Phase 3 Clinical Trial of Tedopi®: OSE Immunotherapeutics Announces Positive Top-Line Results for Step-1 of its trial 'Atalante 1' in Non-Small Cell Lung Cancer

- **Step-1 primary endpoint met: 12-month survival rate in Tedopi® treated patients;**
- **Complete analysis of Step-1 results and further discussions with regulatory agencies will determine the best options for additional clinical development of Tedopi® and potential partnership plans;**
- **Due to the current COVID-19 outbreak and its potential impact on Step-2 of Atalante 1, voluntary definitive suspension of recruitment motivated by the risks for the patients and on the data integrity of this now cancelled Step-2.**

Nantes, France, April 1st, 2020 – 6:00 p.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today announced that the primary endpoint was met in the predefined Step-1 analysis of its Phase 3 clinical trial of investigational product Tedopi®, called Atalante 1, in HLA-A2 positive non-small cell lung cancer (NSCLC) patients after failure from immune checkpoint inhibitors (PD-1/PD-L1).

Considering the population of the treated patients in both trial arms randomized at least 12 months before the time of the Step-1 analysis (N=99), the primary objective of Step-1 of the Atalante 1 trial planned in the protocol was met:

In the Phase 3 Step-1 analysis, the statistically positive preliminary results show at least 12-month survival for 29 patients out of 63 patients in the Tedopi® arm, corresponding to a 12-month survival rate of **46%** with the lower limit (33%) of the 95% confidence interval* [33% - 59%], above the pre-specified futility boundary of 25%.

The observed rate of **46**% is also above the assumption of a survival rate of 40% specified for the alternative efficacy hypothesis in the protocol.

In the chemotherapy control arm the results show at least 12-month survival for 13 patients out of 36 patients, corresponding to a 12-month survival rate of **36%**.

Alexis Peyroles, CEO of OSE Immunotherapeutics, said: *"We are very pleased with these positive results for Tedopi in Step-1 and with a 10% absolute difference in 12-month survival rate versus chemotherapy in NSCLC patients after failure of checkpoint inhibitor treated in Atalante 1 Step-1 trial. This outcome confirms the therapeutic value of our neoepitope product in a patient*

population for whom there are no registered product today and who needs new therapeutic options. Based on these positive results, we are now eager to engage in discussions with regulatory authorities to evaluate Tedopi's current clinical results and agree upon the best options for further development to maximize on the product's positive data in terms of benefit/risk ratio. In parallel, given the significant value added by positive Step-1 results, we continue exploring potential partnership opportunities for Tedopi."

As explained in the recent press release from March 26, 2020, the Company together with the Independent Data Monitoring Committee (IDMC) and the Steering Committee of the trial have reviewed the potential impact of the COVID-19 outbreak on the Atalante 1 trial. As of today, there is ongoing concern that trial data may be markedly impacted given the current worldwide COVID-19 pandemic and the increased risk for patients with NSCLC as COVID-19 can cause serious pulmonary complications in this immunocompromised patient population. In addition, recommendations from several medical societies include voluntary holds on recruitment of new patients in oncology trials for the time being, due to patient safety concerns.

Consequently, following the recommendation from both IDMC and Steering Committee of Atalante 1, OSE Immunotherapeutics voluntarily decided to terminate patient screening and accrual in the initially planned and now cancelled Step-2. Further analysis of the positive Step-1 data will commence while engaging with regulatory agencies on the best development path forward for the product given the significant unmet medical need in the NSCLC patient population post-checkpoint inhibitor therapy failure.

*The 95% confidence interval (CI) is a range of values which has a 95% chance of containing the true value of the estimated parameter. With less rigor, it can be said that the CI represents the range of values within which it is 95% certain to find the true value sought. It provides a visualization of the uncertainty of the estimate.

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: positive results for Step-1 of the ongoing Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure; voluntary definitive suspension of new patient accrual (cancellation of Step-2 initially planned in the clinical trial) due to Covid-19. Tedopi® is also in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo®; continuation of screening but temporary pause of patient accrual in the study by the GERCOR, study sponsor. BI 765063 (OSE-172) (anti-SIRPa monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim; this checkpoint inhibitor is currently under Phase 1 clinical trial in advanced solid tumor; due to the COVID-19 crisis, temporary suspension of new screening and new inclusions in the study. BiCKI® is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) is partnered with Servier under a two-step license option agreement. The Phase 1 clinical phase of OSE-127 is completed and has shown positive results; two independent Phase 2 studies planned

in ulcerative colitis (OSE sponsor) and Sjögren's syndrome (Servier sponsor) to start in 2020; subject to the evolution of the COVID-19 situation.

For more information: **https://ose-immuno.com/en/**

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Forward-looking statements

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