



## OSE Immunotherapeutics Presented Positive Correlation Between Neoepitope Response and Increased Survival for NSCLC Patients Treated with Tedopi®

### *At the 34th SITC Annual Meeting*

Nantes, France, November 11, 2019 – 8:00 a.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE), today announced that new clinical and preclinical data on its products in immuno-oncology - Tedopi®, BI 765063 (OSE-172) and the BiCKI® platform - were presented at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting, held November 6 – 10, 2019 in National Harbor, Maryland, USA.

The poster (P339), entitled *“Survival is improved by antigen-specific cytotoxic T lymphocytes (CTL) responses after treatment with the neoepitope-based vaccine Tedopi® in HLA-A2 positive advanced non-small cell lung cancer (NSCLC) patients,”*\* reported on immunogenicity assays that have been conducted to explore the predictive effect of the type and number of neoepitopes on overall survival. The results presented demonstrated that in advanced non-small cell lung cancer (NSCLC) patients, survival was significantly prolonged in patients immunized with the combination of neoepitopes used in Tedopi®.

*“The new exploratory data from translational analysis demonstrate that neoepitope combination Tedopi® increases the recognition of cancer cells by antigen-specific CD8 T cells with a favorable correlation with patients’ survival. This supports the mechanism of action of Tedopi® of increasing the tumor antigen presentation and activation of T-cell priming, leading to an anti-tumoral effect and potentially combatting the main resistance mechanisms to immune checkpoint inhibitors. We are encouraged by these findings and look forward to confirming the correlation between neoepitope response and survival in further translational investigations,”* said Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics.

Tedopi®, a combination of neoepitopes, is currently being evaluated 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.

The second poster (P428) presented was a BI 765063 Phase 1 trial-in-progress presentation entitled: *“A phase 1 study evaluating BI 765063, a first in class selective myeloid SIRPα inhibitor, as stand-alone and in combination with BI 754091, a PD-1 inhibitor, in patients with advanced solid tumours.”*\*\* BI 765063, a first-in-class monoclonal antibody antagonist targeting the SIRPα receptor expressed on myeloid pro-tumor suppressive cells, is being developed in partnership with Boehringer Ingelheim. The ongoing Phase 1 trial conducted in patients with advanced solid tumors is a dose finding study of BI 765063 administered as a single agent and in combination with Boehringer Ingelheim’s monoclonal antibody PD-1 antagonist BI 754091, a T-lymphocyte checkpoint inhibitor.

The third poster (P256), entitled *“A novel bifunctional anti-PD-1 / IL-7 fusion protein potentiates effector function of exhausted T cell and disarms Treg suppressive activity,”* \*\*\* focuses on OSE's proprietary bispecific checkpoint inhibitor (BiCKI®) platform. BiCKI® antibodies are based on anti-PD-1 backbone (OSE-

279) selected based on optimized bioproduction capacity. The first cytokine selected to be paired with the anti-PD-1 in the bispecific antibody is interleukin-7 (IL-7), which has been shown to improve immune functions and cancer immunotherapy efficacy. The poster reports preclinical evidence that OSE's bifunctional anti-PD1/IL-7 favors the T cell effector over regulatory immune balance by stimulating effector T cell functions while disarming regulatory T cells.

*\* Benjamin Besse, Enriqueta Felip, Giuseppe Giaccone, Rafal Dziadziuszko, Elisabeth Quoix, Werner Hilgers, Federico Cappuzzo, Christophe Borg, Jordi Remon, Nicolas Poirier, Dominique Costantini, Bérangère Vasseur, Santiago Viteri*

*\*\* Nuria Kotecki, Philippe Cassier, Jean Pierre Delord, Stéphane Champiat, Christiane Jungels, Armelle Vinceneux, Iphigenie Korakis, Richard Huhn, Nicolas Poirier, Dominique Costantini, Bérangère Vasseur, Aurélien Marabelle*

*\*\*\* Aurore Morello, Justine Durand, Caroline Mary, Virginie Thepenier, Margaux Seite, Géraldine Teppaz, Nicolas Poirier*

#### **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<sup>®</sup>, 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<sup>®</sup>. 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<sup>®</sup> 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.

Click and follow us on Twitter and LinkedIn



#### **Contacts**

OSE Immunotherapeutics  
Sylvie Détry  
Sylvie.detry@ose-immuno.com  
+33 153 198 757

French Media: FP2COM  
Florence Portejoie  
fportejoie@fp2com.fr  
+33 607 768 283

U.S. Media: LifeSci Public Relations  
Darren Opland, Ph.D.  
darren@lifescipublicrelations.com  
+1 646 627 8387

U.S. and European Investors  
Chris Maggos  
chris@lifesciadvisors.com  
+41 79 367 6254

#### **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.