Innate Immunotherapeutics

ABN 16 165 160 841

ASX RELEASE **21 July 2017**

No change to outcome of MIS416 trial in patients with SPMS following additional data analysis

Summary:

- *As announced 27 June, analysis of Phase 2B trial data on a total enrolled patient population basis show no clinically meaningful or statistically significant differences in measures of neuromuscular function or patient-reported outcomes*
- *Further analysis of patients who adhered to the trial protocol (the per protocol population) has not changed these disappointing trial outcomes*
- *Initial analysis at the level of individual patient has not identified a responder subpopulation.*

Innate Immunotherapeutics Limited (ASX Code: IIL) advises that further analysis of data from its Phase 2B randomised, double-blind, placebo-controlled trial of the efficacy and safety of MIS416 in the treatment of subjects with secondary progressive multiple sclerosis (SPMS) has not altered the initial finding that MIS416 treatment failed to show clinically meaningful or statistically significant differences in measures of neuromuscular function or patient reported outcomes.

Following the initial analysis of the Phase 2B data on a total enrolled patient population basis, the Company has now completed an analysis of efficacy assessments for the per protocol population. This population comprises patients who completed at least 75% of the study and otherwise adhered to all significant aspects of the trial protocol. The population comprised 43 subjects in the MIS416 treatment group and 27 subjects in the placebo group.

This per protocol population analysis showed no clinically meaningful or statistically significant differences in measures of neuromuscular function or patient-reported outcomes.

Also following the initial analysis, the Company sponsored an analysis of the trial results at the patient level to see if there was a group of clinical responders which might not have been evident from the top line population-based analysis. The first report from this subsequent analysis does not indicate that such a responder group exists. The detailed results from this analysis have not yet been received but there is nothing to currently suggest that the final outcome will be any different.

This apparent lack of efficacy at either the overall study population level or the individual patient level is extremely disappointing and inconsistent with previous clinical experience and the reporting of MIS416 treatment benefits by many compassionate use patients over the past eight years.

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"All previous reports of MIS416 making a meaningful difference in the lives of many patients must either be dismissed as a very robust placebo effect or the trial failure is attributable to some other reason. It is my view that there may be other reasons," said Simon Wilkinson, Innate Immunotherapeutics' Chief Executive Officer.

"Patients with SPMS have a complex mix of symptoms and their disease can't be monitored by a simple blood test or MRI scan. We used the best assessment tools available as recommended by expert practitioners in MS but we suspect they weren't sensitive enough to pick up the small but potentially significant changes that can lead to a substantial impact on patients' activities of daily living and quality of life," said Wilkinson.

The Company's Chairman, Michael Quinn added: "Whatever the possible explanations, we have not delivered a result that would support our continued trialling of MIS416 in patients with SPMS. "We now need to look to the future of Innate. In doing so we are mindful of the interests of our shareholders and other committed stakeholders including patients still receiving MIS416 on compassionate use grounds in Australia and New Zealand".

Over the next two to three months the Company will actively review other possible applications for MIS416 as well as the potential value of Innate as a vehicle for a new technology.

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