

MEMORANDUM OF RECORD

TELECONFERENCE WITH BLA 125586 PORTOLA PHARMACEUTICALS INC.

FEBRUARY 15, 2018

PORTOLA ATTENDEES:

Bill Lis, CEO

John Curnutte, MD, EVP Research and Development

Jack Lawrence, MD, CMO

Patrick Yue, MD, Senior Director, Clinical Development

Stuart Connolly, MD, ANNEXA-4, Principal Investigator

Michele Bronson, PhD, Program Lead

Janice Castillo, SVP Regulatory Affairs

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FDA ATTENDEES:

Bindu George, MD, Clinical Reviewer

Mikhail Ovanesov, PhD, CMC Reviewer, Chairperson

Ramani Sista, PhD, Director, Division of Regulatory Project Management

Tejashri Purohit-Sheth, MD, Director DCEPT

Kimberly Benton, PhD, Deputy Director OTAT

Jean Gildner, MSHS, MT (ASCP), Regulatory Project Manager

Discussion:

FDA requested this teleconference to discuss with Portola Pharmaceutical Inc. the need for the applicant to propose a Randomized Controlled Trial (RCT) as soon as possible in support of the ANDEXXA program. FDA stressed that this study is needed to support effectiveness of the product.

FDA suggested that while the original BLA was currently still under review the most productive approach to this request was to submit a study design for comments to the FDA so an agreement can be reached before the action date of May 4, 2018.

Applicant requested a Face to Face meeting to further discuss the RCT. FDA denied this request as the applicant needed to submit a study design first as well as additional requested data from outstanding Information Requests.