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, Mitchell Anscher, 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