

## ASX Announcement

07 October 2025

## First Patients Approved for Special Access Program

*A pivotal step towards Phase 2 Clinical Trial of StemSmart™ for Crohn's Disease*

### Highlights

- **First 3 patients in Cohort 1 with fistulising Crohn's disease have been approved for treatment by the Therapeutic Goods Administration ("TGA").**
- **TGA approval is required for treating patients with unapproved therapies under the Special Access Program Category B pathway.**
- **The Program commenced following the acquisition of Isopogen WA Ltd by NeuroScientific<sup>1,2</sup>, which treats patients with fistulising Crohn's disease with the Company's StemSmart™ patented stem cell technology.**
- **Manufacturing technology transfer to manufacturing partner, Q-Gen Cell Therapeutics ("Q-Gen"), is currently on track to support clinical scalability and future commercialisation.**
- **Approved patients in Cohort 1 will progress towards treatment with StemSmart™ mesenchymal stem cells ("MSCs") in line with the Program.**
- **Patient recruitment momentum is progressing, as further TGA approvals are anticipated.**

**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 provide an update on the progress of the Special Access Program (the "**Program**") for patients with fistulising Crohn's disease.

The first 3 patients in **Cohort 1 with fistulising Crohn's disease** have been approved by the TGA for treatment with the patented StemSmart™ MSC technology ("**StemSmart™**").

These approvals represent a major milestone in the progress of the Company's Program, which was initiated following the acquisition of StemSmart™ from Isopogen WA Ltd<sup>1</sup>.

**NSB Chief Executive Officer Nathan Smith Commented:** *"I am extremely excited with the TGA approval to treat patients with StemSmart™ as we advance the Special Access Program towards*

<sup>1</sup> ASX Announcement (16 April 2025) – "NeuroScientific to Acquire Leading Stem Cell Technology"

<sup>2</sup> ASX Announcement (27 June 2025) – "StemSmart Acquisition Complete"

completion by mid-2026. This milestone, alongside our progress in transferring the manufacturing technology to Q-Gen in parallel, paves the way towards initiation of our Phase 2 clinical trial next year.”

## StemSmart™ Advancing Next-Generation Cell Therapy

StemSmart™ is derived from adult human donor bone marrow. The mesenchymal stem cells (“MSCs”) are isolated and grown in culture, before the patented StemSmart™ manufacturing process is applied to improve the cells’ clinical efficacy. Early indications from a previous Phase 2 trial in refractory Crohn’s disease suggest StemSmart™ is potent, efficacious and safe<sup>1</sup>.

Patients across Australia have already received compassionate access treatment with StemSmart™, demonstrating multiple strong positive clinical responses in severe, treatment-resistant conditions<sup>1</sup>.

## 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 are often resistant to current therapies. Outcomes of this Program are intended to support the development of the future Phase 2 clinical trial in the broader indication of refractory Crohn’s disease, planned for 2026.

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

With notification that patients in Cohort 1 have received approval by the TGA, the health practitioner is able to progress toward treating the approved patients with StemSmart™ in coordination with NSB.

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<sup>2</sup>

- **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.

For more information, please contact:

**Nathan Smith**

Chief Executive Officer

NeuroScientific Biopharmaceuticals Ltd

[ir@neuroscientific.com](mailto:ir@neuroscientific.com)

**Jane Morgan**

Investor & Media Relations

Jane Morgan Management

[jm@janemorganmanagement.com.au](mailto:jm@janemorganmanagement.com.au)

## 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. Outcomes of this Program are intended to support the development of the future Phase 2 clinical trial in the broader indication of refractory Crohn's disease, planned for 2026. 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

# NeuroScientific

---

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.