SynOx Therapeutics Completes Enrollment in Registrational Phase 3 TANGENT Clinical Trial Significantly Ahead of Timeline

Top-Line Results from Study Evaluating Emactuzumab for Tenosynovial Giant Cell Tumours (TGCT) Expected in First Quarter of 2026

DUBLIN, IRELAND, OXFORD, UK, and PHILADELPHIA, PA -- August 5, 2025 – SynOx Therapeutics Limited ("SynOx"), a late-stage clinical biopharmaceutical company developing emactuzumab for Tenosynovial Giant Cell Tumours (TGCT), today announced completion of patient enrolment in the TANGENT study. TANGENT is the company's global, multi-centre, randomized, double-blind, placebo-controlled registrational Phase 3 trial of emactuzumab in patients with TGCT who are not amenable to or who would not benefit from surgery. SynOx expects to report top-line data from the study in the first quarter of 2026.

Emactuzumab is a potentially best-in-class CSF-1 receptor (CSF-1R) inhibiting monoclonal antibody (mAb). Clinical evaluation to date has demonstrated the compound to be a promising, next-generation mAb therapy with the potential to offer a short treatment cycle, rapid onset and long duration of response that differentiates it from chronically administered oral agents. This potentially best-in-class profile helped drive strong interest in the TANGENT trial among patients and clinical investigators across sites in the United States, Canada, Europe and Asia, leading to rapid study enrollment.

"Completion of enrollment in our registrational TANGENT trial marks an important milestone for SynOx and for the TGCT community," said Elyse Seltzer, M.D., Chief Medical Officer of SynOx Therapeutics. "We are deeply grateful to the patients, families, investigators, and clinical sites whose dedication has made this study possible and allowed SynOx to fully enroll the trial significantly ahead of our projected timeline. We remain committed, data permitting, to delivering a much-needed new treatment option for this debilitating condition."

"This is a transformational time for SynOx as we advance emactuzumab through its pivotal Phase 3 program," said Ray Barlow, Chief Executive Officer of SynOx. "We're excited about the next steps and look forward to delivering top-line data that we hope demonstrate how emactuzumab can transform care for patients with this grievous disease."

About the TANGENT Study

TANGENT (ClinicalTrials.gov Identifier: NCT05417789) is a randomized, double-blind, placebo-controlled Phase 3 trial evaluating the efficacy and safety of emactuzumab in patients with TGCT who are not amenable to or would not benefit from surgery. Patients who consent and meet eligibility criteria are randomized in a 2:1 fashion to receive either emactuzumab (1000 mg every two weeks for five doses) or matched placebo.

The primary endpoint is objective response rate (ORR) as assessed by RECIST criteria at six months post-randomization. Key secondary endpoints include patient-reported outcomes (PROMIS-PF), functional assessments of range of motion, pain, stiffness, durability of response, and safety. Patients are followed for two years from randomization, with those demonstrating disease progression after the six-month assessment eligible to receive open-label emactuzumab during follow-up.

SYNOX THERAPEUTICS LTD | Registered in Ireland | Company no. 661961 | 3 Dublin Landings, North Wall Quay, Dublin 1, D01 C4E0, Ireland
SYNOX THERAPEUTICS UK LTD | Registered in England & Wales | Company no. 13318557 | John Eccles House, Robert Robinson Avenue, Oxford Science Park, Oxford, OX4 4GP, UK
www.synoxtherapeutics.com | enquiries@synoxtherapeutics.com

About TGCT

Tenosynovial Giant Cell Tumour (TGCT), previously termed pigmented villonodular synovitis (PVNS), is a rare, non-malignant but aggressively growing tumour of the synovium, tendon sheaths, and bursa membranes primarily located in knee, hip, and ankle joints and caused by excessive production of CSF-1. It is a chronically debilitating disease that causes loss of function of the affected joints, as well as pain, stiffness, and limited range of motion. While most patients undergo surgery, more than 50% of those with diffuse TGCT experience tumour recurrence within three years. If left untreated, TGCT can cause joint deformity, degenerative changes, and even lead to arthrodesis or amputation in severe cases.

About Emactuzumab

CSF-1 (or macrophage colony-stimulating factor) is a cytokine that binds to the CSF-1 receptor (CSF-1R), expressed on macrophages and other immune cells. Emactuzumab is a humanised IgG1 monoclonal antibody (mAb) targeting CSF-1R, designed to inhibit and deplete macrophages in tumour tissue. Originally developed by Roche, emactuzumab has shown substantial efficacy in clinical studies in TGCT, including an objective response rate of ~71%, rapid tumour reduction, functional improvement, and good tolerability with a manageable safety profile.

Earlier this year, SynOx received Fast Track Designation (FTD) from the U.S. Food and Drug Administration (FDA) for emactuzumab in the treatment of TGCT, recognizing the serious unmet medical need in this condition. Emactuzumab has also received Orphan Medicinal Product designation from the European Medicines Agency. SynOx is actively exploring further development opportunities for emactuzumab in other macrophage-driven diseases.

About SynOx Therapeutics

SynOx Therapeutics Limited is a Dublin, Oxford and Philadelphia-based, late-stage clinical biopharmaceutical company developing emactuzumab, a next-generation, best-in-class monoclonal antibody against CSF-1R, for the treatment of Tenosynovial Giant Cell Tumour (TGCT) and other CSF-1-related and macrophage-driven disorders. SynOx is led by an experienced team of industry professionals with a successful track record of developing and bringing products to commercialization. The company is backed by a strong syndicate of premier life science investors including Forbion, Gilde Healthcare, HealthCap, Bioqube Ventures and Medicxi.

Contacts:

SynOx Therapeutics
Ray Barlow
Chief Executive Officer
Tel: +44 (0) 208 058 5619
Email: enquiries@synoxtherapeutics.com

Vida Strategic Partners (on behalf of SynOx)
Tim Brons (Media)
415-675-7402
tbrons@vidasp.com