OSE Immunotherapeutics Reports First Half 2019 Results and Provides a Corporate Update

- **Major clinical progress with four differentiated therapeutic programs in immuno-oncology and autoimmune diseases;**
- **Received €25 M in milestones from collaborations with Servier and Boehringer Ingelheim**
- **€16 M turnover and €26.5 M available cash as of June 30, 2019 covering financial needs until the end of 2020;**
- **Continued success as a result of dynamic partnership business model based on innovative products that generates non-dilutive revenues and finances R&D programs.**

Nantes, France, September 5, 2019 – 6 p.m. CET - OSE Immunotherapeutics (ISIN: FR0012127173; Euronext: OSE) today reported its consolidated half-year financial results as of June 30, 2019 and provided an update on the key milestones reached during H1 2019.

"Over the past 18 months, the Company has shown positive turnover and financial results, providing a solid financial position. H1 2019 has seen continued execution of our partnership-focused business model with a number of key milestones achieved on our innovative portfolio in immuno-oncology and autoimmune diseases. We are very pleased with the progress of our products developed in collaboration with Boehringer Ingelheim (BI 765063) and with Servier (OSE-127) which generated an additional €25 million in milestone payments during H1 2019. We are actively pursuing our clinical advances with Tedopi®, in Phase 3 in non-small cell lung cancer after failure to previous immune checkpoint inhibitors and in Phase 2 in combination with Opdivo® in pancreatic cancer, and continue to explore partnership opportunities for FR104, ready to enter Phase 2 in autoimmune diseases or in transplantation. These achievements, along with multiple ongoing clinical studies aim to demonstrate the potential value of OSE assets in multiple indications, clearly positioning OSE Immunotherapeutics as an emerging leader in the immuno-oncology and autoimmune spaces", said Alexis Peyroles, chief executive officer of OSE Immunotherapeutics.

Major clinical progress with four differentiated therapeutic programs in immuno-oncology and autoimmune diseases

Tedopi®, a combination of 10 neoepitopes intended to induce specific T lymphocyte activation, is OSE's most advanced product and is currently in Phase 3 in non-small cell lung cancer (NSCLC) following failure on immune checkpoint inhibitor treatment (PD-1/PD-L1), called Atalante 1. Tedopi® is also in Phase 2 in combination with Opdivo® (nivolumab) in patients with pancreatic cancer, a trial sponsored by the GERCOR cooperative group in oncology and supported by Bristol-Myers Squibb.

- On June 20, 2019, the Independent Data Monitoring Committee (IDMC) reviewed safety data from the Atalante 1 Phase 3 trial in NSCLC and recommended the continuation of patient recruitment,

without any modifications. NSCLC is a large patient population with no currently approved therapeutic option, and with strong clinical need.

- The Japanese Patent Office and the United States Patent and Trademark Office (USPTO) have issued, respectively in January and June 2019, notice of allowance for a new patent family related to Tedopi®, for use in the treatment of brain metastasis originating from cancers, including NSCLC, in HLA-A2 positive patients. These patents will provide protection covering the use of Tedopi® in that indication until 2034, further strengthening Tedopi's intellectual property in immuno-oncology.

BI 765063 (formerly OSE-172), a myeloid checkpoint inhibitor and selective SIRPα antagonist, being developed in partnership with Boehringer Ingelheim, is in Phase 1 testing in advanced solid tumors.

- In June 2019, the first patient was enrolled and dosed in the first-in-human Phase 1 trial, 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. 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, is in Phase 1 for the treatment of autoimmune diseases. This first-in-human dose-escalation study aims to evaluate the safety and tolerability of single- and multiple-ascending intravenous and subcutaneous doses of OSE-127 in 63 healthy volunteers, the first of which were dosed in December 2018.

- In May 2019, the USPTO issued a first notice of allowance for a patent application covering OSE-127 that will cover it until at least 2035. This new patent validates the product's novel and differentiated mechanism of action as an IL-7R full-antagonist, which has been shown to induce a powerful antagonistic effect on effector T lymphocytes responsible for causing autoimmune pathologies.

FR104, a monoclonal antibody antagonist of CD28, is a Phase-2 ready asset with potential to be developed in either autoimmune disease or in transplant surgery.

- In April 2019, the Canadian Intellectual Property Office granted a patent that covers the product and its therapeutic applications in T-lymphocyte-mediated autoimmune diseases, chronic inflammatory diseases and graft applications. At the same time, the USPTO has also issued a notice of allowance providing additional protection covering the use of FR104 in the treatment of T-lymphocyte-mediated chronic inflammatory diseases. Therapeutic applications of FR104 are thus covered through 2031.

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

- As a results of its partnership agreements, OSE Immunotherapeutics has received €25 million in milestone payments during H1 2019 (a €10 million payment from Servier upon exercise of first of two steps of a global licensing option agreement for OSE-127; €15 million in payments from Boehringer

Ingelheim upon Clinical Trial Authorization and first dosing of a patient in the Phase 1 clinical trial of BI 765063).

- OSE Immunotherapeutics is evaluating the best options for continuing sustainable development of FR104, a Phase 2-ready asset, in autoimmune diseases or in transplantation, including worldwide partnering opportunities. Furthermore, the Company is exploring partnership opportunities for its most advanced product Tedopi, in Phase 3 in NSCLC and in Phase 2 in pancreatic cancer.

Research & Development

Based on OSE's diverse scientific and technological platforms (neoepitopes, agonist or antagonist monoclonal antibodies), the Company is pursuing advancement of new innovative research programs.

- The Company disclosed in March 2019 its novel bispecific checkpoint inhibitor (BiCKI®) platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. BiCKI represents the second generation of PD-(L)1 inhibitors that have been used to increase antitumor efficacy in hard to treat cancers by addressing untapped immune evasion mechanisms.
- A new research collaboration agreement was concluded in March 2019 with premier cancer research hospital, Léon Bérard Cancer Center in Lyon, France, to use artificial intelligence-based bioanalysis and bioinformatics to analyse gene expression in the human tumor microenvironment and the composition of tumor infiltrates. The findings from this collaboration will be used for the selection and validation of innovative targets for early development of new drug candidates from the platform of bispecific fusion proteins targeting PD-1 and innovative targets (BiCKI).
- OSE will participate to the "DC-Target" project, selected by the French National Research Agency in July 2019 as part of the "AAPG 2019" call for proposals. This research program, coordinated by the Léon Bérard Cancer Center, aims to identify new targets of therapeutic interest expressed by myeloid cells (tumor associated macrophages, myeloid-derived suppressive cells and dendritic cells) through in depth characterization of the role of each cell by single cell RNAseq (scRNAsed – Cellenion) and gene editing.

Scientific publications

- In April 2019, an article entitled: *"IL-7 receptor influences anti-TNF responsiveness and T cell gut homing in inflammatory bowel disease,"* was published in the *Journal of Clinical Investigation* (JCI), presenting data on OSE -127, the Company's full-antagonist monoclonal antibody targeting IL-7R. The article reports on research led by the OSE Immunotherapeutics team, in collaboration with multiple international expert partners, that further supports the product's potential for the treatment of chronic inflammatory bowel diseases and confirms the novel and differentiated mechanism of action of OSE-127, currently being investigated in an ongoing Phase 1.
- In July 2019, the Company announced a first publication in the *American Journal of Transplantation* on the role of SIRPα, a receptor expressed by myeloid lineage cells and the target of selective SIRPα antagonist BI 765063 (OSE-172). The article, entitled *"SIRPα/CD47 axis controls the maintenance of transplant tolerance sustained by myeloid-derived suppressor cell,"* describes findings showing the role of the SIRPα/CD47 axis in the induction and maintenance of acquired

immune tolerance and highlights the mechanism of action of innovative myeloid checkpoint inhibitor BI 765063, currently in Phase 1 testing.

General Meeting

- On June 26, 2019, the Company's shareholders approved the appointment of Nicolas Poirier, Ph.D., as director, representing the employee shareholders. Nicolas Poirier has been chief scientific officer of OSE Immunotherapeutics since 2016. His role has been to implement innovative therapeutic strategies on new targets and pathways in immunology addressing severe pathologies with high therapeutic need, thus making a robust contribution to the Company's growth. Along with his R&D team, Dr. Poirier continues pursuing the identification of novel preclinical targets and translating them into first-class clinical-stage immunotherapies.

H1 2019 Results

The key figures of the 2019 consolidated half-year results are reported below:

In k€	June 30, 2019	June 30, 2018
Operating result	3,918	10,230
Net result	514	8,877

In k€	June 30, 2019	December 31, 2018
Available cash*	26,527	12,433
Consolidated balance sheet	94,950	76,903

As of June 30, 2019, available cash* amounted to €26.5 million, giving a financial visibility until the end of 2020.

During the first semester of 2019, additional cash influx of €25 million has been generated by milestone payments related to partnerships (€15 million from Boehringer Ingelheim upon CTA for the Phase 1 trial with BI 765063 and upcoming first patient dosed and €10 million from Servier upon exercising of the first option under the two-step option within global license agreement).

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

The turnover amounted to €16 million due to the upfront payment from the collaboration agreement with Boehringer Ingelheim. During the first half of 2019, the Company recorded a consolidated net result of €514 K.

Current operating expenses were €12 million (versus €10.3 million for the same period of 2018) of which 84% are related to R&D. They include €9.2 million of R&D expenses, in line with the broadening and progress of OSE's pipeline.

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

The Board of Directors of September 5, 2019 has approved the Company's semester accounts as of June 30, 2019. The full "Semester financial report" (Regulated information) is available on : **http://ose-immuno.com/en/rapports-financiers-et-document-de-reference/**. 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 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) after checkpoint inhibitor failure (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.

Click and follow us on Twitter and LinkedIn

Contacts

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

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

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

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.

CONSOLIDATED PROFIT & LOSS

In K€	H1 2019	H1 2018
Turnover	15,979	20,608
OPERATING INCOME - RECURRING	**15,979**	**20,608**
Research & Development expenses	(9,189)	(7,978)
Overhead expenses	(2,199)	(1,731)
Expenses related to share-based payments	(673)	(542)
OPERATING PROFIT/LOSS - RECURRING	**3,919**	**(10,357)**
Other operating income - Badwill	0	0
Other operating expenses	(0)	(127)
OPERATING RESULT	**3,918**	**10,230**
Financial income	143	27
Financial expenses	(74)	(174)
PROFIT/LOSS BEFORE TAX	**3,987**	**10,083**
INCOME TAX	**(3,472)**	**(1,207)**
CONSOLIDATED NET RESULT	**514**	**8,877**
Of which consolidated net result attributable to shareholders	***514***	***8,877***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	14,820,345	14,505,935
- The basic and diluted result per common share (€/share)	0.03	0.61
- Diluted result per share	0.03	0.57

In K€	H1 2019	H1 2018
NET RESULT	**514**	**8,877**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(17)	(13)
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	(24)	(4)
Other comprehensive income in the period	**(41)**	**(17)**
GLOBAL PROFIT/LOSS	**473**	**8,860**

CONSOLIDATED BALANCE SHEET

ASSETS in K€	June 30, 2019	December 31, 2018
NON-CURRENT ASSETS		
R&D expenses acquired	52,600	52,600
Tangible assets	993	904
Rights of use	1,828	
Financial assets	141	103
Deferred tax assets	276	272
TOTAL NON-CURRENT ASSETS	***55,838***	***53,879***
CURRENT ASSETS		
Trade receivables	1,178	2,253
Other current assets	6,921	3,834
Current tax eceivables	4,487	4,504
Current financial assets	2,965	2,861
Cash and cash equivalents	23,562	9,573
TOTAL CURRENT ASSETS	***39,112***	***23,024***
TOTAL ASSETS	**94,950**	**76,903**

EQUITY & LIABILITIES in K€	June 30, 2019	December 31, 2018
SHAREHOLDERS' EQUITY		
Stated capital	2,993	2,963
Share premium	21,678	21,708
Merger premium	26,827	26,827
Treasury stock	(149)	(168)
Reserves and retained earnings	10,096	4,934
Consolidated result	514	5,490
TOTAL SHAREHOLDERS' EQUITY	***62,770***	***61,754***
NON-CURRENT DEBTS		
Non-current financial liabilities	4,493	3,832
Lease non current liabilities	1,551	
Non-current deferred tax liabilities	5,189	2,050
Non-current provisions	291	233
TOTAL NON-CURRENT DEBTS	***11,523***	***6,074***
CURRENT DEBTS		
Current financial liabilities	656	628
Lease current liabilities	289	
Trade payables	6,247	6,555
Current tax liabilities	92	86
Other payables	1,281	1,231
Other debts and accruals	12,092	575
TOTAL CURRENT DEBTS	***20,657***	***9,075***
TOTAL LIABILITIES	**94,950**	**76,903**