

ASX RELEASE

28 February 2017

## **Phase 2B trial of MIS416 in patients with secondary progressive multiple sclerosis on schedule to complete by end of April 2017**

Innate Immunotherapeutics Limited (ASX Code: IIL) confirms that the clinical phase of the Phase 2B trial of MIS416 in patients with secondary progressive multiple sclerosis (SPMS) will be completed by the end of April as scheduled.

Innate is conducting an exploratory double blinded, 2:1 randomised, placebo controlled study into the safety and efficacy of the Company's drug candidate MIS416 when administered once weekly over a twelve month period. Ninety three patients with SPMS have been enrolled into the study between late 2014 and April 2016. The final sixteen patients will complete the study over the next eight weeks with the last patient scheduled to complete their last study visit on 19 April.

To date no safety related concerns have arisen during the study. The independent Data Safety Monitoring Board, which is responsible for periodically reviewing trial safety data, has met on three occasions as required by their charter and has expressed no concerns regarding the conduct or safety outcomes of the trial.

Following the final patient visit, the Company expects it will take up to four months to complete the entry, monitoring, and analysis of the large amount of data the study has generated. Each patient generates approximately 400 pages of data over the full course of the study. The final Clinical Study Report should be released in late August or during September. Initial 'topline' data may become available prior to the release of the final report and if so, this will be released to the market at that time.

The Company continues to receive a high level of interest from the majority of patients who have already completed the trial and who want post-study access to MIS416. The Company is working closely with the patients' general practitioners to ensure that such access can be arranged whenever possible.

CEO Simon Wilkinson commented, "The participants in this study endure a wide range of MS related debilitating symptoms and we deeply appreciate the commitment and fortitude with which so many of them have adhered to the requirements of what is an intensive course of treatment and tests over a 52 week period."

- End

### **About Innate Immunotherapeutics**

Innate Immunotherapeutics Limited is an Australian biotechnology company with an exciting technology that targets the human innate immune system. The innate immune system is the body's first line of defence against external disease causing pathogens such as bacteria and viruses, and internally caused diseases such as cancer. Disorders of the immune system can also cause or contribute to diseases such as multiple sclerosis. While the innate immune system is responsible for mounting the body's initial defence against threats, it also plays a critical role in controlling the overall immune response and many for the body's tissue protective and reparative functions.

### **SPMS - The Significant Unmet Medical Need**

Multiple sclerosis is a chronic disabling condition where the body's immune system attacks the myelin sheath surrounding nerve fibres. The damaged myelin forms scar tissue which distorts or interrupts nerve impulses, disrupting the ability of parts of the nervous system to communicate properly. This can result in a wide range of symptoms, including loss of balance, muscle coordination, difficulty walking, slurred speech, tremors, stiffness, cognitive impairment, depression, fatigue and bladder problems.

Within 15 years of being diagnosed with the early 'relapsing-remitting' stage of MS, and despite the 13 drugs approved to treat this early stage of disease, about 60% of sufferers go on to develop a more advanced progressive form of disease - SPMS. After 20 years the number of SPMS sufferers increases to about 75%. **There are currently no approved drugs for the effective ongoing treatment of SPMS.** The Company's clinical development of MIS416 seeks to address this important unmet medical need and significant commercial opportunity.

### **About MIS416**

The microparticle, MIS416, is a biologically derived novel immune modulator which can uniquely target both the regulatory and defensive functions of the innate immune system. MIS416 targets myeloid cells, a sub-set of innate immune cells not currently targeted by any other drugs in development for the treatment of SPMS. Myeloid cells can play an important role inside the brain of a patient with SPMS by down regulating inflammation, helping clear myelin debris, and upregulating tissue repair processes.

### **For Further Information**

Simon Wilkinson, CEO

+64 21 661 850

[www.innateimmuno.com](http://www.innateimmuno.com)