NeuroScientific

ASX:NSB

ASX Announcement
13 January 2026

Successful Clinical Results Achieved under Special Access Program

Highlights

- **Successful Clinical results from Fistulising Crohn's Disease patients treated with StemSmart™ through Special Access.**
- **Of the 4 patients treated in Cohort 1 (refer ASX Announcement 23 May 2025) with NSB's StemSmart™ MSC product in the Special Access Program for fistulising Crohn's disease, 3 have had a successful Clinical Response.**
- **A 4th patient had a partial response to StemSmart™ treatment and improved, with further clinical assessments ongoing.**
- **Successfully achieving a Clinical Response in 3 patients, and a partial response in the remaining patient, is significant and provides critical validation for the StemSmart™ platform in a real-world setting.**
- **Clinical Response is defined as either closure of ≥50% of fistula openings or a decrease in fistula discharge in a patient of ≥50% as assessed by the treating physician or qualified investigator[1].**
- **The treatment data from this Special Access Program will directly inform the study design of NSB's planned later phase clinical trials, planned to commence 2H 2026.**
- **Phase 2 start-up activities are well underway including for the establishment of commercial manufacturing, clinical trial development and regulatory planning.**
- **These results set the foundation for entry into the ~US$13 billion Global Crohn's disease market[2].**
- **StemSmart™ is positioned as a platform cell therapy with additional clinical opportunities to address unmet needs where there is chronic inflammation in conditions such as organ transplant immune tolerance, lung inflammatory disease and graft-vs-host disease.**

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific", "NSB" or the "Company"), an innovative Australian biotechnology company developing novel technologies targeted at immune-mediated inflammatory diseases, is pleased to announce that three (3) of four (4) patients (which form Cohort 1), have demonstrated a successful "Clinical Response" following treatment with the Company's patented StemSmart™ mesenchymal stem cell (**"MSC"**) therapy. In addition, a 4th patient of the cohort improved after treatment demonstrating a partial response, and further clinical measures are being conducted and considered.

This is a remarkable result for patients who are living with debilitating complications of inflammatory bowel disease, which is often resistant to currently available approved therapies.

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The patients were approved by the TGA for treatment using the StemSmart™ therapy under the Special Access Scheme ("SAS") Category B pathway. This pathway provides potential treatment options for patients where no effective conventional therapy alternatives exist or are effective 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 Executive Officer, Mr Nathan Smith, commented:

> "*These treatment results provide critical validation of the StemSmart™ MSC platform in presenting a potential therapeutic solution to patients with debilitating fistulising Crohn's disease that have limited effective treatment options.*
>
> *This data, along with our previous clinical trial results in refractory Crohn's disease, provides a strong foundation for our commercialisation plans for StemSmart™ moving forward.*
>
> *Together, these early outcomes allow us to advance the development of a novel therapeutic in a responsible, informed, and patient-centred fashion as it supports and accelerates our progress toward clinical trial work later this year.*"

NSB Chief Medical Officer, Dr Cathy Cole, commented:

> "*The response rate to StemSmart™ MSC treatment seen in these patients in a real-world setting is exceptional, given the serious, debilitating and long-standing adverse nature of their condition. If you consider that for these fistula patients treated with StemSmart™, there were limited treatment options available, then the response to treatment is truly outstanding and offers hope for clinical recovery when there was previously little.*"

NSB's StemSmart™ product is derived from adult human donor bone marrow-sourced MSCs that is produced using a patented manufacturing process 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].

Fistulising Crohn's disease represents one of the most severe and debilitating complications of inflammatory bowel disease, which is often resistant to currently available approved therapies. 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 data generated through this Program will support the development of a specific later phase clinical trial in fistulising Crohn's Disease and a Phase 2 clinical trial in the broader indication of refractory Crohn's disease, planned to commence in the second half of this calendar year. The Phase 2 study in refractory Crohn's disease is projected to treat patients in multiple jurisdictions, including the U.S. and Australia, to support future commercialisation plans.

Manufacturing technology transfer, clinical development, and regulatory planning is already underway and progressing to support the planned clinical trials.

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)
[2] ASX Announcement (11 November 2025)

This announcement is intended to lift the Company's Trading Halt applied for and granted on Friday 9 January 2026.

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

Please see below link for an update from NSB CEO – Nathan Smith:

https://youtu.be/KTMOejiriVM

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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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