

OSE Immunotherapeutics Announces €10.7 Million in Additional Public Funding, via Bpifrance, to Finance Further Development of CoVepiT, its Multi-Target and Multi-Variant COVID-19 Vaccine in Phase 1 Clinical Phase

- CoVepiT is a SARS-CoV-2 vaccine activating T cell defences through CD8 T cell multi-epitopes.
- CoVepiT epitopes* are selected from 11 viral protein targets designed to cover all initial and new emerging SARS-CoV-2 variants.
- CoVepiT, a second-generation vaccine, potentially provides a long-term cellular immunity with memory T cells.



Nantes, France, May 18, 2021 - OSE Immunotherapeutics (ISIN: FRO012127173; Mnemo: OSE) today announced it has obtained a public funding of €10.7 million under the “Capacity Building” call for projects, operated on behalf of the French government by Bpifrance as part of the “Programme d’investissements d’avenir” (PIA) and of the plan “France Relance” to support further development of its program on CoVepiT, its multi-variant vaccine against COVID-19, currently in Phase 1 clinical trial.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, comments: *“We thank the French government and Bpifrance to show once more their confidence in OSE and to support us with an additional funding that will help enlarge the clinical development of CoVepiT, subject to positive results of the Phase 1 ongoing in Belgium, with a potential expansion of further clinical trials to other European countries. In parallel, we are making great progress with our vaccine industrialisation, a critical part of its development, with in particular the manufacturing of a new clinical batch to be ready on time for launching the next clinical phases.”*

The ongoing Phase 1 clinical trial** aims at evaluating the safety, reactogenicity and immunogenicity of CoVepiT in healthy adult volunteers. This study is based on the results from preclinical and human *ex vivo* studies (CoVepiT 1) demonstrating that CoVepiT has the potential to generate sentinel memory T cells with long-term protective effect against COVID-19. Targeting 11 virus proteins (including Spike, M, N and several non-structural proteins), this second-generation vaccine is designed to cover all initial and novel SARS-CoV-2 variants.

In December 2020, OSE Immunotherapeutics obtained a first funding of up to €5.2 million under the PSPC-COVID call for projects from the French state, operated on behalf of the French government by Bpifrance as part of the “Programme d’investissements d’avenir” (PIA). This funding was designed in particular to support the CoVepiT 1 study, the manufacturing of a clinical batch according to Good Manufacturing Practices and a Phase 1 clinical trial.

* *T Epitope: small fragment of protein (8 and 11 amino acids in length) recognized by the immune system.*

** *To read more: clinicaltrials.gov*

ABOUT CoVepiT

CoVepiT is a next-generation multi-target, multi-variant vaccine against SARS-CoV-2. The vaccine candidate was designed using optimized epitopes selected after screening more than 67,000 global SARS-CoV-2 genomes, as well as those of previous human-infective CoVs, SARS and MERS, to identify vaccine targets with the lowest chance of natural mutation. Targeting 11 virus proteins including Spike, M, N and several non-structural proteins, this second-generation vaccine covers all initial and novel SARS-CoV-2 variants identified globally to date. In preclinical testing, CoVepiT demonstrated the ability to activate T cell defenses through CD8 T-cell multi-epitope responses for long-term T memory cell immunity.

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 Phase 2 in ovary cancer (TEDOVA, sponsor ARCAGY-GINECO)
Due to the COVID-19 crisis, accrual of new patients in TEDOPaM should restart in 2021.
- **CoVepiT**: a prophylactic second-generation vaccine against COVID-19, developed using SARS-CoV-2 optimized epitopes against multi variants. Positive preclinical and human ex vivo results in August 2020. In clinical Phase 1.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb on 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; 2nd generation of PD-(L)1 inhibitors to increase antitumor efficacy.

Auto-immunity and inflammation platform

- **FR104** (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplantation market; ongoing Phase 1/2 in renal transplant (sponsored the Nantes University Hospital); Phase 2-ready asset in a niche indication in autoimmune diseases.
- **OSE-127/S95011** (humanized monoclonal antibody targeting IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; in Phase 2 in ulcerative colitis (OSE sponsor) and an independent Phase 2a planned in Sjögren's syndrome (Servier sponsor).
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

For more information:

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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...). For more information, please visit: www.bpifrance.fr/presse.bpifrance.fr - Follow us on Twitter: @Bpifrance - @BpifrancePresse

ABOUT THE “PROGRAMME D’INVESTISSEMENT D’AVENIR” (PIA)

Committed for 10 years and managed by the General Secretariat for Investment with the Prime Minister, the PIA finances innovative projects, contributing to the transformation of the country, to sustainable growth and to the creation of the jobs of tomorrow. From the emergence of an idea to the dissemination of a new product or service, the PIA supports the entire innovation life cycle, between public and private sectors, alongside economic, academic, regional and European partners. These investments are based on a demanding doctrine, open selective procedures, and principles of co-financing or returns on investment for the State. The fourth PIA (PIA4) has €20 billion in commitments over the 2021-2025 period, of which €11 billion will help support innovative projects under the French recovery plan. The PIA will continue to provide long-term support for innovation, in all its forms, so that France can strengthen its positions in sectors of the future, in the service of competitiveness, ecological transition, and the country's independence economy and organizations.

More information on: www.gouvernement.fr/secretariat-general-pour-l-investisment-sgpi

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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 2021, including the annual financial report for the fiscal year 2020, 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.