SynOx Therapeutics Further Strengthens Executive Team with Appointments of U.S.-Based Chief Medical Officer and Chief Commercial Officer

Additions of Elyse Seltzer, M.D., as CMO and Robert Francomano as CCO Strengthen Company's Presence in the U.S.

Seasoned Team to Drive Forward Pivotal Phase 3 Trial of Emactuzumab in Patients Suffering from Tenosynovial Giant Cell Tumours (TGCT)

DUBLIN, IRELAND and OXFORD, UK, November 7, 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 the appointments of Elyse Seltzer, M.D., as Chief Medical Officer (CMO) and Robert Francomano as Chief Commercial Officer (CCO). These strategic hires come at a pivotal time as SynOx accelerates the clinical development of emactuzumab, a potentially best-in-class CSF-1R inhibiting monoclonal antibody. The company recently announced that the first patients have been dosed in its Phase 3 registrational study of emactuzumab for the treatment of Tenosynovial Giant Cell Tumours (TGCT).

Dr. Seltzer brings more than 20 years of expertise in clinical development and regulatory strategy across various therapeutic areas to SynOx. She most recently served as a Senior Therapeutic Subject Matter Expert at Biomedical Advanced Research and Development Authority (BARDA), where she supported collaborations between the U.S. government and biotech and pharmaceutical companies on treatments for emerging infectious diseases and acute respiratory distress syndrome (ARDS). Previously, Dr. Seltzer held key leadership roles including Chief Development Officer at Urogen Pharma, where she oversaw the development and approval of Jelmyto® for urologic oncology, and Chief Medical Officer at Nabriva Therapeutics, where she led the successful development of Xenleta®, approved for the treatment of community-acquired bacterial pneumonia. SynOx believes that Dr. Seltzer's strategic experience, which spans early-stage research to late-stage clinical trials and commercialization, will be instrumental in advancing the company's clinical programs, including the recently initiated Phase 3 TANGENT trial for emactuzumab in TGCT.

Mr. Francomano joins SynOx as a highly accomplished leader in the global commercialization of oncology and rare disease therapies. With a proven track record in driving revenue growth and executing successful global product launches, he will spearhead the company's commercial strategy. Prior to joining SynOx, he served as CCO at SELLAS Life Sciences, where he established a fully integrated commercial framework underpinned by diagnostic and AI-driven demand generation strategies. Mr. Francomano also previously held the position of the CCO at Stemline Therapeutics, where he led the corporate transformation from a clinical-stage entity to one with a full commercial infrastructure and capability in the U.S. and EU. Successful execution led the company to exceed revenue targets and deliver one of the industry's top-ranked product launches for first launch biotechnology organizations. SynOx expects that his experience will be vital in preparing for the potential commercialization of emactuzumab and expanding the company's footprint in the global market.

"We are thrilled to welcome Elyse and Robert to the SynOx leadership team as we continue to work to strategically build out our presence within the key U.S. market. Their extensive expertise in clinical development and commercialization will be crucial as we advance emactuzumab towards regulatory submissions and potential commercial launch in both the U.S. and globally," said Ray Barlow, Chief Executive Officer of SynOx Therapeutics. "With the recent closing of our $92M Series B financing and launch of the registrational TANGENT Phase 3 trial, we are working diligently to accelerate development of our clinical programs and bring novel therapies to patients suffering from TGCT and other debilitating diseases."

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SynOx recently announced the initiation of the TANGENT study, 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).

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[1]. 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[2]. 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.

[1] Lin F, et al. JHEOR, 2022..

[2] 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

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