Emails and responses sent to FDA

From: Lisa Cosgrove [mailto:Lisa.Cosgrove@umb.edu]
Sent: Monday, April 02, 2018 8:37 AM
To: Muoio, Brendan <Brendan.Muoio@fda.hhs.gov>
Cc: floriannaudet@gmail.com
Subject: researchers have a question about digital aripiprazole

Dear Dr. Muoio

We are currently working on a meta-analysis to assess the efficacy of digital aripiprazole (Abilify MyCite) in psychiatric disorders (Protocol registration: PROSPERO 2018 CRD42018089515 / Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018089515).

We carried out a literature search aimed at identifying the studies eligible for our analysis. This search was conducted in PubMed, Embase and the Cochrane Library. We also searched Clinicaltrials.gov and other relevant websites. We also searched in the "FULL PRESCRIBING INFORMATION" released by the FDA (available here: https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.171264742.738365284.1522312048-723914994.1522312048).

Based on our searches we have the following questions:

1) Can you confirm that the FDA was not aware of other clinical studies than the one listed in the FULL PRESCRIBING INFORMATION? If the FDA is aware of other studies, can you provide the references for these other studies?

2) Can you confirm that all studies referenced in the paragraph 'Clinical Studies' were studies about aripiprazole tablets and not about the more specific digital aripiprazole?

3) Was there an advisory committee meeting? We were not able to find any report or notes.

Thank you for your time and assistance. We look forward to hearing from you.

Sincerely,

Lisa Cosgrove, PhD. University of Massachusetts-Boston USA
Florian Naudet, MD, PhD, University of Rennes, France
Allen Shaughnessy, PharmD, MMedEd. Tufts University, Boston, MA, USA
Ioana Alina Cristea, PhD. Babes-Bolyai University, Romania
Barbara Mintzes, PhD. University of Sydney, Australia

Response:
CDER DRUG INFO <DRUGINFO@fda.hhs.gov>

Reply all|
Mon 5/14/2018 11:44 AM
To:
Lisa Cosgrove
Inbox

Dear Dr. Cosgrove,

Thank you for your patience as we consulted experts within the agency for assistance.

The FDA review package will contain studies that the company (Otsuka Pharmaceutical Company) conducted on Abilify MyCite (NDA 207202). Since the review documents are not yet available on the Drugs@FDA Abilify MyCite page, you may consider submitting a Freedom of Information Act (FOIA) request for the information. See How to Make a FOIA Request for instructions and a link to the online submission form.

Should you require additional details regarding the studies that the company conducted, you may contact them directly for information, or search PubMed for published literature.

Based on our search of the Psychopharmacologic Drugs Advisory Committee (AC) meeting materials, it does not appear that an AC meeting was held for Abilify MyCite.

If you have not already done so, please see the NDA 207202 approval letter which may contain information relevant to your research.

Best regards,

Danielle
Pharmacist | Drug Information Specialist
Division of Drug Information | Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter @FDA_Drug_Info

Emails and Responses sent to Otsuka and Proteus

Mon 4/2/2018 8:43 AM
From: Lisa Cosgrove [mailto:Lisa.Cosgrove@umb.edu]
Sent: Monday, April 2, 2018 8:43 AM
To: Whitefield, Kimberly <Kimberly.Whitefield@otsuka-us.com>
Cc: floriannaudet@gmail.com
Subject: researchers have a question about digital aripiprazole

Dear Ms. Whitefield

We are currently working on a meta-analysis to assess the efficacy of digital aripiprazole (Abilify MyCite) in psychiatric disorders (Protocol registration: PROSPERO 2018 CRD42018089515 / Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018089515).

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Based on our searches we have the following questions:

1)Are you aware of any clinical studies concerning digital aripiprazole that were unpublished and not registered on ClinicalTrials.gov?

2) Can you confirm that the studies listed in the FDA's FULL PRESCRIBING INFORMATION were studies about aripiprazole tablets and not about the more specific digital aripiprazole?

We look forward to hearing from you and appreciate your time and assistance.

Sincerely,
Lisa Cosgrove, PhD

Lisa Cosgrove, PhD. University of Massachusetts-Boston USA
Florian Naudet, MD, PhD, University of Rennes, France
Allen Shaughnessy, PharmD, MMedEd. Tufts University, Boston, MA, USA
Ioana Alina Cristea, PhD. Babes-Bolyai University, Romania
Barbara Mintzes, PhD. University of Sydney, Australia

Response:

Peters-Strickland, Tim <Tim.Peters-Strickland@otsuka-us.com>

Fri 4/6/2018, 11:34 AM

Dear Dr. Cosgrove—here are responses to your questions.

1. No.
2. Yes

Let me know if you need anything further.

Kind Regards

Mahalo Timothy Peters-Strickland, MD
Phone: 609-249-6559 / **Cell: 609-955-0461** / Fax: 609-249-0559
Administrative Assistant: Marlene Gerardi 609-608-4545
Marlene.Gerardi-CW@otsuka-us.com

Reply all|
Mon 4/2/2018 8:46 AM
To:
efox@proteus.com
Cc:
floriannaudet@gmail.com
You forwarded this message on 5/5/2018 9:34 AM

Dear Ms. Fox

We are currently working on a meta-analysis to assess the efficacy of digital aripiprazole (Abilify MyCite) in psychiatric disorders (Protocol registration: PROSPERO 2018 CRD42018089515 / Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018089515).

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Based on our searches we have the following questions:

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2) Can you confirm that the studies listed in the FDA's FULL PRESCRIBING INFORMATION were studies about aripiprazole tablets and not about the more specific digital aripiprazole?

We look forward to hearing from you and appreciate your time and assistance.

Sincerely,
Lisa Cosgrove, PhD

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Florian Naudet, MD, PhD, University of Rennes, France
Allen Shaughnessy, PharmD, MMedEd. Tufts University, Boston, MA, USA
Ioana Alina Cristea, PhD. Babes-Bolyai University, Romania
Barbara Mintzes, PhD. University of Sydney, Australia

|
Sat 5/5/2018, 1:46 PM
HI Lisa,

I'm sorry for the delay. I sent your note upon receipt to my partner counterpart, Kimberly Whitefield, at Otsuka, the maker of Abilify MyCite®. We aren't involved with any trials of Abilify MyCite, but if there's anything to be shared, Kimberly or someone at Otsuka should be able to help you. I've copied Kimberly.

Kind regards,

Emily

Emily Fox
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