OSE Immunotherapeutics Reports 2019 Financial Results and Provides Business Update Expectations for Potential Impact of COVID-19 on the Company's Clinical Development Activities

- **Strong clinical progress in lead assets Tedopi®, OSE-127 and BI 765063**
- **Bispecific antibody platform BiCKI®: First project selected, cytokine IL-7 to be paired with anti-PD-1**
- **€5 million milestone payment from Servier accelerated and now expected by the start of a Phase 2 with OSE-127 in Sjögren's syndrome**
- **FY 2019 turnover of €26 million**
- **2019 year-end cash position of €25.8 million**
- **Expected €3 million research tax credit and Servier milestone to provide funding until Q1 2021**

Nantes, France, March 26, 2020 – 6:00 p.m. CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today reported its consolidated annual financial results for 2019 and provided an update on key achievements, as well as the company's outlook for its agonist and antagonist immunotherapies for cancers and autoimmune diseases.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: *"The current COVID-19 situation is a major public health concern and also an important factor impacting our ongoing and upcoming clinical trials. Health agencies and expert groups have said in the past few days that the continuation of clinical trials in hospitals would be very disrupted due to the mobilization of medical teams, containment and the potential risks associated with the epidemic of COVID-19 for fragile patients. Our short-term priority is to do our part to ensure healthcare systems have the resources to fight COVID-19 and to reduce the demands on healthcare professionals, while safeguarding patients currently taking part in our clinical trials.*

"OSE Immunotherapeutics made significant clinical progress with our lead assets in immuno-oncology and auto-immune diseases in 2019 and early 2020.

"In 2019, our drug candidates being developed with partners Boehringer Ingelheim and Servier generated €25 million in milestone payments and both achieved key clinical milestones: initiation of the ongoing Phase 1 trial of myeloid checkpoint inhibitor BI 765063 in advanced solid tumors and completion of Phase 1 trial of anti-IL-7 receptor antagonist OSE-127 with positive results. Based on these results, two Phase 2 studies with OSE-127 are planned to start in 2020. Furthermore, a recent amendment to our license option agreement with Servier on OSE-127 confirms our partner's commitment and strong belief in the potential of the product.

"In 2020, we plan to continue the company's value creation by advancing our clinical and preclinical programs while adapting our organization to the COVID-19 crisis. In line with our business model, we will continue to secure financial resources to invest in R&D to discover and develop novel therapeutics for patients. In particular, the milestone payment associated with the recently-amended agreement with Servier on OSE-127 will reinforce our cash position and flexibility

to progress on our development strategy. With these considerations in mind, we have provided expectations for the impact that COVID-19 could have on our clinical programs, given the current assessment of the situation. We continue to monitor the situation and will provide updates on any changes in timelines as they arise."

2019 KEY ACHIEVEMENTS

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 Immunotherapeutics' most advanced drug candidate and is currently in a Phase 3 pivotal clinical trial, called Atalante 1, to treat non-small cell lung cancer (NSCLC) following failure of immune checkpoint inhibitor treatment (PD-1/PD-L1). Due to the COVID-19 outbreak situation and associated considerations of the safety of trial participants, compliance with good clinical practice (GCP), and risks to trial integrity during the COVID-19 pandemic following the specific guidelines of regulatory agencies, OSE Immunotherapeutics is reviewing the potential impact of this outbreak on the Atalante 1 trial. The Company will provide an update on the status of this review and on the results of the trial's pre-defined step 1 as soon as possible in the coming next weeks.

Tedopi® also is in Phase 2 development in combination with Opdivo® (nivolumab) in patients with pancreatic cancer, called TEDOPaM, a trial sponsored by the GERCOR cooperative group in oncology and supported by Bristol Myers Squibb. Patients screening and accrual in the TEDOPaM study are expected to be impacted by the COVID-19 situation in the coming months.

The Company will maintain an open dialogue with updates to these and other trials as more clarity arises on the overall impact this public health crisis has on expected timelines.

- Tedopi®'s intellectual property in immuno-oncology in HLA-A2 positive patients has been further strengthened and extended by notice of allowance in Japan and in the U.S. for a new patent family related to Tedopi® for use in the treatment of brain metastasis originating from cancers, including NSCLC. It was also strengthened by issuance in Japan of a new patent family protecting the product's method for inducing early T-lymphocyte memory response for use in the treatment of cancer.
- A new licensing deal was signed 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 and HalioDx, an immuno-oncology diagnostic company, have initiated a collaboration to conduct a translational investigation of immune biomarkers as part of the ongoing Phase 3 clinical trial of Tedopi® in NSCLC patients. This investigation is focused on identifying potential immune biomarkers in NSCLC. Based on the data generated, the collaboration aims at defining the profile of responder patients to Tedopi® treatment in advanced lung cancer.

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

- The first patient was enrolled and dosed in June 2019 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. The trial is expected to be

impacted by the COVID-19 situation with regard to the screening and accrual of new patients in Q2 2020. Further updates will be made when available

- OSE Immunotherapeutics received a €5.4 million payment from Bpifrance triggered by the successful completion of development milestones related to its collaborative program, called EFFI-CLIN, focused on evaluating BI 765063.

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

- The United States Patent and Trademark Office (USPTO) issued a first notice of allowance for a patent application covering OSE-127 and protecting the product until at least 2035. This new patent validates the product's novel and differentiated mechanism of action as the only full-antagonist of IL-7R in clinical development, a target which has been shown to induce a powerful antagonistic effect on effector T-lymphocytes responsible for causing autoimmune pathologies.
- The Phase 1 clinical study of OSE-127 was completed end of 2019 with positive results showing a good safety and tolerability profile for the product. 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 (OSE sponsored) and Sjögren's syndrome (Servier sponsored).
- 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 planned in 2020 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 pratices during clinical research and patients' care.

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

- 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 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 revenues to broaden R&D programs

- OSE Immunotherapeutics received €25 million in milestone payments during H1 2019 (€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 global partnership opportunities for Tedopi®, currently in Phase 3 in NSCLC and in Phase 2 in pancreatic cancer.

Research & Development

Focused on novel target discovery to generate innovative agonists or antagonists of the immune response, the Company is pursuing advancement of new innovative research programs.

- The Company disclosed 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. 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.
- A new research collaboration agreement was concluded with premier cancer research hospital, Léon Bérard Cancer Center in Lyon, France, to use artificial intelligence-based bioanalysis and bioinformatics to analyze 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 Immunotherapeutics' "DC-Target" project was selected by the French National Research Agency to be awarded a grant of up to €800,000 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 through in-depth characterization of the role of each cell by single cell RNAseq (scRNAseq - Cellenion) and gene editing.
- Early 2020, the Company signed a drug development collaboration with innovative deep technology French start-up MAbSilico to use artificial intelligence-based solution for the development of monoclonal antibodies, including novel bispecific antibodies (BiCKI® platform).

Governance

- Nicolas Poirier, Ph.D., Chief Scientific Officer of OSE Immunotherapeutics, was additionally appointed as Director, representing the employee shareholders.
- Walter Flamenbaum resigned from the Company's Board of Directors on February 19, 2020.

2019 RESULTS

A meeting of the Board of Directors of OSE Immunotherapeutics was held on March 26, 2020 according to the ordinance n° 2020-321. Following the opinion of the Audit Committee, the Board approved the annual and consolidated financial statements prepared under IFRS at 31 December 2019.

The key figures of the 2019 consolidated annual results are reported below (and presented in the attached tables):

In k€	December 31, 2019	December 31, 2018
Current operating result	(1 469)	4,974
Operating result	(1 472)	4,847
Net result	(4,652)	5,490
Available cash*	25,842	12,433
Consolidated balance sheet	88,933	76,903

As of December 31, 2019, the Company's available cash* amounted to €25.8 million, giving financial visibility until Q1 2021 taking into account €3 million from research tax credit and an additional planned milestone payment of €5 million from Servier, following amendment to the global license option agreement on OSE-127, and expected at the start of a Phase 2 in Sjögren's syndrome.

During 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). Moreover, the Company received a €5.4 million payment from Bpifrance triggered by the successful completion of development milestones related to its collaborative program EFFI-CLIN, program focused on evaluating BI 765063.

This available cash will enable the Company to finance its clinical development costs and R&D costs on earlier stage products until Q1 2021 at least. If there are significant delays or clinical trial holds as a result of COVID-19, our cash runway will be extended beyond the current Q1 2021 projection, given that the bulk of our expenses are mainly related to clinical development expenditures.

The turnover amounted to €26 million due to the milestone payments from the collaboration agreement with Boehringer Ingelheim and Servier. During 2019, the Company recorded a consolidated operating loss of (€1.5) million.

Current operating expenses were €27.4 million (€19.5 million in 2018) of which 81% related to R&D. Among R&D expenses of €21.6 million, 85% are dedicated to the Company's ongoing clinical projects, in line with the broadening and progress of its pipeline.

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

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 a two-step licensing option agreement. The Phase 1 clinical phase of OSE-127 is completed and has shown positive results; two independent Phase 2 studies planned in ulcerative colitis (OSE sponsor) and Sjögren's syndrome (Servier sponsor) to start in 2020, subject to the evolution of the COVID-19 situation.

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 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.

APPENDICES

CONSOLIDATED PROFIT & LOSS

P&L IN K€	December 31, 2019	December 31, 2018
Turnover	25 952	24 456
Other operating income	0	0
Total Revenues	**25 952**	**24 456**
Research and development expenses	(21 655)	(15 057)
Overhead expenses	(3 898)	(3 448)
Expenses related to shares payments	(1 868)	(977)
OPERATING PROFIT/LOSS - CURRENT	**(1 469)**	**4 974**
Other operating products (badwill)	0	0
Other operating expenses	(2)	(127)
OPERATING PROFIT/LOSS	**(1 472)**	**4 847**
Financial products	221	86
Financial expenses	(213)	(227)
PROFIT/LOSS BEFORE TAX	**(1 464)**	**4 707**
Income Tax	(3 188)	783
NET PROFIT/LOSS	**(4 652)**	**5 490**
Of which consolidated net result attributable to shareholders	***(4 652)***	***5 490***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	**14 892 496**	**14 634 760**
Basic earnings per share	**(0,31)**	**0,38**
Diluted earnings per share	**(0,31)**	**0,35**

IN K€	2019	2018
NET RESULT	**(4652)**	**5 490**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(43)	(42)
Amounts not to be recycled in the income statement:	(37)	12
Actuarial gains and losses on post-employment benefits		
Other comprehensive income in the period	**(80)**	**(30)**
GLOBAL PROFIT/LOSS	**(4 732)**	**5 460**

CONSOLIDATED BALANCE SHEET

ASSETS IN K€	December 31, 2019	December 31, 2018
Intangible assets	52 600	52 600
Tangible assets	1 009	904
Right-of-use assets	1 692	0
Financial assets	287	103
Differed tax assets	283	272
TOTAL NON CURRENT ASSETS	***55 871***	***53 879***
Trade receivables	747	2 253
Other current assets	6 474	3 834
Tax accounts receivables	0	4 504
Current financial assets	0	2 861
Cash and cash equivalents	25 842	9 573
TOTAL CURRENT ASSETS	***33 062***	***23 024***
TOTAL ASSETS	**88 933**	**76 903**

EQUITY & LIABILITIES in K€	December 31, 2019	December 31, 2018
SHAREHOLDERS' EQUITY		
Stated capital	3 001	2 963
Share premium	21 670	21 708
Merger premium	26 827	26 827
Treasury stock	(148)	(168)
Reserves and retained earnings	11 838	4 934
Consolidated result	(4 652)	5 490
TOTAL SHAREHOLDERS' EQUITY	***58 536***	***61 754***
NON-CURRENT DEBTS		
Non-current financial liabilities	9 211	3 832
Non-current lease liabilities	1 413	0
Non-current deferred tax liabilities	5 066	2 010
Non-current provisions	377	233
TOTAL NON-CURRENT DEBTS	***16 067***	***6 074***
CURRENT DEBTS		
Current financial liabilities	548	628
Current lease liabilities	309	0
Trade payables	6 918	6 555
Corporate income tax liabilities	20	86
Social and tax payables	1 723	1 231
Other debts and accruals	4 812	575
TOTAL CURRENT DEBTS	***14 330***	***9 075***
TOTAL LIABILITIES	**88 933**	**76 903**

CONSOLIDATED CASH FLOW STATEMENT

In K€		December 31, 2019	December 31, 2018
	CONSOLIDATED RESULT	**(4 652)**	**5 490**
+/-	Depreciation, amortization and provision expenses	323	116
+	Amortization on "right-of-use"	251	0
+/-	Shares based payments (1)	1 511	845
	CASH FLOW BEFORE TAX	**(2 568)**	**6 450**
+	Financial charges	30	(783)
-	Income tax expenses	3 188	0
-	Tax paid	(70)	
+/-	Working capital variation (2)	8 555	(4 590)
	CASH FLOW FROM OPERATING ACTIVITIES (A)	**9 135**	**1 077**
-	Tangible assets increase	(336)	(593)
+/-	Financial assets variation	2 861	40
+/-	Mutual finds units accounted in current financial assets	34	22
+/-	Loans and advances variation	(184)	(27)
	CASH FLOW FROM INVESTING ACTIVITIES (B)	**2 375**	**(558)**
+	Capital increase (including share premium)	0	23
+/-	Own shares transactions	0	(67)
+	Warrant subscription	0	7
+	Loans subscription	5 628	0
-	Loans repayment	(455)	(485)
-	Lease debt repayment (3)	(251)	0
-	Financial charges	164	(71)
	CASH FLOW FROM FINANCING ACTIVITIES (C)	**4 759**	**(592)**
+/-	Currency translation transactions (D)	0	0
	CASH VARIATION E = (A + B + C + D)	**16 269**	**(73)**
	CASH OPENING BALANCE (F)	9 573	9 646
	CASH CLOSING BALANCE (G)	25 842	9 573
	DIFFERENCE: E (G-F)	0	0

(1) Warrants and free shares awards granted in 2019 and valuated for 1 511 K€

(2) Mainly explained by:

- *Decrease of trade receivable for 1 506 K€*
- *Decrease of other current assets for 1 864 K€*
- *Increase of trade accounts payable for 363 K€*
- *Increase of social and tax payable for 493 K€*
- *Increase of other debts for 4 237 K€*

(3) Explained by IFRS16 application, which corresponds to reimbursement of lease debt for 251 K€

As of December 31, 2019, the available cash is as follows:

In K€	December 31, 2019	December 31, 2018
Cash & equivalents according to IAS 7	25 842	9 573
Current financial assets	0	2 861
AVAILABLE CASH	**25 842**	**12 433**