OSE Immunotherapeutics Presents Clinical Abstracts on Tedopi® at the ASCO 2023 Annual Meeting

Tedopi® is the Company's Most Advanced Product in Clinical Development

- **ATALANTE-1, a Phase 3 clinical trial with positive results comparing Tedopi® to chemotherapy in non-small cell lung cancer (NSCLC) after failure to immunotherapy:**
  - **New data on prognostic factors of overall survival supporting Tedopi®'s mechanism of action in improving patients' overall survival.**
- **TEDOVA, a Phase 2 clinical trial sponsored and conducted by the French oncology cooperative group ARCAGY-GINECO and supported by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., and OSE Immunotherapeutics:**
  - **An innovative combination approach in ovarian cancer with high unmet medical need.**
  - **180 patients planned and first results expected H1 2025.**

Nantes, France – June 6, 2023, 7:30 a.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) presented a poster and a publication in abstract book featuring Tedopi®, an immunotherapy activating tumor specific T-cells, in non-small cell lung cancer (NSCLC) and in ovarian cancer at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting held June 2 - 6.

ADDITIONAL DATA FROM THE POSITIVE PHASE 3 CLINICAL TRIAL IN NSCLC, ATALANTE-1

The publication- abstract "# e21037", ***"Prognostic factors of overall survival (OS) in non-small cell lung cancer (NSCLC) patients after failure on immune checkpoint inhibitors (IO) treated with anticancer vaccine OSE2101 or chemotherapy (CT) in phase 3 ATALANTE-1 randomized trial",*** reported an analysis performed to identify the prognostic factors of overall survival (OS) in each treatment group of the Phase 3 clinical trial of Tedopi® (Atalante-1) in HLA-A2+ patients with advanced or metastatic non-small cell lung cancer (NSCLC), led by Pr. Benjamin Besse, Gustave Roussy cancer center, Principal Investigator of the study.

Tedopi® is the first cancer vaccine that has shown positive and clinically meaningful efficacy results associated with a better safety and quality of life profile in monotherapy versus active comparator (chemotherapy-based standard of care) in third line with secondary resistance to immune checkpoint inhibitors in advanced or metastatic NSCLC (Phase 3 trial ATALANTE-1). Classical baseline factors (disease stage, histology) and treatment effect including best response, safety and ECOG* Performance Status (PS) deterioration were studied in this analysis and correlated to OS.

The analysis concludes that prognostic factors of OS differ between the cancer vaccine Tedopi® and the standard chemotherapy treatment. The maintenance of a good ECOG PS was associated with longer survival for Tedopi®, and the best response to treatment was the main prognostic factor for chemotherapy. These results support the mechanism of action of Tedopi® in improving OS by controlling tumor growth regardless of best response.

Dr. Silvia Comis, Head of Clinical Development of OSE Immunotherapeutics, commented: *"Following the positive results presented at the ASCO and ESMO 2022, these additional data showing how Tedopi® improves OS strengthen the data basis to better understand the benefit of Tedopi® on OS in NSCLC patients with secondary resistance to anti-PD-1 treatments. We look forward to advancing the clinical development of Tedopi® in second line through a confirmatory pivotal Phase 3".*

TEDOVA PHASE 2 CLINICAL TRIAL IN OVARIAN CANCER

The poster entitled***, "TEDOVA/GINECO-OV244b/ENGOT-ov58 trial: Neo-epitope-based vaccine OSE2101 alone or in combination with pembrolizumab vs best supportive care (BSC) as maintenance in platinum-sensitive recurrent ovarian cancer with disease control after platinum"***, presented by Dr. Alexandra Leary, from Gustave Roussy cancer center (Villejuif, France) and Principal Investigator of TEDOVA study, featured the ongoing Phase 2 international randomized open-label clinical trial, sponsored and conducted by ARCAGY-GINECO (Poster Bd # 310a).

Dr Alexandra Leary commented: "*Our patients with ovarian cancer do not respond to checkpoint inhibitors alone as these tumors are 'immune cold', not likely to trigger a strong immune response and usually not responding to immunotherapy. The objective of TEDOVA is to turn ovarian cancer into an 'immune hot' tumor by using Tedopi®, a combination of tumor associated neo-epitopes that have been optimized to break immunological self-tolerance. TEDOVA is the first trial evaluating such an innovative approach in ovarian cancer. We thank the international gynecological oncology community for their support and enthusiasm in promoting and conducting this research, moreover, helping to better understand this particularly aggressive disease."*

** The ECOG score is a performance scale used to quantify the general health condition of a patient.*
It is subdivided into 5 grades from 0 to 5, ranging from fully active (0) to fully disabled, then to death (5).

PRESENTATION DETAILS

"Prognostic factors of overall survival (OS) in non-small cell lung cancer (NSCLC) patients after failure on immune checkpoint inhibitors (IO) treated with anticancer vaccine OSE2101 or chemotherapy (CT) in phase 3 ATALANTE-1 randomized trial." [NCT02654587]

Benjamin Besse, Paris-Saclay University, Institut Gustave Roussy, Villejuif, France

- Date: June 4, 8:00 – 11:00 am CET
- Abstract # e21037
- Session Type: Publication Only
- Session Title: Publication Only: Lung Cancer—Non-Small Cell Metastatic
- Track: Lung Cancer
- Sub Track: Non-Small Cell Lung Cancer - Advanced/Metastatic Disease

"TEDOVA/GINECO-OV244b/ENGOT-ov58 trial: Neo-epitope-based vaccine OSE2101 alone or in combination with pembrolizumab vs best supportive care (BSC) as maintenance in platinum-sensitive recurrent ovarian cancer with disease control after platinum." [NCT04713514]

Alexandra Leary, Gustave-Roussy Cancer Campus, Villejuif, and GINECO, Paris, France

- Date: June 5, 1:15 – 4:15 pm CET
- Abstract # TPS5618
- Poster Bd # 310a
- Session Type: Poster Session
- Session Title: Gynecologic Cancer
- Track: Gynecologic Cancer
- Sub Track: Ovarian Cancer

ABOUT NON-SMALL CELL LUNG CANCER

Lung cancer is the leading cause of cancer mortality (18.0% of the total cancer deaths) with an estimated 2.2 million new cancer cases per year and with 1.8 million deaths. Lung cancer is the second most commonly diagnosed form of cancer after prostate cancer in men, and the third one in women, after breast and colorectal cancers. Among this population, 85% of lung cancer fall into the non-small cell lung cancer (NSCLC) form. About 58% are diagnosed at metastatic stage with a 5-year survival rate at 7%. Patients with HLA-A2 positive NSCLC represent 45% of this population. Over half of the patients will eventually develop secondary resistance to ICIs. Median overall survival after failure to immunotherapy is low with significant adverse events, thus a high unmet need for innovative therapeutic strategies to improve patient outcomes and enhance their quality of life. The targeted population for Tedopi® in second line could be estimated up to 100,000 patients per year in 7 major markets across the US, Europe, China and Japan.

ABOUT OVARIAN CANCER

Worldwide, ovarian cancer is the seventh most common cancer and the eighth leading cause of cancer death in women. The five-year survival rate for ovarian cancer worldwide is 30-40%. In 2020, there were nearly 313,000 new cases diagnosed*. Once the first relapse has occurred, ovarian cancer is managed as a chronic disease, requiring iterative lines of platinum-based chemotherapy. After 6 cycles, chemotherapy is stopped and one of the major priorities is to extend "chemotherapy-free" intervals for the patients by proposing maintenance strategies with targeted therapies (PARP inhibitors or bevacizumab). By the time patients with ovarian cancer present with first or second relapse, they will have received BOTH a PARP inhibitor and bevacizumab, thus patients progressing post-PARP inhibitors and bevacizumab represent an area of unmet medical need, they are offered chemotherapy alone with no maintenance strategy. The TEDOVA trial adresses these women.

* *World Cancer Research Fund International*

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation. The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127** - *lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); ongoing Phase 2 in Ulcerative Colitis (sponsor OSE Immunotherapeutics); ongoing preclinical research in leukemia (OSE Immunotherapeutics).
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **OSE-172/BI 765063** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; international Phase 1b ongoing clinical trial in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. BiCKI-IL-7 is the most advanced BiCKI® candidate targeting anti-PD1xIL-7.
- **Myeloid platform** focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com
Click and follow us on Twitter and LinkedIn

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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 May 2, 2023, including the annual financial report for the fiscal year 2022, 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.