UCB, Inc. – 1950 Lake Park Drive – Smyrna, Georgia 30080

31 January 2020

Dr. Sally Seymour, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy and Rheumatology Products
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

BLA 125160
Cimzia® (certolizumab pegol)
200 mg/mL Solution for Injection
Sequence No. 0620

With reference to:
IND 009869
Sequence No. 1550

SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS
RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Dear Dr. Seymour:

Reference is made to IND 009869 and to BLA 125160 for Cimzia (certolizumab pegol) approved on 13 May 2009 (BLA 125160/S-080) for the treatment of adults with moderately to severely active rheumatoid arthritis.

Reference is made to the Notification of Non-Compliance with PREA, received by UCB on 20 December 2019. With this letter, under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c(d)(1)], UCB is providing written response to the Notification of Non-Compliance with PREA.

Reference is made to the original PMR (PMR 2563-1) issued subsequent to the Biologics License Application approval (BLA 125160/S-080) for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), stated as follows:

> *Assessment of pharmacokinetic (PK/PD) parameters and dosing, safety, tolerance, and immunogenicity in the pediatric population ≥2 to <17 year with polyarticular JIA.*
>
> *Protocol Submission:* *October 2009*
> *Study Start Date:* *December 2010*
> *Final Report Submission:* *October 2015*

Pursuant to PMR 2563-1, [redacted] (b) (4) . Reference is made to the deferral extension submitted 15 May 2014 (Seq. 0333) and granted by FDA on 26 June 2014, extending the final report submission deadline

until 31 December 2016. Reference is made to the supplemental BLA (BLA 125160/S-275; Seq. 0426) submitted on 27 May 2016 and subsequent decision by FDA on 22 Mar 2017 that the supplement could not be approved, and the pediatric study requirement was not fulfilled. This decision directly resulted in delayed fulfillment of the pediatric assessment for UCB.

UCB consulted with FDA on 15 November 2017, 09 October 2018, and 21 January 2020 to agree on an appropriate path forward. Based on the most recent Agency feedback in January 2020, UCB proposes to pursue a (b) (4) approach for Cimzia in pJIA to fulfill its PREA PMR. The final report is proposed to be submitted by (b) (4).

A request for deferral extension is included with this submission in Module 1.9.2. Further details on the Cimzia JIA program history relating to the delay and the proposed (b) (4) approach are included therein. UCB proposes that a new study, in part, will fulfill UCB's PREA requirement in pJIA. This study is described in the deferral extension request, with further details provided in an outline in Module 1.9.6.

UCB respectfully requests that public posting of this Response Letter to the Notification of Non-Compliance with PREA be delayed until the request for deferral extension, in accordance with 505B(a)(3)(B)(i), has been evaluated by FDA; in such case that the request for deferral extension is denied, the Sponsor understands this response will be posted publicly.

All of the data and information contained in the attached materials are privileged and confidential as trade secrets and commercial information of UCB, Inc.

Under no condition is the disclosure of any portion of the attached materials to any person or entity other than the Food and Drug Administrations authorized without prior consent of the applicant.

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Should you require additional information, please contact the undersigned at 770-970-8387 or via email at jennifer.king@ucb.com.

For technical questions relating to this submission, please contact Monika Wrobel, Submission Manager, at 770-970-8966 or via email at monika.wrobel@ucb.com.

Sincerely,

(See appended electronic signature page)

Signed by or on behalf of

Jennifer King
Immunology Regulatory Sciences Lead, Americas

Desk Copy:
Nina Ton
Senior Regulatory Project Manager

Approval Signatures

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Document Approvals	
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