Boehringer Ingelheim and OSE Immunotherapeutics advance clinical development of first-in-class SIRPα cancer immunology treatment BI 770371

Ingelheim, Germany and Nantes, France, 3 July 2024 – Today Boehringer Ingelheim and OSE Immunotherapeutics SA (OSE), a clinical stage biotech company (ISIN: FR0012127173; Mnemo: OSE), announced that Boehringer 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.

Immuno-oncological therapies achieve sustained remission only in 15-20% of all cases of cancer. Boehringer Ingelheim is on a mission to significantly increase this share. With its immuno-oncology research, Boehringer is developing various complementary approaches to activate the immune system against cancer cells. Blocking the SIRPα immune checkpoint is one of these approaches.

"We are very excited about progressing the SIRPα program which was initiated by OSE." said **Vittoria Zinzalla, Global Head of Translational Medicine and Clinical Pharmacology at Boehringer Ingelheim**. *"With the positive data from our first clinical studies and the switch to an improved antibody we hope to achieve our aim of accelerating and expanding our pipeline of first-in-class cancer therapies to transform the lives of patients affected by cancer."*

Nicolas Poirier, CEO of OSE Immunotherapeutics, commented: "*We are thrilled to see the SIRPα project moving forward in clinical development in immuno-oncology and the expansion in CRM diseases. This brings us one step closer to achieving our aim of providing this selective SIRPα innovation for the benefit of more patients."*

SIRPα is a receptor expressed on macrophages, which can recognize, engulf, and destroy cancer cells. The binding of this receptor to its binding partner, cluster of differentiation 47 (CD47), stops this immune activity. This is why many cancer cells display CD47 on their surface to escape detection and destruction by the immune system. Blocking SIRPα enables macrophages to enhance their immune activity and destroy cancer cells.

Boehringer Ingelheim is further strengthening its comprehensive immuno-oncology pipeline with the progression of this program to accelerate next-generation cancer therapies to address high unmet patient needs. Boehringer will be solely responsible for all further development and potential future commercialization.

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 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.).
- **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 four 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 770371** (licensed to Boehringer Ingelheim) is the most advanced candidate from this 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.