

Jointly Organized by the National Cancer Institute Brain Malignancies Steering Committee Clinical Trials Planning Meeting team (NCI BMSC CTPM) and Accelerate Brain Cancer Cure (ABC²)

Thursday, September 19, 2013 – Friday, September 20, 2013

Welcome Reception: Westfields Marriott Hotel, Chantilly, VA

General Session: Steven F. Udvar-Hazy Center, Chantilly, VA

Breakout Sessions for NCI BMSC CTPM: Hilton Washington Dulles Hotel, Herndon, VA

Agenda

Wednesday, September 18th

6:00 – 10:00 PM **Welcome Reception, Westfields Marriott, Lower Rotunda area**

Thursday, September 19th

General Session: Steven F. Udvar-Hazy Center, Chantilly, VA, Executive Boardroom

7:30 – 8:00 AM **Registration and Continental Breakfast**

8:00 – 8:10 AM *Chairs Welcome Remarks* Al Yung, Ian Pollack, Max Wallace

8:10 – 8:35 AM *An Overview of Genomics of GBM and Therapeutic Opportunities* Ingo Mellinghoff

8:35 – 8:55 AM *Clinical Aspects and Pitfalls in Clinical Trials of Targeted Therapies in GBM* Tim Cloughesy

8:55 – 9:20 AM *Practical Aspects of Incorporating Genotyping into Clinical Trials* Jason Huse, Keith Ligon

9:20 – 9:40 AM *An Overview of Novel Adaptive Trial Designs* Brian Alexander

9:40 – 10:05 AM *Experience with Battle and I-Spy* Don Berry

10:05 – 10:40 AM *Imaging Biomarkers: MRI and PET* Whitney Pope

10:40 – 10:55 AM **Break**

10:55 – 11:15 AM *An Overview of T Cell Immunomodulatory Approaches* Pam Sharma

11:15 – 11:35 AM *Challenges in Response Assessment Including Imaging, Pseudoprogression* Ben Ellingson

11:35 – 11:55 AM	<i>Monitoring of Immune Related Toxicities</i>	Sapna Patel
11:55 – 12:15 PM	<i>Pediatric Immunotherapy Trials: Special Issues and Challenges</i>	Duane Mitchell

Thursday, September 19th, continued

12:15 – 12:35 PM	<i>Clinical Trial Issues (Panel Discussion)</i>	Lead by Mark Gilbert
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Topics Include:

- *Newly Diagnosed versus Recurrent*
- *Impact of Patients Immune Function*
- *Is a Single Arm “Pilot” Study Possible?*

12:35 – 1:45 PM	Lunch	
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1:45 – 2:05 PM	<i>Regulatory Aspects – Input from the FDA</i>	Martha Donoghue
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2:05 – 2:25 PM	<i>Industry Aspects</i>	TBD
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2:25 – 3:00 PM	Break to Travel for the Breakout Sessions NCI BMSC will travel to the Hilton Washington Dulles Hotel ABC ² will remain at the Steven F. Udvar-Hazy Center	
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NCI BMSC CTPM Breakout Sessions: Hilton Washington Dulles Airport Hotel

3:00 – 4:15 PM	Piedmont Room I <i>Proposed Trial Designs</i>	Mark Gilbert, Patrick Wen
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Panel discussion to outline proposed trials for preliminary feedback from CTEP and other participants - Input from FDA and industry

4:15 – 6:15 PM	Breakout sessions to Present and further develop the Novel Trials Design	
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	Piedmont Room I <i>Immunotherapy-Based Trial</i>	Mark Gilbert
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	Piedmont Room II <i>Signal Transduction Modulation-Based Trial</i>	Patrick Wen, Eva Galanis
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2:40 – 5:20 PM	ABC² Breakout Session Steven F. Udvar-Hazy Center, Executive Boardroom <i>Toward Precision Medicine: Moving Brain Cancer Genomics from Bench to Clinic</i> <i>Introduction</i>	
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	<i>A View from the Beginning</i>	Donald W. (Will) Parsons
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	<i>Identifying, Validating and Targeting Genomic Drivers of GBM</i>	Antonio Iavarone
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Discussion

Thursday, September 19th, continued

6:30 – 10:00 PM **Cocktails & Dinner at the Steven F. Udvar-Hazy Center**

Friday, September 20th

General Session: Steven F. Udvar-Hazy Center, Chantilly, VA, Executive Boardroom

8:00 – 8:30 AM **Continental Breakfast**

8:30 – 8:40 AM *Chairs Introduction* Al Yung, Ian Pollack, Max Wallace

8:40 – 9:40 AM *Immunotherapy-Based Trial Design* Mark Gilbert

9:40 – 10:40 AM *Signal Transduction Modulation-Based Trial* Patrick Wen

10:40 – 11:00 AM *Toward Precision Medicine Report Out* Max Wallace

11:00 – 11:15 AM **Break**

11:15 AM – 12:00 PM *Panel Discussion* Immunotherapy Panel

12:00 – 12:45 PM *Panel Discussion* Signal Transduction Modulation Panel

12:45 – 1:00 PM *Concluding Remarks* Al Yung, Ian Pollack

1:00 PM **Adjourn**