Monday, May 13, 2024
6:00 – 7:30 AM US PDT
9:00 – 10:30 AM US EDT
2:00 – 3:30 PM UK
3:00 – 4:30 PM Europe
6:30 – 8:00 PM India
9:00 – 10:30 PM China
10:00 – 11:30 PM Japan/Korea

BSTP & IATP Educational Webinar

Translational Considerations of NonClincial Findings in AAV-vector Gene Therapy

This webinar will provide a detailed look at the nonclinical studies employed to characterize the emergent nonclinical, nonhuman primate microscopic finding of dorsal root ganglia toxicity in a preclinical program and how these findings influenced clinical monitoring and product label for the AAV9 gene therapy product onasemnogene abeparvovec indicated for spinal muscular atrophy. The natural of history of spinal muscular atrophy will be briefly reviewed along with the components of the AAV9 gene therapy construct and the nonclinical program developed to support its development. Finally, we will review, from a translational medicine and toxicology perspective, the potential for and considerations of potential clinical translation of nonclinical nonhuman primate microscopic DRG findings.

Emily Meseck

Dr. Emily Meseck is the Global Head of Portfolio Pathologist in the Preclinical Safety Group at the Novartis Institutes for Biomedical Research in East Hanover NJ. Formerly, she held a range of positions in industry at large contract research organizations and in pharmaceutical companies. Dr. Meseck has held several leadership positions in the Society of Toxicologic Pathology, including president, scientific symposium planning committee member, member and now chair of the INHAND GESC and roles in Diversity, Inclusion and Belonging efforts in the S TP. A Diplomate of the American College of Veterinary Pathologists as well as the American Board of Toxicology (ABT), Dr. Meseck received her DVM and anatomic pathology residency training at Cornell University College of Veterinary Medicine.

Tukov, Francis Fonyuy

Dr. Francis Tukov is an experienced board-certified toxicologist with several years of experience in preclinical drug development spanning several therapeutic areas including Gene Therapy. Dr. Tukov is currently a Director of Preclinical Safety Assessment at Novartis Institutes for Biomedical Research in East Hanover, NJ. He has extensive experience and knowledge on the drug development process, including design and execution (including data interpretation) of non-clinical safety and efficacy studies of drug candidates for a variety of modalities, global health authority interactions and preparation of submission packages. In addition, he has prior extensive experience as a researcher and Study Director/Study Monitor for nonclinical toxicology studies in major disease areas. Since 2019, Dr. Tukov has been leading all Preclinical safety efforts supporting the development of IV onasemnogene abeparvovec (Zolgensma®), the first replacement gene therapy product for the treatment of spinal muscular atrophy. Dr. Tukov continues to lead the preclinical safety activities related to Zolgensma post-marketing and the development of Intrathecal (IT) onasemnogene abeparvovec and other gene therapy related projects at Novartis. Dr. Tukov received his DVM in 1995 and obtained a PhD in Pharmacology/Toxicology in 2003.

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Deadline to Register is Friday, May 10th

This webinar will be recorded for future viewing