OSE Immunotherapeutics Announces >90% of Responders Maintained Symptomatic Remission Through Extension Period on Lusvertikimab

- Lusvertikimab well tolerated over the 24-week additional treatment period.
- Oral presentation at DDW 2025 of clinical data from the anti-IL-7R mAb Lusvertikimab open-label extension of the phase 2 CoTikiS study in ulcerative colitis.[1,2]
- Full clinical data package for study demonstrates potential of a first-in-class monotherapy with a novel mechanism of action in chronic and inflammatory diseases.

NANTES, France – May 5, 2025, 6:30 p.m. CET - OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) announced that over >90% of people living with ulcerative colitis (UC) who achieved a clinical response after 10 weeks of treatment with Lusvertikimab maintained symptomatic remission for an additional 24 weeks. Of the participants who did not reach symptomatic remission in the first 10 weeks of treatment with either dose of Lusvertikimab, 61% had achieved remission after a further 24 weeks on the 850 mg dose. Lusvertikimab was well tolerated over the 24-week extended treatment period.[1]

These findings from the open-label extension (OLE) of the Phase 2 CoTikiS study of the anti-IL-7 receptor monoclonal antibody Lusvertikimab in UC,[2] were presented at Digestive Disease Week in San Diego (May 3 – 6, 2025).[1] These build on results from the earlier induction phase presented at the ECCO 2025 congress in February.[3]

Sonya Montgomery, Chief Development Officer of OSE Immunotherapeutics, commented: "*These new data provide insights into the longer-term benefits and safety of Lusvertikimab in UC, with 89% of patients continuing into the OLE period and 87% completing it. More than 90% of Lusvertikimab patients in symptomatic remission following induction reported a durable response to treatment, and Lusvertikimab also demonstrated very good safety and tolerability over the course of the study, which included 24 weeks on the high dose for all patients.*

"We also observed an increase in symptomatic remission rates across groups in the OLE, with the 850 mg induction phase dose group showing this deepening of effect after one additional dose. The OLE data support the potential of Lusvertikimab as a monotherapy with a positive impact on symptom management and patient quality of life."

Arnaud Bourreille, Associate Professor in Gastro-Enterology at CHU Nantes and principal investigator of the study, commented: *"Despite the broad range of approaches to manage ulcerative colitis, remission of symptoms can be hard to reach, with only 25-30% of people typically able to achieve and maintain remission of symptoms on any one treatment.[4,5] For people living with ulcerative colitis, these findings are an important step towards challenging this therapeutic ceiling."*

Findings from the OLE period, extending from Week 10 to Week 34, complete the CoTikiS dataset which provides a compelling Phase 2 efficacy and safety data package for Lusvertikimab in UC.

Sonya Montgomery added: *"The complete CoTikiS results give us confidence in Luservtikimab's novel mechanism of action benefiting ulcerative colitis patients, and its potential in other chronic autoimmune and inflammatory diseases where there is a strong biological rationale. The CoTikiS clinical results support progressing Luzvertikimab's development and brings us closer to our goal of delivering a long-acting therapy designed to treat the underlying disease pathophysiology."*

OVERVIEW OF COTIKIS EXTENSION PERIOD (OLE) FINDINGS[1]

Lusvertikimab demonstrated a deepening of treatment response and durable response, with a high rate of symptomatic remission.[1]

- **89%** of participants entered the OLE period and 87% of them completed the study.
- Rates of symptomatic remission[6] improved for all dose groups in the OLE period, suggesting a deepening of efficacy. For participants who had received the 850 mg dose from the beginning of the study, rates plateaued already after Week 14; rates of symptomatic remission continued to improve through week 26 for the 450 mg induction group (10 weeks of 450 mg, 16 weeks of 850 mg dosing) and through week 34 for the group receiving placebo in the induction phase (10 weeks of placebo, 14 weeks of 850 mg Lusvertikimab).
- **92%** of participants who had achieved symptomatic remission with either dose of Lusvertikimab in the induction period maintained it through the OLE period[7] including 100% of those who achieved remission in the 850 mg dose group.
- **61%** of participants who had not achieved symptomatic remission with either dose of Lusvertikimab in the induction period went on to achieve it during the OLE period.
- **85%** of participants who had been in the placebo arm during the induction period went on to achieve symptomatic remission after receiving 850 mg in the OLE period.
- **82%** of participants achieved remission of rectal bleeding by the end of the OLE.
- Lusvertikimab was well tolerated over a 34-week treatment period, with a good safety profile and without a higher rate or severity of infection.

ABOUT THE COTIKIS STUDY[1-3]

CoTikiS, a randomized, double-blind, placebo-controlled 50-week clinical study,[2] consisted of:

- A 10-week induction period evaluating two doses (450 mg or 850 mg) of Lusvertikimab versus placebo;
- A 24-week OLE period in which **all** participants received Lusvertikimab 850 mg infusions every four weeks; and
- A 16-week safety follow-up period without treatment.

Findings from the induction phase of the CoTikiS study were presented in February at the 2025 ECCO congress. Both doses met the primary efficacy endpoint (improvement in Modified Mayo Score at Week 10) and

demonstrated statistically significant and clinically meaningful results on secondary clinical, endoscopy and histology endpoints.[3]

REFERENCES / FOOTNOTES

1. Bourreille A et al., Oral presentation #913, Digestive Disease Week, 5 May 2025, San Diego, USA.
2. Bourreille A et al., *J Crohn's & Colitis* 2025; 19(1):i71–i72. doi: 10.1093/ecco-jcc/jjae190.0036.
3. EU Clinical Trials Register: CoTikiS study record (2020-001398-59), available via www.clinicaltrialsregister.eu [Accessed May 2025].
4. Yanofsky R & Rubin DT, *J Can. Assoc. Gastroenterology* 2025;8(S2):S6–S14, doi: 10.1093/jcag/gwae058.
5. Le Berre C et al. *Lancet* 2023;402(10401):571–584, doi: 10.1016/S0140-6736(23)00966-2.
6. Symptomatic remission on Mayo patient-reported outcomes 2, PRO2 (stool frequency subscore + rectal bleeding subscore) = 0 or 1 and rectal bleeding subscore = 0.
7. Responders are defined as patients with endoscopic score of 0 or 1 at Week 10.

ABOUT DIGESTIVE DISEASE WEEK (DDW)

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 3-6, 2025. The meeting showcases nearly 6,000 abstracts and over 1,000 invited talks on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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 LinkedIn.

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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.

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