

ASX Announcement

13 October 2026

US FDA Provides Positive Feedback on Planned Phase 2 Crohn's Disease Trial

FDA supports proposed trial design, existing human data package and StemSmart™ release testing strategy ahead of planned IND submission

Highlights

- United States Food & Drug Administration (FDA) has provided positive feedback following the Pre-Investigational New Drug (Pre-IND) meeting for NSB's Phase 2 clinical trial in Crohn's Disease.
- Following review of NSB's clinical program briefing package, the FDA provided positive responses to 6 of the 7 questions posed by NSB, including agreement with the proposed Phase 2 clinical design.
- The FDA agreed that the current weight-of-evidence from humans previously treated with StemSmart™ was sufficient, that no additional non-clinical studies were required and that the Company's proposed release-testing strategy for StemSmart™ was acceptable.
- The Pre-IND meeting represents an important regulatory milestone for NSB's planned Phase 2 clinical trial of StemSmart™ in patients with refractory Crohn's disease in the United States.
- NSB continues to progress preparations for the planned Phase 2 clinical trial, with trial initiation targeted by the end of CY2026, subject to completion of regulatory, manufacturing and operational requirements.
- 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 a positive outcome from 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 United States and Australia.

Following review of NSB's clinical program briefing package, the FDA provided a favourable response to 6 of the 7 questions posed by NSB.

Among the key positive responses provided by the FDA were:

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- Agreement with the design of NSB's Phase 2 clinical trial in refractory Crohn's disease.
- Agreement that current weight-of-evidence data in humans previously treated with StemSmart™ was sufficient and did not require additional non-clinical studies.
- Agreement with the release testing strategy for StemSmart™ product.

The one outstanding matter the FDA requires to be addressed relates to the control strategy for manufacturing, to ensure the product is free from viral contamination. NSB agrees with the FDA's feedback and is implementing the required testing with minimal impact to timelines.

Feedback from NSB's regulatory consultants highlighted that the response from the FDA on the briefing package was very positive and also remarked that NSB was fortunate the FDA had granted the face-to-face Pre-IND meeting, as they have been very selective in granting these meetings in lieu of written responses in recent months.

NSB Chief Executive Officer, Mr Nathan Smith, commented:

"The excellent outcome from our Pre-IND meeting with the US FDA demonstrates the exceptional work the NSB team has done to ensure StemSmart™ is suitable for use in the planned Phase 2 clinical trial in treatment-resistant Crohn's disease in the US. The achievement of another pivotal milestone in NSB's clinical development for our patented StemSmart™ technology platform takes us one step closer to providing a potential treatment option for patients with this debilitating disease."

Pre-IND Meetings with the US FDA are an important regulatory milestone where the federal agency reviews the clinical, scientific, and product development of prospective treatments such as StemSmart™ and provides guidance ahead of a future IND submission. NSB intends to initiate the Company's Phase 2 clinical trial in Australia and the United States by the end of CY2026 to treat patients suffering from refractory Crohn's disease with StemSmart™.

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 safe².

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.

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