From:	Ahmed, Narin
To:	Gildner, Jean; Patel, Manisha; Riggins, Cindy
Cc:	Giordano, Erica
Subject:	RE: BLA 125646 Information Request
Date:	Tuesday, June 20, 2017 2:41:26 PM
Attachments:	image001.png
Sensitivity:	Confidential

Dear Jean,

Yes, that would be possible.

Thank you for your flexibility.

Best regards,
Narin

Narin Ahmed (Hussain), Pharm.D.
Sr. Associate Director, Regulatory Affairs
Novartis Pharmaceuticals Corporation
Global Drug Development, CAR-T Program
One Health Plaza, 315/3650A
East Hanover, NJ 07936
USA
Phone +1-862-778-5739
Fax +1-973-781-7173
narin.ahmed@novartis.com
www.novartis.com

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Tuesday, June 20, 2017 2:37 PM
To: Ahmed, Narin <narin.ahmed@novartis.com>; Patel, Manisha <manisha.patel@novartis.com>; Riggins, Cindy <cindy.riggins@novartis.com>
Cc: Giordano, Erica <Erica.Giordano@fda.hhs.gov>
Subject: RE: BLA 125646 Information Request
Sensitivity: Confidential

HI Narin,

Can you complete the response by June 30th?

Thanks,
Jean

From: Ahmed, Narin [mailto:narin.ahmed@novartis.com]
Sent: Tuesday, June 20, 2017 2:32 PM
To: Gildner, Jean; Patel, Manisha; Riggins, Cindy
Cc: Giordano, Erica
Subject: RE: BLA 125646 Information Request
Sensitivity: Confidential

Dear Jean,

Would it be possible to receive an extension to the June 26th due date for this request? Many of our team members will be at EHA this week so it would be helpful if we have a bit more time.

Thank you.

Best regards,
Narin

Narin Ahmed (Hussain), Pharm.D.
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From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Tuesday, June 20, 2017 1:50 PM
To: Patel, Manisha <manisha.patel@novartis.com>; Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Cc: Giordano, Erica <Erica.Giordano@fda.hhs.gov>
Subject: BLA 125646 Information Request
Sensitivity: Confidential

Dear Manisha,

Please find the following information request. Please respond by Monday, June 26, 2017. Please acknowledge receipt of the email and the ability to meet the due date.

1. ***Please clarify whether patients that receive tisagenlecleucel in the commercial setting will be enrolled in the Phase IV registry – B2401, and patients who receive this product prior to approval would continue to be followed under IND protocol B2205B If this is correct, please ensure that any references to the LTFU B2205B are removed from the B2401 protocol/procedures. The protocol for B2401 should be written as a stand-alone document.***
2. ***The specific details of replication competent retrovirus (RCR) testing and persistence specified in the LTFU protocol (pages 16-***

17) should be incorporated into the Phase IV registry protocol B2401 for the commercial product. In addition, please provide a detailed description of the procedures that will be used for collecting patient samples for tests of RCR and vector persistence in the commercial setting.

3. ***Please enumerate any differences in the planned patient follow-up between B2401 and B2205B and provide a brief explanation for such differences.***

If you have any questions please feel free to contact me.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)
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Center for Biologics Evaluation and Research
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U.S. Food and Drug Administration
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