Innate Immunotherapeutics receives FDA clearance for MIS416 Investigational New Drug application

Innate Immunotherapeutics Limited (ASX Code: IIL) is pleased to confirm it has received clearance from the U.S. Food and Drug Administration (FDA) for the Company's Investigational New Drug (IND) application lodged last month.

The successful opening of an IND in the U.S. is a further important milestone in the ongoing clinical development of the Company's lead drug candidate MIS416.

MIS416, a novel modulator of innate immunity, recently completed a Phase 2B safety and efficacy trial in patients suffering from secondary progressive multiple sclerosis (SPMS). The study was conducted at five sites in Australia and two sites in New Zealand. The company has previously advised that the trial results are expected in the third quarter of this year.

The IND application process requires the sponsor of a drug development programme to submit detailed information to the FDA, and clearance from the FDA must be obtained before a drug candidate can enter clinical trials in the U.S..

Information submitted as part of an IND application includes details about the composition of the drug, how the drug is manufactured, results from preclinical safety studies, and results from previous human clinical trials.

Commenting on the IND clearance from the FDA, Innate Immunotherapeutics' CEO Simon Wilkinson said: "Opening an IND in the U.S. at this time is particularly important for the Company and the culmination of years of work. It allows us to meet with the FDA following the release of our Phase 2B data, and discuss the design of a Phase 3 study. We can also establish whether MIS416 would qualify for one of the FDA's expedited approval programmes which exist to help drugs for serious conditions get to market faster".

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About Innate Immunotherapeutics
Innate Immunotherapeutics Limited is an Australian biotechnology company with a novel 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. While innate immunity is responsible for mounting these important and immediate defences, it also plays a critical role in controlling the overall immune response as well as many for the body's tissue protective and reparative functions. The Company’s lead drug candidate MIS416 can trigger these anti-inflammatory and reparative functions inside the central nervous system. This makes MIS416 a highly relevant drug candidate for the treatment of secondary progressive multiple sclerosis and other neurological conditions where inflammation inside the CNS contributes to disease pathology.

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.

For Further Information
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