NeuroScientific

ASX:NSB

ASX Announcement
26 May 2026

Remarkable Results from Patients treated with StemSmart under the Special Access Program

4 out of 5 patients (80%) achieved a successful Clinical Response

Highlights

- **Completion of NSB's Special Access Program provides exceptional outcomes for Fistulising Crohn's Disease patients treated with StemSmart™.**
- **Five (5) patients in total received NSB's StemSmart™ MSC product under the Special Access Program, with all showing improvement and 4 of 5 (80%) achieving a successful Clinical Response, with no serious adverse events.**
- **NSB's StemSmart™ MSC product demonstrated clinically meaningful therapeutic results in younger adults who are living with the debilitating complications of fistulising Crohn's disease; a remarkable result for these patients who are resistant to currently available approved therapies.**
- **Clinical Response is defined as either the closure of ≥50% of fistula openings, or a ≥50% decrease in fistula discharge in a patient, as assessed by the treating physician or qualified investigator[1].**
- **Following the exceptional results of the Special Access Program, NSB has initiated development of a pivotal Phase 2 clinical trial in fistulising Crohn's disease, taking place in Australia and anticipated to commence 2H CY2026.**
- **This Australia-only Phase 2 clinical trial in fistulising Crohn's disease will aid in NSB's pursuit of achieving Marketing Authorisation in Australia and will be conducted in parallel with the broader refractory Crohn's disease Phase 2 clinical trial for the US & Australia.**
- **Results in NSB's early work with StemSmart™ set the foundation for the Company's anticipated entry into the global Crohn's disease market, which is totalled at ~US$13 billion[1, 2].**
- **StemSmart™ is a patented stem cell technology, positioned as a platform cell therapy, with additional clinical opportunities to address unmet needs where there is acute and chronic inflammation in conditions such as organ transplant immune tolerance, lung inflammatory disease, and graft-vs-host disease (GvHD).**

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific", "NSB" or the "Company"), an innovative Australian biotechnology company developing novel technologies

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targeted at immune-mediated inflammatory diseases, is pleased to announce the exceptional outcomes for patients with fistulising Crohn's disease from the Company's Special Access Program using its patented StemSmart™ mesenchymal stem cell (**"MSC"**) therapy.

Of the five (5) total patients aged 18-49 (3 male) treated with StemSmart™, all of the patients responded to MSC therapy, with 4 (80%) patients demonstrating a Clinical Response, defined by either the closure of ≥50% of fistula openings or a decrease of ≥50% in fistula discharge, as assessed by the treating physician or qualified investigator[1]. All patients experienced a reduction in their fistula discharge, with 4 patients achieving the ≥50% threshold for a Clinical Response, while the remaining 1 patient did not meet the threshold and showed a partial response.

Additionally, this positive clinical response was further supported by patient assessment using internationally recognised scoring systems for Crohn's disease. All patients showed improvement in Crohn's Disease Activity Index (CDAI), Perianal Disease Activity Index (PDAI) and Inflammatory Bowel Disease Questionnaire (IBDQ) Quality of Life Index. Radiological imaging via MRI indicated a trend toward healing of fistulas for all patients but was considered too early in the treatment to observe fistula closure.

All patients had at least one seton removed, which is a significant indicator of fistula healing. Setons are surgical implants that ensure drainage and help prevent infection of fistulas. Furthermore, the treatment was safe and well tolerated, with no serious adverse events observed.

The patients participating in the Special Access Program were younger adults living with fistulising Crohn's disease, one of the most severe and debilitating complications of inflammatory bowel disease, as well as a complex and chronic condition that is often resistant to conventional treatments.

Each of the patients was approved by the TGA for treatment using the StemSmart™ therapy under the Special Access Scheme ("SAS") Category B pathway, initially starting in October of CY2025[4]. This pathway provides potential treatment options for patients where existing conventional therapies have been ineffective, or where no effective alternatives for therapy exist, in an attempt to address unmet medical needs for those with serious and life-threatening conditions.

Addressing the results and the SAS Program, NSB Chief Medical Officer, Dr Cathy Cole, commented:

> *"A clinical response rate of 80% to a novel treatment for a serious, debilitating and long-standing medical condition, that largely affects younger adults, is exceptional. Considering these fistula patients receiving StemSmart™ were treated in a real-world setting and had limited treatment options available, the response is outstanding and offers hope for clinical recovery when there was previously little. We can confidently proceed to our phase 2 trials informed on frequency and timing of doses of MSC and MRI assessments. In keeping with our total experience to date, there are no safety concerns."*

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As a result of the successful Special Access Program and the demonstrated clinical response, NSB has initiated its development of a Phase 2 clinical trial, specifically for fistulising Crohn's disease patients in Australia.

The data from the Special Access Program and earlier clinical work with the StemSmart™ MSC product will inform the emerging study design of the anticipated Phase 2 clinical trial, specifically regarding key methodological factors such as the induction considerations, dosing schedules, and the timing of MRI scans.

The anticipated clinical trial is intended to provide pivotal clinical data to support NSB's work to position StemSmart™ for Marketing Authorisation in Australia as a future treatment option for patients with fistulising Crohn's disease.

The Australia-only Phase 2 clinical trial is planned for initiation by 2H CY2026 and will be developed in parallel with the previously-announced[3] Phase 2 clinical trial in US & Australia for the broader indication of refractory Crohn's disease.

Addressing the anticipated fistulising Crohn's disease clinical trial commencing later this year, NSB Chief Executive Officer, Mr Nathan Smith, commented:

> *"The outstanding results from the initial patients in the Special Access Program have highlighted the opportunity for NSB to conduct an Australian clinical trial for fistulising Crohn's disease; an incredibly debilitating condition with a patient population that has very few effective treatment options available to them. The pivotal data generated from this planned trial will assist NSB in its aim to obtain Marketing Authorisation for StemSmart™ to potentially benefit Australian patients and provide a pathway to commercialisation of our technology earlier than previously forecasted."*

Addressing the Company's recent progress, NSB's Non-Executive Chairman, Mr Robert McKenzie, commented:

> *"Our medical & scientific teams' response to these initial results indicates that NSB is making momentous progress. The clinical success of StemSmart™ in this difficult to treat patient group is significant and reinforces NSB's commitment to the development of StemSmart™ for the benefit of patients."*

About StemSmart™ and the Special Access Scheme

NSB's StemSmart™ product is derived from adult human donor bone marrow-sourced MSCs and is produced using a patented manufacturing process that has been designed to improve therapeutic

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

The patients in this Program have received treatment using NSB's StemSmart™ therapy under the Special Access Scheme Category B pathway, which 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 successful outcome of the SAS program satisfies the Performance Shares Milestone as outlined in ASX Announcement dated 16 April 2025.

StemSmart™ Key Addressable Markets[1, 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
- **Graft-versus-Host-Disease (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] https://www.globaldata.com/store/report/crohns-disease-dynamic-market-forecast-to-2026/
[3] ASX Announcement (13 January 2026) – *"Successful Clinical Results Achieved under Special Access"*
[4] ASX Announcement (7 October 2025) – *"First Patients Approved for Special Access Program"*

This announcement is intended to lift the Company's Trading Halt, applied for and granted yesterday, 25 May 2026.

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-in-class 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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