

附件 1

2019 年 6 月 29 日

June 29, 2019

08:30-11:50 Section 1: 免疫原性评价现状/ Current Status of Immunogenicity Evaluation

08:30-08:40: 会议开幕/ Opening Ceremony

马璟（中国药理学会药物毒理专业委员会）/ Professor. Jing Ma (Toxicology Professional Committee, China Pharmacological Society)

08:40-09:10: CDE 对于免疫原性评价的期待/ CDE perspective on immunogenicity testing.

TBD（国家食品药品监督管理局药品审评中心）/ TBD (Center For Drug Evaluation, China)

09:10-09:50: 临床免疫原性评价现状和挑战/ Current status and challenges of clinical immunogenicity evaluation.

赵小平（国家上海新药安全评价研究中心（上海益诺思生物技术股份有限公司））/ Dr. Xiaoping Zhao (National Shanghai Center for New Drug Safety Evaluation and Research (Shanghai Innostar Biotech Co., Ltd.))

09:50-10:10: 茶歇/ Tea Break

10:10-10:50: 2019 版 FDA 指导原则解读/ Interpretation of FDA Guidance issued 2019.

任欣怡（国家上海新药安全评价研究中心（上海益诺思生物技术股份有限公司））/ Dr. Xinyi Ren (National Shanghai Center for New Drug Safety Evaluation and Research (Shanghai Innostar Biotech Co., Ltd.))

10:50-11:30: 生物药开发中免疫原性风险的评估/ Immunogenicity risk assessment during biologic drug development.

Dr. Sheng Dai (Boehringer Ingelheim)

11:30-11:50: 提问环节/ Q&A

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13:00-17:10 Section 2: 免疫原性分析方法、样品分析及数据解读/ Immunogenicity Testing, Sample Analysis and Interpretation of Data

13:00-13:40: 非临床免疫原性评价/ Immunogenicity evaluation in nonclinical.

马璟（中国药理学会药物毒理专业委员会）/ Professor. Jing Ma(Toxicology Professional Committee, China Pharmacological Society)

13:40-14:20: 早期临床免疫原性风险的把控/ Risk assessment and control in early clinical trail.

申屠建中（浙江大学医学院附属第一医院）/ Jianzhong Shentu(The First Affiliated Hospital of Medical School of Zhejiang University)

14:20-15:00: 免疫原性方法学验证的实施和考量/ Implementation and consideration of assay validation.

任欣怡（国家上海新药安全评价研究中心（上海益诺思生物技术股份有限公司））/ Dr. Xinyi Ren(National Shanghai Center for New Drug Safety Evaluation and Research(Shanghai Innostar Biotech Co., Ltd.))

15:00-15:20: 茶歇/ Tea Break

15:20-16:00: 中和抗体：选择抗体的挑战、方法和期待/ Challenges, modulates, expectations and the way to select antibody in Nab studies.

Dr. Weifeng Xu(Merck & Co. Inc.)

16:00-16:40: 临床免疫原性的“阴阳真假”问题-临界值的确定及其他/ Negative and positive of Clinical Immunogenicity - Cut Point Determination and Beyond

曾荣（安渡生物）/ Dr. Rong Zeng(Amador Bioscience)

16:40-17:10: 提问环节/ Q&A

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08:00-12:00 Section 3: 免疫原性的评估及案例分享/ Immunogenicity Testing Strategy and Case Study

08:00-08:40: 利用算法，对蛋白药物免疫原性风险预测和改造/ In silico analysis of immunogenicity risk and computationally-guided deimmunization of biologics
Professor. Chris Bailey-Kellogg(Dartmouth College)

08:40-09:20: 利用人 PBMC，通过实验方法对蛋白药物免疫原性进行评价/ Preclinical immunogenicity assessment of protein therapeutics by using human PBMC,
Professor. Karl Griswold(Dartmouth College)

09:20-09:40: 茶歇/ Tea Break

09:40-10:20: 腺病毒为载体的基因治疗的免疫原性评价/Immunogenicity assessment of AAV-based gene therapy.
Dr. Ronghua Meng (Spark Therapeutics,Inc.)

10:20-11:00: 生物类似药的临床免疫原性评价/ Immunogenicity evaluation of biosimilar drugs in clinical study.
Dr. Yong Chen (AstraZeneca,Inc.)

11:00-11:40: TBD

11:40-12:00: 提问环节/ Q&A