

14 August 2018

Mr. George Tharian  
Adviser, Listings Compliance (Sydney)  
Australian Securities Exchange

**RESPONSE TO ASX AWARE QUERY**

Dear George,

We refer to your letter dated 10 August 2018 and respond as follows to your questions and requests for information.

***QUESTION 1. Based on the abovementioned information, it appears that Innate was aware of the Relevant Information prior to requesting the Trading Halt. Please explain why Innate did not request the Trading Halt prior to 12.26pm on 23 June 2017, commenting specifically on why Innate did not request the Trading Halt prior to the commencement of trading.***

**RESPONSE**

It is important to note that the dates referred to in Section A of the background recitals of your letter, which are extracts from the Indictment 18 CRIM of the United States District Court Southern District of New York in the matter of *USA v Christopher Collins, Cameron Collins and Stephen Zarsky* (the “Indictment”) have been date adjusted for the purposes of providing a courtroom chronology in a US (East Coast) timeframe.

The Company’s CEO received the initial drug trial results on **Friday 23 June 2017** through a telephone call which ended at 8:30am AEST, and not on 22 June as referred to in the Indictment. The Company, its Directors, Officers and Staff had no knowledge whatsoever of the initial drug trial results prior to Friday 23 June 2017 (AEST).

The Company conducted a Phase 2B clinical trial of its drug candidate MIS416 in patients with secondary progressive multiple sclerosis (SPMS) which commenced in the clinic in October 2014, with the last patient completing their last study related clinical visit in April 2017.

A chronology of the relevant events on **Friday 23 June 2017** is set out in the table below (all times referred to below are expressed in AEST):

Time	Action
<b>8:00am</b> <b>8:30am</b>	<p>– Dr. Michael Silverman (one of the study’s independent experts) contacted the Company’s CEO by telephone and during the course of a 30 minute discussion advised that the preliminary independent analysis of the top line data from the Phase 2B clinical trial that he and Dr. Gary Cutter had conducted indicated, among other things, a negative primary end-point trial result.</p> <p>This preliminary analysis of the topline data was sent to the CEO, and no other Company Directors, Officers or Staff, immediately following that telephone call.</p>

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<p><b>8:55am</b></p>	<p>The CEO compiled a brief summary of the preliminary analysis which was emailed to the Board of Directors at 8:55am. At this time the Company's Staff had not been advised of the results and the CEO considered that the results remained strictly confidential and secure.</p> <p>In this regard the Company had previously imposed a Closed Period on all Staff effective from 2 June and all Directors from 8 June 2018, in anticipation of when initial outcome data from the trial might become available. This prohibited any trading in the Company's shares until after the results of the clinical trial, whenever they came to hand, had been released to the market.</p> <p>It should be noted that the clinical trial had run for a thirty month period and that an immense amount of blinded data had been generated during the course of the trial which required a significant amount of independent analysis on completion of the study before any conclusions could be made.</p> <p>Interpreting results from a clinical trial is a complicated matter. In this particular situation, the top-line analysis was additionally complicated given the large number of separate measures used as study endpoints to determine (or not) drug efficacy. SPMS is a difficult disease to study and it would not be unexpected for a Phase 2B trial to provide multiple insights into future drug-development strategy, beyond the primary end-point. This also needed to be understood, both for the market and patients.</p>
<p><b>9:22am</b></p>	<p>CEO advised the Chairman that U.S. East Coast based Drs. Silverman and Cutter, who had carried out the independent preliminary expert analysis of the topline data, would make themselves available to the Board to explain their analysis and answer any questions concerning the approach they had taken to the analysis. Given the negative results, which were highly unexpected in light of previous human experience with the drug, the CEO and Chairman considered that it was important for all Directors to convene together to hear from these independent expert advisors to get a better understanding of their analysis of the trial results.</p> <p>Following distribution of the brief summary of the topline data to the Board, the CEO commenced a more detailed review of the top line data.</p>
<p><b>11.28am</b></p>	<p>Dr. Robert Peach, a Non-Executive Director and an experienced drug developer, based in San Diego, was contacted to review the data and validate the conclusions reached by Drs Silverman and Cutter. In particular, Dr. Peach was asked to review the analytical assumptions behind the top-line analysis.</p>
<p><b>11:47am</b></p>	<p>The CEO sent a further email to the Board with his further observations concerning the results and his initial thoughts about the next steps for the Company and proposed that a full Board meeting be convened on Saturday 24 June 2018 to consider the Company's position and to hear from Drs. Silverman and Cutter.</p> <p>It should be noted that at that time, coordination of a Board meeting required scheduling participants in New Zealand, Australia and on both the east and west coasts of America. By this time on Friday 23 June 2017 it was not possible to convene a full Board meeting until the following day.</p>

	<p>Having had time to initially confirm the apparent robustness of the independent data analysis and conclusions, provide rapid and appropriate feedback to the Company's directors, and make arrangements for a full Board meeting the following day (Saturday 24 June), the Chairman and CEO discussed a market announcement. They considered whether it would be possible to prepare a meaningful announcement in accordance with the high standards that apply to the announcement of clinical trial results within a short time frame, particularly given the complexity of the trial.</p> <p>A further complicating factor was the potential impact of the apparent negative efficacy result on patients still being administered the study drug on a compassionate use basis. Compassionate use patients are an extremely vulnerable stakeholder group and from a medical ethics perspective, the directors strongly felt that further clinical guidance from Dr Silverman was warranted. It was decided that an accurate and fulsome announcement could not be responsibly released in a timely fashion that day.</p>
<b>Approximately 12.15pm</b>	The CEO contacted the Company Secretary, advised him of the initial trial results and of the plan for a Board meeting the next morning, and requested that he immediately contact the ASX to seek a Trading Halt.
<b>12:22pm</b>	The Company Secretary contacted the Company's Listing Adviser at the ASX to advise that the Company requested a trading halt and provided brief details of the circumstances and the Company's reasons for requesting a trading halt.
<b>12:26pm</b>	The Company Secretary submitted the Company's written request for a Trading Halt to the ASX. Shortly thereafter the Company's Listing Adviser at the ASX called the Company Secretary to discuss the Company's request for a trading halt in further detail.
<b>Approximately 12.36pm</b>	The ASX paused trading in the Company's shares.
<b>12:53pm</b>	The ASX posted its announcement to the market confirming that a Trading Halt had been granted.

### Summary

In consideration of the extremely challenging circumstances outlined above and bearing in mind:

- a) the complexities associated with the analysis and interpretation of clinical trial results; and
- b) the need to consider very large amounts of patient data obtained over a 30 month period; and
- c) the need for the Board to receive and have a reasonable opportunity to consider the clinical trial results, including any potential signals that might indicate a go-forward strategy for the drug; and
- d) the interests of numerous stakeholders including those patients continuing on drug post-trial and on compassionate grounds;

the Company believes that it acted diligently and appropriately in seeking a Trading Halt from the ASX, having made first contact with the ASX within 4 hours of the CEO concluding the phone call giving the Company first notice of the trial results. During this timeframe the Company operated on the basis that the trial results remained strictly confidential and secure and under a reasonably presumed basis of Board confidentiality.

***QUESTION 2. Did Mr Christopher Collins' Relevant Interest (as defined in section 9 of the Corporations Act) in securities of Innate change during the relevant Closed Period as it relates to the Announcement.***

**RESPONSE**

Mr Collins' Relevant Interest in securities of Innate did not change during the relevant Closed Period as it relates to the Announcement. It is worth noting that in the lead-up to the events in the question, Mr. Collins had never sold a share in the Company. Any trading by Mr Collins' adult children did not affect Mr Collins' Relevant Interest, for the reasons set out below

It is our understanding that the obligation to disclose a Director's interests in securities in ASX Appendix 3Y is related to the Director's obligations under section 205G of the Corporations Act. Both the ASX Appendix 3Y and the Corporations Act deal with a specific obligation to disclose a director's "relevant interests". The definitions of "relevant interests" are set out in sections 608 and 609 of the Corporations Act and are explained in ASIC Regulatory Guide 193. These definitions focus on control of voting rights and control of the disposal of securities. Shares held by a spouse or child are not included in the definition of "relevant interest" and therefore not automatically caught by this requirement. It is our understanding that shares held by a spouse or child will only be drawn into a director's relevant interest if the director exercises "control" over or has power to control the way in which those family members exercise their rights as shareholders.

Repetitive market disclosures of Mr. Collins' interest in securities were made through the lodgement of Appendix 3Y documents in accordance with ASX Listing Rules as well as in numerous corporate presentations and annual reports and on the Company's website.

On 6 February 2017 the ASX requested that the Company confirm with Mr. Collins that all notifiable interests had been disclosed in the Appendix 3Y documents lodged by the Company concerning Mr Collins, with particular reference to his adult children.

At that time the Company notified Mr. Collins of the ASX request and he responded confirming that "my adult children own their Innate shares free and clear of any control or involvement by me. They can buy and/or sell at their own discretion". This information was conveyed to the ASX on 7 February 2017.

At the time Mr. Collins also confirmed that neither of his adult children had lived at home for over 6 years, that each had their own careers and that neither was financially dependent on Mr Collins.

It was always the Company's understanding that Mr. Collins did not "control" the voting rights or have power to dispose of his adult children's shares in the Company.

**QUESTION 3. If the answer to question 2 is “yes”, please explain why an Appendix 3Y was not lodged within the required timeframe under Listing Rule 3.19A.2.**

**RESPONSE**

Not applicable as there was no change in Mr Collins’ Relevant Interest in securities of Innate.

**QUESTION 4. Please confirm that Innate is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.**

**RESPONSE**

The Company believes that it is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

**QUESTION 5. Please confirm that Innate’s responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its Board or an officer of Innate with delegated authority from the board to respond to ASX on disclosure matter.**

**RESPONSE**

The Company’s responses contained herein to the questions and requests for information set out in your letter dated 10 August 2018 have been reviewed and approved by the Company’s Board.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Andrew Cooke', with a stylized flourish at the end.

**Andrew J Cooke**  
Non-Executive Director  
Company Secretary



10 August 2018

**Mr Andrew Cooke**

Director/Company Secretary  
Innate Immunotherapeutics Limited  
Suite 226  
55 Flemington Road  
North Melbourne VIC 3051

By email

Dear Mr Cooke

**Innate Immunotherapeutics Limited ("Innate"): aware query**

ASX Limited ("ASX") refers to the following:

- A. The below excerpts from sealed Indictment 18 CRIM 567 of the United States District Court Southern District of New York in the matter of United States of America v Christopher Collins, Cameron Collins, and Stephen Zarsky:
  - a) [Paragraph 15] *"The initial Drug Trial results were made available by trial administrators to Innate's CEO on June 22, 2017. These results established that MIS416 lacked therapeutic value in the treatment of SPMS";* and
  - b) [Paragraph 20] *"On or about 22 June, 2017 at approximately 6:55PM [8:55AM AEST], Innate's CEO sent an email describing the Drug Trial results to the company's Board of Directors, including Christopher Collins, the defendant. The email explained to Innate's Board of Directors for the first time that the Drug Trial had been a failure."*
- B. Innate's request to ASX for a trading halt in connection with Innate's receipt of results from its Phase 2B trial of MIS416 ("Relevant Information"), received by ASX on 23 June 2017 at 12:26pm AEST, shortly after which its securities were placed in trading halt ("Trading Halt").
- C. Innate's announcement entitled "Innate Immunotherapeutics announces top-line results for trial of MIS416 in patients with secondary progressive multiple sclerosis" ("Announcement") lodged on the ASX Market Announcements Platform and released at 9.11am AEST on 27 June 2017, which lifted the Trading Halt.
- D. The significant fall in the price of Innate's securities from a high of \$0.6925 on 23 June 2017 to a low of \$0.031 on 27 June 2017.
- E. Innate's Securities Trading Policy ("Securities Trading Policy") lodged on the ASX Market Announcements Platform on 20 May 2014, which provides, among other things, that [Clause 4(d)] "Key Management Personnel [directors, executives or senior managers] must refrain from dealing in Company Securities during the following periods ("Closed Periods")... fourteen (14) days prior to, and one (1) day after, the release of any planned announcements relating to clinical results."
- F. Listing Rule 3.1, which requires a listed entity to give ASX immediately any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.
- G. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

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*“an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity”*

and section 4.4 in Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B “When does an entity become aware of information”*.

- H. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

*“3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:*

*3.1A.1 One or more of the following applies:*

- *It would be a breach of a law to disclose the information;*
- *The information concerns an incomplete proposal or negotiation;*
- *The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
- *The information is generated for the internal management purposes of the entity; or*
- *The information is a trade secret; and*

*3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and*

*3.1A.3 A reasonable person would not expect the information to be disclosed.”*

Having regard to the above, ASX asks Innate to respond separately to each of the following questions and requests for information:

1. Based on the abovementioned information, it appears that Innate was aware of the Relevant Information prior to requesting the Trading Halt. Please explain why Innate did not request the Trading Halt prior to 12.26pm on 23 June 2017, commenting specifically on why Innate did not request the Trading Halt prior to the commencement of trading.
2. Did Mr Christopher Collins’ Relevant Interest [as defined in section 9 of the Corporations Act] in the securities of Innate change during the relevant Closed Period as it relates to the Announcement.
3. If the answer to question 2 is “yes”, please explain why an Appendix 3Y was not lodged with ASX within the required timeframe under Listing Rule 3.19A.2.
4. Please confirm that Innate is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
5. Please confirm that Innate’s responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of Innate with delegated authority from the board to respond to ASX on disclosure matters.

#### **When and where to send your response**

This request is made under, and in accordance with, Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by not later than 12 noon AEST on Tuesday, 14 August 2018.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform under Listing Rule 18.7A. Accordingly, your response should be in a form suitable for release to the market.

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Your response should be sent to me by e-mail. It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

**Suspension**

If you do not respond to this letter by the deadline set out above or if ASX does not consider your response to be satisfactory, ASX is likely to suspend trading in Innate's securities under Listing Rule 17.3.

If you have any queries or concerns about any of the above, please contact me immediately.

Yours sincerely

*[Sent electronically without signature]*

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**George Tharian**

Adviser, Listings Compliance (Sydney)