



# OSE Immunotherapeutics Announces Manufacturing Agreement with Cenexi for Clinical Batches of CoVepiT, OSE's Multi-Target Second-Generation COVID-19 Vaccine

Nantes, France and Fontenay-sous-Bois, France – June 30, 2021, 7:30AM CET - OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) and Cenexi, a French contract development and manufacturing organization (CDMO), today announced the signature of an agreement whereby Cenexi will manufacture clinical batches of CoVepiT, OSE Immunotherapeutics' vaccine candidate against COVID-19 currently in Phase 1 clinical trial, which will be used in the product's development phases.

Under this agreement, Cenexi will manufacture and process the peptides, produce the sterile emulsion and package the clinical batches of CoVepiT being used in the ongoing Phase 1 clinical trial and potentially for further clinical phases, subject to positive results of the Phase 1. The manufacturing line for this product has been set up at Cenexi's manufacturing site in Hérouville-Saint-Clair in Normandy, France, which has an available filling capacity of 40 million bottles per year.

Christophe Durand, Chief Executive Officer of Cenexi, comments: "This manufacturing collaboration with OSE is a strong symbol of our ability to meet demanding needs. The skills and flexibility of our teams allow us to adapt to innovative challenges and cutting-edge technical requirements to actively participate in industrialization of a potential future vaccine against COVID-19."

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: "We are delighted with this collaboration with Cenexi, which benefits from the expertise and know-how required to support us on the industrial manufacturing of clinical batches, a major component through the ongoing Phase 1 and all the potential additional development phases of CoVepiT."

CoVepiT is currently in a Phase 1 clinical trial to evaluate the safety, reactogenicity and immunogenicity of two dose regimen of the vaccine in 48 healthy adult volunteers, previously vaccinated or not by an authorized COVID-19 vaccine. This trial is based on the results from preclinical and human ex vivo studies demonstrating its 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 or upcoming SARS-CoV-2 variants.

## ABOUT CoVepiT

CoVepiT is a next-generation multi-target, multi-variant vaccine against SARS-CoV-2 in clinical Phase 1. 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 Cenexi**

Cenexi is a French Contract Development and Manufacturing Organization (CDMO) processing in Europe. With 1,500 employees and a €210 million turnover, the company is experiencing steady growth with four manufacturing sites (Fontenay-sous-Bois, Osny and Hérouville-Saint-Clair in France, Braine-l'Alleud in Belgium) and a development and industrial transfer site.

Founded in 2004, the Cenexi Group is positioned in the very active international market for drugs with major therapeutic indications, drawing on its spirit of innovation and its extensive expertise in manufacturing and product development. The orientations of the new management team of the group breathe new life into the company, in particular by strengthening its sterile expertise which represents 65% of its activity. Cenexi is endowed with the production capacities of numerous galenic forms with a strong expertise in cytotoxic products (including hormonal products).

#### **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<sup>®</sup> (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.
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- 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.

- In Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- 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 in advanced solid tumors; positive Phase 1 results in monotherapy and BI 765063 dose escalation study ongoing in combination with Ezabenlimab (PD-1 antagonist).
- **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**<sup>®</sup>: 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 efficacity.

## Auto-immunity and inflammation platform

- FR104 (anti-CD28 monoclonal antibody): Licensing partnership agreement with Veloxis in the organ transplant market; ongoing Phase 1/2 in renal transplant (sponsored by 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: Click and follow us on Twitter and LinkedIn







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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.