# OSE Immunotherapeutics Presents Preclinical Data on mRNA Therapeutic Platform for the Treatment of Inflammatory and Autoimmune Disorders *at the FOCIS Annual Meeting, San Francisco (June 18 – 21)*

**NANTES, France, June 20, 2024 – 7:30am CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE)**, presented a poster on preclinical data on its 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 (June 18 – 21, 2024).

IL-35 (Interleukin-35) is an immunosuppressive cytokine [(1)] capable of potently inhibiting immune-related inflammation by acting on multiple immune cells (T cells, Myeloid cells, B cells). IL-35 can promote differentiation of T and B cells into regulatory functional state to limit inflammatory response. IL-35 has demonstrated in preclinical studies a key role in controlling several immune related disorders including autoimmune diseases, infectious diseases, and cancer.

OSE Immunotherapeutics' **mRNA therapeutic platform** has been designed for the local delivery of mRNA into inflammatory tissue using lipid nanoparticles. mRNA encodes for immunotherapy to locally suppress immune response for the treatment of inflammatory and autoimmune diseases. This platform has the potential to deliver innovative immunotherapeutic drugs and to address new biology that cannot be targeted with standard biologic treatments.

The poster, entitled: *"Local delivery of IL-35 mRNA therapeutic using lipid-based nanoparticles vector demonstrates high efficacy to suppress autoimmune Hepatitis"* featured main preclinical data:

- IL-35 mRNA therapy using lipid nanoparticles vector allows a selective delivery and local expression of IL-35 immunosuppressive cytokine into the liver.
- IL-35 mRNA therapy can suppress acute and chronic autoimmune hepatitis inflammation in different mouse preclinical models associated with inhibition of T and B cell activation.
- Specific inhibition of autoantibodies has been observed following mRNA IL-35 treatment in chronic hepatitis inflammatory model.

Aurore Morello, Head of R&D of OSE Immunotherapeutics, comments: "*We are very pleased to share, for the first time with the international scientific community, our research data on the IL-35 mRNA therapy. Our R&D team is developing next-generation immunotherapy medicines modulating immune cell responses in the field of immuno-inflammation and immuno-oncology. 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".*

(1) *Hu S. et al Frontiers in Pharmacology 2021: The Role of IL-35 in the Pathophysiological Processes of Liver Disease*

## About Autoimmune Hepatitis

Autoimmune hepatitis (AIH) is a severe life threatening chronic progressive immune-mediated inflammatory disorder of the liver. The body's immune system attacks (auto antibodies) the hepatocytes, the cells of the liver, which causes the liver to become inflamed. AIH can cause scarring of the liver and ultimately lead to cirrhosis and liver failure if the treatment is not sufficient. The first line treatment is high dose of corticoids or azathioprine with some specific risks associated as they are chronically used.

AIH is an orphan disease. Approximately 10 to 40 percent of people with AIH go into remission. However, most people (75 to 80 %) must eventually restart treatment because the disease becomes active again. Relapse typically occurs within the first 6 to 12 months after treatment is stopped. Relapse is more likely in those who have cirrhosis on the initial liver biopsy.

Epidemiology: global pooled incidence and prevalence of AIH were found to be 1.28 cases per 100,000 inhabitant-years and 15.65 cases per 100,000 inhabitants *(Global incidence and prevalence of auto-immune hepatitis, 1970-2022: a systematic review and meta-analysis, Hahn et al Lancet 2023).* There are approximately 60,000 to 70,000 adults in the United States with a history of AIH approximately 30,000 to 35,000 adults are not responding to current first- and second-line treatments and need new therapeutic options *(Current and Emerging Treatments for Autoimmune Hepatitis, Weinberg EM et al. Gastroenterology and Hepatology 2024).* Europe analysis have revealed a range of 1.1 to 2.56 incidence and a prevalence of 17.3 to 18.3 per 100,000 individuals.

## 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 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**

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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.