SynOx Therapeutics Receives Fast Track Designation from U.S. Food and Drug Administration for Emactuzumab for Tenosynovial Giant Cell Tumours (TGCT)

DUBLIN, IRELAND and OXFORD, UK, April 14, 2025 – SynOx Therapeutics Limited ("SynOx"), a late-stage clinical biopharmaceutical company developing of emactuzumab for Tenosynovial Giant Cell Tumours (TGCT), today announced that the United States Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to emactuzumab for the treatment of TGCT patients that are not amenable to or who would not benefit from surgery. Emactuzumab, a potentially best-in-class CSF-1 receptor (CSF-1R) inhibiting monoclonal antibody, is currently being evaluated in the TANGENT study, a global, multi-centre, randomized, double-blind, placebo-controlled registrational Phase 3 trial.

TGCT 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 for patients causing loss of function of the affected joints, as well as pain, stiffness and limited range of motion. Receipt of FTD for TGCT was supported by data from Phase 1/2 clinical studies demonstrating rapid, robust tumour reduction and durable response combined with a manageable safety profile. Emactuzumab has also previously received Orphan Medicinal Project designation from the European Medicines Agency.

"The granting of FTD for emactuzumab in TGCT highlights the devastating toll that this disease has on patients, as well as the critical need that remains for new treatment options," said Elyse Seltzer, M.D., Chief Medical Officer of SynOx Therapeutics. "Based on our clinical work to date, we believe that emactuzumab has significant potential to address key patient needs by offering an effective, short-course treatment with rapid onset and a durable response that allows individuals suffering from TGCT to better manage their disease and move forward with their lives. We look forward to completing the ongoing TANGENT study and progressing emactuzumab toward potential commercialization."

About Fast Track Designation

The FDA grants Fast Track designation to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need. Fast Track status allows for enhanced communication and collaboration between the FDA and drug developers, potentially speeding up the delivery of life-saving treatments to patients.

About Tenosynovial Giant Cell Tumour (TGCT)

Tenosynovial Giant Cell Tumour (TGCT), previously termed pigmented villonodular synovitis (PVNS), is a type of tumour that affects the soft tissue lining of joints and tendons. TGCTs are categorised as fibrohistiocytic tumours by the WHO classification and are subclassified based on growth patterns (localised and diffuse types) and location (tendon sheath, intra- and extra-articular forms). TGCTs are locally destructive and can be aggressive. The disease causes significant joint pain, stiffness, loss of function and reduced quality of life. 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.

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About CSF-1 and 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 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. Emactuzumab may also have utility in other macrophage-driven diseases, and SynOx is actively exploring further development opportunities in these areas.

Additional details regarding the ongoing registrational Phase 3 TANGENT study can be found on ClinicalTrials.gov (Identifier: NCT05417789).

About SynOx Therapeutics
SynOx Therapeutics Limited is a Dublin and Oxford-based, late-stage clinical biopharmaceutical company developing emactuzumab, a 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.

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