FDA-AACR Public Workshop on

OPTIMIZING DOSAGES FOR ONCOLOGY DRUG PRODUCTS: QUANTITATIVE APPROACHES TO SELECT DOSAGES FOR CLINICAL TRIALS

DAY 1 – Thursday, February 15, 8 a.m. – 5 p.m. | Grand Hyatt Washington

Welcome:
Patricia M. LoRusso, DO, PhD (hc), FAACR, *Yale Cancer Center*

Opening Remarks:
Marc Theoret, MD, *FDA*

Overview of Workshop:
Stacy S. Shord, PharmD, *FDA*

Session 1: Selecting Dosages for Dose-Escalation Portion of First-In-Human Trials

Session 1A: Utilizing Nonclinical Data and Modeling to Support Dosage Selection for First in Human Trials

Moderator:
Hao Zhu, PhD, *FDA*

Introductory Speaker:
Applications of Model-Based Approaches to Select the Starting Dosages for First-In-Human Trials: Alex Phipps, PhD, *AstraZeneca*

Additional Panelists:
- Matthew Thompson, PhD, *FDA*
- Jiang Liu, PhD, *FDA*
- Ralph Parchment, PhD, *NCI Frederick National Laboratory*
- Manish Gupta, PhD, *Genmab*

Session 1B: Alternative Designs for Dose-Finding Trials: Ending Reliance on Short-Term Safety

Moderator:
Patricia M. LoRusso, DO, PhD (hc), FAACR, *Yale Cancer Center*

Introductory Speaker:
How to Pivot Beyond Rule-Based and Model-Based Determinations to Support Dosage Selection: Ying Yuan, PhD, *MD Anderson*

Additional Panelists:
- Jonathon Vallejo, PhD, *FDA*
- Jamie Brewer, MD, *FDA*
- Amit Roy, PhD, *PumasAI*
- Bruno Gomes DVM, PhD, *Roche*
- Brian Koffman, MDCM (retired), MSEd, *CLL Society*

Session 2: Selecting Dosages for Additional Exploration Based on Nonclinical and Early Clinical Data

Session 2A: Evaluating and Modeling All Early Data to Select Recommended Phase II Dose

Moderator:
Olanrewaju Okusanya, PharmD, MS, *FDA*

Introductory Speaker:
Modeling-Based Approaches Incorporating Emerging Clinical Data and Relevant Non-Clinical Data to Support Dosage Selection: Gabby Patilea-Vrana, PhD, *Pfizer*

Additional Panelists:
- Jerry Yu, PhD, *FDA*
- Atiqur Rahman, PhD, *FDA*
- Lillian Siu, MD, *Princess Margaret Cancer Center*
- Manju George, MVSc, PhD, *COLONTOWN*

Session 2B: Novel Trial Designs to Enhance Dose-Selection Decision Making

Moderator:
Timothy Yap, MBBS, PhD, *MD Anderson*

Introductory Speakers:
Using Novel Activity and Safety Endpoints in Clinical Trials to Support Dosage Selection: Anthony "Nino" Sireci, MD, MS, *Loxo@Lilly*

Utilizing Randomized Dosage Comparison and Controlled Backfill to Gain Greater Understanding of Dose- and Exposure-Response Relationships for Safety and Activity: Alexia Iasonos, PhD, *Memorial Sloan Kettering Cancer Center*

Additional Panelists:
- Mallorie Fiero, PhD, *FDA*
- Nicole Gormley, MD, *FDA*
- Vishal Bhatnagar, MD, *FDA*

Day 1 Wrap-Up and Day 2 Preview
Raj Madabushi, PhD, *FDA*

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DAY 2 – Friday, February 16, 8 a.m. – 1 p.m. | Grand Hyatt Washington

Welcome:
Qi Liu, PhD, *FDA*

Section 3: Selecting Dosages for Registrational Trials

Session 3A: Considering the Totality of Efficacy and Safety Data to Aide Registrational Trial Designs

Moderator:
Stacy S. Shord, PharmD, *FDA*

Introductory Speakers:
Using Modeling-Based Approaches to Understand Dose- and Exposure-Response Relationships for Activity: Jin Y. Jin, PhD, *Genentech*

Using Pharmacokinetic-Pharmacodynamic Modeling and Simulation to Understand Dose and Exposure-Response Relationships for Adverse Reactions: Scott Van Wart, PhD, *Enhanced Pharmacodynamics*

Additional Panelists:
- Youwei Bi, PhD, *FDA*
- Cara Rabik, MD, PhD, *FDA*
- W. Douglas Figg, PharmD, *NCI*
- Julia Maues, *Patient Centered Dosing Initiative*

Session 3B: Implementing Seamless and Adaptive Registrational Trial Designs

Moderator:
Geoff Oxnard, MD, *Loxo@Lilly*

Introductory Speaker:
Adaptive Phase 2/3 Designs with Dose Selection: A Statistical Perspective: Cong Chen, PhD, *Merck*

Additional Panelists:
- Joyce Cheng, PhD, *FDA*
- Mirat Shah, MD, MHS, *FDA*
- Mehdi Lahmar, MD, PhD, *Boehringer Ingelheim*
- Debbie Pickworth, *BRAF Bombers & American Lung Association*

Closing Remarks, Lessons Learned and Next Steps

Moderator:
Patricia M. LoRusso, DO, PhD (hc), FAACR, *Yale Cancer Center*

Additional Panelists:
- Atiqur Rahman, PhD, *FDA*
- Jin Y. Jin, PhD, *Genentech*
- Julia Maues, *Patient Centered Dosing Initiative*
- Geoff Oxnard, MD, *Loxo@Lilly*
- Alex Phipps, PhD, *AstraZeneca*
- Lillian Siu, MD, *Princess Margaret Cancer Center*

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