

APPROVED

By Jean Gildner at 1:54 pm, Jul 19, 2016

From: [Yao, Michael \(CBER\)](#)
To: larmour@vcel.com
Cc: maguilera@vcel.com; [Schneider, Bruce](#); [Gildner, Jean](#)
Subject: FW: Request for additional clinical information
Date: Friday, May 27, 2016 2:47:00 PM
Importance: High

Hi Lorien,

Please see below email regarding request for additional clinical information. Thanks.

Michael

From: Yao, Michael (CBER)
Sent: Friday, May 27, 2016 2:41 PM
To: Margarita Aguilera
Cc: Schneider, Bruce; Yao, Michael (CBER)
Subject: RE: Request for additional clinical information
Importance: High

Hi Margarita,

Could you ask your team to provide following information:

Regarding subsequent surgical procedures in SUMMIT study, please provide following information:

1. Please list what kind of subsequent surgical procedures (SSPs) involved in 13 subjects?
2. Please summarize when in the course of the study period did SSPs occur?
3. Please comment on "how did SPPs affect interpretability of the efficacy results, either favorably or unfavorably?"

Please make a table if it is possible.

Thanks.

Michael

From: Margarita Aguilera [<mailto:maguilera@vcel.com>]
Sent: Friday, May 27, 2016 10:43 AM
To: Yao, Michael (CBER)
Cc: Schneider, Bruce
Subject: RE: Request for additional clinical information

Dear Dr. Yao,

Please disregard the early termination attachment included with my email yesterday in response to your 23 May 2016 request for information. I inadvertently included this file that has been previously sent to you in respond to another query.

Thanks and regards,
Margarita

Margarita Aguilera, M.Sc.
Senior Regulatory Consultant – Vericel Corporation
64 Sidney Street
Cambridge, MA 02139
maguilera@vcel.com;
Telephone: (617) 588-5661
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From: Margarita Aguilera
Sent: Thursday, May 26, 2016 4:51 PM
To: 'Yao, Michael (CBER)'
Cc: Schneider, Bruce
Subject: RE: Request for additional clinical information

Dear Dr. Yao,

Attached please find responses to the questions raised in your email dated May 23, 2016.

Please let me know if additional information or clarification is needed.

Regards,
Margarita

Margarita Aguilera, M.Sc.
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From: Yao, Michael (CBER) [<mailto:Michael.Yao@fda.hhs.gov>]
Sent: Thursday, May 26, 2016 2:03 PM
To: Margarita Aguilera
Cc: Schneider, Bruce
Subject: RE: Request for additional clinical information

Thanks.

Michael

From: Margarita Aguilera [<mailto:maguilera@vcel.com>]
Sent: Thursday, May 26, 2016 2:02 PM
To: Yao, Michael (CBER)
Cc: Schneider, Bruce
Subject: RE: Request for additional clinical information

Dear Dr. Yao,

Thanks for resending. I will discuss with the team and get back to you as soon as possible.

Regards,
Margarita

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From: Yao, Michael (CBER) [<mailto:Michael.Yao@fda.hhs.gov>]
Sent: Thursday, May 26, 2016 2:00 PM
To: Margarita Aguilera
Cc: Schneider, Bruce
Subject: FW: Request for additional clinical information
Importance: High

Hi Margarita,

Have you received below request for the clinical information?

Thanks

Michael

From: Yao, Michael (CBER)
Sent: Monday, May 23, 2016 11:02 AM
To: 'Margarita Aguilera'
Cc: Schneider, Bruce; Gildner, Jean
Subject: RE: Request for additional clinical information

Margarita,

Thanks for your response. BTW, we still have following questions to you:

1. Regarding subject screen and re-screen, please provide tabulation of reasons for screen failure in 45 or so subjects out of the original 189 subjects. Also, please provide details of rescreen (tabulation).
2. Please indicate where we can find information on the randomization procedure, in particular, how the surgeon was informed of the randomization assignment during the arthroscopy procedure.
3. Also, for those subjects with prior surgery to the index knee (prior to screening), please provide information regarding the type of surgery for each subject, along with subject number.

Thanks,

Michael

From: Margarita Aguilera [<mailto:maguilera@vcel.com>]
Sent: Sunday, May 22, 2016 10:04 PM
To: Yao, Michael (CBER)
Cc: Schneider, Bruce; Gildner, Jean
Subject: RE: Request for additional clinical information

Dear Dr. Yao,

This is to acknowledge receipt of your request for information. I will get back to you with additional information on Monday.

Regards,
Margarita

Margarita Aguilera, M.Sc.
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From: Yao, Michael (CBER) [<mailto:Michael.Yao@fda.hhs.gov>]
Sent: Friday, May 20, 2016 9:02 PM
To: Margarita Aguilera
Cc: Schneider, Bruce; Gildner, Jean
Subject: Request for additional clinical information
Importance: High

Hi Aguilera,

Please provide following information for us:

1. Regarding clinical evaluation in SUMMIT study, do you have clinical data (KOOS pain and function) before visit 6 (week 24)? If so, please provide a summary for FDA review.
2. Please provide subgroup analysis by number of lesions and by subject age, using some reasonable cut-off determine "younger" vs "older."

Thanks.

Michael