

## OSE Immunotherapeutics announces the online publication of positive Phase 1 clinical results with FR104 in the Journal of Immunology

Nantes, November 17, 2016 - OSE Immunotherapeutics SA (ISIN : FR0012127173 ; Mnémo : OSE), announced today the online publication\* in « The Journal of Immunology » of positive results from a Phase 1 clinical trial of FR104 conducted in healthy subjects. Data published have shown a good tolerance and an immunosuppressive activity.

FR 104 is a monoclonal antibody and an antagonist of CD28. This pegylated monovalent antibody inhibits selectively the CD28 receptor and has potential clinical applications in auto-immune diseases and transplantation.

The clinical and biological safety of this new product has shown to be very good in 64 healthy subjects who were administered single or repeated ascending doses of the product. Moreover, the first data of clinical activity arising from this study, challenged with a KLH test, clearly demonstrated an inhibition of the antibody response versus KLH and in a dose-dependent manner.

*« We have demonstrated a good clinical safety of FR104 on an immunological target of high interest. This study has also confirmed immunosuppressive activity; this key step is a strong basis to pursue the development in immune-mediated diseases »,* comments Bernard Vanhove, Chief Operating Officer of OSE Immunotherapeutics, in charge of R&D. *« I warmly thank our team, Inserm UMR1064, the Nantes University, Nantes University Hospital as well as institutions involved in very early stage, for their commitment to the project (Atlanpole Biotherapies, « Région Pays de la Loire », the Loire Atlantique Department, the National Research Agency and the Foundation for Medical Research). I also thank our industrial partner, Janssen Biotech Inc., in charge of pursuing the product's development ».*

Maryvonne Hiance, Vice-President and Director of Strategy of OSE Immunotherapeutics adds :

*« We are very pleased with these first results. They illustrate the implementation of a public-private joint research laboratory within the international hub of the Nantes region which contributes to the growth of the French Biotech ».*

### **\*First-in-Human Study in Healthy Subjects with FR104, a Pegylated Monoclonal Antibody Fragment Antagonist of CD28**

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#### 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<sup>®</sup>**, 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** - a **Phase 2 with Tedopi<sup>®</sup> in combination with a checkpoint inhibitor** in NSCLC is considered in 2017 - the product is also **considered in other cancer indications.**
- **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
- **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- $\alpha$  receptor** - **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 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.

<sup>\*</sup>Citi Research Equity  
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More information: <http://ose-immuno.com>

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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.