FDA-NRC Workshop: Enhancing Development of Targeted Alpha Emitting Radiopharmaceuticals, Special Session on Actinium-225

Wednesday, September 22, 2021
09:00 am EST to 4:30 pm EST
Virtual Workshop

Objectives
1. Develop collaborative approaches among stakeholders in development of novel drug products.
2. Expedite regulatory reviews and increase the overall efficiency of the development process to ensure timely access for patients to novel therapies.

Welcome and Introductions

9:00am - 9:15am  Louis Marzella, FDA
Kevin Williams, NRC
Cathy S. Cutler, Brookhaven National Laboratory

Session I:  Targeted Alpha Emitters with Focus on Actinium-225 Radiotherapies

9:15am - 9:45am  The Clinical Evolution of Alpha Particle Radiopharmaceutical Therapy: Focus on Actinium-225
Richard Wahl, MD, Society of Nuclear Medicine and Molecular Imaging

Session II: Novel Radiopharmaceuticals: Standards Development, Product Quality Considerations, Supply and Demand

Moderator: Danae Christodoulou, FDA

9:45am - 10:05am  Product Quality Considerations in Actinium-225 Radiopharmaceuticals
•  Ravindra Kasliwal, FDA

10:05am - 10:25am  High Energy Accelerator Production of Actinium-225 to Meet Clinical Demand
•  Cathy S. Cutler, Brookhaven National Laboratory

10:25am - 10:45am  Realizing the Becquerel for Actinium-225: The Current Landscape and the Road to a New National Activity Standard in the U.S.A.
•  Denis Bergeron, Research Chemist, National Institute of Standards and Technology

10:45am - 11:15am  Session II Panel:
Danae Christodoulou, Ravindra Kasliwal, Cathy Cutler, Denis Bergeron,
Roy Copping, Eva Birnbaum
11:15am - 12:00pm  Lunch

Session III. Clinical Considerations for Development of Novel Radiopharmaceuticals

Moderator Louis Marzella, FDA

12:00pm - 12:20pm  Alpha-emitting Therapeutic Radiopharmaceuticals: Nonclinical Studies Prior to Initiating a Human Study, Dose Selection, and Impact of Impurities.
• Haleh Saber, FDA

12:20pm - 12:40pm  Challenges to Safety Assessments in Early Phase Clinical Trials for Radiopharmaceuticals
• Mitchell Anscher, FDA

12:40pm - 1:00pm  Dosimetry for Radiopharmaceutical Therapy
• Donika Plyku, FDA

1:00pm - 1:20pm  Dosimetry of Alpha Emitters and Caution for Extravasation.
• Kish Chakrabarti, FDA

1:20pm - 1:50pm  Session III Panel:
Louis Marzella, Haleh Saber, Anthony Fotenos, Donika Plyku, Kish Chakrabarti,

1:50pm - 2:05pm  Break

Session IV. User and Industry Perspective

Moderator Michelle Hammond, NRC

2:05pm - 2:25pm  Targeted Alpha Therapy (TAT) Use of Actinium-225: Regulatory Interactions Now and Tomorrow
• Victor Paulus, Fusion Pharmaceuticals, Inc.

2:25pm - 2:45pm  Industry Experience in the Development and Clinical Testing of Actinium-225-based Radio-conjugates
• Mark S. Berger, MD, Actinium Pharmaceuticals, Inc.

2:45pm - 3:05pm  Clinical Utilization of Actinium-225 Alpha for Targeted Therapies: Potential and Challenges
• Neeta Pandit-Taskar, MD, Memorial Sloan Kettering Cancer Center

3:05pm - 3:25pm  Radiation Safety Considerations for Novel Radionuclide Therapies
• Megan Shober, Wisconsin Radiation Protection Section

3:25pm - 3:55pm  Session IV Panel:
Michelle Hammond, Victor Paulus, Mark Berger, Neeta Pandit-Taskar, Megan Shober,

3:55pm - 4:15pm  Closing Remarks
• Lisa Dimmick, NRC