OSE Immunotherapeutics Announces Historic H1 2024 Results and Provides Corporate Update

Financial and business highlights

- **Total H1 2024 incomes of €82.5 million thanks to Company's new partnerships.**
- **New strategic partnership with AbbVie for up to $713 million, including $48 million received upon signature.**
- **Major partnership expansion with Boehringer Ingelheim:**
  - **Amendment of the collaboration and licensing agreement on first-in-class SIRPα compounds developed both in immuno-oncology and now expected in Phase 2 in cardiovascular-renal-metabolic diseases: a one-time payment of €25.3 million.**
  - **New asset acquisition of a preclinical program from the OSE's cis- targeting anti-PD1/cytokine platform: €13.5 million received upon signature and €17.5 potential near-term milestone.**
- **€8.4 million in non-dilutive funding under the "i-Démo" call for projects as part of the "France 2030" program to support the registration Phase 3 clinical trial of cancer vaccine Tedopi®.**
- **Level of cash of €80.7 million as of June 30, 2024: €25.9 million available cash[1] + €54.9 million financial assets[2], providing solid financial position and visibility to support implementation of the strategy until 2027. This cash position also includes the research tax credit of €5.8 million received in June 2024.**

Clinical pipeline highlights

- **Positive efficacy and safety results from the Phase 1/2 clinical trial evaluating PD1-antagonist antibody OSE-279 monotherapy in solid tumors.**
- **Positive results from the FIRsT Phase 1/2 study from first use of FR104/VEL-101 immunotherapy in renal transplantation.**

Main post-semester highlights

- **First positive efficacy results from the CoTikiS Phase 2 study evaluating IL-7R antagonist Lusvertikimab in ulcerative colitis.**
- **Global launch of Artemia Phase 3 registration study for cancer vaccine Tedopi® in second-line non-small cell lung cancer.**

[1] Cash & cash equivalent

[2] Non-current & current financial assets are deposit which maturity > 3 months (IAS 7); classified as non-current for deposits with maturities > 12 months

NANTES, France, September 26, 2024 – 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today reported its consolidated half-year financial results and provided updates on key milestones achieved during the H1 2024 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: *"The major milestones achieved during H1 2024 are paving the way for a transformative year for OSE. During this period, thanks to the OSE teams, the Company made significant outstanding progress.*

The half-year has seen continued execution of our partnership-focused business model through three strategic pharmaceutical agreements with major partners, AbbVie and Boehringer Ingelheim, related to our differentiated immunological pipeline. These key achievements trigger a solid financial position supporting the Company's growth, relying on our promising clinical and preclinical proprietary programs in immuno-inflammation and immuno-oncology conducted and supported by highly skilled OSE teams.

We also achieved two significant inflection points on our late-stage proprietary clinical assets. In immuno-inflammation, the positive clinical efficacy and safety results for Lusvertikimab in ulcerative colitis represent a strong catalyst for potential future partnership opportunities. We have generated exciting data that we plan to communicate with our investigators at an upcoming global medical conference. In immuno-oncology, the international registration study Artemia for cancer vaccine Tedopi® in second-line non-small cell lung cancer treatment is now on track globally. In parallel, in order to ensure continuous portfolio development, we continue accelerating and strengthening first-in-class preclinical programs from our innovative research platforms".

Anne-Laure Autret-Cornet, Chief Financial Officer of OSE Immunotherapeutics, said: *"With more than €90 million non-dilutive cash-in in 2024, our financial visibility is strongly reinforced until 2027. This allows us to prioritize funding of our recently globally launched Artemia Phase 3 registration study for our cancer vaccine Tedopi® in lung cancer and to further invest in our other proprietary clinical products and innovative R&D engine to increase the value and interest of our assets."*

THREE PHARMACEUTICAL AGREEMENTS SIGNED DURING H1 2024 PROVIDING A SOLID FINANCIAL POSITION TO SUPPORT IMPLEMENTATION OF THE STRATEGY UNTIL 2027

- In February 2024, OSE Immunotherapeutics and AbbVie concluded a strategic partnership to develop OSE-230 (renamed ABBV-230), a monoclonal antibody designed to resolve chronic and severe inflammation.

  Under the terms of the agreement, AbbVie received an exclusive global license to develop, manufacture and commercialize ABBV-230. OSE Immunotherapeutics received a $48 million upfront payment and will be eligible to receive up to an additional $665 million in clinical development, regulatory and commercial milestones. In addition, OSE Immunotherapeutics will be eligible to receive potential tiered royalties on global net sales of ABBV-230.

- In May 2024, OSE Immunotherapeutics and Boehringer Ingelheim expanded their partnership through the addition of two new projects:

  - A new preclinical program will be launched to develop immune-cell activating treatments based on OSE's cis-targeting[3] anti-PD1/cytokine platform via an asset acquisition.

[3] Cis-targeting: Bispecific antibodies have the capability to target cells either in a cis- or in a trans-binding orientation. During trans-binding, the antibody recognizes two different antigens, each expressed on a different cell population, and can link two different cell populations with each other (e.g. T-cell engagers). Cis-binding bispecific antibody targets two antigens expressed on the very same cell enabling preferential activation of the desired immune cell types while minimizing the activation of others (Segués A. et al. International Review of Cell and Molecular Biology 2022).

Under the terms of this preclinical asset acquisition, OSE Immunotherapeutics received €13.5 million in upfront payment and a potential near-term milestone of EUR 17.5 million.

- An amendment to the existing collaboration and license agreement for the anti-SIRPα immuno-oncology compounds BI 765063 and BI 770371 (being investigated in Phase 1b clinical studies in advanced solid tumors), development will now also be pursued in cardiovascular-renal-metabolic (CRM) diseases with the initiation of a Phase 2 clinical study planned for end of 2024.

  Under the terms of this amendment, the parties agreed on partial royalty buy-out monetizing with a one-time payment of EUR 25.3 million. Furthermore, Boehringer is granted an option for an additional buy-out during further development triggering a one-time payment plus the increase of one sales milestone. All other agreed development, regulatory and sales milestone payments of up to €1.1 billion remain as agreed between the parties under the initial agreement.

UPDATE ON CLINICAL PROGRESS IN IMMUNO-ONCOLOGY AND IMMUNO-INFLAMMATION

First positive efficacy results from the Phase 2 clinical trial evaluating Lusvertikimab in ulcerative colitis.

- Following completion of enrolment in March 2024, OSE Immunotherapeutics announced in July first positive efficacy results for Lusvertikimab in the Phase 2 trial for the treatment of ulcerative colitis (CoTikiS study):
  - Lusvertikimab demonstrated significant efficacy during the 10 week-induction phase of treatment measured by the improvement of the Modified Mayo Score, in the randomized double blind study,
  - A favorable safety and tolerability profile was observed in the whole patient population across the two doses tested and during the open label phase of treatment.

Global launch of the Artemia Phase 3 registration trial for the off-the-shelf neo-epitope-based cancer vaccine Tedopi® in second-line non-small cell lung cancer (NSCLC) after secondary resistance to immune checkpoint inhibitors (ICI).

- In September 2024, the Company launched its international Phase 3 clinical trial named 'Artemia' of Tedopi® in second-line treatment in HLA-A2 positive patients with metastatic NSCLC. This dossier, reviewed and accepted in 14 countries by international health agencies (US FDA, Canada, Europe and the United Kingdom) is a pivotal study supporting the registration of Tedopi®, in parallel with the companion diagnostic for HLA-A2 positive patients.
- Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.

OSE-279, proprietary anti-PD1: positive efficacy and safety results from Phase 1/2 study in advanced solid tumors.

- In February 2024, updated positive results from Phase 1/2 of OSE-279 were presented at the ESMO Targeted Anticancer Therapy Congress. These results showed a good pharmacokinetic/pharmacodynamic (PK/PD) and manageable safety profile in line with previous anti-PD1 development and with a high signal of efficacy in the first 20 patients representing 13 different tumor types.

Positive Phase 1/2 analysis from first use of FR104/VEL-101 immunotherapy in kidney transplantation.

- In June 2024, OSE Immunotherapeutics and Nantes University Hospital presented positive data from the completed Phase 1/2 clinical trial FIRsT evaluating FR104/VEL-101 in patients undergoing renal transplant at the « American Transplant Congress » (ATC) in Philadelphia. The data showed the safety of the product

used in combination and the first signs of efficacy with no episodes of acute rejection after one year follow-up in the 8 patients of the study who completed 1-year treatment.

Two additional oral communications were presented during this congress:

- A communication presented by OSE partner Veloxis Pharmaceuticals, featured the results from its Phase 1 dose escalation clinical trial evaluating the safety, tolerability, pharmacodynamics and pharmacokinetics of single ascending doses of subcutaneous administration of FR104/VEL-101 in healthy participants.
- A communication presented by the group of Pr. Richard Pierson (Massachusetts General Hospital, Harvard university, Boston, USA), reported on the positive preclinical efficacy data of FR104/VEL-101 injection in monotherapy or in combination with anti-CD40L antibody to protect from acute and chronic heart allograft rejection.

Advancement of clinical development of first-in-class SIRPα cancer immunology treatment BI 770371

- In July 2024, Boehringer Ingelheim and OSE Immunotherapeutics announced that Boehringer Ingelheim will be progressing their first-in-class SIRPα immuno-oncology program into the next phase in clinical development. As part of the program, Boehringer will move forward with an improved next generation SIRPα inhibitor antibody, which will now be tested in a Phase 1b study in solid tumors.
- The initiation of a Phase 2 study in cardiovascular-renal-metabolic (CRM) diseases is planned for the end of 2024.

PROGRESS ON EARLY-STAGE PROGRAMS

- In April 2024, novel data in the peer-reviewed *Journal of Immunology* on a first-in-class research program with CLEC-1, its novel myeloid immune checkpoint target for cancer immunotherapy. The collaborative work with Dr Elise Chiffoleau's team at the Center for Translational Research in Transplantation and Immunology has shown, for the first time, that CLEC-1 acts as an immune checkpoint for the control of acute immune responses in the context of sterile inflammation.
- In June 2024, the Company presented preclinical data on novel mRNA (messenger RiboNucleic Acid) Therapeutic platform for the treatment of inflammatory and autoimmune disorders at the Federation of Clinical Immunology Societies (FOCIS) annual meeting held in San Francisco.

  The mRNA therapeutic platform has been designed for the local delivery of mRNA into inflammatory tissue using lipid nanoparticles. This platform has the potential to deliver innovative immunotherapeutic drugs and to address new biology that cannot be targeted with standard biologic treatments. This novel IL-35 mRNA therapeutics is generating potential opportunities for the treatment of inflammatory and autoimmune disorders, in particular in autoimmune hepatitis, a severe immune-mediated inflammatory disorder of the liver with strong unmet medical need.
- In June 2024, OSE Immunotherapeutics also entered into a commercial and revenue sharing agreement with leading global cancer center Memorial Sloan Kettering Cancer Center (MSK).

  This exclusive and worldwide agreement covers OSE Immunotherapeutics' patent rights and jointly owned OSE/MSK patent rights in the field of Chimeric Antigen Receptor (CAR) cell therapy for the treatment of Interleukin-7 Receptor (IL-7R) expressing cancers, in particular hematological tumors such as Acute Lymphoblastic Leukemia. As part of this agreement, MSK will lead the research, development, and commercialization efforts, and subsequently share potential future revenues with OSE Immunotherapeutics.

CORPORATE GOVERNANCE

- Marc Dechamps, Martine George, Markus Goebel and Cécile Nguyen-Cluzel were appointed new independent Directors of OSE Immunotherapeutics on June 19, 2024. Together, they bring a wealth of experience from leadership roles in the biopharmaceutical and health financial industry reenforcing the key strategic skills of the Board.
- The newly installed Board appointed Didier Hoch as its Chairman. He succeeds Dominique Costantini who did not run for a new mandate at the 2024 Shareholders' meeting.

H1 2024 RESULTS

The key figures of the 2024 consolidated half-year results are reported below:

In k€	June 30, 2024	June 30, 2023
Operating result	63,321	(13,504)
Net result	57,175	(11,860)
In k€	June 30, 2024	December 31, 2023
Available cash and cash equivalents	25,856	18,672
Financial assets (deposit > 3 months)	49,890	0
Consolidated balance sheet	140,921	82,054

As of June 30, 2024, available cash [(1)] and financial assets [(2)] amounted to €80.7 million, giving a financial visibility until 2027.

During the first half of 2024, the Company secured:

- $48 million upfront payment as part of global license and collaboration agreement with AbbVie for ABBV-230 (formerly OSE-230), a novel monoclonal antibody for the treatment of chronic inflammation.
- €13.5 upfront payment as part of a purchase agreement with Boehringer Ingelheim of a novel cis-targeting anti-PD-1/cytokine asset developed by OSE.
- €25.3 million one-time payment as part of an amendment of the existing collaboration and licensing agreement with Boehringer Ingelheim for the anti-SIRPα immuno-oncology compounds BI 765063 and BI 770371.
- €5.8 million in 2023 research tax credit.
- €8.4 million in public funding under the "i-Démo" call for projects as part of the plan "France 2030" to support the registration Phase 3 clinical trial of cancer vaccine Tedopi® in NSCLC. This financing will be spread over the life of the project.

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 2024, the Company recorded a consolidated net result of €57.2 million.

Current operating expenses were €19.3 million (versus €14.9 million for the same period in 2023) of which 77% are related to R&D.

The Board of Directors of September 26, 2024, has approved the Company's semester accounts as of June 30, 2024. 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.

CONSOLIDATED PROFIT & LOSS

In K€	H1 2024	H1 2023
Turnover	69,046	1,358
Other products	13,527	0
OPERATING INCOME - RECURRING	**82,573**	**1,358**
Research & Development expenses	(13,884)	(9,693)
Overhead expenses	(4,286)	(3,604)
Expenses related to share-based payments	(1,082)	(1,562)
OPERATING PROFIT/LOSS - RECURRING	**63,321**	**(13,501)**
Other operating income and expenses	0	(4)
OPERATING RESULT	**63,321**	**(13,504)**
Financial income	391	2,658
Financial expenses	(2,998)	(1,608)
PROFIT/LOSS BEFORE TAX	**(2,606)**	**(11,943)**
INCOME TAX	**3,540**	**84**
CONSOLIDATED NET RESULT	**57,175**	**(11,860)**
Of which consolidated net result attributable to shareholders	***57,175***	***(11,860)***
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	21,759,035	18,624,665
• The basic and diluted result per common share (€/share)	2.63	(0.64)
• Diluted result per share	2.27	(0.64)

In K€	H1 2024	H1 2023
NET RESULT	**57,175**	**(11,860)**
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	42	(7)
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits		0
Other comprehensive income in the period	**(42)**	**(7)**
GLOBAL PROFIT/LOSS	**57,217**	**(11,867)**

CONSOLIDATED BALANCE SHEET

ASSETS in K€	June 30, 2024	December 31, 2023
NON-CURRENT ASSETS		
Acquired R&D costs	45,211	46,401
Tangible assets	386	464
Rights of use	3,261	3,606
Financial assets	6,084	910
Deferred tax assets	195	195
TOTAL NON-CURRENT ASSETS	***55,136***	***51,576***
CURRENT ASSETS		
Trade receivables	4,966	982
Other current assets	54,963	10,824
Cash and cash equivalents	25,856	18,672
TOTAL CURRENT ASSETS	***85,785***	***30,478***
TOTAL ASSETS	**140,921**	**82,054**

EQUITY & LIABILITIES in K€	June 30, 2024	December 31, 2023
SHAREHOLDERS' EQUITY		
Stated capital	4,366	4,330
Share & Merger premium	76,822	76,643
Treasury stock	(393)	(408)
Reserves and retained earnings	(56,522)	(34,587)
Consolidated result	57,175	(23,003)
TOTAL SHAREHOLDERS' EQUITY	***81,448***	***22,975***
NON-CURRENT DEBTS		
Non-current financial liabilities	37,152	35,508
Non-current lease liabilities	2,812	3,032
Non-current deferred tax liabilities	1,658	1,311
Non-current provisions	464	429
TOTAL NON-CURRENT DEBTS	***42,086***	***40,280***
CURRENT DEBTS		
Current financial liabilities	3,236	6,403
Current lease liabilities	685	858
Trade payables	8,344	9,299
Corporate income tax liabilities	0	20
Social and tax payables	2,219	1,867
Other debts and accruals	2,901	351
TOTAL CURRENT DEBTS	***17,387***	***18,799***
TOTAL LIABILITIES	**140,921**	**82,054**

About OSE Immunotherapeutics

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

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): most advanced therapeutic cancer vaccine in development; positive results from a randomized Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in third-line secondary resistance after checkpoint inhibitor failure. Ongoing randomized registration Phase 3 study (Artemia) in second-line NSCLC in HLA-A2+ patients with secondary resistance. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-127** - *Lusvertikimab* (humanized monoclonal antibody antagonist of IL-7 receptor); Positive Phase 2 (CoTikiS) study in Ulcerative Colitis; ongoing preclinical research in leukemia.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 in solid tumors.
- **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); successful Phase 1 in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **Anti-SIRPα monoclonal antibody** developed in partnership with Boehringer Ingelheim in advanced solid tumors and cardiovascular-renal-metabolic diseases (CRM); positive Phase 1 dose escalation results in monotherapy and in combination; Phase 2 in CRM diseases planned to be initiated end of 2024.
- **ABBV-230** (ChemR23 agonist mAb) developed in partnership with AbbVie in chronic inflammation.

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

- **Pro-resolutive mAb platform** focused on targeting and advancing inflammation resolution and optimizing the therapeutic potential of targeting Neutrophils and Macrophages in I&I. **ABBV-230** (licensed to AbbVie) is the first candidate generated by the platform, additional discovery programs ongoing on new pro-resolutive GPCRs.
- **Myeloid Checkpoint platform** focused on optimizing the therapeutic potential of myeloid cells in IO by targeting immune regulatory receptors expressed by Macrophages and Dendritic cells. **BI 765063** and **BI 770371** (licensed to Boehringer Ingelheim) are the most advanced candidates generated by the platform. Ongoing additional discovery programs, in particular with positive preclinical results obtained in monotherapy with new anti-**CLEC-1** mAbs.
- **BiCKI® Platform** is a bifunctional fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy by "cis-potentiating" tumor-specific T cells. A first program has been acquired by Boehringer Ingelheim.
- **mRNA Therapeutic platform** allows local delivery into the inflammatory site of innovative immunotherapies encoded by RNA to locally controls and/or suppress immune responses and inflammation.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com. Click and follow us on X 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 April 30, 2024, including the annual financial report for the fiscal year 2023, 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.