

Fast ForwardSM

Accelerating Commercial Development Fund

This project is funded through a collaboration between Fast Forward, LLC, established by the National MS Society to speed potential therapies into drug development and clinical trials, and EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany. Fast Forward and EMD Serono committed \$3 million in 2009 to support innovative early-stage projects directed towards the development of therapies to prevent treat, or reverse nervous system damage in MS. This was the first "Request for Proposals" (RFP) issued under the auspices of a multi-year collaboration between Fast Forward and EMD Serono to accelerate innovation and commercial development of MS therapies. Merck KGaA, the parent corporation of EMD Serono, Inc., will provide up to \$19 million in total funding for the collaboration.

<i>Primary Investigator</i> Simon Wilkinson Innate Therapeutics Limited Auckland, New Zealand	<i>Project Title</i> Phase IIA clinical trial of natural nanocomplex MIS416	<i>Amount to be Committed</i> \$550,000 Term – 15 months
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About the Company

Innate Therapeutics is a public, unlisted biopharmaceutical development company based in Auckland, New Zealand. The company was originally incorporated in May 2000 under the name Virionyx Corporation Limited. Innate Therapeutics has designed and manufactured a unique "immunomodulator microparticle" technology that can modify the body's natural immune responses. They are testing this technology to induce the human immune system to fight certain cancers and infections, or turn off certain immune mechanisms that lead to autoimmune diseases. Innate Therapeutics has selected multiple sclerosis as the first disease market to enter with its lead drug candidate, MIS416.



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Project Background & Goals

Multiple sclerosis involves an immune attack that is launched against the brain and spinal cord. Damage to nerve fibers – axons – is believed to underlie the progression of disease, but no current treatments have been shown to significantly and directly prevent or reverse this damage. Innate Therapeutics has developed a unique compound called MIS416 – a microparticle derived from a naturally occurring bacteria which triggers two distinct and important signaling pathways within the immune system. Laboratory experiments using MIS416 indicate that the compound may have multiple mechanisms of action relative to halting the progression of multiple sclerosis. In MS-like animal disease models, MIS416 has been shown to reduce the incidence and severity of disease.

Since late 2008, MIS416 has been used “on a compassionate basis” to treat six people with the progressive form of MS in New Zealand. Such use of an unapproved, experimental medicine is permitted in New Zealand under certain circumstances. There are suggestions from this use that certain symptoms, such as mobility problems or numbness, are being helped, but larger, controlled studies are needed to validate these findings. With funding from the Fast Forward/EMD Serono partnership, Innate Therapeutics is about to conduct a small initial phase 2 study in approximately 25 people with primary-progressive or secondary-progressive MS. The primary goal of the study is to assess safety; however investigators will also be looking at several clinical measures to gauge possible beneficial treatment-related effects.

Preventing or reversing MS progression is a critical goal of MS research. This clinical trial in progressive MS should contribute significantly to this goal.