NeuroScientific

ASX:NSB

ASX Announcement
13 August 2026

Pre-IND Meeting with US FDA Scheduled

Critical regulatory milestone for planned Phase 2 clinical trial in the United States for Refractory Crohn's disease

Highlights

- **United States Food & Drug Administration (FDA) has scheduled the Pre-Investigational New Drug (Pre-IND) meeting for 31 August 2026 for NSB's Phase 2 clinical trial.**
- **The Pre-IND meeting with the US FDA is an important regulatory milestone that ensures the clinical design of the planned Phase 2 clinical trial for treating refractory Crohn's disease with NSB's StemSmart™ is suitable for US patients.**
- **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, which is the focus of NSB's initial clinical trial.**

NeuroScientific Biopharmaceuticals Limited (ASX:NSB) ("NeuroScientific", "NSB" 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 that it has received the confirmed date for its Pre-Investigational New Drug (Pre-IND) meeting with the United States Food & Drug Administration (FDA) relating to the Company's planned Phase 2 clinical trial targeting refractory Crohn's disease for patients in the US and Australia.

Pre-IND Meetings with the US FDA are a critical regulatory milestone where the federal agency reviews the clinical, scientific, and product development of prospective treatments like StemSmart™ to ensure suitability for a future IND submission. NSB intends to submit an IND application for approval by late CY 2026[1] for the Company's Phase 2 clinical trial to treat patients in Australia and the US suffering from refractory Crohn's disease with StemSmart™.

NSB Chief Executive Officer, Mr Nathan Smith, commented:

> *"Our upcoming Pre-IND meeting with the US FDA marks an important milestone in NSB's clinical development for our patented StemSmart™ technology platform. Interfacing with the FDA on the development of StemSmart at this time is critical to ensuring that the planned clinical trial design is of a standard to support clinical translation of the product. Outcomes from the Pre-IND meeting will strengthen our ongoing Phase 2 clinical trial preparatory activities, which are progressing rapidly as we plan for IND approval by later this year."*

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NSB's StemSmart™ product is derived from adult human donor bone marrow-sourced mesenchymal stem cells (MSCs) and 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[2].

[1] ASX Announcement (13 January 2026) – *"Successful Clinical Results Achieved under Special Access"*
[2] ASX Announcement (16 April 2025) – *"NeuroScientific to Acquire Leading Stem Cell Technology"*

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

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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
NSB 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 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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