NeuroScientific

ASX:NSB

ASX Announcement
11 November 2025

NSB Progresses through Clinical Development Program with Fourth Patient Commencing Treatment Under Special Access Scheme

Treatment results will directly support a Phase 2 Clinical Trial of StemSmart™

Highlights

- **Four patients in Cohort 1 with fistulising Crohn's disease are now undergoing treatment with NSB's patented StemSmart™ MSC product.**
- **Real-world treatment data from this Special Access Program will directly inform design of NSB's planned Phase 2 clinical trial.**
- **First round of patient treatment results expected in January 2026.**
- **Special Access Scheme Category B provides treatment for patients with no effective conventional therapy alternatives.**
- **Manufacturing technology transfer, clinical development, and regulatory planning are underway to support the planned Phase 2 clinical trial.**
- **StemSmart™ is positioned as a platform cell therapy with additional commercial upside opportunities across organ transplant immune tolerance, lung inflammatory disease and graft-vs-host disease.**

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific" or the **"Company"),** an innovative Australian biotechnology company developing novel technologies targeted at immune-mediated inflammatory diseases, is pleased to advise that the fourth patient has commenced treatment under the Special Access Program (the "**Program**") for Company's patented StemSmart™ mesenchymal stem cell (**"MSC"**) therapy for patients with fistulising Crohn's disease[3].

This marks continued progress as the Company advances towards the Phase 2 clinical trial, which is planned to commence in CY2026.

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Patients treated under the TGA Special Access Scheme Category B pathway are those with severe and conventional treatment-resistant disease who have exhausted previous treatment and medical options.

The Special Access Scheme Category B pathway, therefore, allows for patients with very poor treatment options or little receptivity to conventional treatments to receive an unapproved therapy upon review and approval by the TGA.

The Program will therefore provide both urgent therapeutic intervention for affected patients and important clinical insights that will directly inform the next stage of development for Neuroscientific.

The initiation of treatment for these 4 patients further builds on the StemSmart™ platform integration following from the acquisition of the technology from Isopogen WA Ltd[1].

NSB Chief Executive Officer Nathan Smith Commented:

"*Treating the fourth patient under the Special Access Program with StemSmart™ marks an important step and meaningful progress for both the patients and clinicians in the Crohn's disease field, a particularly debilitating form of the chronic disease.*

"*We believe StemSmart™ has the potential to offer a new therapeutic option in an area where there are limited effective treatments. The outcomes from this Program will provide direct guidance towards our Phase 2 clinical trial design, which we anticipate initiating in the second half of 2026.* "

StemSmart™ Advancing Next-Generation Cell Therapy

StemSmart™ is derived from adult human donor bone marrow-sourced MSCs and manufactured using a patented enhancement process designed to improve therapeutic activity and clinical response.

Early indications from a previous Phase 2 trial in refractory Crohn's disease suggest StemSmart™ is potent, efficacious and safe[1].

Patients across Australia have already received compassionate access treatment with StemSmart™, with multiple patients reporting positive clinical responses in severe, conventional treatment-resistant conditions[1].

Addressing an Unmet Need in Crohn's Disease

Fistulising Crohn's disease represents one of the most severe and debilitating complications of inflammatory bowel disease, which is often resistant to current approved therapies.

Data generated through this Program is intended to support and de-risk the development of a Phase 2 clinical trial in the broader indication of refractory Crohn's disease.

Patients that qualify for treatment with StemSmart™ under the Program must be approved by the Australian TGA under Category B of the Special Access Scheme. The Category B pathway is required to access unapproved therapeutic goods in Australia for the treatment of patients and requires clinical justification from a health practitioner.

Additional patients to be treated under the Program will receive MSC therapy as clinical products become available from East Metropolitan Health Service, a TGA certified manufacturer, following quality assurance clearance of existing in-process products currently held in storage or, alternatively, from Isopogen's TGA certified contracted manufacturer (Queensland Institute of Medical Research) on its certification to manufacture StemSmart™.

StemSmart™ Key Addressable Markets[2]

- **Crohn's Disease:** Global market US$13.8 billion by 2026;
- **Kidney Transplant:** Global market for organ transplant immuno-suppressants, increasing to US$7.2 billion by 2030 (majority for renal);
- **Lung Disorders:** Global market US$33 billion by 2034; and
- **GvHD**: Global market increasing to US$5.31 billion in 2032.

[1] ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology"*
[2] ASX Announcement (27 June 2025) – *"StemSmart Acquisition Complete"*
[3] ASX Announcement (7 October 2025) – *"First Patients Approved for Special Access Program"*

This announcement is authorised by the Board of NeuroScientific Biopharmaceuticals Ltd.

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About NeuroScientific Biopharmaceuticals Ltd

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. NSB applies advanced preclinical and translational strategies to support the development of first-inclass or best-in-class biologics addressing significant unmet clinical need.

Targeting Crohn's Disease with StemSmart™ Technology

Following the acquisition of Isopogen WA Ltd, NSB is prioritizing the application of its proprietary StemSmart technology through a SAS program targeting fistulising Crohn's disease—a severe and treatment-resistant form of the condition. Favourable outcomes will support the Company's progression to a Phase 2 clinical trial to further evaluate safety and preliminary efficacy in refractory and/or fistulising Crohn's disease. This initiative aligns with NSB's broader strategy to obtain regulatory and reimbursement approval for its MSC therapy both in Australia and internationally, with the goal of making the treatment available to patients with fistulising and refractory Crohn's disease, for whom current therapies remain inadequate.

About EmtinB™

EmtinB™ is a peptide-based compound that binds to surface-based cell receptors from the LDLR family, activating intracellular signalling pathways that stimulate neuroprotection, neuroregeneration and modulate neuroinflammation. EmtinB™ is modelled on a specific active domain of the complex human protein called Metallothionein-IIA, which is produced as part of the human body's innate immune response to cell injury. Our preclinical research has established that EmtinB™ is highly specific and selective for its target receptor, safe and well tolerated at high concentrations.

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 presentation 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.

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