OSE Immunotherapeutics Announces H1 2023 Results and Provides Corporate Update

Financial highlights

- **Financial visibility secured over the next 12 months, until Q4 2024, supported by additive financing secured in H1-2023 and reduction of operating expenses.**
- **€15 million available cash as of June 30, 2023, supplemented by R&D tax credit of €5.4 million and additive financing secured post-H1-2023 for almost €14 million, including a capital increase of €11.6 million driven by the bridge financing announced in Q2 2023 and amended [(1)] in September 2023 to support clinical programs.**

Clinical pipeline highlights

- **Tedopi® (T-cell specific immunotherapy - cancer vaccine): Based on final results of positive data on survival, safety and quality of life from the first Phase 3 trial in 3rd line in non-small cell lung cancer published in the international leading medical journal 'Annals of Oncology', confirmatory Phase 3 in preparation for 2024 in 2nd line, combined with a strategy of unique companion diagnostic development. Completion of patient enrollment in the Phase 2 in pancreatic cancer announced in May 2023, clinical readout expected in 2024.**
- **OSE-127/Lusvertikimab (IL-7R antagonist antibody): Phase 2 in ulcerative colitis with last patient enrollment expected in Q4 2023 and top-line results in the next months.**
- **OSE-172/BI765063 (SIRPα antagonist antibody): Ongoing clinical expansion trial in advanced solid tumors by Boehringer Ingelheim.**
- **FR104/VEL-101 (CD28 antagonist antibody): Ongoing Phase 1/2 study in kidney transplantation with last patient enrollment completed in July 2023. International Phase 2 study in kidney transplantation under preparation by Veloxis.**
- **OSE-279 (PD1 antagonist antibody): Phase 1/2 clinical trial in solid tumors and lymphomas initiated in Q4 2022. First clinical results will be presented in international conference in October 2023.**

Nantes, France – September 27, 2023, 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today announces its consolidated half-year financial results and provides updates on key milestones achieved during H1 2023 as well as the Company's outlook for its immunotherapies in immuno-oncology and immuno-inflammation.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics comments: *"OSE's key priorities for 2023 and beyond will lie in the successful conduct of the new Tedopi® pivotal Phase 3 program, along with the maximization of the near-term value of Lusvertikimab while strengthening our partnership business-model assuring recurrent revenues from our first-in-class programs. The full funding of these strategic programs will be secured in due course through additional financial resources to deliver on our goals for the benefit of both the patients and our stakeholders. OSE has today a solid late-stage clinical and preclinical diversified portfolio in immuno-oncology (IO) and immuno-inflammation (I&I). The increased interest of the scientific and medical community in cancer vaccine, in particular Tedopi®, encourages us to stay strategically focused and committed to make our drug candidate available to all eligible cancer patients in secondary resistance. We also look forward to the Lusvertikimab Phase 2 data readouts in ulcerative colitis in the next months and to generate additive value in both I&I and IO with our pre-IND OSE-230 and BiCKI®-IL7 programs. In parallel, at research level, we will continue to strengthen our first-in-kind platform built at the intersection of Antibody Engineering, Data Science, Artificial Intelligence (AI) and novel RNA Therapeutics technologies which is generating exciting clinical opportunities for future next-generation immunotherapies."*

Anne-Laure Autret-Cornet, Chief Financial Officer of OSE Immunotherapeutics, adds: *"We have strengthened our cash position and secured new financing in H1-2023 to extend our financial visibility for over the next 12 months. In parallel, we significantly reduced our cash burn compared to last year after a strict review of strategic expenses and prioritization for out-licensing. This financial strategy allows us to pursue strategic investments on Tedopi® and Lusvertikimab while pursuing innovative research programs to increase their value and interests. Our force is based on our recurrent €20 million average annual turnover these last 5 years, driven mainly by collaborations and licensing agreements with pharma companies. This business model based mostly on non-dilutive revenues remains our priority and will be further reinforced."*

CLINICAL PROGRESS IN IMMUNO-ONCOLOGY AND IMMUNO-INFLAMMATION

PROPRIETARY ASSETS

Tedopi®, T-cell epitope-based therapeutic cancer vaccine

Most advanced therapeutic cancer vaccine in clinical development. Confirmatory Phase 3 study with a companion diagnostic strategy under preparation to support the registration of Tedopi® as a potential new standard of care in second line for non-small cell lung cancer (NSCLC) patients in secondary resistance to immune checkpoint inhibitors (ICI) based on positive regulatory advice from FDA and EMA; Authorizations for compassionate use in NSCLC in third line in France, Italy and Spain.

- In September, positive Phase 3 data from Tedopi® in HLA-A2 lung cancer patients with resistance to previous immunotherapy were published in the peer-reviewed journal 'Annals of Oncology'.
- In July, the United States Patent and Trademark Office granted a new patent protecting Tedopi® for its use in cancer patients after failure with PD1/PD-L1 immune checkpoint inhibitor treatment and providing protection until year 2037 in the US.
- In June, the Company received €1.5 million in funding from Bpifrance for the development of a companion diagnostic for Tedopi® in NSCLC. This test will be used to identify HLA-A2 positive NSCLC patients eligible for treatment with Tedopi® in the next pivotal Phase 3 clinical trial under preparation.

- In June, OSE Immunotherapeutics presented a poster at the ASCO (American Society of Clinical Oncology) annual meeting showing new data on prognostic factors of overall survival from the ATALANTE-1 Phase 3 study in NSCLC highlighting the correlation between Tedopi®'s mechanism of action and patients' overall survival.
- In May, patient enrollment was completed in TEDOPaM Phase 2 clinical trial (sponsored by the oncology group GERCOR) evaluating Tedopi® in advanced pancreatic cancer. A total of 136 patients were recruited and the final results are expected in 2024.
- In March, the Spanish Drug Agency has made a new early access program available allowing access to Tedopi® through a Special Situation Authorization [(1)] in the treatment of advanced or metastatic NSCLC after ICI failure. This Special Situation Authorization was based on the positive clinical data from the initial Phase 3 trial of Tedopi® (ATALANTE-1) in third line treatment and the high unmet need for these patients.

[(1)] *The Special Situation Authorization (Real Decreto 1015/2009) is intended to provide early access to medicines for patients with a severe or rare disease with high unmet need and for which no authorized therapeutic alternatives are available.*

Lusvertikimab (OSE-127), IL-7 Receptor (IL-7R) antagonist

Most advanced Interleukin-7 antagonist immunotherapy in clinical development with a strong biological rationale in refractory IBD patients.

- In July, the trial's Independent Drug Safety Monitoring Board (DSMB) provided a positive recommendation on the continuation until its completion of the Phase 2 clinical trial on Lusvertikimab in ulcerative colitis. Last patient enrollment is expected for Q4 2023.
- In July, positive opinion for Orphan Drug Designation was granted by the European Medicines Agency to Lusvertikimab in the treatment of Acute Lymphoblastic Leukemia based on preclinical results presented and awarded at last American Society of Hematology (ASH) annual conference (December 2022) in New Orleans (US).
- In May, OSE Immunotherapeutics earned the full worldwide rights on Lusvertikimab for all indications.
- In March, positive Phase 1 results on Lusvertikimab for the treatment of chronic autoimmune diseases were published and selected as 'Top Read' in the peer-reviewed journal "Journal of Immunology".

OSE-279, proprietary PD1 antagonist

High affinity PD1 antibody, recent patent granted in US, Europe, China, Japan

- In December 2022, first patient dosed in a Phase 1/2 clinical trial in patients with advanced solid tumors or lymphomas.
- First clinical data will be presented at AACR-NCI-EORTC (Boston, 11 – 15th October 2023).

PARTNERED ASSETS

BI 765063, first-in-class SIRPα inhibitor on the SIRPα/CD47 myeloid pathway in advanced solid tumors, developed in partnership with Boehringer Ingelheim

- Phase 1b clinical expansion trial initiated in May 2022 with BI 765063, sponsored and conducted by Boehringer Ingelheim in advanced hepatocellular carcinoma and head and neck cancer.
- In April, a poster highlighting the predictive response biomarkers from Phase I clinical trial of BI765063, stand-alone and in combination with ezabenlimab, has been presented at the AACR 2023 annual conference (Orlando).

FR104/VEL-101, a monoclonal antibody antagonist of CD28, developed in partnership with Veloxis Pharmaceuticals, Inc. in kidney transplantation

- In July, patient enrollment was completed in the FIRsT Phase 1/2clinical trial evaluating FR104/VEL-101 in renal transplantation, sponsored and conducted by the University Hospital of Nantes. A longer-term follow-up assessment will be performed one year after transplantation.
- International Phase 2 clinical trial in kidney transplantation is under preparation by Veloxis.

RESEARCH PROGRAMS

OSE-230, novel monoclonal antibody to activate a pro-resolutive GPCR target (ChemR23), a novel and innovative approach in the management of the resolution of neutrophil-mediated chronic and severe inflammation

- In July, the second peer-reviewed results on OSE-230 were published in the leading journal "Frontiers in Immunology" after a publication in "Sciences Advances" (Trilleaud et al. 2021).
- In June, a poster highlighting the innovative mechanism of action on neutrophils and inhibition of the pathogenic NETosis process was presented at the FOCIS 2023 annual conference (Boston).

CLEC-1, novel myeloid immune checkpoint target in immune-oncology

- In April, two posters reporting the latest research updates on CLEC-1 were presented at the 2023 American Association for Cancer Research (AACR) meeting.
- In November 2022, publication in the peer-reviewed journal "Sciences Advances" of fundamental discoveries and preclinical results showing that CLEC-1 is a novel myeloid checkpoint interacting with a new ligand and highlighting the therapeutic potential of CLEC-1 antagonist antibodies as innovative cancer immunotherapy.

BiCKI®IL-7v, a novel bispecific therapy combining anti-PD-1 and the cytokine IL-7

- In June, an invited oral communication and a poster reporting the differentiated advantages of the IL-7 cytokine to sustain long-term survival and functions of tumor-reactive T lymphocytes were presented at the annual cytokine-based drug development summit (Boston) and at the Antibody Engineering and Therapeutics 2023 Europe conference (Amsterdam).

Novel RNA Therapeutics & Artificial Intelligence innovative research programs

- OSE Immunotherapeutics is building a first-in-kind research platform at the intersection of Antibody Engineering, Data Science and Artificial Intelligence (AI) development programs dedicated to

monoclonal antibodies (AI programs initiated in 2020 and reinforced in 2021 with the MabSilico collaboration). This cutting-edge platform adds novel RNA Therapeutics and RNA Delivery methods recently patented by our research team to continue to develop next-generation immunotherapy medicines modulating immune cell responses in the field of immuno-inflammation and immuno-oncology.

- In August, OSE Immunotherapeutics received a grant from the French Government and Region Pays de la Loire to support the Company's research programs in the field of RNA Therapeutics.

CORPORATE GOVERNANCE

Eric Leire was appointed independent Director of OSE Immunotherapeutics on June 22, 2023.

Eric Leire is a Medical Doctor and American and French citizen. He brings a professional international experience, both in the US and in Europe, in listed biotechnology and pharmaceutical companies. He is currently President and Chief Executive Officer of Genflow Biosciences Ltd. Through his active experience in venture capital funds in the health field (Medwell Capital, Canada and Biofund Venture, Denmark), he has contributed to develop biotech companies.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, was appointed as Director and Anne-Laure Autret-Cornet, Chief Financial Officer, as Director representing the employee shareholders.

H1 2023 RESULTS

The key figures of the 2023 consolidated half-year results are reported below:

In k€	June 30, 2023	June 30, 2022
Operating result	(13,504)	(3,425)
Net result	(11,860)	(1,979)
In k€	June 30, 2023	December 31, 2022
Available cash	15,018	25,620
Consolidated balance sheet	80,391	91,781

As of June 30, 2023, available cash amounted to €15 million, giving a financial visibility until Q4 2024.

During the first half of 2023, OSE Immunotherapeutics secured:

- (1) **An equity financing line** with Vester Finance, set up on April 27, 2023. This financing has triggered at the end of September a capital increase of €11.6 million (without any discount on the share price at the date of signature). To supplement its financial resources and in order to extend its financial visibility until the fourth quarter of 2024, OSE Immunotherapeutics signed on 27 September 2023, an extension to this equity financing line agreement with Vester Finance, at the same conditions[1].

[1] *These conditions are described in the Company's press release dated April 27, 2023. The shares will therefore be issued on the basis of the lowest average daily price weighted by volumes over the period of the two trading sessions preceding each issue, reduced a maximum discount of 6%, in compliance with the price rule and the ceiling set by the general meeting. Under the terms of the delegation granted by the general meeting, the issue price of the shares must be "at least equal to the weighted average of the prices of the last three trading sessions preceding the fixing of the issue price, possibly reduced by a maximum discount of 20%".*

This extension, approved by the Board of Directors of September 27, 2023, acting on delegation from the general assembly meeting of shareholders of June 22, 2023[2], relates to a maximum of 900,000 shares of the Company, representing a maximum of 4,16% of the share capital, that Vester committed to subscribe on its own initiative, over a maximum period of 24 months, subject to certain usual contractual conditions.

Assuming that the totality of this additional line of financing is used in full, a shareholder holding 1.00% of the capital of OSE Immunotherapeutics before its establishment, would see his stake increase to 0.96% of the capital on an undiluted basis[3] and 0.96% of the share capital on a diluted basis[4].

This transaction does not give rise to the preparation of a prospectus subject to the approval of the "Autorité des Marchés Financiers", based on Article 1 of the Prospectus Regulation granting an exemption when a transaction relates to a dilution less than 20% of the Company's share capital.

The number of shares issued under this agreement and admitted to trading will be communicated monthly on the Company's website.

- **Loans and "PGE Resilience**"

  The Company obtained the formal agreement on loans for a total amount of €5.3 million with the collective support of "La Région Pays de la Loire", Bpifrance and its banking pool composed by banks CIC, Crédit Mutuel and BNP to finance its strategic R&D programs. Favorable conditions were granted for these loans, with an interest range of 2-4% and reimbursement timelines within 3 to 5 years. Part of these loans is composed by a "PGE Resilience" ("Prêt Garanti par l'État") loan guaranteed by the French State, implemented in the context of the Ukrainian crisis.

  At the end of June 2023, €3.1 million have been drawdown. The balance has been received in Q3 2023.

- €1.5 million in **funding from Bpifrance** for the development of a companion diagnostic for the cancer vaccine Tedopi® in non-small cell lung cancer.

This available cash will enable the Company to finance its clinical development and R&D costs for earlier stage products.

During the first half of 2023, the Company recorded a consolidated net result of €-11,9 million.

Current operating expenses were €14.9 million (versus €19.4 million for the same period in 2022) of which 77% are related to R&D. After a strategic review of costs and programs, operating expenses dropped dawn by 25% compared to H1 2022.

The Board of Directors of September 27, 2023, has approved the Company's semester accounts as of June 30, 2023. The full "Half-year financial report" (Regulated information) is available on: https://www.ose-immuno.com/en/financial-documents/. The limited review procedures on the consolidated accounts have been performed. The report on this limited review is being issued.

[2] *21st resolution: delegation of capital increase with elimination of shareholders' preferential subscription rights for the benefit of categories of people meeting specific characteristics. Vester Finance falls well into the targeted category as a regular investor in so-called "small cap" growth companies, particularly in the health or biotechnology sector.*

[3] *Based on the 21,641,101 shares issuable upon exercise of the dilutive instruments issued by the Company to date.*

[4] *Based on the 1,830,000 shares that may be issued upon exercise of the dilutive instruments issued by the Company to date.*

CONSOLIDATED PROFIT & LOSS

In K€	H1 2023	H1 2022
Turnover	1,358	16,047
OPERATING INCOME - RECURRING	**1,358**	**16,047**
Research & Development expenses	(9,693)	(14,395)
Overhead expenses	(3,604)	(3,813)
Expenses related to share-based payments	(1,562)	(1,182)
OPERATING PROFIT/LOSS - RECURRING	**(13,501)**	**(3,341)**
Other operating income and expenses	(4)	(84)
OPERATING RESULT	**(13,504)**	**(3,425)**
Financial income	2,658	2,023
Financial expenses	(1,608)	(708)
PROFIT/LOSS BEFORE TAX	**(11,943)**	**(2,110)**
INCOME TAX	**84**	**132**
CONSOLIDATED NET RESULT	**(11,860)**	**(1,979)**
Of which consolidated net result attributable to shareholders	***(11,860)***	***(1,979)***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	18,624,665	18,527,401
• The basic and diluted result per common share (€/share)	(0,64)	(0,11)
• Diluted result per share	(0,64)	(0,11)

In K€	H1 2023	H1 2022
NET RESULT	**(11,860)**	**(1,979)**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(7)	46
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	0	34
Other comprehensive income in the period	**(7)**	**(13)**
GLOBAL PROFIT/LOSS	**(11,867)**	**(1,992)**

CONSOLIDATED BALANCE SHEET

ASSETS in K€	June 30, 2023	December 31, 2022
NON-CURRENT ASSETS		
Acquired R&D costs	47,604	48,784
Tangible assets	589	743
Rights of use	3,712	4,236
Financial assets	587	635
Deferred tax assets	184	182
TOTAL NON-CURRENT ASSETS	***52,676***	***54,581***
CURRENT ASSETS		
Trade receivables	234	403
Other current assets	12,463	11,177
Cash and cash equivalents	15,018	25,620
TOTAL CURRENT ASSETS	***27,714***	***37,200***
TOTAL ASSETS	**80,391**	**91,781**

EQUITY & LIABILITIES in K€	June 30, 2023	December 31, 2022
SHAREHOLDERS' EQUITY		
Stated capital	3,806	3,705
Share premium	39,169	38,784
Merger premium	26,827	26,827
Treasury stock	(483)	(549)
Reserves and retained earnings	(34,932)	(18,349)
Consolidated result	(11,860)	(17,760)
TOTAL SHAREHOLDERS' EQUITY	***22,529***	***32,658***
NON-CURRENT DEBTS		
Non-current financial liabilities	34,310	37,231
Non-current lease liabilities	3,157	3,586
Non-current deferred tax liabilities	1,430	1,514
Non-current provisions	423	524
TOTAL NON-CURRENT DEBTS	***39,320***	***42,856***
CURRENT DEBTS		
Current financial liabilities	5,433	3,093
Current lease liabilities	858	883
Trade payables	9,421	8,539
Corporate income tax liabilities	18	21
Social and tax payables	2,662	2,916
Other debts and accruals	151	816
TOTAL CURRENT DEBTS	***18,542***	***16,268***
TOTAL LIABILITIES	**80,391**	**91,781**

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

Contacts

OSE Immunotherapeutics
Sylvie Détry
sylvie.detry@ose-immuno.com

Nicolas Poirier
Chief Executive Officer
nicolas.poirier@ose-immuno.com

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

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 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.