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Innate Tumbles 93% On MIS416 Fail For Multiple Sclerosis

Innate fell 93 percent on news its trial of MIS416 for secondary progressive multiple sclerosis showed no “clinically meaningful or statistically significant” efficacy.

Innate said the 12-month, 93-patient, phase IIb, randomized, double-blind, placebo-controlled trial of weekly injections “did not show clinically meaningful or statistically significant differences in measures of neuromuscular function or patient reported outcomes”.

Innate chief executive officer Simon Wilkinson told a teleconference that he was “extremely disappointed for secondary progressive multiple sclerosis patients for whom there are no treatment alternatives”.

“These results were a shock and not what we expected,” Mr Wilkinson said. “The results don’t align with reports from patients in the compassionate use program.”

Mr Wilkinson said that on all efficacy measures including brain volume changes, cranial magnetic resonance imaging and patient reporting there was no significant difference between the 62-patient MIS416 group and the 31 placebo group.

Innate said that 17 MIS416 patients and four placebo patients prematurely discontinued treatment, which Mr Wilkinson said was “a little on the high side but not greatly so” for the severely disabled cohort.

The company said that measures of neuromuscular function included measures of upper extremity function and strength, walking speed and distance, visual acuity, and two

measures of cognitive processing speed and the analysis showed “no overall clinically meaningful or statistically significant differences across the multiple measures of neuromuscular function assessed during the trial”.

Innate said that patient-reported outcome questionnaires comprising the Multiple Sclerosis Impact Scale, as well as fatigue and pain measures showed no overall clinically meaningful or statistically significant differences and the expanded disability status scale (EDSS) score showed no change between the two groups.

The company said that a separate analysis of possible treatment effect was underway on the per-protocol population of patients who followed the trial protocol and completed at least 75 percent of the required study visits.

“There is nothing to suggest at this time that this analysis will result in a favourable conclusion,” Innate said.

The company said there was “at least one treatment-related adverse event in 60 of the 63 patients in the MIS416 group and 23 of the 31 placebo group patients, with at least one treatment related serious adverse event in 16 MIS416 patients and five in the placebo group, which was expected to show that the higher incidence in the MIS416 group could be associated with the previously observed fever, chills, muscle weakness response to initial MIS416 dosing, with ongoing further analysis of the findings.

Innate said that as there were no dose limiting safety concerns, it had advice that there was no immediate need to halt the compassionate use program.

Mr Wilkinson said that the company’s priority was “to decide if there was any clinical future for MIS416” and the company would review the results to see if there was any sub-group that had a response and whether there was any biomarker for responders.

Mr Wilkinson said that the review would take about six weeks.

In 2013, Innate raised $10 million at 20.1 cents a share to list on the ASX and hit a high of $1.83 in January 2017 on news that Republicans close to US President Donald Trump including Health Secretary Dr Tom Price were shareholders, with New York Congressman Chris Collins a founding director (BD: Dec 18, 2013; Jan 22, 27, 31, Mar 31, 2017).

Innate closed down 59.1 cents or 92.3 percent to 4.9 cents with 128.1 million shares traded.