OSE Immunotherapeutics Announces that its Partner Boehringer Ingelheim Will Present Early Clinical Evidence of Innate Immune Modulation and Anti-Tumor Activity via SIRPα Blockade in Two Ongoing Trials at ASCO 2025

- **BI 765063 in combination with programmed cell death-1 (PD1) inhibitor antibody ezabenlimab + cetuximab demonstrated a well-tolerated safety profile and potentially promising efficacy signals as second-line treatment in patients with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).**

- **Next generation SIRPα inhibitor BI 770371 was shown to be well tolerated alone and in combination with PD1 inhibitor ezabenlimab in a dose escalation trial in patients with advanced solid tumors. BI 770371 is currently being further investigated in a Phase 1b study in first-line patients with R/M HNSCC.**

Nantes, France, 23 May 2025 – **OSE Immunotherapeutics** (ISIN: FR0012127173; Mnemo: OSE), today proudly announced that its partner **Boehringer Ingelheim** will present new clinical data from two early-stage trials targeting the signal regulatory protein α (SIRPα) innate immune checkpoint at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, May 30 - June 3, 2025, in Chicago, IL, USA.

In a Phase 1b study conducted by Boehringer, its potential, first-in-class SIRPα monoclonal antibody, BI 765063, demonstrated a manageable safety profile as well as preliminary signs of immune activation and additive antitumor activity when combined with PD-1 inhibitor ezabenlimab and cetuximab in patients with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).[1]

Additionally, in an open-label, Phase I trial conducted by Boehringer, its next-generation SIRPα monoclonal antibody, BI 770371, alone and in combination with the PD-1 inhibitor ezabenlimab, was shown to be well tolerated in patients with advanced solid tumors. There were no dose-limiting toxicities in either treatment arm, and the maximum tolerated dose was not reached in either group.[2]

“The preliminary results from these early-stage programs are encouraging and further strengthen Boehringer’s robust immuno-oncology pipeline aimed at accelerating next-generation cancer therapies to address high unmet patient needs,” said Mike Akimov, Head of Medicine, Therapy Area Oncology at Boehringer Ingelheim. “Boehringer is developing various complementary approaches to activate the immune system against cancer cells and SIRPα blockade paired with a PD-1 inhibitor is a promising strategy. We look forward to seeing if this dual activation may lead to a broader and more sustained anti-tumor response as the programs progress.”

BI 765063 and BI 770371 are designed to block the “don’t eat me” signal that cancer cells use to hide from the immune system. By targeting SIRPα, these antibodies help immune cells like macrophages recognize and destroy tumor cells, bolstering the body’s natural defenses.[3]

[1] Link to the abstract
[2] Link to the abstract
[3] Lopez-Yrigoyen, M., et al. (2017). Anti-SIRPα antibody immunotherapy enhances neutrophil and macrophage antitumor activity. Proceedings of the National Academy of Sciences, 114(33), 201710877. https://doi.org/10.1073/pnas.1710877114*:contentReference[oaicite:2]{index=2}

Both antibodies have been developed in partnership with OSE Immunotherapeutics, with Boehringer solely responsible for future clinical development and commercialization. Boehringer will move forward with the improved next generation SIRPα inhibitor antibody BI 770371, which will now be tested in a Phase 1b study.

Presentation Details:

Title: An Open-Label, Phase Ib Trial of the SIRPα Inhibitor BI 765063 in Combination with the PD-1 Inhibitor Ezabenlimab and Cetuximab in Patients (pts) with Head and Neck Squamous Cell Carcinoma
Abstract Number: 6019
Session Type/Title: Rapid Oral Abstract – Developmental Therapeutics – Immunotherapy
Date/Time: 01 June 2025 – 11:30am – 1:30pm CDT

Title: An Open-label, Phase I Trial of the SIRPα Monoclonal Antibody, BI 770371, Alone and in Combination with the PD-1 Inhibitor Ezabenlimab in Patients with Advanced Solid Tumors
Abstract Number: 2515
Session Type/Title: Rapid Oral Abstract – Developmental Therapeutics – Immunotherapy
Date/Time: 01 June 2025 – 11:15am – 12:45pm CDT

Boehringer Ingelheim
Boehringer Ingelheim is a biopharmaceutical company active in both human and animal health. As one of the industry's top investors in research and development, the company focuses on developing innovative therapies that can improve and extend lives in areas of high unmet medical need. Independent since its foundation in 1885, Boehringer Ingelheim takes a long-term perspective, embedding sustainability along the entire value chain. More than 54,400 employees serve over 130 markets to build a healthier, more sustainable and equitable tomorrow. Learn more at https://www.boehringer-ingelheim.com (Global).

OSE Immunotherapeutics
OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology (IO) and immuno-inflammation (I&I) that address the unmet patient needs of today and tomorrow. We partner with leading academic institutions and biopharmaceutical companies in our efforts to develop and bring to the market transformative medicines for people with serious diseases. OSE Immunotherapeutics is based between Nantes and Paris and is quoted on Euronext.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.com. Click and follow us on 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 considering 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, 2025, including the annual financial report for the fiscal year 2024, 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.