OSE Immunotherapeutics Reports 2018 Financial Results and Business Update

- **Four differentiated therapeutic programs progressing through clinical studies in immuno-oncology and autoimmune diseases**
- **OSE's partnership business model based on innovative products; Multiple validating partnering milestones generated €35 million in non-dilutive funds from April 2018 to March 2019**
- **Turnover of €24.5 million and net profit of €5.5 million**
- **2018 year-end cash position of €12.4 million and additional milestone payments from Servier and Boehringer Ingelheim received in 2019 provide funding until end of 2020**

NANTES, France, March 28, 2019, 6:00 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today reported its consolidated annual financial results as of December 31, 2018 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, *"OSE Immunotherapeutics achieved a number of important milestones in 2018, including expanding the clinical investigation of our lead product Tedopi, which is now being studied in Phase 3 and Phase 2 trials. We have further validated our business model by signing a landmark partnership deal with Boehringer Ingelheim for BI 765063 (OSE-172). In addition, we regained full control of FR104, a Phase 2-ready therapeutic candidate with broad potential to treat autoimmune diseases and secured preclinical validation of mechanisms of action for OSE-127 and BI 765063, both now in clinical phase status. These achievements, with multiple first- or best-in-class assets in clinical testing in multiple indications, provide a solid foundation to further accelerate OSE's growth as an emerging leader in the immuno-oncology and autoimmune spaces in 2019."*

KEY ACHIEVEMENTS

- **Tedopi® (neoepitopes)**
  - **Progressed ongoing Phase 3 clinical trial in non-small cell lung cancer (NSCLC) after failure with PD-1/PD-L1 immune checkpoint inhibitors.**
  - **Received Clinical Trial Authorization (CTA) for a Phase 2 trial in pancreatic cancer in combination with checkpoint inhibitor Opdivo®.**

- **BI 765063/OSE-172 (selective SIRPa-antagonist and myeloid checkpoint inhibitor)**
  - **Entered global immuno-oncology agreement with Boehringer Ingelheim to develop BI 765063 in solid tumors. Assuming all milestones are met, OSE stands to receive more than €1.1 B.**
  - **Received CTA for a Phase 1 trial in advanced solid tumours.**
  - **Set to receive milestone payments of a total of €15 M upon CTA receipt for the Phase 1 trial and the upcoming first dosing of a patient.**

- **BICKI®, novel bispecific checkpoint inhibitor platform technology**
  - **Unveiled a new bispecific fusion protein platform built on the key backbone component anti-PD-1 and targeting innovative targets.**

- **OSE-127 (IL-7R antagonist)**
  - **Received CTA for a Phase 1 trial for the treatment of autoimmune diseases and announced that the first healthy volunteers were dosed.**
  - **Awarded milestone payment of €10 M (€12 M VAT included) upon exercise of the first option exercised by Servier under the two-step option within the global license agreement.**

FINANCIAL HIGHLIGHTS

- **Turnover of €24.5 M due to the signature of a global license and collaboration agreement with Boehringer Ingelheim in April 2018 and the method of revenue recognition used for Servier upfront under the license agreement.**
- **Net profit of €5.5 M including a research tax credit of €4.8 M.**
- **Available cash as of December 31, 2018 of €12.4 M. Additional €10 M cash revenues received in early 2019 due to milestone payments related to partnerships with Servier; Additional cash influx of €15 M expected from Boehringer Ingelheim in the form of a milestone payment upon dosing of first patient in the Phase 1 trial of BI 765063 (OSE-172).**
- **Financial viability until end of 2020.**

KEY 2018 ACHIEVEMENTS

Tedopi®*, combination of optimized neoepitopes that induce specific T lymphocyte activation in immuno-oncology, in advanced lung cancer and in pancreatic cancer*

- Progressed an ongoing Phase 3 trial in patients with advanced and metastatic NSCLC who have failed a previous treatment with immune checkpoint inhibitors in Europe, in the U.S. and in Israel.
- Received a €435k grant from Bpifrance through the Eurostars European Programme to lead a research program within a consortium of five partners. The project aims to validate an immune algorithm specific to Tedopi® and establish precision medicine targeting for the product. It will be conducted in conjunction with the Phase 2 clinical trial for Tedopi® in pancreatic cancer.
- Received CTA by the French health agency (November 2018) for a Phase 2 trial evaluating Tedopi® in combination with Bristol-Myers Squibb's Opdivo® (nivolumab), an immune checkpoint inhibitor, versus Folfiri (a combination chemotherapy with folinic acid, fluorouracil and irinotecan) in advanced or metastatic pancreatic cancer. Oncology group GERCOR is sponsoring the clinical trial as part of PRODIGE intergroup.

BI 765063 (OSE-172)*, SIRPa antagonist and checkpoint inhibitor targeting suppressive myeloid/macrophage cells, in various solid tumors*

- Entered into a global license and collaboration agreement with Boehringer Ingelheim in April 2018 to develop checkpoint inhibitor BI 765063 (OSE-172) in advanced solid tumors.

- In March 2019, OSE was granted French and Belgian clinical trial authorization (CTA) to initiate a Phase 1 clinical trial of BI 765063 administered as a single agent and in combination with Boehringer Ingelheim's monoclonal antibody PD-1 antagonist BI 754091, a lymphocyte T checkpoint inhibitor.
- Under the terms of the agreement, OSE has received a €15 M upfront payment from Boehringer Ingelheim; the clinical trial authorization received in March 2019 and the upcoming first dosing of a patient has triggerred milestone payments of a total of €15 M. OSE Immunotherapeutics stands to receive from Boehringer Ingelheim more than €1.1 B upon reaching pre-specified development, registration and sales milestones, plus royalties on worldwide net sales.

***BiCKI®** platform, a novel bispecific checkpoint inhibitor platform targeting PD-1 and innovative targets*

- Disclosed its novel novel bispecific checkpoint inhibitor (BiCKI®) platform at the World Immunotherapy Congress (March 2019). This bispecific fusion protein platform is 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.

***OSE-127**, humanized monoclonal antibody antagonist of the interleukin-7 receptor (IL-7R), in inflammatory bowel diseases*

- Received Belgian CTA for a Phase 1 clinical trial (November 2018) for the treatment of autoimmune diseases and first healthy volunteers enrolled and dosed (December 2018).
- First option exercised under the two-step global option and license agreement exercised by Servier (February 2019) for clinical development and potential commercialization of OSE-127 to treat autoimmune diseases, which triggered a €10 M (€12 M VAT included) milestone payment to OSE from Servier.
- Published peer-reviewed article in *Nature Communications* highlighting the differentiated mechanism of action of OSE-127 as a full-antagonist of IL-7R that shows antigen-specific blockade of memory T cells

***FR104**, CD28-antagonist, in rheumatoid arthritis*

- Regained the worldwide rights to FR104 from Janssen Biotech, Inc. (November 2018) effective December 31, 2018. Janssen's decision to return the program to OSE Immunotherapeutics was based on its own internal strategic review and prioritization of its portfolio. OSE recovered FR104 all intellectual property rights that had been licensed to Janssen, data, filings and materials developed by Janssen relating to the FR104 program.
- OSE is currently evaluating the best options for continuing a sustainable development of FR104 including worldwide partnering opportunities. Positive results from FR104's Phase 1 proof of clinical concept study taken together with the preclinical safety profile and efficacy data in multiple preclinical models of autoimmune/inflammatory diseases further support continued clinical development of this Phase 2 ready asset.

GOVERNANCE

- Appointment of Dominique Costantini as chairman of the board of directors and appointment of Alexis Peyroles as chief executive officer.

2018 ANNUAL RESULTS

Meeting of Board of Directors of OSE Immunotherapeutics was held on March 28, 2019. Following the opinion of the Audit Committee, the Board approved the annual and consolidated financial statements prepared under IFRS at 31 December 2018.

The key figures of the 2018 consolidated annual results are reported below (and presented in the attached tables):

In k€	12/31/2018	12/31/2017
Current operating result	4 974	-12 626
Operating result	4 847	-12 626
Net result	5 490	-10 503
Available cash*	12 433	12 528
Consolidated balance sheet	76 903	77 353

As of December 31, 2018, available cash* amounted to €12.4 M. In addition, 2018 research tax credits amounted to €4.8 M.

During the first semester of 2019, additional cash influx of €25 M will be generated by milestone payments related to partnerships (€15 M from Boehringer Ingelheim upon CTA for the Phase 1 trial with BI 765063 and upcoming first patient dosed and €10 M 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.

Operating expenses amounted to €19.5 M (€19.3 M in 2017), of which 77 % are related to R&D. R&D expenses were up €15.1 M, in line with the broadening and progress of OSE's pipeline.

The consolidated balance sheet amounted to €76.9 M compared to €77.4 M as of December 31, 2017, which is quite stable.

* *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 autoimmmune 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®. FR104 (an anti-CD28 mAb) has successfully completed Phase 1 testing and has potential to treat autoimmune diseases. BI 765063 (OSE-172) (anti-SIRPa monoclonal antibody) is under a license and collaboration agreement with Boehringer Ingelheim ; this checkpoint inhibitor has received CTA from French and Belgian health authorities for a Phase 1 clinical trial in multiple cancer indications. BiCKI® is a bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) and targeting innovative targets. 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 Linkedln

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 2018, including the annual financial report for the fiscal year 2017, 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 KEUROS	12/31/2018	12/31/2017
Turnover	24 456	6 682
Other operating income	0	0
Total Revenues	**24 456**	**6 682**
Research and development expenses	(15 057)	(14 641)
Overhead expenses	(3 448)	(3 161)
Expenses related to shares payments	(977)	(1 505)
OPERATING PROFIT/LOSS - CURRENT	**4 974**	**(12 626)**
Other operating products (badwill)	0	0
Other operating expenses	(127)	0
OPERATING PROFIT/LOSS	**4 847**	**(12 626)**
Financial products	86	70
Financial expenses	(227)	(185)
PROFIT/LOSS BEFORE TAX	**4 707**	**(12 741)**
Income Tax	783	2 238
NET PROFIT/LOSS	**5 490**	**(10 503)**
Of which consolidated net result attributable to shareholders	***5 490***	***(10 503)***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	**14 634 760**	**14 360 869**
Basic earnings per share	**0,38**	**(0,73)**
Diluted earnings per share	**0,35**	

IN K€	2018	2017
NET RESULT	**5 490**	**(10 503)**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(42)	92
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	12	0
Other comprehensive income in the period	**(30)**	**93**
GLOBAL PROFIT/LOSS	**5 460**	**(10 410)**

CONSOLIDATED BALANCE SHEET

ASSETS IN KEUROS	12/31/2018	12/31/2017
Intangible assets	52 600	52 600
Tangible assets	904	429
Financial assets	103	77
Deffered tax assets	272	261
TOTAL NON CURRENT ASSETS	***53 879***	***53 367***
Trade receivables	2 253	127
Other current assets	3 834	5 715
Tax accounts receivables	4 504	5 615
Current financial assets	2 861	2 882
Cash and cash equivalents	9 573	9 646
Total current assets	23 024	23 986
TOTAL ASSETS	76 903	77 353

EQUITY & LIABILITIES in K€	12/31/2018	12/31/2017
SHAREHOLDERS' EQUITY		
Stated capital	2 963	2 898
Share premium	21 708	21 743
Merger premium	26 827	26 855
Treasury stock	(168)	(191)
Reserves and retained earnings	4 934	14 644
Consolidated result	5 490	(10 503)
TOTAL SHAREHOLDERS' EQUITY	**61 754**	***55 446***
NON-CURRENT DEBTS		
Non-current financial liabilities	3 832	4 296
Non-current deferred tax liabilities	2 010	2 866
Non-current provisions	233	247
TOTAL NON-CURRENT DEBTS	**6 074**	***7 410***
CURRENT DEBTS		
Current financial liabilities	628	589
Trade payables	6 555	8 776
Corporate income tax liabilities	86	1
Social and tax payables	1 231	1 060
Other debts and accruals	575	4 071
TOTAL CURRENT DEBTS	**9 075**	***14 497***
TOTAL LIABILITIES	**76 903**	**77 353**

CONSOLIDATED CASH FLOW STATEMENT

	In kEuros	2018	2017
	Consolidated result	**5 490**	**(10 503)**
+/-	Depreciation, amortization and provision expenses	116	123
-	Badwill	0	0
+	Derecognition of asset	0	0
+/-	Shares based payments (1)	845	1 373
+/-	Other calculated income and expenses	0	0
	Cash flow before tax	**6 450**	**(9 007)**
+	Financial charges	0	0
-	Income tax expenses (included deferred tax)	(783)	(2 238)
	CASH FLOW FROM OPERATING ACTIVITIES (A)	**5 668**	**(11 245)**
-	Paid taxes		
+/-	Working capital variation (2)	(4 590)	3 249
	CASH FLOW FROM INVESTING ACTIVITIES (D)	1 077	(7 996)
-	Tangible assets increase	(593)	(353)
+/	Current financial assets variation	22	(2)
+/-	Non-current financial assets variation	40	(10)
+/-	Change in scope of consolidation	0	0
+/-	Loans and advances variation	(27)	66
	CASH FLOW FROM INVESTING ACTIVITIES (E)	**(558)**	**(299)**
+	Capital increase (including share premium)	23	17
+/-	Own shares transactions	(67)	(67)
-	Capital increase and merger expenses	0	0
+	Warrant subscription (3)	7	18
+	Loans subscription	0	3 564
-	Loans repayment	(485)	(465)
-	Financial charges	(71)	(11)
+/-	Other flows from financing activities	0	0
	CASH FLOW FROM FINANCING ACTIVITIES (F)	**(592)**	**3 056**
+/-	Currency translation transactions (G)	0	0
	CASH VARIATION H = (D + E + F + G)	**(73)**	**(5 239)**
	CASH OPENING BALANCE (I)	9 646	14 885
	CASH CLOSING BALANCE (J)	9 573	9 646
	DIFFERENCE : H (J-I)	0	0

(1) Warrants and free shares awards granted in 2018 and valuated for 845 K€

(2) Mainly explained by :

- *Decrease of trade receivable for 2 126 k€*
- *Increase of other current assets for 1 881k€*
- *Increase of tax accounts receivable for 1 111 k€*

- *Adjustment of deferred tax for 783 k€*
- *Decrease of other non-current liabilities for 857k€*
- *Increase of non-current financial debt for 134k€*
- *Decrease of trade accounts payable for 2 221k€*
- *Increase of social and tax payable for 171 k€*
- *Decrease of other debts for 3 496 k€*
- *Deferred tax income for 74k€*

(3) 12 000 warrants subscripted with an unit value of 0.60€

As of December 31, 2018 the available cash is as follows:

In kEuros	12/31/2018	12/31/2017
Cash & equivalents according to IAS 7	9 573	9 646
Current financial assets	2 861	2 882
Available Cash	**12 433**	**12 528**