

RESPONSE TO ACCC'S REQUEST FOR FURTHER INFORMATION DATED 21 JUNE 2022

Red is confidential to Celgene and Natco/Juno (not to be shared with the public)

Green is confidential to Celgene (not to be shared with Natco/Juno or the public)

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1. Introduction

- 1.1 This document sets out Celgene's response to the further information requested by the ACCC in its letter dated 21 June 2022 (**Further RFI**).
- 1.2 Defined terms in this document have the same meaning as set out in the application for authorisation dated 3 December 2021.

2. Celgene's Response

- 2.1 Questions 1 – 4 of the ACCC's Further RFI are as follows:

1. *With respect to lenalidomide:*

a) [Confidential to Celgene]

b) [Confidential to Celgene]

2. *With respect to pomalidomide,* [Confidential to Celgene]

3. [Confidential to Celgene]

[Confidential to Celgene]

4. [Confidential to Celgene]

- 2.2 Based on the Further RFI, Celgene understands that the ACCC considers the information requested, has a "*bearing on the nature and extent of competition*" and "*is necessary to assess the Application*".
- 2.3 As Celgene has explained in its responses to the Draft Determination (section 3) and the ACCC's request for information dated 6 June 2022 (**RFI**), Celgene's view is that the information requested in the RFI and Further RFI cannot enable the ACCC to determine the nature and extent of generic competition fundamentally because the assessment is an entirely hypothetical exercise. The information therefore will not assist the ACCC to assess the Proposed Conduct.
- 2.4 However, Celgene has provided factual evidence regarding [Confidential to Celgene] by way of the declaration of Prudence Smith dated 15 June 2022, as well as the expert evidence in the declaration of Mr O'Toole, which, using real and relevant market examples, demonstrates a clear relationship between the number of generic participants and the price of the pharmaceutical product over time. It is this information that responds directly to the ACCC's information needs. To the extent the ACCC considers it requires additional information [Confidential to Celgene], Celgene is not able to, nor would it ever be in a position to, provide such information.

- 2.5 In an effort to assist the ACCC in conducting its assessment of the Proposed Conduct, Celgene has written to each of the parties with ARTG registrations in respect of lenalidomide and/or pomalidomide (being Sandoz Pty Ltd, Teva Pharma Australia Pty Ltd, Cipla Australia Pty Ltd, Dr Reddy's Laboratories (Australia) Pty Ltd and Luminaire Pty Ltd).
- 2.6 Celgene has requested that each of these parties contact the ACCC directly and provide the following information regarding their **[Confidential to Celgene]**:
- (a) **[Confidential to Celgene]**;
 - (b) **[Confidential to Celgene]**; and
 - (c) **[Confidential to Celgene]**.
- 2.7 While Celgene will not have any visibility over any response that these parties choose to provide, we trust that the ACCC will find these responses to be of assistance in its consideration of the Proposed Conduct.