30 a.m. CET – **OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE), today announces that the Independent Data Monitoring Committee (IDMC) has recommended to the trial's steering committee that accrual of the Tedopi® Phase 3 trial for the treatment of advanced non-small cell lung cancer (NSCLC) could resume with a specified new recruitment strategy focused on a subgroup of patients who have failed a previous treatment with PD-1/PD-L1 immune checkpoint inhibitors (ICI). The PD-1/PD-L1 ICI class is becoming a new standard of care for patients with advanced NSCLC, demonstrating efficacy versus chemotherapy in first- and second-line treatment.

There continue to be no safety concerns, as safety data remain similar to what was expected for Tedopi® based on the results of previous clinical trials.

In June 2017, the IDMC's previous recommendation led the Company to temporarily pause accrual, while patients already enrolled in the trial were allowed to continue receiving study treatments until longer-term data were available.

The IDMC's most recent recommendation also includes maintaining the hold on accrual of patients who have not received prior treatment with immune checkpoint inhibitors.

Following formal approval from the Competent Authorities, patient accrual will resume exclusively in the group previously defined in the protocol: patients who have previously failed an ICI treatment. This patient group represents a specific population for which there are currently no approved treatment options, and for which a significant clinical need exists.

"The potential benefit of our Tedopi® neoepitope product in patients who have previously failed ICI treatment is supported by a strong immunological rationale, and could provide a breakthrough therapy following PD-1 or PD-L1 tumor progression. We are very pleased to be able to reopen recruitment in this Tedopi® study with an accrual strategy that appropriately leverages the rapidly-changing clinical practice in NSCLC," said Dominique Costantini, M.D., chief executive officer of OSE Immunotherapeutics."

***The company will hold a call on December 7, 2017 at 2:30pm CET.**

Dial-in for the call : FR: 01 72001510; UK: (44) 2030432440; USA toll free : (1) 8778874163

PIN code: 68006109#

ABOUT OSE Immunotherapeutics

Our ambition is to become a world leader in activation and regulation immunotherapies:

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, autoimmune diseases and transplantation. The company has several scientific and technological platforms: neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical portfolio offers a diversified risk profile.

In immuno-oncology:

- **Tedopi Phase III trial in advanced NSCLC:** after temporary pause of new patient accrual end of June 2017, new recruitment strategy defined in December 2017 to focus the trial on patients who failed a previous treatment with a PD-1/PD-L1 immune checkpoint inhibitor. Enrollment will resume after formal approval of the new recruitment strategy from the Competent Authorities.
  Phase II with Tedopi® in combination with an immune checkpoint inhibitor planned in advanced pancreatic cancer, in collaboration with GERCOR, a cooperative group of clinical research.
- OSE-172 (Effi-DEM), new generation checkpoint inhibitor targeting myeloid cells via the SIRP-α receptor - In preclinical development for several cancer models. Clinical program planned end of 2018.
- **OSE-703 (Effi-3**), cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a research collaboration with Memorial Sloan Kettering Cancer Center, New York.

In auto-immune diseases and transplantation:

- **FR104, CD28-antagonist in immunotherapy** - Phase 1 trial completed – For the treatment of autoimmune diseases and for use with transplantation - Licensed to Janssen Biotech Inc. to pursue clinical development. Phase 2 planned end of 2018 in rheumatoid arthritis.
- **OSE-127 (Effi-7), interleukin receptor-7 antagonist -** In preclinical development for inflammatory bowel diseases and other autoimmune diseases. Clinical phase planned end of 2018. License option agreement with Servier for the development and commercialization.

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter global agreements at different stages of development with major pharmaceutical players.

Immunotherapy is a highly promising and growing market. By 2023 Immunotherapy of cancer could represent nearly 60% of treatments against less than 3% at present * and the projected market is estimated at $67 billion in 2018 **. There are more than 80 autoimmune diseases that represent a significant market including major players in the pharmaceutical industry with sales towards $10 billion for the main products. The medical need is largely unmet and requires the provision of new innovative products involved in the regulation of the immune system.

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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 Reference Document filed with the AMF on 28 April 2017 under the number R.17-038, including the annual financial report for the fiscal year 2016, 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.