

## OSE Immunotherapeutics Announces Results of 2020 Virtual Combined General Meeting

**Nantes, France, June 16, 2020, 6:00PM CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnémo: OSE) today announced that all the resolutions submitted to a vote at the Combined General Shareholders' Meeting were approved as proposed by OSE Immunotherapeutics' Board of Directors. The Company conducted the General Meeting virtually following the provisions of the French ordinances related to Covid-19, dated March 25, 2020.

The results of each resolution voted on can be found on the Company's website in the "Investor – General Shareholders' Meeting" section: <https://ose-immuno.com/en/general-shareholders-meetings/>.

A total of 103 shareholders voted by mail, in accordance with the terms and conditions indicated in the notice of the Meeting. In total, the shareholders who voted hold 9 323 962 shares (representing 61,65 % of the share capital) and 14 190 017 voting rights (representing 67,58 % of the voting rights).

During the virtual meeting, Dominique Costantini, Chairman, and Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, provided an overview of the Company's latest advances and growth strategy.

Alexis Peyroles, CEO of OSE Immunotherapeutics, commented: *"2019 and the first semester of 2020 were marked by major clinical progress. Specifically, Tedopi® showed positive results in Step-1 of its Phase 3 clinical trial in NSCLC patients after failure of checkpoint inhibitor treatments. This confirms the clinical benefit Tedopi® can provide in patients with advanced stage cancer and who need new therapeutic options."*

*In 2019, our partnered products also achieved key clinical milestones: BI 765063 entered Phase 1 in advanced solid tumors in partnership with Boehringer Ingelheim, and OSE-127 has shown positive Phase 1 results in partnership with Servier. The OSE-127 results provide a firm foundation for two Phase 2 trials planned to start in 2020: in ulcerative colitis, sponsored by OSE, and in Sjögren's syndrome, sponsored by Servier.*

*Our cash position, recently reinforced by a € 7 million non-dilutive loan agreement granted by the French State, provides us with financial visibility until Q3 2021 to advance our clinical and preclinical programs in immuno-oncology and autoimmune diseases, as well as our recently-announced development of a prophylactic vaccine against the pandemic virus SARS-CoV-2. This cash position and flexibility should be further reinforced by the milestone payment which*

*is due at first patient-in in the Sjögren's Phase 2a study, demonstrating the resilience of our business model.*

*We continue to create value for all OSE's stakeholders by advancing our differentiated development programs based on quality science."*

### **Latest major clinical advances of four differentiated therapeutic programs in immuno-oncology and autoimmune diseases**

**Tedopi<sup>®</sup>** is a combination of 10 neoepitopes intended to induce specific T-lymphocyte activation

- The Company's most advanced product demonstrated positive top-line results for the Step-1 of its 'Atalante-1' Phase 3 clinical trial in patients with non-small cell lung cancer (NSCLC) following immune checkpoint inhibitor treatment failure (PD-1/PD-L1). The Step-1 results show primary endpoint met with at least 12-month survival in Tedopi<sup>®</sup> treated patients. Based on these positive data, OSE Immunotherapeutics will engage in discussions with regulatory authorities to determine the best options for Tedopi<sup>®</sup>. In parallel, given the significant value added by positive Step-1 results, the Company continues exploring potential partnership opportunities for the product.

Due to the COVID-19 outbreak and its potential impact on Step-2 of Atalante 1, voluntary definitive stop of recruitment was decided early April 2020, motivated by the risks for the patients and on the data integrity of this now cancelled Step-2 part of the study.

- **Tedopi<sup>®</sup>** is also in a Phase 2 clinical trial, called TEDOPaM, in patients with pancreatic cancer in monotherapy and in combination with Opdivo<sup>®</sup> (nivolumab), a trial sponsored by the GERCOR cooperative group in oncology and supported by Bristol Myers Squibb. Due to the COVID-19 situation, patient screening and accrual in the TEDOPaM study has been impacted by the COVID-19 situation and are currently suspended.

**BI 765063** (OSE-172), a myeloid checkpoint inhibitor being developed in partnership with Boehringer Ingelheim

- BI 765063 is in an ongoing Phase 1 clinical trial in advanced solid tumors. The study is a first-in-human dose finding study of BI 765063 administered as a single agent and in combination with Boehringer Ingelheim's monoclonal PD-1 antibody antagonist, BI 754091, a T lymphocyte checkpoint inhibitor. The trial aims to characterize safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of the immunotherapy in patients with advanced solid tumors.

**OSE-127**, a monoclonal antibody antagonist of the interleukin-7 (IL-7) receptor being developed in partnership with Servier

- The Phase 1 clinical study of OSE-127 was completed at the end of 2019. The results demonstrated a good safety and tolerability profile for OSE-127. All pharmacokinetic and pharmacodynamic parameters were consistent and demonstrated a dose-proportionality across the several dose-levels up to 10 mg/kg.

- Based on these positive data, two Phase 2 trials are planned to start in 2020: in ulcerative colitis, sponsored by OSE and in Sjögren's syndrome sponsored by Servier.  
The initiation of both Phase 2 clinical trials is subject to the evolution of the COVID-19 situation and will take place once all preparatory steps are achieved and once hospitals and healthcare professionals are able to ensure safe practices during clinical research and patients' care.

## **Research & Development**

- In May 2020, OSE Immunotherapeutics announced its commitment to the fight against COVID-19 through initiation of a prophylactic vaccine program. CoVepiT vaccine technology leverages the Company's expertise in peptide selection and optimization and proprietary Memopi® technology to explore a T lymphocyte immune response for COVID-19. First preclinical results are expected in H2 2020 and, if they are positive, clinical trial could possibly start by year's end.
- Identification of a new myeloid checkpoint target CLEC-1 (a C type lectin receptor) and of the first monoclonal antibody antagonists of CLEC-1 blocking the "Don't eat me" signal represent a novel approach in cancer immunotherapy. These findings come from a research program conducted by OSE's R&D team in collaboration with Dr Elise Chiffolleau (*Center for Research in Transplantation and Immunology, UMR - INSERM 1064, Nantes University Hospital*)
- Preclinical progress confirm that bispecific antibody checkpoint inhibitor platform BiCKI® and bifunctional therapy targeting PD-1 and IL-7, BiCKI®-IL-7 has the potential overcome resistance mechanisms to anti-PD(L)-1 therapies and could potentially address the needs of a patient population in immune escape from checkpoint inhibitor treatment.
- Latest data on CLEC-1, BiCKI® and BiCKI®-IL-7 have been selected for oral and poster presentations at the 2020 American Association of Cancer Research (AACR) Virtual Annual Meeting II to be held end of June.
- Based on OSE's diverse scientific and technological platforms (neoepitopes, immune response agonist and antagonist monoclonal antibodies), the Company is pursuing new innovative research programs.

## **A dynamic partnership business model based on innovative products to generate non-dilutive revenues and to finance its R&D programs**

- In March 2020, OSE Immunotherapeutics and Servier signed an amendment to the two-step global licensing option agreement for OSE-127. Under this amendment, both companies have agreed to modify the provisions regarding the potential exercise of the option, amending step 2 of the option agreement, making OSE eligible to receive a €5 million milestone payment from Servier upon the enrollment of the first patient in the Phase 2a clinical study in Sjögren's syndrome and the remaining €15 million payment upon exercise of an option at the completion of both Phase 2 clinical trials, and in priority upon completion of the Phase 2a clinical study in Sjögren's syndrome. The previous version of the agreement had the full €20 million milestone payment due upon completion of Phase 2 clinical study in ulcerative colitis.

The initiation of both Phase 2 clinical trials is subject to the evolution of the COVID-19 situation and will take place once all preparatory steps are achieved and once hospitals and healthcare professionals are able to ensure safe practices during clinical research and patients' care.

- A new licensing deal was signed in November 2019 with Chong Kun Dang (CKD) Pharmaceutical Corporation for potential registration and commercialization of Tedopi® in South Korea. Financial terms of the contract include both upfront and short-term milestone payments of €1.2 million with total milestone payments of €4.3 million, as well as royalties on sales and transfer price in the high twenties percentage.
- OSE Immunotherapeutics is evaluating the best options for continuing sustainable development of FR104, a Phase 2-ready asset, in autoimmune diseases and/or in transplantation, including worldwide partnering opportunities. The Company is also exploring global partnership opportunities for Tedopi® on the heels of positive Step-1 results of Phase 3 in NSCLC and with an ongoing Phase 2 in pancreatic cancer.

## 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 several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical and preclinical portfolio has a diversified risk profile:

- **Tedopi®** (innovative combination of neoepitopes) : the company's most advanced product ; **positive results for Step-1 of the Phase 3 trial** (Atalante 1) in **Non-Small Cell Lung Cancer** post checkpoint inhibitor failure; due to Covid-19, voluntary definitive stop of new patient accrual in the Step-2 initially planned in the trial. In **Phase 2 in pancreatic cancer** (TEDOPaM, sponsor GERCOR) in combination with checkpoint inhibitor Opdivo®.
- **BI 765063** (OSE-172, anti-SIRPα monoclonal antibody): developed in **partnership with Boehringer Ingelheim**; myeloid checkpoint inhibitor in **Phase 1 in advanced solid tumors**.
- **FR104** (anti-CD28 monoclonal antibody): **positive Phase 1 results; Phase 2-ready asset in autoimmune diseases or in transplantation**.
- **OSE-127** (humanized monoclonal antibody targeting IL-7 receptor): developed in **partnership with Servier**; **positive Phase 1 results**; two independent **Phase 2** planned in **ulcerative colitis** (OSE sponsor) and in **Sjögren's syndrome** (Servier sponsor) to start in 2020.
- **BiCKI®**: **bispecific fusion protein** platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2<sup>nd</sup> generation of PD-(L)1 inhibitors to increase **antitumor efficacy**. **Additional innovative research programs**.
- **CoVepiT**: a **prophylactic vaccine** against **COVID-19**, developed using SARS-CoV-2 optimized neo-epitopes. **First preclinical results expected start of H2 2020, possible clinical trial by year end.**  
*Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127 could be impacted during the coming months.*

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

Click and follow us on Twitter and LinkedIn



## Contacts

**OSE Immunotherapeutics**  
Sylvie Détry

**U.S. Media: LifeSci Communications**  
Darren Opland, Ph.D.



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

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

darren@lifescicomms.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 Universal Registration Document filed with the AMF on 15 April 2020, including the annual financial report for the fiscal year 2019, 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.