OSE Immunotherapeutics Reports First-Half 2018 Results and Provides a Corporate Update

Key Highlights:

- **Entered into a global immuno-oncology agreement in April 2018 with Boehringer Ingelheim to develop myeloid checkpoint inhibitor OSE-172 able to modulate the SIRPa/CD47 axis; a third strategic structuring partnership; assuming all development, registration and commercialization milestones are met, OSE stands to receive more than €1.1 billion**
- **Progressed international Phase 3 clinical trial of Tedopi® in patients with NSCLC who have failed a previous treatment with PD-1/PD-L1 immune checkpoint inhibitors, a population with a large unmet medical need**
- **Next steps focus on further clinical development of four products and on expansion of developmental pipeline**
- **Generated a net profit of €8.9 M due to the partnership signed with Boehringer Ingelheim**
- **Available cash as of June 30, 2018 of €18.6 M (including current financial assets of €2.9 M) and financial viability until H2 2019. Additional cash influx of €27 M could be generated by milestone payments related to partnerships**

Nantes, September 6, 2018 – 6:00PM CET– OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE), today reported its consolidated half-year financial results as of June 30, 2018 and provided an update on the key milestones reached during the 2018 first semester.

"With the completion of our license and collaboration agreement with Boehringer Ingelheim for OSE-172 in April, the first half 2018 marks an important second phase of growth for the Company, supported financially by our strategic partnerships and accompanied by a strengthened management team. Of significant note, the Company generated a financial profit of 8.9 million euros, which is a remarkable financial achievement for OSE," commented Alexis Peyroles, CEO of OSE Immunotherapeutics.

"We are focused on making significant clinical progress with four of our products, including three with our pharmaceutical partners: the initiation of a Phase 1/2 study of OSE-172 and a Phase 1 study of OSE-127 and the preparation of the entry into Phase 2 study with FR104. Furthermore, we were very pleased to receive the approval from the FDA and the EMA to actively advance the Tedopi® Phase 3 trial in advanced non-small cell lung cancer in patients with immune escape after checkpoint inhibitors, a population for which no approved treatment is currently available. We also plan to start a Phase 2 trial of Tedopi® combination therapy in pancreatic cancer by the end of 2018, a trial sponsored by the oncology group GERCOR. In the long term, our R&D teams are conducting innovative research to identify key targets of interest and develop new antibodies as candidates for clinical development in immuno-oncology," Mr. Peyroles continued.

Key First-Half 2018 Achievements

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

- Entered a global license and collaboration agreement with Boehringer Ingelheim to develop OSE-172. Under the terms of the agreement, OSE Immunotherapeutics has received a €15 million upfront payment from Boehringer Ingelheim, and will receive potential additional short-term milestones of up to €15 million upon initiation of a phase 1 clinical study. OSE Immunotherapeutics stands to receive more than €1.1 billion upon reaching pre-specified development, registration and sales milestones, plus royalties on worldwide net sales (cf. press release of April 4, 2018).
- Expected to initiate clinical phase by the end of 2018, with potential application in various solid tumors, in partnership with Boehringer Ingelheim.

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

- Progressed an ongoing Phase 3 trial in patients with advanced and metastatic non-small cell lung cancer (NSCLC) who have failed a previous treatment with immune checkpoint inhibitors in Europe and in the U.S. Received approval from Israeli competent authorities to expand enrolment of the trial in this additional country.

- Received a €435,000 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®, combined with a PD-1 checkpoint inhibitor, in pancreatic cancer. This study, sponsored by the oncology cooperative group GERCOR, is expected to initiate in 2018.

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

- Presented new preclinical data further supporting the potential of OSE-127 for the treatment of inflammatory bowel diseases at the annual congress of the American Association of Immunologists.
- Plans to initiate clinical phase in ulcerative colitis by the end of 2018, in partnership with Servier.

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

- Preparation for entry into a Phase 2 clinical trial in rheumatoid arthritis, in partnership with Janssen Biotech.

Moreover, the Company is continuing advancement of its innovative research program based on its several scientific and technological platforms (neoepitopes, agonist or antagonist monoclonal antibodies) positioned to fight cancer and autoimmune diseases.

THE TEAMS

- Appointed Dominique Costantini as chairman of the board of directors and appointment of Alexis Peyroles to chief executive officer, a natural and seamless evolution following three structuring license agreements driving the next steps of the Company's growth.
- Strengthened the management team with the additions of Bérangère Vasseur, M.D., chief medical officer immuno-oncology (broad experience in oncology development while at Roche and at several biotechnology companies) and Emilienne Soma, PharmD, Ph.D., director of pharmaceutical program development (experience in R&D management and in alliances in several biotechnology companies).

2018 Half-Year Results

The key figures of the 2018 consolidated half-year results are reported below:

In k€	06/30/2018	06/30/2017
Operating result	10 230	-7 336
Net result	8 877	- 6 340

In k€	06/30/2018	12/31/2017
Available cash*	18 647	12 528
Consolidated balance sheet	84 625	77 353

As of June 30, 2018, available cash* amounted to €18.6 million, giving a financial visibility until the second semester of 2019. Moreover, this cash could be reinforced by milestone payments provided by the partnerships with Boehringer Ingelheim, up to €15 million upon initiation of a Phase 1 of OSE-172, and with Servier, up to €12 million upon achievement of a new development step of OSE-127.

Of note, the development costs of the licensed projects are supported by the company's partners: totally by Boehringer Ingelheim for OSE-172 and by Janssen Biotech for FR104, and partially by Servier for OSE-127. In parallel, the two public grants obtained, EFFIMab for OSE-127 and EFFI-CLIN for OSE-172, enable to reinforce these funding.

The turnover amounted to €20.6 million, compared to €2.08 million as of June 30, 2017, due to the upfront payment from the collaboration agreement with Boehringer Ingelheim. During the first half of 2018, the Company recorded a net profit of €8.9 million.

Current operating expenses were €10.2 million, stable compared as of June 30, 2017. They include €8 million of R&D expenses during the first half of 2018. Over the same period of 2017, R&D expenses amounted to €7.9 million.

The consolidated balance sheet amounted to €84.6 million compared to €77.4 million as of December 31, 2017. This increase is mainly due to the cash received from the agreement with Boehringer Ingelheim.

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

The Board of Directors of September 6, 2018 has approved the Company's semester accounts as of June 30, 2018. 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 autoimmmune diseases. Neoepitopes innovation (Tedopi®) is today in Phase 3 in advanced lung cancers (NSCLC) after checkpoint inhibitors failure (anti PD-1 and anti PD-L1). A global license and collaboration agreement was signed in April 2018 with Boehringer Ingelheim to develop checkpoint inhibitor OSE-172 (anti-SIRPa monoclonal antibody), for the treatment of advanced solid tumors. An option to license was exercised in July 2016 by Janssen Biotech to continue clinical development of FR104 (an anti CD28 mAb) in auto-immune diseases after positive phase 1 results. A 2-step license option was signed in 2016 with Servier Laboratories to develop OSE-127 (monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor) to develop the product up to the completion of a phase 2 clinical trial planned in autoimmune bowel diseases; in parallel, Servier plans a development in the Sjogren's syndrome. The company has several scientific and technological platforms: neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical portfolio offers a diversified risk profile.

Click and follow us on Twitter and Linkedln

Contacts

OSE Immunotherapeutics
Sylvie Détry
Sylvie.detry@ose-immuno.com
+33 143 297 857

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 guaranteeing 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.

CONSOLIDATED PROFIT & LOSS

In K€	S1 2018	S1 2017
Turnover	20 608	2 849
Other recurring operating income	0	0
OPERATING INCOME - RECURRING	**20 608**	**2 849**
Research & Development expenses	(7 978)	(7 880)
Overhead expenses	(1 731)	(1 784)
Expenses related to share-based payments	(542)	(521)
OPERATING PROFIT/LOSS - RECURRING	**(10 357)**	**(7 336)**
Other operating income - Badwill	0	0
Other operating expenses	(127)	(0)
OPERATING RESULT	**10 230**	**(7 336)**
Financial income	27	32
Financial expenses	(174)	(38)
PROFIT/LOSS BEFORE TAX	**10 083**	**(7 342)**
INCOME TAX	**(1 207)**	**1 002**
CONSOLIDATED NET RESULT	**8 877**	**(6 340)**
Of which consolidated net result attributable to shareholders	***8 877***	***(6 340)***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	14 505 935	14 334 114
- The basic and diluted result per common share (€/share)	0,61	(0,44)

In K€	S1 2018	S1 2017
NET RESULT	**8 877**	**(6 340)**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(13)	19
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	(4)	7
Other comprehensive income in the period	**(17)**	**26**
GLOBAL PROFIT/LOSS	**8 860**	**(6 314)**

CONSOLIDATED BALANCE SHEET

ASSETS in K€	06/30/2018	12/31/2017
NON-CURRENT ASSETS		
Intangible assets	52 600	52 600
Tangible assets	817	429
Financial assets	58	77
Deferred tax assets	265	261
TOTAL NON-CURRENT ASSETS	***53 739***	***53 367***
CURRENT ASSETS		
Trade receivables	3 402	127
Other current assets	8 837	5 715
Current tax eceivables	0	5 615
Current financial assets	2 889	2 882
Cash and cash equivalents	15 758	9 646
TOTAL CURRENT ASSETS	***30 886***	***23 986***
TOTAL ASSETS	**84 625**	**77 353**

EQUITY & LIABILITIES in K€	06/30/2018	12/31/2017
SHAREHOLDERS' EQUITY		
Stated capital	2 932	2 898
Share premium	21 709	21 743
Merger premium	26 855	26 855
Treasury stock	(194)	(191)
Reserves and retained earnings	4 589	14 644
Consolidated result	8 877	(10 503)
TOTAL SHAREHOLDERS' EQUITY	***64 768***	***55 446***
NON-CURRENT DEBTS		
Non-current financial liabilities	4 103	4 296
Non-current deferred tax liabilities	3 500	2 866
Non-current provisions	271	247
TOTAL NON-CURRENT DEBTS	***7 874***	***7 410***
CURRENT DEBTS		
Current financial liabilities	650	589
Trade payables	8 247	8 776
Current tax liabilities	270	1
Other payables	961	1 060
Other debts and accruals	1 855	4 071
TOTAL CURRENT DEBTS	***11 983***	***14 497***
TOTAL LIABILITIES	**84 625**	**77 353**