OSE Immunotherapeutics Reports First Half 2020 Results and Corporate Update

- **Positive results for Step-1 of Phase 3 clinical trial of Tedopi® in non-small cell lung cancer**
- **Positive preclinical and in human ex vivo results with CoVepiT vaccine against COVID-19; clinical entry expected by the end of 2020 or early 2021**
- **Two Phase 2 clinical trials with OSE-127 planned to start in Q4 2020 in ulcerative colitis and in the Sjögren syndrome**
- **Strong progress on BiCKI®, bi-specific platform, and CLEC-1 antagonist preclinical programs in immuno-oncology**
- **€7 million non-dilutive loan agreement guaranteed by the French State obtained**
- **€5.8 M turnover and €22.9 M available cash as of June 30, 2020 covering financial needs until Q3 2021**

Nantes, France, September 17, 2020, 6:00PM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today reported its consolidated half-year financial results as of June 30, 2020 and provided updates on key milestones reached during H1 2020.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: *"The first half of 2020 was prolific and marked by major clinical and preclinical achievements in our ongoing programs and rapid progress for the development of a 2nd generation and multi-target COVID-19 vaccine, named CoVepiT.*

"We reported positive clinical data, with Tedopi® from 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 cancer and who need new therapeutic options.

The positive results from an OSE-127 Phase 1 trial, provide a firm foundation for the two Phase 2 trials planned to start in Q4 2020 and conducted in partnership with Servier: for ulcerative colitis, sponsored by OSE, and for Sjögren's syndrome, sponsored by Servier.

Since our initial program announcement in May, we have rapidly advanced our fight against COVID-19 with the publication of positive preclinical results this past August. Based on these results, a Phase 1/2 clinical study evaluating CoVepiT's efficacy is expected to be initiated by the end of 2020 or early 2021.

"Our cash position has been reinforced by a €7 million non-dilutive loan agreement granted by the French State. This should be further strengthened the €5 milestone payment from Servier, due at first patient-in for the Sjögren's Phase 2a study. This provides us with financial flexibility until Q3 2021 and will allow us to advance our clinical and preclinical programs in immuno-oncology and autoimmune diseases as well as the clinical development of our CoVepiT prophylactic vaccine for which we hope to secure additional funding from public authorities."

Clinical advances of four differentiated therapeutic programs in immuno-oncology and autoimmune diseases

Tedopi® *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 NSCLC following immune checkpoint inhibitor treatment failure (PD-1/PD-L1).The primary criteria of Step-1 was met, Tedopi® demonstrating a 12-month survival rate for 46% of the patients treated, higher than the pre-specified efficacy rate of 40% and above the pre-specified futility boundary of 25%. Following these positive data, OSE Immunotherapeutics will determine the best options for the product moving forward.
- **Tedopi®** is also in a Phase 2 clinical trial for patients with pancreatic cancer called TEDOPaM and sponsored by the GERCOR cooperative group in oncology. Due to the COVID-19 restrictions, patient screening and accrual in the TEDOPaM study 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*

- Based on the positive safety and tolerability data from the Phase 1 clinical study, two separate Phase 2 trials are planned to start in Q4 2020: in ulcerative colitis, sponsored by OSE and in Sjögren's syndrome sponsored by Servier.

Research & Development

CoVepiT*, a 2nd generation multi-target vaccine against COVID-19, developed using SARS-CoV-2 optimized neo-epitopes*

- In August 2020, positive data from preclinical and human *ex vivo* studies with CoVepiT have been published online in BioRxiv. The data supports CoVepiT as a potential as novel and differentiated COVID-19 vaccine designed against multiple SARS-CoV-2 targets with technology known to induce memory T lymphocytes. The results show that CoVepiT provides tissue-resident memory sentinel T cell response with long-term protective immunity in barrier tissues such as the respiratory tract and the lung. A Phase 1/2 clinical study evaluating CoVepiT's efficacy is expected to be initiated by the end of 2020 or early 2021.
- OSE Immunotherapeutics received a grant of up to €200,000 from Nantes Metropole, the metropolitan area of Nantes community, dedicated to the development of its prophylactic vaccine CoVepiT.

New data on ***CLEC-1****,* ***BiCKI®*** *and* ***BiCKI®-IL-7*** *presented at the 2020 American Association of Cancer Research (AACR) Virtual Annual Meeting II held end of June 2020.*

- Identification and characterization 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 Chiffoleau *(Center for Research in Transplantation and Immunology, UMR - INSERM 1064, Nantes University Hospital).*

- Preclinical progress has confirmed that bispecific platform BiCKI®, and especially bifunctional therapy targeting PD-1 and IL-7, BiCKI®-IL-7, have the potential to 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.

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 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, planned to start in Q4 2020, 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.

H1 2020 Results

The key figures of the 2020 consolidated half-year results are reported below:

In k€	June 30, 2020	June 30, 2019
Operating result	(7,085)	3,918
Net result	(3,114)	514

In k€	June 30, 2020	December 31, 2019
Available cash*	22,920	25,842
Consolidated balance sheet	90,745	88,933

As of June 30, 2020, available cash* amounted to €22.9 million, giving a financial visibility until Q3 2021.

In May, OSE received €7 million non-dilutive loan agreement guaranteed by the French State, signed with a pool of French banks, providing the company with further financing to advance its clinical and preclinical development programs. This loan is part of a loan facility guaranteed by the French State ("Prêt Garanti par l'Etat") and was implemented in the context of the COVID-19 pandemic.

During the first semester of 2020, additional cash influx of €3.1 million has been generated by the payment of the 2019 research tax credit.

This available cash will enable the Company to finance its clinical development costs and R&D costs for earlier stage products.

The turnover amounted to €5.8 million due to the reinvoicing of development costs of BI 765063 to the Company's partner Boehringer Ingelheim, the sales of OSE-127 vials to its partner Servier and the spreading of a milestone payment triggered by the exercise of option 1 under the two-step option agreement with Servier in February 2019.

During the first half of 2020, the Company recorded a consolidated net result of - €3,1 million.

Current operating expenses were €12.9 million (versus €12 million for the same period of 2019) of which 77% are related to R&D.

**Available cash and cash equivalents and current financial assets*

The Board of Directors of September 17, 2020 has approved the Company's semester accounts as of June 30, 2020. The full "Semester financial report" (Regulated information) is available on : **https://ose-immuno.com/en/financial-statements/**. The consolidated accounts have been subject to a limited review by the Statutory Auditors.

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.
  In **Phase 2 in pancreatic cancer** (TEDOPaM, sponsor GERCOR) in monotherapy and in combination with checkpoint inhibitor Opdivo®.
- **BI 765063** (OSE-172, anti-SIRPα mAb on SIRPα/CD-47 pathway): developed in **partnership with Boehringer Ingelheim**; myeloid checkpoint inhibitor in **Phase 1 in advanced solid tumors**.
- **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 Q4 2020.
- **FR104** (anti-CD28 monoclonal antibody): **positive Phase 1 results**; **Phase 2-ready asset in autoimmune diseases or in transplantation**.
- **BiCKI®**: **bispecific fusion protein** platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2nd generation of PD-(L)1 inhibitors to increase **antitumor efficacity**. **Additional innovative research programs**.
- **CoVepiT**: a **prophylactic vaccine** against **COVID-19**, developed using SARS-CoV-2 optimized neo-epitopes. **Positive preclinical and human ex vivo results in August 2020**, **clinical trial expected to start end of 2020/early 2021**.
  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/**
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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 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.

CONSOLIDATED PROFIT & LOSS

In K€	H1 2020	H1 2019
Turnover	5,849	15,979
OPERATING INCOME - RECURRING	**5,849**	**15,979**
Research & Development expenses	(9,087)	(9,189)
Overhead expenses	(2,672)	(2,199)
Expenses related to share-based payments	(1,176)	(673)
OPERATING PROFIT/LOSS - RECURRING	**(7,085)**	**3,919**
Other operating income and expenses	0	0
OPERATING RESULT	**(7,085)**	**3,918**
Financial income	28	143
Financial expenses	(150)	(74)
PROFIT/LOSS BEFORE TAX	**(7,208)**	**3,987**
INCOME TAX	**4,094**	**(3,472)**
CONSOLIDATED NET RESULT	**(3,114)**	**514**
Of which consolidated net result attributable to shareholders	***(3,114)***	***514***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	15,087,010	14,820,345
- The basic and diluted result per common share (€/share)	(0.21)	0.03
- Diluted result per share	(0.21)	0.03
In K€	**H1 2020**	**H1 2019**
NET RESULT	**(3,114)**	**514**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(16)	(17)
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	1	(24)
Other comprehensive income in the period	**(15)**	**(41)**
GLOBAL PROFIT/LOSS	**(3,129)**	**473**

CONSOLIDATED BALANCE SHEET

ASSETS in K€	June 30, 2020	December 31, 2019
NON-CURRENT ASSETS		
R&D expenses acquired	52,600	52,600
Tangible assets	993	1,009
Rights of use	3,095	1,692
Financial assets	607	287
Deferred tax assets	167	283
TOTAL NON-CURRENT ASSETS	***57,463***	***55,871***
CURRENT ASSETS		
Trade receivables	3,318	747
Other current assets	7,045	6,474
Cash and cash equivalents	22,920	25,842
TOTAL CURRENT ASSETS	***33,283***	***33,062***
TOTAL ASSETS	**90,745**	**88,933**

EQUITY & LIABILITIES in K€	June 30, 2020	December 31, 2019
SHAREHOLDERS' EQUITY		
Stated capital	3,089	3,001
Share premium	21,583	21 ,670
Merger premium	26,827	26,827
Treasury stock	(143)	(148)
Reserves and retained earnings	8,181	11,838
Consolidated result	(3,114)	(4,652)
TOTAL SHAREHOLDERS' EQUITY	***56,423***	***58,536***
NON-CURRENT DEBTS		
Non-current financial liabilities	16,152	9,211
Non-current lease liabilities	2,570	1,413
Non-current deferred tax liabilities	802	5,066
Non-current provisions	460	377
TOTAL NON-CURRENT DEBTS	***19,984***	***16,067***
CURRENT DEBTS		
Current financial liabilities	532	548
Current lease liabilities	575	309
Trade payables	7,810	6,918
Corporate income tax liabilities	3	20
Social and tax payables	2,465	1,723
Other debts	2,955	4,812
TOTAL CURRENT DEBTS	***14,339***	***14,330***
TOTAL LIABILITIES	**90,745**	**88,933**