

OSE Immunotherapeutics Reports on First-Half 2017 Financial Results and Provides Update on Clinical Advances of its Product Portfolio

- **Tedopi® (neoepitopes):** Phase 2 clinical trial in combination with an immune checkpoint inhibitor proposed in advanced or metastatic pancreatic cancer by the GERCOR cooperative oncology group
- **Tedopi®:** Phase 3 clinical trial in advanced or metastatic lung cancer: temporary pause of patient accrual and new analysis planned in Q4 2017 in treated patients
- **FR104 (CD28-antagonist):** Phase 2 clinical initiation expected in 2018 in rheumatoid arthritis by licensee Janssen Biotech
- **OSE-172 (SIRP α -antagonist, myeloid checkpoint inhibitor):** Initiation of Phase 1/2 clinical trial expected in 2018 in immuno-oncology; €9.2 million new funding received in July 2017 from Bpifrance
- **OSE-127 (IL-7R antagonist):** Initiation of Phase 1 clinical trial expected in 2018 in autoimmune diseases; €2.6 million milestone payment received from Bpifrance
- A €2.8 million turnover (due to the spread of €10.25 million of revenue from the license option on OSE-127 signed with Servier)
- Available cash as of June 30, 2017 of €20.5 million (including current financial assets), excluded 2016 research tax credit payment of €2.65 million expected S2 2017; Financial visibility until S2 2018

NANTES, France, Sept. 7, 6 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE) today reported its consolidated half-year financial results as of June 30, 2017 and provided an update on the clinical milestones of its product portfolio reached during the 2017 first semester.

The full “Semester financial report” (Regulated information) is available on the company’s website (<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.

Dominique Costantini, CEO of OSE Immunotherapeutics, comments: *“This first half of 2017 was marked by significant clinical milestones in the OSE portfolio. We confirm the interest of Tedopi® neoepitopes in a new indication, despite the temporary pause of patient inclusion in the Phase 3 trial in lung cancer at the end of June. Indeed, we have just come to an agreement on a clinical trial project with Tedopi® in combination with a checkpoint inhibitor in pancreatic cancer, a trial proposed by GERCOR, a group of experts internationally recognized in this pathology with a high therapeutic need.*

We expect to enter the clinic in 2018 with OSE-172, our new checkpoint inhibitor in immuno-oncology, and OSE-127, an IL-7R antagonist, in autoimmune diseases.

Our license agreement confirms the clinical progress of FR-104, CD28-antagonist, planned in Phase 2 in 2018 by Janssen Biotech. This license and the license option with Servier on OSE-127 give us access to recurring revenue. The current cash position, the expected research tax credit, and the public fundings obtained allow us to have a strong financial position to sustain progress of our clinical programs and innovative new research programs. The company has several scientific and technological platforms, neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases."

FIRST-HALF 2017 KEY ACHIEVEMENTS

Tedopi® (OSE-2101), a combination of optimized neoepitopes to induce specific T-cell activation in immuno-oncology.

On June 23, 2017, the company decided to temporarily halt patient enrolment in the Phase 3 clinical trial while continuing treatment for patients with advanced and metastatic cancer already enrolled. The decision was based on an emerging benefit/risk balance of the experimental treatment. During the fourth quarter of 2017, a complementary review of more mature clinical data will be conducted and a decision will be made about the continuation of the trial. The trial may continue as originally designed or the enrolment criteria may be amended to enrol only certain patient sub-groups.

Moreover, the company recently announced a collaboration with the GERCOR oncology cooperative group involved in digestive cancer to evaluate Tedopi® in locally advanced or metastatic pancreatic cancer. This is a Phase 2 trial of maintenance therapy with Tedopi® alone or in combination with a PD-1 checkpoint inhibitor versus Folfiri*, in patients with stable disease after four months of standard chemotherapy with Folforinox**.

* *Folfiri: chemotherapy combining folinic acid, fluorouracil and irinotecan*

** *Folforinox: chemotherapy combining folinic acid, fluorouracil, irinotecan and oxaliplatin*

OSE-172 (Effi-DEM), a new checkpoint inhibitor targeting suppressive myeloid/macrophage cells.

New preclinical data presented at immuno-oncology and immunology international congresses have shown the strong impact of OSE-172 on the tumor micro-environment by targeting suppressive myeloid cells through a specific blockade of SIRPa. OSE-172 has a unique and advantageous pharmacologic profile and is highly selective at promoting T lymphocytes that destroy cancer cells.

In July, the company has received a €9.2 million grant from Bpifrance as part of a collaborative program (EFFI-CLIN) to support the development of OSE-172 planned to enter human clinical phase trials in 2018. This program will include product manufacturing, translational studies and a clinical program planned through phase 2.

OSE-127 (Effi-7), a humanized monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R).



New positive clinical results and translational data, presented in June at the Federation of Clinical Immunology Societies conference, have shown a differentiated mechanism of action for OSE-127 able to fight pathologic local homing of inflammatory T lymphocytes, key players in the chronicity of inflammatory bowel disease.

In June, the company has received a €2.597 payment from Bpifrance, after achieving a milestone in the collaborative EFFIMab project developing OSE-127 in ulcerative colitis.

OSE-703 (Effi-3), a cytotoxic monoclonal antibody targeting the alpha-chain of the receptor for interleukin-7.

In June, the company entered into a research collaboration with Memorial Sloan Kettering Cancer Center (MSKCC) in New York. The goal of this collaboration is to explore the efficacy profile and the development potential of immunotherapy with OSE-703 in solid tumors. The research is being conducted by Prasad S. Adusumilli, M.D., an expert in tumor immunology and in the development of chimeric antigen receptor T-cell (CAR T-cell) immunotherapy.

THE TEAMS

The R&D team was strengthened with talented new team members with extensive scientific and industry experience to support advancement of OSE's ongoing programs.

Two new independent directors were appointed during the General Shareholders' Meeting of June 14: Brigitte Dréno, M.D., and Diane Kathryn Jorkasky, M.D., who bring their skills and strong track record in scientific innovation and international scope to enrich the board's expertise and support the company's growth. These nominations follow the departures of David de Weese and Jean Théron who have completed their respective terms as board members. They both continue to collaborate with OSE Immunotherapeutics: David de Weese as censor of the board for one year and Jean Théron as a consultant and international business contributor.

2017 SEMESTER RESULTS

The key figures of the 2017 consolidated half-year results are reported below:

<i>In k€</i>	06/30/2017	06/30/2016
Operating result	-7 336	22 290
Net result	- 6 340	24 506

<i>In k€</i>	06/30/2017	12/31/2016
Available cash*	20 523	17 766
Consolidated balance sheet	79 447	89 547



As of June 30, 2017, available cash* amounted to €20.5 million including the payment early 2017 of an amount of €10.25 million triggered by the license option agreement on OSE-127 (Effi-7) signed with Servier at the end of December 2016, and the payment in June of a €2.597 grant from BPIfrance following the completion of a milestone related to EFFIMab, the collaborative program on OSE-127.

This available cash of €20.5 million does not include the 2016 research tax credit of €2.65 million expected in second half of 2017, securing a financial visibility until second half of 2018.

The turnover amounted to €2.8 million, mainly due to the spread of €10.25 million of revenue from the license option signed with Servier. The operational result amounted to €-7.3 million, in line with the acceleration of R&D portfolio development towards clinical phases.

Current operating expenses represented €10.2 million, including €7.9 million of R&D expenses over the first half of 2017. Current operating expenses amounted to €3.3 million for the same period in 2016. Following merger of OSE Pharma with Effimune that occurred in May 2016, Effimune, back then, only contributed for the month of June 2016 to the operating expenses, which explains the increase of current operating expenses in 2017.

The consolidated balance sheet amounted to €79.5 million against €89.5 million as of December 31, 2016, a decrease due to the payment of €10.25 million received from Servier in January 2017.

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

About OSE Immunotherapeutics

Our ambition is to become a world leader in activation and regulation immunotherapies.

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, autoimmune diseases and transplantation. 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 product portfolio is well-balanced, with a diversified risk profile ranging from clinical trials to R&D:

In immuno-oncology:

- **Tedopi®**, a combination of 10 optimized neo-epitopes to induce specific T activation in immuno-oncology – Registration Phase 3 trial in advanced NSCLC in EU/US in HLA A2+ patients; follow-up of patients already included ongoing after temporary pause of new patient accrual end of June 2017 - Orphan Status in the US. A Phase 2 with Tedopi® in combination with an immune checkpoint inhibitor is planned in locally advanced and metastatic pancreatic cancer, in collaboration with GERCOR, an oncology cooperative group of clinical research.
- **OSE-172** (Effi-DEM), new generation checkpoint inhibitor targeting myeloid cells via the SIRP- α receptor - In preclinical development for several cancer models.
- **OSE-703** (Effi-3), cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a research collaboration with Memorial Sloan Kettering Cancer Center, New York.

In auto-immune diseases and transplantation:

- **FR104**, CD28-antagonist in immunotherapy - Phase 1 trial completed – For the treatment of autoimmune diseases and for use with transplantation - Licensed to Janssen Biotech Inc. to pursue clinical development.



- **OSE-127** (Effi-7), interleukin receptor-7 antagonist - In preclinical development for inflammatory bowel diseases and other autoimmune diseases. License option agreement with Servier for the development and commercialization.

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter global agreements at different stages of development with major pharmaceutical players.

Immunotherapy is a highly promising and growing market. By 2023 Immunotherapy of cancer could represent nearly 60% of treatments against less than 3% at present * and the projected market is estimated at \$67 billion in 2018 **. There are more than 80 autoimmune diseases that represent a significant market including major players in the pharmaceutical industry with sales towards \$10 billion for the main products. The medical need is largely unmet and requires the provision of new innovative products involved in the regulation of the immune system.

*Citi Research Equity

**BCC Research

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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 28 April 2017 under the number R.17-038, including the annual financial report for the fiscal year 2016, 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

In K€	S1 2017	S1 2016
Turnover	2 849	39
Other recurring operating income	0	-
OPERATING INCOME - RECURRING	2 849	39
Research & Development expenses	(7 880)	(1 958)
Overhead expenses	(1 784)	(952)
Expenses related to share-based payments	(521)	(405)
OPERATING PROFIT/LOSS - RECURRING	(7 336)	(3 276)
Other operating income - Badwill	(0)	34 365
Other operating expenses	0	(8 800)
OPERATING RESULT	(7 336)	22 290
Financial income	32	60
Financial expenses	(38)	(17)
PROFIT/LOSS BEFORE TAX	(7 342)	22 333
INCOME TAX	1 002	2 173
CONSOLIDATED NET RESULT	(6 340)	24 506
<i>Of which consolidated net result attributable to shareholders</i>	(6 340)	24 506
Net earnings attributable to shareholders		
Weighted average number of shares outstanding - The basic and diluted result per common share (€/share)	14 334 114 (0,44)	10 740 952 2,28
In K€	S1 2017	S1 2016
NET RESULT	(6 340)	24 506
<i>Amounts to be recycled in the income statement:</i>		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	19	3
<i>Amounts not to be recycled in the income statement:</i>		
Actuarial gains and losses on post-employment benefits	7	(8)
Other comprehensive income in the period	26	(5)
GLOBAL PROFIT/LOSS	(6 314)	24 500

CONSOLIDATED BALANCE SHEET

ASSETS in K€	06/30/2017	12/31/2016
NON-CURRENT ASSETS		
Intangible assets	52 600	52 600
Tangible assets	119	110
Financial assets	96	142
Deferred tax assets	155	157
TOTAL NON-CURRENT ASSETS	52 970	53 009
CURRENT ASSETS		
Trade receivables	19	12 318
Other current assets	5 936	2 529
Current tax receivables	0	3 925
Current financial assets	2 886	2 881
Cash and cash equivalents	17 637	14 885
TOTAL CURRENT ASSETS	26 478	36 538
TOTAL ASSETS	79 447	89 547

EQUITY & LIABILITIES in K€	06/30/2017	12/31/2016
SHAREHOLDERS' EQUITY		
Stated capital	2 875	2 858
Share premium	21 747	21 748
Merger premium	26 855	26 855
Treasury stock	(222)	(168)
Reserves and retained earnings	13 730	(7 434)
Consolidated result	(6 340)	20 666
TOTAL SHAREHOLDERS' EQUITY	58 646	64 525
NON-CURRENT DEBTS		
Non-current financial liabilities	3 345	1 197
Non-current deferred tax liabilities	3 999	5 003
Non-current provisions	190	158
TOTAL NON-CURRENT DEBTS	7 533	6 358
CURRENT DEBTS		
Current financial liabilities	537	587
Trade payables	4 170	4 256
Current tax liabilities	2	8
Other payables	743	3 148
Other debts and accruals	7 816	10 664
TOTAL CURRENT DEBTS	13 269	18 663
TOTAL LIABILITIES	79 447	89 547