SynOx Therapeutics Adds New Investor and Capital to Series B Financing, Raising Total to $92 Million, and Doses First Patients in Phase 3 Trial

Gilde Healthcare Leads Series B Extension, Joining Premier Syndicate of Leading Life Science Investors

Funding Supports Registrational Phase 3 TANGENT Trial of Emactuzumab, a Best-in-Class CSF-1 Receptor Targeted Antibody, for the Treatment of Tenosynovial Giant Cell Tumour

TANGENT Study Underway with First Patients Dosed

DUBLIN, IRELAND and OXFORD, UK, October 30, 2024 – SynOx Therapeutics Limited ("SynOx"), a late clinical-stage biopharmaceutical company developing a novel treatment for CSF-1 related and macrophage-driven disorders, today announced that it has raised additional funding in a final close of its Series B financing. The Series B extension was led by new investor Gilde Healthcare and brings the total capital raised by SynOx in the round to $92 million including earlier investments from Forbion, HealthCap and Bioqube Ventures. Proceeds from the financing are supporting a registrational Phase 3 clinical trial of emactuzumab, a potentially best-in-class CSF-1 receptor (CSF-1R) inhibiting monoclonal antibody for the treatment of Tenosynovial Giant Cell Tumour (TGCT).

In conjunction with the closing of the Series B extension, SynOx today announced that the first patients have been dosed in its Phase 3 registrational study of emactuzumab. The study, named TANGENT, is a global, multi-centre, randomized, double-blind, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of emactuzumab in patients with TGCT. The study's primary outcome measure is overall response rate (ORR). Investigators will also assess several secondary outcomes including functional and quality of life measurements, impact on tumour volume, and duration of response. Investigators expect to enrol approximately 130 patients in the trial. Additional study details can be found on ClinicalTrials.gov (Identifier: NCT05417789).

TGCT is a rare, non-malignant but aggressively growing tumour of the synovium, 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, pain, stiffness and limited range of motion. Emactuzumab specifically inhibits CSF-1R and earlier clinical work in TGCT[1] showed it to be a highly effective, next-generation therapy with a short treatment cycle, rapid onset of action and long duration of response.

"We are pleased to add Gilde Healthcare to our impressive investor syndicate and are appreciative for their support of our team and our vision for the potential of emactuzumab to address the unmet needs, and improve the quality of life, of TGCT patients around the world," said Ray Barlow, Ph.D., Chief Executive Officer of SynOx. "The dosing of patients in the TANGENT trial marks an important milestone for SynOx and is a testament to the dedication and hard work of our team. We look forward to efficiently conducting this study and continuing to pursue our goal of advancing emactuzumab toward market for TGCT patients in desperate need of new treatment options."

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As part of the Series B extension, Arthur Franken, general partner at Gilde Healthcare, will join the SynOx Board of Directors. Mr. Franken brings more than two decades of venture and growth capital investment expertise, including several public listings and trade sales.

"We are pleased to join SynOx as an investor and help support the late-stage development of emactuzumab, which we believe has a best-in-class profile as a CSF-1R targeted antibody. Importantly, we also believe that the SynOx team is well positioned to successfully complete clinical development of emactuzumab and deliver this important treatment option to TGCT patients," said Mr. Franken.

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 locally destructive and can be aggressive tumours. TGCT is a chronically debilitating disease which often impacts patients throughout their lives. It causes loss of function of the affected joints, pain, stiffness, limited range of motion and a significant impact on the quality of life as a result. Most patients receive surgical intervention, with three-year post-surgery recurrence rates in more than 50% of patients[2]. Symptoms typically progress slowly but can be aggressive and destructive. If left untreated complications include moderate to severe joint deformity, degenerative articular changes, and osteoarthritis, which if severe enough, can lead to cortical bone destruction and occasionally the need for arthrodesis or amputation.

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 certain other cells, with effects on production, differentiation, and function of these cells. Emactuzumab is a humanised IgG1 CSF-1R targeted antibody that inhibits and depletes macrophages in the tumour tissue. Importantly, emactuzumab has the potential to offer a short course of treatment. The compound was originally discovered and developed by Roche and has been tested in several Phase 1/1b studies as a monotherapy and in combination with other agents, including chemotherapeutics and immunotherapies.

In clinical studies as a monotherapy in 63 patients with TGCT, emactuzumab has shown a substantial effect on tumour response (ORR ~71%) while being well tolerated[1]. Phase I/II studies indicated good tolerability and a manageable safety profile and substantial preliminary efficacy in TGCT patients with rapid, robust tumour reduction, clinical benefit and durable response. Emactuzumab may also have utility in other macrophage-driven diseases, including graft-versus-host disease, and the company is actively considering potential options in these areas.

About SynOx Therapeutics

SynOx Therapeutics Limited is a Dublin and Oxford-based, late clinical-stage 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 commercializing novel therapeutics. The company is backed by a strong syndicate of premier life science investors including Forbion, HealthCap, Bioqube Ventures, Gilde Healthcare and Medicxi.

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[1] *Cassier et al., "Long-term clinical activity, safety and patient-reported quality of life for emactuzumab-treated patients with diffuse-type tenosynovial giant-cell tumour," European Journal of Cancer 141:162-170, 2020.*
[2] *Lin F, et al. JHEOR, 2022.*

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