StemSmart™ Manufacturing Milestone Achieved with TGA Inspection Completed

TGA Inspection is a major step towards the supply of StemSmart™ for Phase 2 clinical trial in Crohn's disease

Highlights:

- **TGA has completed its inspection of Q-Gen Cell Therapeutics (Q-Gen), the manufacturing partner for Miro Sciences' StemSmart™ product.**
- **The completion of the TGA inspection of StemSmart™ manufacturing at Q-Gen marks a major operational milestone for the supply of StemSmart™ for future clinical trials.**
- **This milestone supports MSX's preparations for its planned Phase 2 clinical trial in refractory Crohn's disease for patients in Australia and the United States following recent positive FDA feedback and the appointment of Southern Star Research as its clinical research organisation.**
- **Q-Gen Cell Therapeutics, located within QIMR Berghofer in Brisbane, is one of the largest cell therapy contract manufacturers in Australia, with 13 cleanrooms dedicated to cell manufacturing and quality control.**
- **StemSmart™ is a patented stem cell technology platform targeting immune-mediated severe inflammatory diseases with a large treatment-resistant population, such as refractory Crohn's disease, the target of MSX's initial clinical trial.**

Miro Sciences (ASX: MSX) (formerly NeuroScientific Biopharmaceuticals (ASX: NSB)) ("Miro Sciences", "MSX" or the "Company"), an innovative Australian biotechnology company developing novel technologies targeted at immune-mediated inflammatory diseases with large treatment-resistant populations, is pleased to announce the completion of the Therapeutic Goods Administration ("TGA") inspection of Miro Sciences' manufacturing partner, Q-Gen Cell Therapeutics ("Q-Gen").

The completion of the TGA inspection at Q-Gen represents an important part of the broader regulatory activities associated with supply of StemSmart™ for MSX's planned Phase 2 clinical trial in refractory Crohn's disease in Australia and the US, subject to regulatory approvals.

The TGA inspection at Q-Gen marks the latest major operational milestone achieved by MSX as it progresses towards initiation of the Phase 2 clinical trial. In October 2026, MSX announced the appointment of Southern Star Research to conduct the Phase 2 clinical trial[1] and the positive feedback from its Pre-Investigational New Drug ("Pre-IND") submission meeting with the FDA[2].

Together, these achievements demonstrate continued and steady progress across the Company's manufacturing, regulatory and clinical operations, with MSX targeting trial initiation by the end of CY2026.

MSX Chief Scientific Officer and inventor of the StemSmart™ technology, Dr Marian Sturm, commented:

> *"The TGA inspection of StemSmart™ manufacturing at Q-Gen demonstrates that we are on target with our technology transfer and represents an important step towards TGA licensure of our MSC product. It is a significant milestone in our preparations for the upcoming clinical trial in refractory Crohn's disease and was only achievable through the hard work of both the MSX and Q-Gen teams, along with ongoing communications with the TGA."*

The TGA performs audit inspections of manufacturing procedures and facilities to ensure compliance with established regulatory standards applicable for clinical trial supply of therapeutic goods for Australian patients. The TGA audit of Q-Gen is one of the critical steps of the manufacturing transfer of MSX's StemSmart™ to Q-Gen to scale up supply of clinical product for the planned Phase 2 clinical trial to treat patients in Australia and the US.

Q-Gen, located within QIMR Berghofer in Brisbane, is one of the largest cell therapy contract manufacturers in Australia, with 13 cleanrooms dedicated to cell manufacturing and quality control. Q-Gen, which holds a TGA licence for cell therapy manufacture and has more than 25 years in cell therapy manufacturing for industry, has the experience, expertise and capacity to manufacture StemSmart™ to meet MSX's commercialisation goals.

MSX's StemSmart™ product is derived from adult human donor bone marrow-sourced mesenchymal stem cells (MSCs) developed at the Royal Perth Hospital in Western Australia. StemSmart™ is produced using a patented manufacturing process that has been designed to improve therapeutic activity and clinical response, as well as modulate pathological immune responses that are often associated with severe and chronic inflammatory conditions. Early indications from a previous Phase 2 trial in refractory Crohn's disease suggest StemSmart™ MSCs are potent, efficacious and safe[3].

[1] ASX Announcement (01 October 2026) – *"Leading CRO Appointed for Phase 2 Crohn's Trial"*
[2] ASX Announcement (13 October 2026) – *"US FDA Provides Positive Feedback on Planned Phase 2 Trial"*
[3] ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology"*

This announcement is authorised by the Board of **Miro Sciences Limited.**

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About Miro Sciences Ltd
Miro Sciences Limited (ASX: MSX), formerly NeuroScientific Biopharmaceuticals Limited (ASX: NSB), is a biotechnology company focused on the development of novel therapeutics targeting immune-mediated inflammatory disorders. The Company's research is centred on modulating pathological immune responses involved in chronic and degenerative conditions, particularly where current therapeutic options demonstrate limited efficacy or durability. MSX applies advanced preclinical and translational strategies to support the development of first-in-class or best-in-class biologics addressing significant unmet clinical need.

Targeting Crohn's Disease with StemSmart™ Technology
MSX is prioritising the application of its proprietary StemSmart™ technology targeting refractory Crohn's - a severe and treatment-resistant form of the condition. NSB's StemSmart™ product is derived from adult human donor bone marrow-sourced MSCs that is produced using a patented manufacturing process developed at Royal Perth Hospital, Western Australia and designed to improve therapeutic activity and clinical response.

The Company is planning Phase 2 clinical trials to further evaluate safety and preliminary efficacy in refractory and/or fistulising Crohn's disease, with the goal of making the treatment available to patients for whom current therapies remain inadequate.

Forward Looking Statements
This announcement may contain certain "forward-looking statements". Forward looking statements can generally be identified by the use of forward-looking words such as, "expect", "should", "could", "may", "predict", "plan", "will", "believe", "forecast", "estimate", "target" and other similar expressions. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions. Forward-looking statements including projections, guidance on future earnings and estimates are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

You are strongly cautioned not to place undue reliance on forward looking statements, including in respect of the financial or operating outlook for the Company. Except as required by law or any relevant listing rules of the ASX, the Company assumes no obligation to provide any additional or updated information or to update any forward-looking statements, whether as a result of new information, future events or results, or otherwise. Nothing in this announcement will, under any circumstances (including by reason of this announcement remaining available and not being superseded or replaced by any other presentation or publication with respect to the Company, or the subject matter of this announcement), create an implication that there has been no change in the affairs of the Company since the date of this announcement.