SynOx Therapeutics announces $75m Series B round to fund Phase 3 trial of potential best-in-class treatment for TGCT

- *Financing co-led by Forbion, HealthCap and new investor Bioqube Ventures*
- *Funds will be used for pivotal trial of potential best-in-class, next-generation treatment for Tenosynovial Giant Cell Tumour*

Dublin, Ireland and Oxford, UK, 22 April 2024: SynOx Therapeutics Limited ("SynOx" or the "Company"), the late-stage clinical biopharmaceutical company, is pleased to announce the close of a $75m Series B financing. The financing was co-led by Forbion, HealthCap and new investor Bioqube Ventures.

The proceeds will be used to generate registrational Phase 3 clinical and CMC data for emactuzumab, SynOx's potentially best-in-class CSF-1(R) inhibiting monoclonal antibody (mAb) for the treatment of Tenosynovial Giant Cell Tumour (TGCT).

TGCT is a type of tumour that affects the soft tissue lining of joints and tendons and is a highly debilitating disease often impacting large, important joints such as the knee, hip and ankle.

TGCT is a chronic disease which often impacts patients throughout their lives. It seriously impacts quality of life by causing significant loss of function of the affected joints, pain, stiffness, and limiting range of motion. While most patients receive surgical intervention, more than 50% of patients with diffuse disease experience tumour recurrence within three years of surgery[1].

Emactuzumab is a novel, next-generation CSF-1R *mAb* with a potentially best-in-class profile. In earlier clinical work in TGCT[2] emactuzumab demonstrated substantial clinical activity with an objective response rate (ORR) of 71%, rapid and robust tumour reduction, a long duration of effect, and significant improvements in functional ability. Importantly, these studies also indicated that emactuzumab has good tolerability and a manageable safety profile. SynOx is initiating a Phase 3 trial (TANGENT) to assess the efficacy and safety of emactuzumab in patients with localized and diffuse TGCT.

As part of the Series B financing both Dr Carlo Incerti, M.D., and Jon Edwards, PhD, have joined the Board of Directors. Dr Incerti has more than three decades of experience in the biopharmaceutical industry and brings an extensive track record in global drug development, including from his time at Sanofi Genzyme where he played a leading role in pioneering therapies for rare and genetic diseases. Jon Edwards brings a decade of therapeutic investment expertise and company creation experience, which includes several public listings and multi-billion-dollar acquisitions.

Ray Barlow, Chief Executive Officer of SynOx Therapeutics, said: *"This is a transformational time for SynOx. This substantial funding will allow us to generate registrational data for emactuzumab in TGCT. As a highly effective, next-generation therapy with a short treatment cycle, rapid onset and long duration of response, we believe that emactuzumab is differentiated from other agents in development and will provide a much needed and valuable option for patients suffering from this grievous disease."*

- [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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Dirk Kersten, General Partner at Forbion, commented: *"We are pleased to continue to support the SynOx team as it moves emactuzumab through to BLA and MAA submissions in TGCT. As a late-stage company with a clinically de-risked asset, focused on an attractive and underserved market, SynOx is a good example of the type of company Forbion Growth would typically invest in."*

Jon Edwards, Bioqube Ventures commented: "*We are excited to join the SynOx syndicate and work with this fantastic team and board. We believe this asset has the potential to generate best-in-class data and are excited to help the team develop the product through approval and launch.*"

Ton Logtenberg, Non-Executive Chair of SynOx Therapeutics, added: "*The support of our existing and new investors is validation of SynOx's strategy and its great potential as a company. I would like to welcome Carlo Incerti and Jon Edwards to the Board of Directors. Their broad experience and knowledge, particularly in driving forward cutting-edge therapies for rare diseases, and executing deals at the highest level, complement the expertise of our existing directors and will be instrumental as we accelerate the late-stage clinical development of emactuzumab."*

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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 commercialisation. It is backed by a strong syndicate of premier life science investors including Forbion, HealthCap, BioQube and Medicxi.

Carlo Incerti, M.D.
Carlo has more than three decades of experience in the biopharmaceutical industry, including in rare disease drug development. Carlo is currently an operating partner at Forbion, a life sciences venture capital firm. Previously, he held several positions of increasing responsibility during his more than 25 years at Sanofi Genzyme, including senior vice president, chief medical officer and head of global medical affairs. Before his industry career Carlo was a practicing endocrinologist and an Associate Professor at the University of Modena and Reggio Emilia, Italy, where he had received his medical degree. Currently he is chairman of the Board at Numab Therapeutics AG, Azafaros B.V., VectorY Therapeutics, and a member of the Board of Dyne Therapeutics.

Jon Edwards
Jon recently joined the Bioqube Ventures team. Previously, he served as Managing Director at Red Tree Venture Capital and was part of the founding team at Medicxi where he was a partner in the London office. He has led multiple investments spanning company formation, syndicated deals, and late-stage crossover/IPO financings. A few notable investments include Impact Biomedicines

(acquired by Celgene), Synthorx (acquired by Sanofi), Phathom Pharmaceuticals (NASDAQ:PHAT), and Checkmate Pharmaceuticals (acquired by Regeneron). Jon conducted his postdoctoral research at MIT and holds a PhD in Biochemistry and Biophysics from the University of North Carolina - Chapel Hill.

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, and intra- and extra-articular forms). 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 3-year post-surgery recurrence rates in more than 50% of patients[3]. 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. Emactuzumab was originally discovered and developed by Roche and has been tested in several phase 1/b 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%) and was well tolerated[2]. Emactuzumab is a novel monoclonal antibody inhibiting CSF-1R that offers a short course of treatment. Phase I/II studies indicated good tolerability and a manageable safety profile and substantial preliminary efficacy in TGCT patients with rapid, robust tumour reduction and durable response. Emactuzumab may also have utility in other macrophage driven diseases and the company is actively considering potential options in these areas.

- [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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