Non-clinical Immunogenicity Assessment of Generic Peptide Products: Development, Validation, and Sampling

Tuesday, January 26, 2021 | 8:45 AM – 4:30 PM

Virtual Only

Agenda

Agenda Item	Title/Presenter	Time (EST)
Opening (15 mins)	**Welcome and opening remarks** Robert Lionberger, Ph.D. Office of Research and Standards/Office of Generic Drugs (OGD)/CDER/FDA	8:45 to 9:00 AM
Intro talk (15 mins)	**Introduction of immunogenicity risk assessment in generic peptide products** Eric Pang, Ph.D. OGD/CDER/FDA Daniela Verthelyi, Ph.D. Office of Pharmaceutical Quality (OPQ)/CDER/FDA	9:00 to 9:15 AM
Session 1: In silico methods to assess binding affinity to MHC: Method validation and MHC selection		
Introduction (10 mins)	Zuben Sauna, Ph.D. Division of Plasma Protein Therapies/Office of Tissues and Advanced Therapies/CBER/FDA	9:15 to 9:25 AM
Talk 1 (20 mins)	**MHC binding, eluted ligands and immunogenicity; benchmarking testing and predictions** Alessandro Sette La Jolla Institute for Allergy and Immunology, USA	9:25 to 9:45 AM
Talk 2 (20 mins)	**The two-faced T cell epitope: predicting immunogenicity and tolerance** Anne S. De Groot, M.D. EpiVax, Inc., USA	9:45 to 10:05 AM
Panel Discussion for Session 1 (25 mins)		10:05 to 10:30 AM
Break (10 mins)		10:30 to 10:40 AM
Session 2: In vitro assays to monitor innate immune activation and inflammation: technical challenges and best practices		
Introduction (15 mins)	Daniela Verthelyi, Ph.D. Office of Biologic Products/OPQ/CDER/FDA	10:40 to 10:55 AM

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Talk 3 (20 mins)	**In Vitro assessment of the innate immune responses to teriparatide using peripheral blood mononuclear cells** Marina A. Dobrovolskaia, Ph.D. Nanotechnology Characterization Laboratory, USA	10:55 to 11:15 AM
Talk 4 (20 mins)	**Whole blood cytokine release assays to assess the risk of innate immune activation to generic peptide products** Jeremy Fry, D.Phil. ProImmune Ltd., UK	11:15 to 11:35 AM
Panel Discussion for Session 2 (25 mins)		11:35 to 12:00 PM
Lunch Break (30 mins)		12:00 to 12:30 PM
Session 3: Assays monitoring antigen-specific T cell activation: technical challenges and validations		
Introduction (10 mins)	Kristina Howard, Ph.D. Office of Clinical Pharmacology/Office of Translational Sciences/CDER/FDA	12:30 to 12:40 PM
Talk 5 (20 mins)	**Ex vivo immunogenicity assays – landscape and limitations** Campbell Bunce, Ph.D. Abzena, UK	12:40 to 1:00 PM
Talk 6 (20 mins)	**T cell immunogenicty assays: time for harmonisation and standardisation** Sofie Pattijn ImmunXpert, Belgium	1:00 to 1:20 PM
Talk 7 (20 mins)	**Human PBMC-based assays for the immunogenicity risk assessment of therapeutic peptides** Noel Smith, Ph.D Lonza, UK	1:20 to 1:40 PM
Panel Discussion for Session 3 (30 mins)		1:40-2:10 PM
Break (10 mins)		2:10-2:20 PM
Session 4: Using non-clinical data to assess immunogenicity risk		
Introduction (15 mins)	Amy Rosenberg, Ph.D. Office of Biotechnology Products/OPQ/CDER/FDA	2:20-2:35 PM
Talk 8 (20 mins)	**Using non-clinical data to assess immunogenicity risk: are we there yet?** Valerie Quarmby, Ph.D., FAAPS Genentech, USA	2:35 to 2:55 PM

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Talk 9 (20 mins)	**Using preclinical risk assessment tools to identify and mitigate risks for therapeutic proteins and peptides** Vibha Jawa, Ph.D. Bristol Myers Squibb, USA	2:55 to 3:15 PM
Talk 10 (20 mins)	**Fit-for-purpose validation of an immunogenicity risk assessment in vitro assay** Sophie Tourdot, Ph.D. Pfizer, USA	3:15 to 3:35 PM
Talk 11 (20 mins)	**Systems immunology applied to the integration of non-clinical immunogenicity data** Tim Hickling, Ph.D. Roche, Switzerland	3:35 to 3:55 PM
Panel Discussion for Session 4 (30 mins)		3:55 to 4:25 PM
Closing (5 mins)	**Closing Remarks** Steve Kozlowski, Ph.D. Office of Biotechnology Products/OPQ/CDER/FDA	4:25 to 4:30 PM