OSE Immunotherapeutics to Present Anti-IL-7R Lusvertikimab Phase 2 Induction Results in Ulcerative Colitis at 20th Congress of ECCO

A clinical abstract on the induction results from the CoTikiS Phase 2 trial of anti-IL-7 Receptor Lusvertikimab in Ulcerative Colitis accepted for Oral Presentation and selected amongst the Top 10 oral abstracts for 20th Congress of European Crohn's and Colitis Organization (ECCO) Highlights.

Research highlights OSE Immunotherapeutics' continued commitment to advancing the treatment and management of IBD.

NANTES, France, December 18, 2024 – 6:00pm CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), today announced that an abstract related to its first in class anti-IL-7 Receptor (IL-7R) Lusvertikimab, has been accepted for Oral Presentation at the 20th congress of the European Crohn's and Colitis Organization (ECCO) being held February 19-22, 2025, in Berlin (Germany).

Details of the presentation:

EC25-1892 - ***"Lusvertikimab, a first-in-class IL7 receptor antagonist, in moderate to severe Ulcerative Colitis: results of a multicenter, randomized, placebo-controlled phase II study"*** has been accepted as an **Oral Presentation in the Scientific Program** and selected amongst the **Top 10 oral abstracts for the Congress Highlights of ECCO'25 video**.

- Presentation number: OP36
- Session name: Sustainability in IBD and beyond - Session 10: Hot topics in IBD
- Session date: 22/02/25; Session time: 08:30 - 10:50; Presentation time: 10:10 - 10:20
- Session hall: Plenary Hall / Hall B

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: *"We are excited to present for the first time at a congress the clinical efficacy and safety data from the induction study in ulcerative colitis. This prestigious scientific meeting gathers the world's leading specialists in Inflammatory Bowel Diseases (IBD). Lusvertikimab, a pure interleukin-7 receptor antagonist mAb that exclusively blocks IL-7 boasts a differentiated mechanism of action and a favorable tolerance profile. We believe Lusvertikimab is uniquely positioned in IBD, with potential also for a broader spectrum of chronic inflammatory and autoimmune diseases."*

Interleukin-7 (IL-7) produced locally by epithelial cells is a crucial survival factor for pathogenic T lymphocytes residing in tissues, such as colitogenic memory T cells[1]. Lusvertikimab is a unique antagonist of IL-7R targeting the CD127 receptor, the alpha chain of the IL-7R, with a differentiated mechanism of action allowing a selective inhibition of the IL-7 biology while sparing TSLP (Thymic Stromal LymphoPoietin) cytokine and growth factor. This allows potent inhibition of pathogenic memory and effector T lymphocytes expressing high level of CD127, while promoting regulatory T cells (Tregs) biology expressing low level of CD127. The protective role of TSLP in intestinal immunity has

been reproducibly described, in particular to instruct Treg generation against commensal bacteria[2] and TSLP inhibition has been reported to exacerbate mucosal inflammation and colitis[3]. This biology together with the results of the CoTikiS study supports the continued clinical development of a pure IL-7 antagonist in IBD, and other diseases where Tregs and microbiota cross-talks are implicated in tissular healing. Interleukin-7 Receptor (IL-7R) overexpression has been associated with numerous diseases[4] and therapeutic areas, with preclinical efficacy already demonstrated in IBD[5], rheumatoid arthritis[6], neuroinflammation[7], airways inflammation[8], dermatology[9], type 1 diabetes[10] and lupus[11].

ABOUT ULCERATIVE COLITIS (UC)

Ulcerative colitis is a chronic disease of the large intestine, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers. This condition is the result of the immune system's overactive response. UC affects 3.3 million patients in the US, Europe and Japan (1). Despite broad therapeutic options, remission rates remain only 25-30% (2) leaving most patients without satisfactory treatments. 15% of patients (3) fail to respond to all therapies and undergo surgery as a last option.

(1) EvaluatePharma
(2) Drugs Context. 2019; 8: 212572 –doi: 10.7573/dic.212572
(3) Scientific Reports volume 10, Article number: 12546 (2020)

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) 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 X and LinkedIn

Contacts

Fiona Olivier
fiona.olivier@ose-immuno.com

Sylvie Détry
sylvie.detry@ose-immuno.com

French Media Contact
FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

U.S. Media Contact
Rooney Partners LLC
Kate Barrette
kbarrette@rooneypartners.com
+1 212 223 0561

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, 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.

---

[1] *Markus F. Neurath, Strategies for targeting cytokines in inflammatory bowel disease, Nat Rev Immunol 2024*

[2] *I Spadoni et al., Dendritic cells produce TSLP that limits the differentiation of Th17 cells, fosters Treg development, and protects against colitis, Mucosal Immunol, 2012*

[3] *Jonathan L Messerschmidt et al., TSLP/dendritic cell axis promotes CD4+ T cell tolerance to the gut microbiome, JCI Insight, 2023*
Betsy C Taylor et al., TSLP regulates intestinal immunity and inflammation in mouse models of helminth infection and colitis, J Exp Med, 2009

[4] *Barata, J. T., S. K. Durum, and B. Seddon. 2019. Flip the coin: IL-7 and IL-7R in health and disease. Nat. Immunol. 20: 1584 1593.*

[5] *Belarif, L., R. Danger, L. Kermarrec, V. Nerri`ere-Daguin, S. Pengam, T. Durand, C. Mary, E. Kerdreux, V. Gauttier, A. Kucik, et al. 2019. IL-7 receptor influences anti-TNF responsiveness and T cell gut homing in inflammatory bowel disease. J. Clin. Invest., 2019.*
Willis, C. R. et al., Interleukin-7 receptor blockade suppresses adaptive and innate inflammatory responses in experimental colitis. J. Inflamm., 2012.

[6] *Sarita A Y Hartgring, Blockade of the interleukin-7 receptor inhibits collagen-induced arthritis and is associated with reduction of T cell activity and proinflammatory mediators, Arthritis Rheum, 2010*
Zhenlong Chen, The novel role of IL-7 ligation to IL-7 receptor in myeloid cells of rheumatoid arthritis and collagen-induced arthritis, J Immunol, 2013

[7] *Li-Fen Lee et al., IL-7 promotes T(H)1 development and serum IL-7 predicts clinical response to interferon-β in multiple sclerosis*

[8] *Hoa Le Mai et al., Targeting the interleukin-7 receptor alpha by an anti-CD127 monoclonal antibody improves allergic airway inflammation in mice, Clin Exp Allergy, 2020*

[9] *Lyssia Belarif et al., IL-7 receptor blockade blunts antigen-specific memory T cell responses and chronic inflammation in primates, Nat Commun, 2018*
Zhenpeng Dai et al., Blockade of IL-7 signaling suppresses inflammatory responses and reverses alopecia areata in C3H/HeJ mice, Sci Adv, 2021

[10] *Li-Fen Lee et al., Anti-IL-7 receptor-α reverses established type 1 diabetes in nonobese diabetic mice by modulating effector T-cell function, Proc Natl Acad Sci U S A, 2012*
Cristina Penaranda, IL-7 receptor blockade reverses autoimmune diabetes by promoting inhibition of effector/memory T cells, Proc Natl Acad Sci U S A, 2012

[11] *Rosana Gonzalez-Quintial et al., Systemic autoimmunity and lymphoproliferation are associated with excess IL-7 and inhibited by IL-7Rα blockade PLoS One, 2011*