OSE Immunotherapeutics and Boehringer Ingelheim expand collaboration to develop first-in-class treatments for cancer and cardio-renal-metabolic diseases

Nantes, France - Ingelheim, Germany - 22 May 2024, 7:30am CET - Today OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) and Boehringer Ingelheim announced a major expansion of their partnership.

Two new projects to develop first-in-class treatments will be added to the ongoing anti-SIRPα immuno-oncology programs. The first involves broadening the therapeutic evaluation of an already partnered asset to reach more patients and the other a new asset acquisition:

- Reflecting an amendment of the existing collaboration and license agreement for the anti-SIRPα immuno-oncology compounds BI 765063 and BI 770371, which are being investigated in Phase I clinical studies in advanced solid tumors, development will now also be pursued in cardiovascular-renal-metabolic (CRM) diseases.
- A new preclinical program will be launched to develop immune-cell activating treatments based on OSE's cis-targeting[1] anti-PD1/cytokine platform via an asset acquisition.

Affecting over one billion lives globally[2], CRM diseases cause 20 million deaths annually. They are interconnected, co-exist, and can amplify one another, resulting in a significant burden on patients' lives. Cancer accounts for nearly 10 million deaths and for many cancer patients there are no or only limited treatment options.

The new development programs bolster Boehringer Ingelheim's pipeline and reflects the company's unwavering commitment to explore and progress new therapies to address unmet patient needs, including in CRM diseases and cancer. The cis-targeting anti-PD1/cytokine platform asset will further enrich Boehringer Ingelheim's array of novel potential immune-modulatory cancer treatments. The development of the ongoing anti-SIRPα compounds for a new indication adds to the company's comprehensive CRM pipeline with the initiation of a Phase 2 clinical study planned for later this year.

"We are very pleased to expand our pipeline of potential first-in-class CRM disease therapies, as well as our pipeline of first-in-class T-cell based anti-cancer therapies," said Clive R. Wood, Corporate Senior Vice President and Global Head of Discovery Research at Boehringer Ingelheim. *"The expansion of our partnership with OSE reflects our joint mission to improving patient outcomes in two of the biggest threats to global health."*

[1] 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).

[2] Schechter M, Melzer Cohen C, Yanuv I, et al. Epidemiology of the diabetes-cardio-renal spectrum: a cross-sectional report of 1.4 million adults. Cardiovascular Diabetology. 2022;21(1):104. doi:10.1186/s12933-022-01521-9

Nicolas Poirier, CEO of OSE Immunotherapeutics, commented: *"We are excited about adding two highly innovative new development programs to our fruitful collaboration with Boehringer Ingelheim. We look forward to working with the scientists at Boehringer Ingelheim on the new development programs that have the potential to bring new breakthrough therapy options to patients with CRM diseases and cancer."*

OSE Immunotherapeutics will receive EUR 13.5. million in upfront payment and a potential near-term milestone of EUR 17.5 million for the purchase of a novel, cis-targeting anti-PD-1/cytokine asset in preclinical stage. Regarding the two ongoing anti-SIRPα programs BI 765063 and BI 770371 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.

About Boehringer Ingelheim

Boehringer Ingelheim is working on breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term, sustainable perspective. More than 53,000 employees serve over 130 markets in the two business units Human Pharma and Animal Health. Learn more at www.boehringer-ingelheim.com.

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): 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): first positive results in the ongoing Phase 1/2 in solid tumors.
- **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); successful Phase 1 in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **BI 765063** and **BI 770371** (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-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. **OSE-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.
- **Cytokine platform** focused on leveraging the Cis-Delivery of cytokine in IO and I&I. BiCKI® 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-7v is the most advanced BiCKI® candidate targeting anti-PD1xIL-7. Ongoing additional discovery programs on Cis-Demasking technologies.

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

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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 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.