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PHARMACEUTICAL & BIOSCIENCE SOCIETY - SAN FRANCISCO BAY

A Member Organization of the Pharmaceutical & BioScience Society, International (PBSS)

WORKSHOP

San Francisco Bay Area Workshop:

Conducting a Successful End-of-Phase2 Meeting with the FDA:

Overview, Strategies, and Perspectives from the FDA and Industry

Date/Time: 8:45 am – 5:00 pm, Sept 18, 2015

Venue: Crowne Plaza Hotel, Foster City, CA

Speakers: *Azin Shahzamani (Genentech/Roche) Yaning Wang, PhD (FDA) Mike Eldon, PhD (Nektar) Terry Sweeney, PhD (Nektar) Ramani Raghavan, PhD (Genentech) Detlef Albrecht, MD*

Organizers: Peter Staehr, MD (Abbott Vascular) Snow Ge, PhD (Nektar) Minli Xie, PhD (Genentech) *Shichang Miao, PhD (ChemoCentryx)*

Fees: Regular - $195; Students & Unemployed - $35; Vendor Show: $475

Registration: *www.PBSS.org*

Workshop Outline:

An End-of-Phase 2 (EOP2) meetings is a meeting between the US FDA and the sponsor of a clinical development program after the completion of the Phase 2 study and prior to the start of the Phase 3 study. It is most useful to the sponsor and should be held before major efforts and resources are committed to specific Phase 3 studies. The purpose of an EOP2 meeting is to determine sufficient safety prior to Phase 3, to evaluate the Phase 3 plan and protocols, the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

This workshop is intended to address the important topics for an effective discussion at an EOP2 meeting and to provide an overview of a successful meeting preparation. Regulatory aspects will be provided from the FDA and the industry perspective. For clinical pharmacology the progress of PK study data and additionally needed studies will be reviewed. The preclinical safety and toxicology as it relates to dose, duration & route of administration will be discussed. In the CMC area the approach to specifications and test methods as well as the formulation to be used in clinical trials and "to be marketed" formulation will be addressed. In the clinical discussion at an EOP2 meeting, agreement needs to be reached with FDA on pivotal study designs, dose selection, patient population and the safety and efficacy endpoints for Phase 3 studies.

Topics:

- Regulatory Overview of End of Phase 2 meeting – What to consider? Industry perspective. - Azin Shahzamani (Genentech/Roche)
- The FDA perspective of a successful EoP2 meeting, how to avoid the common mistakes; and Phase 3 dose selection aspects - Yaning Wang (FDA)
- DMPK & Clinical pharmacology aspects and strategy - Mike Eldon, PhD (Nektar)
- Nonclinical safety and toxicology aspects and strategy- Terry Sweeney, PhD (Nektar)
- CMC aspects and strategy - Ramani Raghavan , PhD (Genentech/Roche)
- Clinical aspects and strategy - Detlef Albrecht, MD