

From: Debra Barrett [/O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBARRETT]
Sent: 2/19/2016 5:32:16 PM
To: Bill Burke [bb@rubicondc.com]
Subject: Fwd: Vantrela ER NDA-Update

DEBRA BARRETT
 EXHIBIT
08146
 Juliana Zajicek, CSR, 01/28/2021

FYI - let grant call you

Sent from my iPhone

Begin forwarded message:

From: Debra Barrett <Debra.Barrett@tevapharm.com>
Date: February 19, 2016 at 5:19:06 PM EST
To: Grant Erdel <Grant.Erdel@tevapharm.com>
Subject: Re: Vantrela ER NDA-Update

Let's go to Woodcock on this but we need more than Malamut and McCormick - maybe Hayden or Ottinger altho Rick is a doc and that's a good thing. Just needs to seem high level.

I would do a couple of things while you're away at GPhA:

- 1) Ask Burke to put in a request for a meeting asap
- 2) ask Rob to map out members we go to?
- 3) ask Jerry and Rob about NGA?
- 4) is there anyway The Alliance can help us here? I know it's a product but it's a bigger issue

Sent from my iPhone

On Feb 19, 2016, at 5:07 PM, Grant Erdel <Grant.Erdel@tevapharm.com> wrote:

Yep, just got sign off to proceed yesterday from regulatory. Lots of boxes to check but they all have been.

I'm moving forward because we need to meet with them about the ad bill anyway. Trying to get Rick malamut and mccormicks availability for the week after next.

Sound right?

Sent from my iPhone

On Feb 19, 2016, at 4:47 PM, Debra Barrett <Debra.Barrett@tevapharm.com> wrote:

Did you ever have that conversation we talked about w brand team about going back to FDA through more political channels?

Sent from my iPhone

PLAINTIFF TRIAL
 EXHIBIT
P-23818_00001

Begin forwarded message:

From: Rob Falb <Rob.Falb@tevapharm.com>

Date: February 19, 2016 at 4:40:17 PM EST

To: Debra Barrett <Debra.Barrett@tevapharm.com>, Grant Erdel <Grant.Erdel@tevapharm.com>, Shannon Dzubin <Shannon.Dzubin@tevapharm.com>, Kaelan Hollon <Kaelan.Hollon@tevapharm.com>, Terri Stewart <Terri.Stewart@tevapharm.com>

Subject: Fwd: Vantrela ER NDA-Update

FYI

Begin forwarded message:

From: "Douglas Harnish" <Douglas.Harnish@tevapharm.com>

To: "James Ottinger" <James.Ottinger@tevapharm.com>, "Susan Franks" <Susan.Franks@tevapharm.com>, "Michael Hayden" <Michael.Hayden@teva.co.il>, "Rob Koremans" <Rob.Koremans@tevapharm.com>, "Mike Derkacz" <Michael.Derkacz@tevapharm.com>, "Richard Nieman" <Richard.Nieman@tevapharm.com>, "Alexander Nikas" <Alexander.Nikas@tevapharm.com>, "Hedva Voliovitch" <Hedva.Voliovitch@teva.co.il>, "Tal Kleinfeld" <Tal.Kleinfeld@teva.co.il>, "Karen Gotting-Smith" <Karen.Gotting-Smith@tevapharm.com>, "Ralph Laufer" <Ralph.Laufer@teva.co.il>, "Francine Del Ricci" <Francine.DelRicci@tevapharm.com>, "Larry Downey" <Larry.Downey@tevapharm.com>, "Richard Malamut" <Richard.Malamut@tevapharm.com>, "Jeffrey Dierks" <Jeffrey.Dierks@tevapharm.com>, "Martijn Negen" <Martijn.Negen@Tevacu.com>, "Matthew Wieman" <Matthew.Wieman@tevapharm.com>, "Matthew Day" <Matthew.Day@tevapharm.com>, "Brian McCormick" <Brian.McCormick@tevapharm.com>, "Mary Bond" <Mary.Bond@tevapharm.com>, "Jeffrey Martini" <Jeffrey.Martini@tevapharm.com>, "Doron Shinar" <Doron.Shinar@teva.co.il>, "Thomas Bradford Barnes" <Brad.Barnes@tevapharm.com>, "Matt Sheehan" <Matt.Sheehan@tevapharm.com>, "Valerie Mulligan" <Valerie.Mulligan@tevapharm.com>, "Maciej Gasior" <Maciej.Gasior@tevapharm.com>, "Dalton Tomlinson" <Dalton.Tomlinson@tevapharm.com>, "Mary Ma" <Yuju.Ma@tevapharm.com>, "Ronghua Yang" <Ronghua.Yang@tevapharm.com>, "Ofer Spiegelstein" <Ofer.Spiegelstein@teva.co.il>, "Yael Marantz" <Yael.Marantz@teva.co.il>, "Tal Lehrmann" <Tal.Lehrmann@teva.co.il>, "Derek Moe" <derek.moe@cimalabs.com>, "Randal A Seburg" <Randal.Seburg@cimalabs.com>, "Meirav Marom" <Meirav.marom@teva.co.il>, "Jill Conner" <Jill.Conner@tevapharm.com>, "Michael Tillinger" <Michael.Tillinger@tevapharm.com>, "Timothy Davenport" <Timothy.Davenport@tevapharm.com>, "Elaine Grotbeck" <Elaine.Grotbeck@cimalabs.com>, "Mingfang Zhu" <Mingfang.Zhu02@tevapharm.com>, "Haixiao Chen" <Haixiao.Chen02@tevapharm.com>, "Natalie Thoma" <Natalie.Thoma@tevapharm.com>, "Laura Rabinovich" <Laura.Rabinovich@tevapharm.com>, "Angela Randall" <Angela.Randall@tevapharm.com>, "Michael Fetell" <Michael.Fetell@tevapharm.com>, "Lydia Wood" <Lydia.Wood@tevapharm.com>, "Kavita Gajria" <Kavita.Gajria@tevapharm.com>, "Jorge Vasquez" <Jorge.Vasquez@tevapharm.com>, "Chinedu Momah" <Chinedu.Momah@tevapharm.com>, "Leslie Marinelli" <Leslie.Marinelli@tevapharm.com>, "Elaine Grotbeck" <Elaine.Grotbeck@cimalabs.com>, "Martha Coble" <Martha.Coble@tevapharm.com>, "Linda A Schneider" <Linda.Schneider@tevapharm.com>, "Thomas Bradford Barnes" <Brad.Barnes@tevapharm.com>, "Michael Tillinger" <Michael.Tillinger@tevapharm.com>, "Jennifer Pansch" <Jennifer.Pansch@tevapharm.com>, "Orna Srur Kidron" <Orna.SrurKidron@teva.co.il>, "Beena Varghese" <Beena.Varghese@tevapharm.com>, "Ryan Lomonaco" <Ryan.Lomonaco@tevapharm.com>, "Chirag Shah" <Chirag.Shah01@tevapharm.com>, "Derek Moe" <derek.moe@cimalabs.com>, "Meirav Marom" <Meirav.marom@teva.co.il>, "Mary Ma" <Yuju.Ma@tevapharm.com>, "Andy Cheadle" <Andy.Cheadle@tevapharm.com>, "Jill Conner" <Jill.Conner@tevapharm.com>, "Sally Selim" <Sally.Selim@tevapharm.com>, "Jeffrey Arcara" <Jeffrey.Arcara@tevapharm.com>, "Heather Schoenly" <Heather.Schoenly@tevapharm.com>, "Deborah Bearer" <Deborah.Bearer@tevapharm.com>, "Christopher Doerr" <Christopher.Doerr@tevapharm.com>, "Brian Kilmartin" <Brian.Kilmartin@tevapharm.com>,

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Subject: Vantrela ER NDA-Update

Everyone

We had a teleconference today at the request of the FDA Division Director, Sharon Hertz. She indicated that the FDA has decided to conduct an Advisory Committee meeting for Vantrela ER. She indicated that the scope of the Ad Comm is only regarding the abuse deterrent data for Vantrela, it will not involve the efficacy or safety data nor involve the application type (505b1 vs 505b2). She didn't believe that any additional data or analysis was required by Teva for the Ad Comm. She indicated the fundamental question posed for the Ad Comm members would be whether our abuse deterrent studies support the AD claims we are seeking.

Dr Hertz indicated that the requirement for this Ad Comm was not recognized or expected, and also conveyed that this was a difficult message to deliver to Teva. She highlighted the Acting Commissioner, Robert Califf's Opioid Action Plan (attached) as a driving force for this request. She understands our frustration, and is looking to schedule this as quickly as possible. However, she is uncertain when she can confirm the timing for the Ad Comm, but indicated it will be several months away.

The Vantrela team will reach out to Legal, Corporate Communications and Government Affairs to discuss other additional activities that can be pursued.

Best regards

Douglas C Harnish, PhD
Sr Director Pain & Migraine
Regulatory Affairs Teva
610-727-6246

<Califf.NEJM.2016.Proactive response to prescription opioid abuse.pdf>