

OSE Immunotherapeutics Presents New Clinical and Preclinical Data on its Immuno-Oncology Portfolio at AACR 2019

- **Oral presentation highlights investigator case reports showing early signs of activity of Tedopi® in patients with non-small cell lung cancer in third-line treatment after checkpoint inhibitor failure**
- **Poster presentation shows new preclinical mechanistic data of BI 765063 (OSE-172), a selective SIRPα antagonist entering Phase 1 clinical development in 2019**

Nantes, France, April 2, 2019, 18:00 p.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE), today announced that new clinical and preclinical data on its products in immuno-oncology, Tedopi® and BI 765063 (OSE-172), were presented at the American Association of Cancer Research (AACR) Annual Meeting, held March 29-April 3, 2019 in Atlanta.

"We are excited about the interesting preliminary data gathered with Tedopi® from investigator case reports of patients with advanced lung cancer in third-line of treatment after failure of checkpoint inhibitors. The data presented show early signs of activity of Tedopi® in three patients, with one patient achieving a partial response and two achieving durable stable disease," said Alexis Peyroles, chief executive officer of OSE Immunotherapeutics. *"The potential benefit of Tedopi® for patients who already have failed other treatments, including checkpoint inhibitors, is an encouraging step to show that Tedopi® may provide a long-term clinical benefit for those suffering from this devastating cancer with a high unmet medical need. Our second presentation contains additional evidence that the selective SIRPα antagonist, BI 765063, has a positive effect on myeloid cell function and the tumor microenvironment which indicates that it may potentially have strong anti-tumor activity."*

Early signs of activity of Tedopi® in patients after failure from previous immune checkpoint inhibitor treatments were delivered in an oral presentation. The presentation described investigator case reports from three patients with NSCLC who achieved clinical benefit in third-line treatment with Tedopi® after progression following previous anti-PD1/anti-PD(L)1 checkpoint inhibitor treatment. Early results showed that one patient achieved a partial response and two other patients achieved stable disease status as measured by RECIST 1.1 criteria. For all three patients, the safety profile was manageable and no patients have withdrawn for toxicity. These data represent initial activity signs in third-line treatment with Tedopi® when given to patients who have failed all previous immune checkpoint inhibitor therapy treatments in advanced NSCLC.

(Link to the presentation: https://ose-immuno.com/en/publications-scientifiques/?published_year=2019&ose_product=).

Tedopi®, a combination of neoepitopes, is currently in an open-label Phase 3 trial in advanced NSCLC for HLA-A2 positive patients who failed previous treatments with checkpoint inhibitors. Tedopi® is also being studied in an ongoing Phase 2 trial in patients with pancreatic cancer.

In a second presentation, data on BI 765063 (OSE-172), the company's first-in-class monoclonal antibody antagonist selectively targeting the SIRPα receptor expressed on myeloid pro-tumor suppressive cells,

included results from human *ex vivo* and preclinical studies. The research concluded that as blockade of SIRP γ prevents T-cell transmigration, the selective anti-SIRP α activity of BI 765063 and its ability to promote T-cell infiltration of solid tumors is crucial for its potential success as a novel cancer therapy.

In March 2019, French and Belgian regulatory agencies granted Clinical Trial Authorization for a Phase 1 trial intended to characterize safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of BI 765063 in patients with advanced solid tumours. In this dose finding study, BI 765063 will be administered as a single agent and in combination with Boehringer Ingelheim's monoclonal antibody PD-1 antagonist BI 754091, a lymphocyte T checkpoint inhibitor. The study will be conducted by OSE as part of its collaboration and license agreement with Boehringer Ingelheim.

Presentation details:

Early signs of activity of Tedopi[®] (OSE2101), a multiple neoepitope vaccine, in a phase 3 trial in advanced lung cancer patients after failure to previous immune checkpoint inhibitors (ATALANTE-1)

<https://www.abstractsonline.com/pp8/#!/6812/presentation/2375>

SIRP α blockade reinvigorates myeloid cells in the tumor microenvironment and reverses T-cell exclusion

<https://www.abstractsonline.com/pp8/#!/6812/presentation/2662>

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company has a diversified first-in-class clinical portfolio consisting of several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. The most advanced therapeutic-candidate, Tedopi[®], is a proprietary combination of 10 neo-epitopes aimed at stimulating T-lymphocytes and is currently in Phase 3 development in non-small cell lung cancer (NSCLC) after checkpoint inhibitor failure (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo[®]. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. BI 765063 (OSE-172) (anti-SIRP α monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim ; this checkpoint inhibitor has received CTA from French and Belgian health authorities for a Phase 1 clinical trial in multiple cancer indications. BiCKI[®] is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) is partnered with Servier under an option agreement up to the completion of a Phase 2 clinical trial planned in autoimmune bowel diseases; in parallel, Servier plans a development in the Sjögren syndrome. OSE-127 is currently under Phase 1 clinical trial.

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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 26 April 2018, including the annual financial report for the fiscal year 2017, 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.