



## **OSE Immunotherapeutics and HalioDx Collaborate to Perform Immune Biomarker Exploratory Work during Atalante 1 Phase 3 Clinical Trial of Tedopi® in Non-Small Cell Lung Cancer**

**Nantes and Marseille, France, November 27, 2019 – 6:00 p.m. CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE), a clinical-stage biotechnology company focused on developing innovative immunotherapies, and **HalioDx**, the immuno-oncology diagnostic company, today announced a collaboration to conduct a translational investigation of immune biomarkers as part of the ongoing Phase 3 clinical trial of neoepitope combination Tedopi® in non-small cell lung cancer (NSCLC) patients.

The collaboration will focus on the testing and analysis of clinical biopsy tissue samples from patients participating in the ongoing Phase 3 Atalante 1 clinical trial. HalioDx will leverage its expertise in proprietary technology immuno-oncology diagnostic platforms to perform immune biomarker exploratory work as part of the clinical trial objectives.

*“We look forward to combining our companies’ innovative approaches, OSE’s neoepitope combination Tedopi® and HalioDx’s pioneering diagnostic applications such as Immunoscore® and Immunosign®, to conduct a translational investigation focused on identifying potential immune biomarkers in NSCLC. Based on the data generated, we aim at defining the profile of responder patients to Tedopi® treatment in advanced lung cancer,”* said Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics.

*“Relapse of NSCLC patients after treatment with PD-1/PD-L1 checkpoint inhibitors (ICI) is today a critical issue to solve. Tedopi® is an exciting and promising approach to overcome ICI resistance. We are delighted to work together with the OSE team to execute this comprehensive biomarker program with the objective to map the immune contexture and identify the responders,”* added Vincent Fert, Chief Executive Officer of HalioDx.

Tedopi® is currently being evaluated in a Phase 3 trial, called Atalante 1, in advanced NSCLC for HLA-A2 positive patients after failure from previous treatment with PD-1/PD-L1 checkpoint inhibitors. Results from the first step of this ongoing Phase 3 trial are expected by the end of Q1 2020. Tedopi® is also being studied in an ongoing Phase 2 trial in patients with pancreatic cancer.

## About HalioDx

### The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists and Biopharma with first-in-class Immune-based diagnostic products and services to guide cancer care and contribute to precision medicine in the era of immuno-oncology and combination therapies. Immunoscore® proprietary technology, pioneered by Jérôme Galon at the Cordeliers Research Center, Paris, France, integrates immunohistochemistry combined with sophisticated algorithm and advanced imaging analysis enabling extraction of spatially organized tissue molecular information. Immunoscore® is a platform for many cancers, as immune response to tumor is a key hallmark of disease progression. HalioDx collaborates with renowned international clinical groups to support clinical utility and ensure rigorous performance validation of its assays in selected cancer indications. HalioDx has an experienced team of more than 165 employees, CLIA-certified laboratories and compliant facilities in Europe and in the US to develop, manufacture, register and market in vitro diagnostic (IVD) products. HalioDx executes biomarker studies and companion diagnostic assay development in conformity with regulations and in partnership with biopharmaceutical companies. The company co-founded the European immunology cluster Marseille Immunopôle (MI).

For more information, please visit our websites [www.halioldx.com](http://www.halioldx.com) and [www.immunoscore-colon.com](http://www.immunoscore-colon.com) and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx) and LinkedIn <https://www.linkedin.com/company/halioldx/>.

*HalioDx® and Immunoscore® are registered trademarks of HalioDx.*

## 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) in patients in failure after checkpoint inhibitor treatment (anti PD-1 and anti PD-L1) and in Phase 2 testing in pancreatic cancer in combination with checkpoint inhibitor Opdivo®. 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 tumors. 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 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 2019, including the annual financial report for the fiscal year 2018, 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.