Preliminary Program

Society for Neuro-Oncology

Presents

2020 Think Tank on Neuro-Oncology Clinical Trails

November 6, 2020

9:00AM-5:00PM US EST

SNO

The Society for NeuroOncology

Society for Neuro-Oncology Presents

2020 Think Tank on Neuro-Oncology Clinical Trails

The Society for Neuro-Oncology is pleased to host the 2020 Think Tank on Neuro-Oncology Clinical Trials, November 6th, 2020 from 9am-5pm EST.

Key neuro-oncology, FDA and industry leaders will address a range of topics that are essential for effective clinical trial design in the treatment of CNS malignancies, including:

- Opportunities to use novel trial design techniques such as synthetic control arms, big data, and artificial intelligence
- The potential role of nuclear imaging and immune imaging
- Pharmacodynamic biomarker development during pre-clinical phase of drug development
- Early phase pre-surgical trials: Phase 0
- Combination trials and changes in how to attribute efficacy and/ or toxicity to individual components of combination therapies
- How to best integrate predictive biomarkers
- What changes are needed to make tangible advances in the field?

Upon the conclusion of the Think Tank, participants will have an improved understanding of the practical aspects of clinical trial designs from topics that include the role of nuclear imaging, pharmacodynamic biomarker development, combination trials, research from other diseases, and predictive biomarkers.

Each session will provide opportunities for discussion and to address questions submitted by the audience. These presentations will also be recorded and available for viewing at the conclusion of the course on the SNO website.

Planning Committee

Stephen Bagley, MD, University of Pennsylvania
Timothy Cloughesy, MD, University of California, Los Angeles
Mustafa Khasraw, MD, Duke University
Patrick Wen, MD, Dana-Farber Cancer Institute

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Schedule

Session 1 Early Phase Evaluation of Novel Therapeutics for GBM: External Control Trials		
9:00-9:10 am	Welcome and Introduction	Patrick Wen, MD, Dana Farber Cancer Institute
9:10-9:20 am	Session 1 Introduction	Brian Alexander, MD, MPH, Dana Farber Cancer Institute Rifaquat Rahman, MD, Dana Farber Cancer Institute
9:20-9:30 am	Introduction to Externally Controlled Studies and Opportunities in Drug Development:	Irmarie Reyes-Rivera, PhD, Associate Group Head, RWD Oncology
9:30-9:40 am	Challenges in Data Access and Data Sharing in Oncology	Bill Louv, PhD, President, Project Data Sphere
9:40-9:50 am Mid-Session Discussion		
9:50-10:05 am	Statistical Considerations for the Use of External Control Data in Oncology Trials	Pallavi Mishra-Kalyani, PhD, US Food and Drug Administration
10:05-10:15 am	Design and Evaluation of an External Control Arm Using Prior Clinical Trials Design	Lorenzo Trippa, PhD, Dana Farber Cancer Institute
10:15-10:25 am	Evaluation of Hybrid Controlled Trials- Leveraging External Data and Randomization	Steffen Ventz, PhD, Harvard T.H. Chan, School of Public Health

10:25-10:45 am

Session 1 Panel Discussion to include Speakers, Panelists, Moderators & Special Invited Guests

Moderators:

Brian Alexander, MD and Rifaquat Rahman, MD

Invited Guests:

Amy Barone, MD, US Food and Drug Administration
Pallavi Mishra-Kalyani, PhD, US Food and Drug Administration
Joyce Cheng, PhD, US Food and Drug Administration
Yuan-Li Shen, PhD, US Food and Drug Administration
Susan Chang, MD, University of California, San Francisco
Karla Ballman, PhD, Weill Cornell Medical College
Steven Piantadosi, MD, PhD, Johns Hopkins Oncology Center
Minesh Mehta, MD, Miami Cancer Institute
Michael Weller, MD, University Hospital Zurich
Martin van den Bent, MD, PhD, Erasmus MC Cancer Institute
Mark Gilbert, MD, National Cancer Institute
Eva Galanis, MD, Mayo Clinic- Rochester
Wolfgang Wick, MD, University Clinic of Heidelberg
E. Antonio Chiocca, MD, PhD, Dana Farber Cancer Institute
Warren Mason, MD, Princess Margaret Cancer Centre
Ralph DeVitto, American Brain Tumor Association

10:45-11:00 am Break

Session 2 Pre-Clinical and Early Clinical Development		
11:00-11:05 am	Introduction to Pre-clinical and Early Clinical Goals or Early Drug Development	Timothy Cloughesy, MD, Ronald Regan UCLA Medical Center
11:05-11:20 am	Illustrative Case: IDH Inhibitors	Ingo Mellinghoff, MD, FACP, Memorial Sloan Kettering Cancer Center
11:20-11:30 am Open Discussion		
11:30-11:40 am	Understanding the Target Drug Relationship: EGFR Example	David Nathanson, PhD, David Geffen School of Medicine at UCLA
11:40-11:45 am	Exposure/Toxicity/Response Relationships: How to Use PK Data to Guide Early Development and Decisions for Later Development	Michelle Rudek, PhD, Pharm.D, Johns Hopkins Kimmel Cancer Center
11:45-11:55 am Open Discussion		
11:55 am-12:00 pm	Pharmacodynamic Endpoints: Tumor Based	Nader Sanai, MD, Barrow Neurological Institute
12:00-12:05 pm	Pharmacodynamic Endpoints: Tumor Microenvironment Based	Robert Prins, PhD, Brain Research Institute, UCLA
12:05-12:10 pm	Imaging: Pharmacodynamic; Early Clinical Effects	Benjamin Ellingson, PhD, UCLA Brain Tumor Imaging Laboratory
12:10-12:20 pm Open Discussion		
12:20-12:25 pm	Toward Precision Medicine: How Imaging Can Play a Role in Patient Selection:	Elisabeth de Vries, MD, PhD, University Medical Center Groningen, Groningen, the Netherlands
12:25-12:30 pm	Clinical Trial Design	Patrick Wen, MD, Dana Farber Cancer Institute

12:30-12:45 pm

Session 2 Panel Discussion to include Speakers, Panelists, Moderators & Special Invited Guests

Moderators:

Timothy Cloughesy, MD and David Nathanson, PhD

Panelists:

Josh Bilenker, MD, Loxo Oncology

Invited Guests:

Keith Ligon, MD, PhD, Dana Farber Cancer Institute
Andrew Lassman, MD, Columbia University Irving Medical Center
Howard Colman, MD, PhD, University of Utah
John de Groot, MD, MD Anderson Cancer Center
Burt Nabors, MD, University of Alabama-Birmingham
Michael Weller, MD, University Hospital Zurich
Amy Barone, MD, US Food and Drug Administration
Eva Galanis, MD, Mayo Clinic- Rochester
Martin Van den Bent, MD, PhD, Erasmus MC Cancer Institute Rotterdam
Elizabeth Gerstner, MD, Massachusetts General Hospital
Lauren Abrey, MD, Novartis Pharma AG
Wolfgang Wick, MD, University Clinic of Heidelberg
Manmeet Ahluwalia, MD, Cleveland Clinic
Priya Kumthekar, MD, Northwestern University
Karey Doll, PhD, Sontag, Brain Tumor Network

12:45-1:00 pm Break

Session 3
Conducting Combination Studies for Glioblastoma

1:00-1:05 pm	Challenges with Clinical Trial Assessing Combination Therapies	Mustafa Khasraw, MD, Duke University
1:05-1:20 pm	Combination Studies, the FDA Perspective	Amy Barone, MD, US Food and Drug Administration
1:20-1:30 pm	A Systematic Review of Combination Trials in Oncology	Aaron Tan, MD, Duke-NUS Medical School
1:30-1:45 pm	Challenges with Combination Studies, Relative Attribution of Efficacy and Toxicity	Don Berry, PhD, Berry Consultants
1:45-1:55 pm Mid-Session Discussion		
1:55-2:00 pm	Immunotherapy-Rationalizing Combination Therapies	Michael Platten, MD, Mannheim University Hospital
2:00-2:10 pm	Challenges with Immunotherapy Combination in GBM	Michael Lim, MD, Stanford University
2:10-2:25 pm	Challenges of Immunotherapy Combinations from the Industry Perspective: The Roche Morpheus Experience	Hila Barak, PhD, Cancer Immunotherapy at Genentech
2:25-2:35 pm	Combination Studies, the Virology (HIV, Hepatitis and COVID-19) Experience	Susanna Naggie, MD, Duke Clinical Research Institute

2:35-2:55 pm

Session 3 Panel Discussion to include Speakers, Moderators & Special Invited Guests

Moderators:

Mustafa Khasraw, MD, Duke University
Michael Platten, MD, Mannheim University Hospital

Panelists:

Howard Colman MD, PhD, Huntsman Cancer Institute
David Ashley, MD, PhD, Duke University
Wolfgang Wick, MD, University Clinic of Heidelberg
Yuan-Li Shen, PhD, US Food and Drug Administration
Pallavi Mishra-Kalyani, PhD, US Food and Drug Administration
Joyce Cheng, PhD, US Food and Drug Administration

Invited Guests:

Susan Chang, MD, University of California, San Francisco
Roger Stupp, MD, Northwestern University
Eva Galanis, MD, Mayo Clinic- Rochester
Minesh Mehta, MD, Miami Cancer Institute
Amy Heimberger, MD, MD Anderson Cancer Center
Vinay Puduvalli, MD, MD Anderson Cancer Center
David Reardon, MD, Dana Farber Cancer Institute
Solmaz Sahebjam, MD, Moffitt Cancer Center
John Simes, BSc (Med), University of Sydney
David Arons, JD, National Brain Tumor Society

2:55-3:10 pm Break

Session 4 Wrap Up: Thinking Outside of the Box		
3:10-3:20 pm	Impact of COVID 19 on Neuro-Oncology Clinical Trials	Eudocia Lee, MD, MPH, Dana Farber Cancer Institute
3:20-3:30 pm	Point/Counterpoint: How Current Standard of Care for GBM Impedes Drug Development	Michael Weller, MD, University Hospital Zurich
3:30-3:40 pm	Point/Counterpoint: Why Current Standard of Care for GBM is Not a Major Impediment to Progress	John Sampson, MD, PhD, Duke Cancer Center
3:40-3:55 pm	Incentivizing Drug Development for GBM: Biopharma/Biotech Perspective	Perry Nisen, MD, PhD, Sofinnova Investments
3:55-4:10 pm	Hallmark of Successful Drug Development	Ronald DePinho, MD, MD Anderson Cancer Center
4:10-4:35 pm **Session 4 Panel Discussion to include Speakers, Moderators & Special Invited Guests** **Moderators:** Stephen Bagley, MD, University of Pennsylvania Wolfgang Wick, MD, University Clinic of Heidelberg **Panelists:** Michael Weller, MD, University Hospital Zurich Gavin Dunn, MD, PhD, Washington University School of Medicine-St. Louis Lauren Abrey, MD, Novartis Pharma AG Howard Fine, MD, Weill Cornell Medicine **Special Guests:** James Perry, MD, Alliance Cancer Specialists Michael Vogelbaum, MD, PhD, Moffitt Cancer Center Nicholas Butowski, MD, University of California, San Francisco Susan Chang, MD, University of California, San Francisco Eva Galanis, MD, Mayo Clinic- Rochester Minesh Mehta, MD, Miami Cancer Institute David Reardon, MD, Dana Farber Cancer Institute Martin Van den Bent, MD, PhD, Erasmus MC Cancer Institute Roger Stupp, MD, Northwestern University Manmeet Ahluwahlia, MD, Cleveland Clinic Stuart Grossman, MD, Johns Hopkins Medicine Burt Nabors, MD, University of Alabama-Birmingham Erik Sulman, MD, PhD, NYU Langone Health Kathy Oliver, International Brain Tumour Alliance		
4:35-4:50 pm	Summary of Key Take-Aways	Mustafa Khasraw, MD, Duke University

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