



## Four Poster Presentations at 2022 ASCO Annual Meeting

- **NSCLC Atalante-1 Phase 3 Trial Beyond Checkpoint Inhibitor Neoepitope Specific Immunotherapy Tedopi® Shows Significant Patient-Reported Outcomes Versus Chemotherapy**
- **Positive Interim Results in Phase 2 Trial with Tedopi® in Pancreatic Cancer in Maintenance Strategy Post-FOLFIRINOX (GERCOR)**

**Live webcast conference call for analysts hosted today, June 7,  
at 6:30 p.m. CET / 12:30 p.m. ET\***

Nantes, France – June 7, 2022, 7:30am CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) and its clinical partners GERCOR, ARCAGY-GINECO and the FoRT Foundation (Fondazione Ricerca Traslazionale), presented four posters featuring neoepitope specific immunotherapy Tedopi® in various cancer indications at the American Society of Clinical Oncology (ASCO) Annual Meeting held June 4 – 7.

- In advanced HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO): Final data of Phase 3 Atalante-1 randomized trial were presented by Pr. Benjamin Besse (Gustave Roussy Institute, Villejuif, France).

This presentation featured final positive Patient Reported Outcomes (PROs) significantly better with Tedopi® than chemotherapy in NSCLC patients in secondary resistance after checkpoint inhibitor failure, as primary analysis (n=118 patients). These PROs results and secondary endpoints were also confirmed as significant in the global population as sensitivity analysis (n=219 patients).

In advanced and metastatic HLA-A2+ NSCLC patients with secondary resistance to immuno-oncology after sequential platinum-based chemotherapy, then checkpoint inhibitors given at least 12 weeks (CT-IO in secondary resistance), Tedopi® significantly improves overall survival and maintains PROs quality of life and safety versus the standard of care (docetaxel or pemetrexed) especially global health status, physical and role functioning scores. Patients presented fewer symptoms with Tedopi® typically related to adverse effects of chemotherapy.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, comments: "*In hard-to-treat population beyond checkpoint inhibitors, these Patient Reported Outcomes with quality-of-life data from Phase 3 Atalante 1 come in addition to the positive trial's principal results which showed significant survival benefits of Tedopi® versus standard of care in advanced NSCLC patients who had failed second-line checkpoint inhibitor treatments. This strengthens the rationale to the early access program for potential filing with the regulatory Agencies end of 2022.*"

- In pancreatic cancer, [the poster](#): “A randomized non-comparative phase II study of maintenance Tedopi® cancer vaccine alone or in combination with nivolumab, or FOLFIRI after induction with FOLFIRINOX in patients with advanced pancreatic ductal adenocarcinoma” was presented by Dr. Anthony Turpin (Lille University Hospital, Lille, France).

This presentation featured the first interim results from this Phase 2 clinical trial of Tedopi® in advanced or metastatic pancreatic cancer. The primary endpoint of the trial is the one-year survival rate (Fleming-futility analysis; null hypothesis <25%), and the key secondary endpoint was the Time to maintenance Strategy Failure (TSF= time maintenance + FOLFIRI reintroduction).

The interim results refer to the 29 randomized HLA-2 positive patients with no progression after 8 cycles of FOLFIRINOX: 9 patients included in standard arm A (FOLFIRI) with 44% of 1-year Overall Survival (OS) rate and one partial response (11%); 10 patients in experimental arm B (Tedopi® monotherapy) with 40% of 1-year OS rate and one partial response (10%); 10 patients in arm C (nivolumab + Tedopi®) with 30% of 1-year OS rate and no partial response.

Tedopi® as maintenance monotherapy showed a favorable safety profile and encouraging time to strategy failure warranting further evaluation. Nivolumab + Tedopi® was associated with poorer outcomes leading to the closing of this arm. Following an Independent Data Monitoring Committee (IDMC) recommendation, the study is ongoing with an amended protocol comparing a maintenance treatment Tedopi® in combination with FOLFIRI versus FOLFIRI chemotherapy after treatment with FOLFIRINOX.

Dominique Costantini, Chief Executive Officer of OSE Immunotherapeutics, comments: *“These first interim results in pancreatic cancer are very interesting for Tedopi in this devastating form of cancer with a generally poor prognosis representing significant unmet medical need. We warmly thank the GERCOR oncology clinician group and the PRODIGE Intergroup, sponsor of the TEDOPaM study, for this first encouraging step shared at the ASCO meeting.”*

In addition, two “Trial in Progress” posters were presented to provide background information and present the study design of the two ongoing clinical trials with Tedopi® in combination with a checkpoint inhibitor, sponsored and conducted by clinician oncology groups:

- **[Combi-TED](#), a trial sponsored and conducted by the Italian foundation FoRT :** “A Multicenter, Phase II, Open Label, Randomized Trial Evaluating Efficacy of Tedopi® Plus Docetaxel Or Tedopi Plus Nivolumab As Second-Line Therapy In Metastatic NSCLC Progressing After First-Line Chemo-Immunotherapy” [[NCT04884282](#)]  
Presented by Dr. Federico Cappuzzo, Director Medical Oncology at Cancer Institute Regina Elena, Roma, Italy, and Chief Investigator of the study
- **[TEDOVA](#), a trial sponsored and conducted by ARCAGY-GINECO :** “Phase 2 clinical trial evaluating neo-epitope combination Tedopi® alone or in combination with Pembrolizumab versus best supportive care as maintenance treatment in platinum-sensitive recurrent ovarian cancer patients with disease control after platinum” [[NCT04713514](#)]



Presented by Dr. Alexandra Leary, Chief Investigator of TEDOVA study from Gustave Roussy cancer center (Villejuif, France)

*\*OSE Immunotherapeutics will hold a conference call on June 7 at 6:30 p.m. CET / 12:30 a.m. ET for analysts to comment on the updated data presented at the 2022 ASCO meeting, and in particular PROs and quality of life data from Phase 3 Atalante 1 clinical trial with Tedopi® in Non-Small Cell Lung Cancer and interim results from Phase 2 TEDOPaM clinical trial in advanced metastatic pancreatic cancer*

*The live webcast will be available at the following link:*

[https://channel.royalcast.com/landingpage/oseimmunotherapeutics-en/20220607\\_1/](https://channel.royalcast.com/landingpage/oseimmunotherapeutics-en/20220607_1/)

## 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 Immuno-Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

### Immuno-Oncology first-in-class products

- **Tedopi®** (innovative neoepitope combination): the Company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure.  
Other ongoing combination trials sponsored by cooperative clinical research groups in oncology:
  - Phase 2 in pancreatic cancer (TEDOPaM), sponsor GERCOR.
  - Phase 2 in ovary cancer, in combination with pembrolizumab (TEDOVA), sponsor ARCAGY-GINECO.
  - Phase 2 in non-small cell lung cancer in combination with nivolumab, sponsor Italian foundation FoRT.
- **BI 765063** (OSE-172, anti-SIRP $\alpha$  mAb on CD47/SIRP $\alpha$  pathway): developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in monotherapy and in combination with ezabenlimab (PD-1 antagonist); ongoing expansion Phase 1. BI sponsored international phase 1b clinical trial ongoing in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) or hepatocellular carcinoma (HCC).
- **OSE-279**, anti-PD1 – advanced preclinical stage.
- **BiCKI®**: bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target (for example: BiCKI®-IL7, preclinical stage) to increase anti-tumor efficacy.

### Immuno-Inflammation first-in-class products

- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor): developed in partnership with Servier; positive Phase 1 results; ongoing Phase 2 in ulcerative colitis (sponsor OSE) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **FR104** (anti-CD28 monoclonal antibody): licensing partnership agreement with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsored by the Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.) ; Phase 2 planned in an autoimmune disease indication.
- **OSE-230** (ChemR23 agonist mAb): preclinical stage therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

**CoVepiT**: a prophylactic second-generation vaccine activating cytotoxic T lymphocytes against COVID-19, developed using optimized epitopes from SARS-CoV2 viral proteins, epitopes non impacted by multi-variants. Shows good tolerance and very good level of T cell immune response. In clinical testing, a long-term memory response was confirmed at 6 months.

For more information: <https://ose-immuno.com/en/>

Click and follow us on Twitter and LinkedIn





## Contacts

### **OSE Immunotherapeutics**

Sylvie Détry  
[sylvie.detry@ose-immuno.com](mailto:sylvie.detry@ose-immuno.com)  
+33 153 198 757

### **Investor Relations**

Thomas Guillot  
[thomas.guillot@ose-immuno.com](mailto:thomas.guillot@ose-immuno.com)  
+33 607 380 431

### **Media**

#### **U.S. Media: LifeSci Communications**

Darren Opland, Ph.D.  
[darren@lifescicomms.com](mailto:darren@lifescicomms.com)  
+1 646 627 8387

Guillaume van Renterghem – LifeSci

Advisors  
[gvanrenterghem@lifesciadvisors.com](mailto:gvanrenterghem@lifesciadvisors.com)  
+41 76 735 01 31

#### **French Media: FP2COM**

Florence Portejoie  
[fportejoie@fp2com.fr](mailto:fportejoie@fp2com.fr)  
+33 607 768 283

## **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 2022, including the annual financial report for the fiscal year 2021, 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.