

DISAPPOINTING TRIAL RESULTS PROMPTS WARNING FROM BIOTECH COMPANY

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MIS416, a potential therapy for secondary progressive MS, has recently finished undergoing phase 2 trials here in Australia and New Zealand. Now Innate Immunotherapeutics, the New Zealand biotech company behind this therapy, has announced the disappointing preliminary top-line results of the trials to their investors.

While the full results have not yet been scientifically published, the company has announced that initial analysis of its phase 2 trial showed no overall clinically meaningful or statistically significant differences between people treated with MIS416 and people treated with placebo.

MIS416 is a microparticle derived from bacteria, combined with two immune-modifying molecules. It acts to stimulate a specific range of responses in one branch of the immune system, known as the innate immune system.

This phase 2 trial was a randomised, double-blind, placebo-controlled trial, meaning that neither the patients nor the doctors treating them knew who was taking MIS416 or who was taking the placebo or mock treatment. The study was designed to test the efficacy and safety of MIS416 treatment of people with secondary progressive MS. It was carried out at five sites in Australia and New Zealand, with a total of 93 subjects with 62 receiving the medication and the remaining 31 receiving the placebo.

To determine the efficacy of MIS416, participants were assessed using multiple measures including walking speed and distance, visual acuity and two measures of cognitive processing speed. Various upper body function and strength tests, as well as patient reported outcomes and MRI analysis.

These disappointing results are surprising given the apparent earlier positive responses with MIS416 during a compassionate use program and a preliminary phase 1b/IIa trial, however, the company is continuing to analyse the results, to investigate if there may have been sub-groups of people that have responded and would benefit from this treatment.

This trial highlights the torturous road which every potential therapy must traverse before it can become a successful treatment. Unfortunately, a large number of these potential therapies fail when put to the test in real life, and this is often despite early promising signs in the lab, or even after promising signs in pre-clinical models and early clinical trials.

Another factor that has dogged clinical trials into progressive forms of MS is the lack of uniform, sensitive assessment tools to measure meaningful changes in the rate of disease progression. This is a major focus for the [International Progressive MS Alliance](#), of which MS Research Australia is a managing member. The Alliance is working hard to address this problem and has funded a major Collaborative Network who are looking at just this issue, as well as major drug discovery programs.

While this might not be the end of MIS416, it highlights the significant challenges we face in bringing treatments for progressive forms of MS to fruition.

To read the official press from Innate Immunotherapeutics [here](#).