PBSS
Pharmaceutical & BioScience Society
San Diego

Dec 4

Dec. 4, 2023
8:45 am-5:25 pm, PT

In-Person Workshop
San Diego: Alexandria at Torrey Pines

Preclinical Development and IND Filing for Antibody-Based Therapeutics:

Nuts, Bolts and Best Practices

Organizers: Robyn Rourick, Genentech; Lilia Koriazova, Erasca; Mangala Hariharan, Mirati Therapeutics; Carolina Caffaro, Janux Therapeutics; Lina Ma, Janux Therapeutics

Henry Chan, PhD
Exec. Director/Discovery Biotherapeutics, BMS

Bench to Bedside: Biotherapeutics preclinical research to IND filing

Lawrence Dearth, PhD
Associate Director, Discovery Biotherapeutics, BMS

Biotherapeutic candidate discovery to lead optimization

Dan Zhu, PhD
Senior Director, Discovery Biotherapeutics, BMS

Non-clinical pharmacology for biotherapeutics

Kaia Sartori, PhD
Lead Consultant, BioData Solutions, LLC.

Pharmacokinetic/Pharmacodynamic and bioanalytical consideratons for successful IND filings

Mangala Hariharan, PhD
Associate Director, Toxicology, Mirati Therapeutics

Preclinical toxicology points to consider for biotherapeutic IND submissions

Sharon Gao, PhD
VP of CMC, Bright Peak Therapeutics

IND-enabling CMC activities for biotherapeutics

Sara Glickstein Bar-Zeev, PhD
Principal Clinical Scientist, Genentech

Clinical Development Plan

Michelle Mazzoni, PhD
Sr. VP, Regulatory and Quality, Capstan Therapeutics

Regulatory strategies and Interactions with FDA: Industry Perspective & How to Prepare for FDA Meeting

Arianne Motter, PhD
PhD, DABT, Senior Toxicologist/CDER/OND/ DPT-ID, FDA

INDs for biologics: The regulatory perspective

Major Sponsors

VeloxityLabs
MYCENAX

Registration: https://www.pbss.org/aspx/homeSD.aspx

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Time (PT)	Topic
8:45-9:00 am	**PBSS Welcome and Introduction** (Shichang Miao, PBSS; Lilia Koriazova, Erasca)
9:00-9:20 am	**Bench to Bedside: Biotherapeutics preclinical research to IND filing** (Henry Chan, Exec. Director/Discovery Biotherapeutics, BMS)
9:20-9:50 am	**Biotherapeutic candidate discovery to lead optimization** (Lawrence Dearth, PhD, Associate Director, Discovery Biotherapeutics, BMS)
9:50-10:25 am	**Non-clinical pharmacology for biotherapeutics** (Dan Zhu, PhD, Senior Director, Discovery Biotherapeutics, BMS)
10:25-10:35 am	**Major Sponsor's Presentation** (Veloxity Labs)
10:35-10:50 am	**Break Period & Vendor Show**
10:50-11:45am	**Pharmacokinetic/Pharmacodynamic and bioanalytical considerations for successful IND filings** (Kaia Sartori, PhD, Lead Consultant, BioData Solutions, LLC.)
11:45-12:35 pm	**Lunch** (Sponsor, TBD)
12:35-1:45 pm	**Preclinical toxicology points to consider for biotherapeutic IND submissions** (Mangala Hariharan, PhD, Associate Director, Toxicology, Mirati Therapeutics)
1:45 - 2:45 pm	**IND-enabling CMC activities for biotherapeutics** (Sharon Gao, VP of CMC, Bright Peak Therapeutics)
2:45 - 2:55 pm	**Major Sponsor's Presentation** (Mycenax)
2:55 - 3:15 pm	**Break Period**
3:15-3:50 pm	**Clinical Development Plan** (Sara Glickstein Bar-Zeev, PhD, Principal Clinical Scientist, Genentech)
3:50-4:20 pm	**Regulatory strategies and interactions with FDA: Industry perspective & how to prepare for FDA meetings** (Michelle Mazzoni, Sr. VP, Regulatory and Quality, Capstan Therapeutics)
4:20-4:55 pm	**INDs for Biologics: The regulatory perspective** (Arianne Motter, PhD, DABT, Senior Toxicologist/CDER/OND/DPT-ID, FDA)
4:55-5:25 pm	**Panel Discussion** (All Speakers)
5:25 - 6:25 pm	**Happy Hour** (Sponsored by Alturas Analytics, Inc.)

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