

## **OSE Immunotherapeutics Receives €5.2 M in Public Funding for the Clinical Development of CoVepiT, its Second Generation COVID-19 Vaccine**



- **CoVepiT demonstrated generation of sentinel memory T cells with long-term protective effect against COVID-19 in preclinical and human ex vivo studies**
- **CoVepiT targets 11 virus proteins to prepare for potential mutations**
- **Clinical trial expected to start in Q1 2021**
- **OSE Immunotherapeutics committed to grant the French government a purchase option on doses of CoVepiT vaccine**

**Nantes, France, December 18, 2020, 7:30AM CET – OSE Immunotherapeutics** (ISIN: FR0012127173; Mnemo: OSE) announces that the Company has obtained funding of €5.2 million under the PSPC-COVID call for projects, operated on behalf of the French government by Bpifrance as part of the *Programme d'investissements d'avenir* (PIA) and led by the *Secrétariat général pour l'investissement* (SGPI), to support its development program on CoVepiT, its second-generation multi-target vaccine against COVID-19.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, commented: *"We warmly thank Bpifrance and the SGPI to support us with a funding that will help accelerate the development of CoVepiT with a clinical Phase 1/2 trial expected to start in Q1 2021. This trial is based on robust preclinical data and the recent results from CoVepiT 1, a human ex vivo study which resulted in the identification of immuno-dominant epitopes generating T memory lymphocytes that have been incorporated in the vaccine composition. These epitopes target 11 virus proteins, covering all initial and novel SARS-CoV-2 variants and potentially providing patients with broad protection against COVID-19 even if it mutates. We are looking forward to testing the vaccine candidate in partnership with the European Hospital Georges-Pompidou and the Clinical Investigation Center Cochin-Pasteur located in Cochin hospital. CoVepiT has been especially designed for people at risk including older adults or populations suffering from severe diseases."*

CoVepiT 1 was a human *ex vivo* clinical study, conducted in 120 convalescent COVID-19 subjects versus unexposed subjects, which enabled OSE to identify T memory immuno-dominant epitopes after infection with COVID-19, selected for their strong immunogenicity potential.

New SARS-CoV-2 mutated variants spread rapidly across Europe, some of them bearing mutations in some key targets of the virus in particular the Spike protein and Nucleoprotein. Based on new analyses of up to 226,000 different virus sequences collected around the world, the OSE bioinformatic team confirmed that mutations did not emerge in the highly stable viral genome region of the 11 targets selected by OSE. This reinforces the multi-epitope approach against these virus proteins to generate a T lymphocyte response and the CoVepiT vaccine continues to cover all previous, novel and current SARS-CoV-2 strains and variants.

The CoVepiT development program will be conducted within a consortium led by OSE Immunotherapeutics, in partnership with the teams of Prof. Eric Tartour, Head of the biological immunology department at the European Hospital Georges-Pompidou-APHP and Professor at University of Paris, in charge of immune-monitoring, and with the teams of Prof. Odile Launay, Professor of infectious and tropical diseases at University of Paris and Coordinator of the Clinical Investigation.

The French State's funding, totaling €5.8 million for the entire consortium and including €5.2 million for OSE Immunotherapeutics, will in particular support the CoVepiT 1 study, the production of a clinical batch according to Good Manufacturing Practices and a Phase 1/2 clinical trial which will assess the safety and immunogenicity of CoVepiT in patients from at-risk populations.

#### **ABOUT BPIFRANCE**

Bpifrance is the French national investment bank: it finances businesses – at every stage of their development – through loans, guarantees, equity investments and export insurances. Bpifrance also provides extra-financial services (training, consultancy.) to help entrepreneurs meet their challenges (innovation, export...).

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#### **ABOUT CoVepiT**

The CoVepiT vaccine is a neoepitope vaccine intended to prophylactically protect against infections with SARS-CoV-2, the virus that causes COVID-19. This vaccine incorporates optimized peptide fragments (neoepitopes) improved using artificial intelligence algorithms to increase immune response and induce strong memory T cell responses. CoVepiT is generated using OSE's proprietary Memopi® technology which has been validated for both safety and efficacy through the step-1 of Phase 3 clinical phase of neoepitope vaccine Tedopi® in patients with non-small lung cancer.

#### **ABOUT OSE IMMUNOTHERAPEUTICS**

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

##### **Vaccine platform**

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; positive results for Step-1 of the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer post checkpoint inhibitor failure.

In Phase 2 in pancreatic cancer (TEDOPaM, sponsor GERCOR) in monotherapy and in combination with checkpoint inhibitor Opdivo®.

- **CoVepiT**: a prophylactic vaccine against COVID-19, developed using SARS-CoV-2 optimized neo-epitopes. Positive preclinical and human ex vivo results in August 2020, clinical trial expected to start in Q1 2021.

#### **Immuno-oncology platform**

- **BI 765063** (OSE-172, anti-SIRPα mAb on the SIRPα/CD47 pathway): developed in partnership with Boehringer Ingelheim; myeloid checkpoint inhibitor in Phase 1 in advanced solid tumors.
- **CLEC-1** (novel myeloid checkpoint target): identification of mAb antagonists of CLEC-1 blocking the “Don’t Eat Me” signal that increase both tumor cell phagocytosis by macrophages and antigen capture by dendritic cells.
- **BiCKI**®: bispecific fusion protein platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2<sup>nd</sup> generation of PD-(L)1 inhibitors to increase antitumor efficacy.

#### **Auto-immunity and inflammation platform**

- **FR104** (anti-CD28 monoclonal antibody): positive Phase 1 results; ongoing Phase 1/2 in renal transplantation, Phase 2-ready asset in a niche indication in autoimmune diseases.
- **OSE-127** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; two independent Phase 2 planned in ulcerative colitis (OSE sponsor) and in Sjögren’s syndrome (Servier sponsor) to start in Q4 2020.
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

*Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127 could be impacted during the coming months.*

For more information:

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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 Universal Registration Document filed with the AMF on 15 April 2020, including the annual financial report for the fiscal year 2019, 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.