

Unblinding Update Email, December 7, 2010 - Laviv

From: Lim, Agnes

Sent: Tuesday, December 07, 2010 10:54 AM

To: 'Jeanne Novak'; Dana Weinberger

Cc: Schneider, Bruce; Zhu, Yao-Yao; Haudenschild, Changting; Lee, Shiohjen; Thomas, John; Tull, Lori

Subject: RE: Unblinding Update

Jeanne; Dana:

You have adequately addressed our questions and comments regarding your proposal to unblind the Biopsy 1 data for the statistical analysis. You may proceed with your plans to unblind the IT-H-001 data.

Please contact us if you have any additional questions. Thank you.

Agnes

, Lori

Cc: Schneider, Bruce; Lim, Agnes; Zhu, Yao-Yao; Thomas, John; Dana Weinberger

Subject: Unblinding Update

Dear Lori,

I just wanted to let you and the FDA team to know that I am in the UK for the next two days at an EMA meeting. Thus, Dana will be contacting you today to check on the status of the review to allow Fibrocell to unblind the IT-H-001 data.

Of course I am available by email and cell phone if I am needed. Otherwise, please note that Dana will be the primary FDA contact for the next two days.

Best regards,

Jeanne

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