OSE Immunotherapeutics Reports on First-Half 2016 Positive Financial Results Driven by Key Clinical Milestones

- **Completion of Phase 1 clinical trial with FR104 and exercise by Johnson & Johnson (Janssen Biotech, Inc.) of the option within its global license agreement to further develop and potentially commercialize FR104 for autoimmune diseases**
- **Pivotal Phase 3 clinical trial of Tedopi® (Atalante 1): ongoing recruitment in Europe and in the U.S. in Non-Small Cell Lung cancer**
- **Preclinical advances and significant results in other development programs**
- **Positive operating result of €22 million due to the license agreement with Johnson & Johnson and to the merger operation**
- **Available cash of €15 million as of 30 June 2016 and €10 million received from Johnson & Johnson in August in payment of exercise of license option, providing a financial visibility until S2 2018**

Nantes, Paris, September 8, 2016 - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnémo: OSE), a biotechnology company developing immunotherapies of activation or regulation in immuno-oncology, auto-immune diseases and transplantation, today reported its consolidated half-year financial results as of June 30, 2016 and provided an update on the key milestones reached during the 2016 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.

"OSE Immunotherapeutics is now well positioned in the field of immunotherapy of activation and regulation. Our agreement for FR104 (CD28-antagonist) with J&J, finalized in June after positive Phase 1 results, underlines the value of our strategic plan to merge with Effimune, as completed on May 31, 2016. The steps we have taken in recent months have significantly strengthened the company, allowing us to continue to develop a leading portfolio of products, ranging from preclinical through to Phase 3, with a team of expert immunologists. With current financial visibility of about 24 months, we are well positioned to take further steps to enhance our value," commented Dominique Costantini, CEO of OSE Immunotherapeutics.

FIRST-HALF 2016 KEY ACHIEVEMENTS

IN IMMUNO-ONCOLOGY

Tedopi®, an innovative combination of neoepitopes, entered an international pivotal registration clinical phase study in advanced lung cancer in early 2016 and recruitment is on-going in Europe and in the US.

Effi-DEM, a new generation checkpoint inhibitor targeting the receptor SIRP-α on the strategic CD47/SIRP-α pathway (blockage of suppressive myeloid and macrophage cells), has shown significant preclinical results in various models of cancer, as presented at several international conferences.

IN AUTOIMMUNE DISEASES

FR104 (CD28-antagonist), was licensed to J&J (Janssen Biotech) at the end of the first semester to pursue clinical development at the conclusion of phase 1 trial.

Effi-7 (blocking the alpha chain of interleukin-7 receptor) has confirmed its efficacy in *in vivo* models of ulcerative colitis, a T-cell mediated disease.

COMPLETION OF MERGER-ABSORPTION of Effimune by OSE Pharma on May 31, 2016, to create OSE Immunotherapeutics.

2016 SEMESTER RESULTS

The key figures of the 2016 consolidated half-year results are reported below:

In k€	06/30/2016	06/30/2015
Operating result	**22 290**	**(2 800)**
Net result	**24 506**	**(2 942)**

In k€	06/30/2016	12/31/2015
Available cash*	**15 275**	**15 133**
Consolidated balance sheet	**82 652**	**16 995**

As of June 30, 2016, available cash* amounted to €15 million. During the last month, this cash was reinforced by the payment of an amount of €10 million triggered by the exercise of the license option on FR104 by J&J in August 2016; the payment of a research tax credit of €2 million is expected by the end of 2016.

The operating result amounted to €22.3 million, mainly due to the exercise of the license option on FR104 by J&J and to the badwill arising from the acquisition of Effimune by OSE Pharma, against an operating loss of €-2.8 million in H1 2015. The exercise of the license option for FR104 has thus confirmed the strategic decision to merge.

Current operating expenses represented €3.3 million, including €2 million of R&D expenses, for the first 6 months of 2016, against €2.8 million for the same period of 2015, in line with the acceleration of R&D portfolio development, and in particular the clinical study Atalante 1 with Tedopi® launched in Europe and in the United States.

The net result amounted to €24.5 million following the merger operation, against €-2.9 million for the same period of last year.

At the same date, the total consolidated balance sheet amounted to €83 million against €17 million as of December 31, 2015, an increase due to the contribution of Effimune's assets following the merger.

**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 led by world-class immunologists and focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, auto-immune diseases and transplantation.

The company has a balanced portfolio of first-in-class products with a diversified risk profile ranging from clinical phase 3 registration trials to R&D:

- **Tedopi®, a combination of 10 optimized neo-epitopes** to induce specific T activation in immuno-oncology - **currently in registration Phase 3 trial advanced NSCLC HLA A2+ patients EU /US -** Orphan Status in the US **- registration expected in 2019**
- **FR104,** CD28-antagonist in immunotherapy - **Phase 1 trial completed** - targets autoimmune diseases and transplantation - **licensed to J&J** to pursue clinical development
- **Effi-7,** interleukin receptor 7 antagonist - **in preclinical development** for inflammatory bowel diseases and other autoimmune diseases
- **Effi-DEM, new generation checkpoint inhibitor** targeting the **SIRP-α receptor on the strategic CD47/SIRP- α pathway - in preclinical development** for immuno-oncology
- **R&D**: candidates targeting new receptors in immuno-oncology

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter into global agreements at different stages of development with major pharmaceutical players, such as the one signed for FR104 with the J&J Group.

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 upper 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*
Since September 1st, 2016, the new company's headquarters are located on: 22, boulevard Benoni Goullin, 44200 Nantes, France

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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 8 June 2016 under the number R.16-052, the consolidated financial statements and the management report for the fiscal year 2015, as well as the Merger Document registered with the AMF on 26 April 2016 under number E.16-026, all 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.