From: Giordano, Erica
To: Patel, Manisha (manisha.patel@novartis.com)
Cc: "Riggins, Cindy"; narin.ahmed@novartis.com
Subject: BL 125646 Clinical Information Request
Date: Wednesday, July 05, 2017 8:49:31 AM
Attachments: image001.png

Good morning,

Please see the information request below and provide a response by 4 pm today, July 5, 2017. As usual please respond directly to this e-mail and follow-up by submitting the information as an amendment to this BLA.

1. We are assessing the use of tocilizumab in CRS as part of our clinical review. As part of the review we identified 2 subjects who received tocilizumab which we require some clarification.

    a. (b) (6) : the CRF reflects a diagnosis of CRS
        i. We are aware that the subject was later determined to be experiencing recurrence of disease. However in the first 1-2 days, the subject was treated for early symptoms consistent with CRS. Please clarify.

    b. (b) (6) : this subject appears to be an initial screening failure but was finally enrolled
        i. Informed Consent – 5/3/16
        ii. Pheresis 9/14/16
        iii. Screening completed 11/4/16
        iv. Enrollment- please confirm date
        v. LD 12/8/16
        vi. Infused 12/15/16
        vii. Grade 3 CRS treated with tocilizumab

        Please clarify why subject not included in the safety and efficacy analysis.

2. Please provide clarification whey the following Grade 3 CRS incidents were not treated with tocilizumab: a. (b) (6)
    a. (b) (6)

Please confirm receipt of this request.

Thank you,

Erica Giordano
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov