FDA-AACR-ASTRO Clinical Development of Drug-Radiotherapy Combinations Workshop

with support from Cancer Research UK Combinations Alliance

February 22-23, 2018 | Bethesda, MD

Purpose: There is great interest among clinicians as well as regulatory authorities to address the lack of drug development for products intended specifically for use with radiation therapy. Emerging from the enthusiasm and momentum of a session at the AACR-sponsored Accelerating Anticancer Agent Development and Validation Workshop (May 3-5, 2017, Bethesda, MD), this two-day workshop will bring together regulatory agencies, industry, and academia to discuss the challenges in greater depth and come up with a path forward.

Workshop Cochairs:

U.S. Food and Drug Administration:

Amanda Walker, MD, Associate Director (acting), Oncology Center of Excellence; Medical Officer, Division of Oncology Products I, Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

American Association for Cancer Research:

Stephen M. Hahn, MD, Deputy President and Chief Operating Officer; Chair and Professor, Department of Radiation Oncology, UT MD Anderson Cancer Center

Theodore S. Lawrence, MD, PhD, Professor and Chair, Department of Radiation Oncology, University of Michigan

American Society for Radiation Oncology:

Marka Crittenden, MD, PhD, Director, Translational Radiation Research, Earle A. Chiles Research Institute., Providence Cancer Center; Radiation Oncologist, The Oregon Clinic

Phuoc T. Tran, MD, PhD, Associate Professor, Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University

AGENDA: FEBRUARY 22, 2018

INTRODUCTION

8:00 AM **Introduction**
AACR Cochair

8:03 AM **Welcome & Introduction**
Amanda Walker, MD, U.S. Food and Drug Administration

8:10 AM **Radiation and Immunotherapy, Improving Collaboration with Industry**
Yaacov Richard Lawrence, MD, Sheba - Tel HaShomer Hospital; Thomas Jefferson University

8:35 AM **NCRI CTRad Recommendations**
Ricky Sharma, MD, PhD, University College London

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SESSION I: PRECLINICAL CONSIDERATIONS **SESSION COCHAIRS: C. NORMAN COLEMAN, MD, & KAYE J. WILLIAMS, PHD**	
9:00 AM	**Past Successes and Failures of Radiation-Drug Combinations** **Paul M. Harari, MD,** University of Wisconsin
9:25 AM	**How Can Preclinical Data Inform Clinical Trials?** **Tim M. Illidge, MD, PhD,** University of Manchester
9:50 AM	**Preclinical Approach to "Repurposing"** **Kevin A. Camphausen, MD,** National Cancer Institute
10:15 AM	**BREAK**
10:25 AM	**NCRI CTRad RadCom Initiative** **Kaye J. Williams, PhD,** University of Manchester
10:50 AM	**FDA Considerations** **Todd R. Palmby, PhD**, U.S. Food and Drug Administration
11:15 AM	**PANEL DISCUSSION and AUDIENCE Q&A**
Moderators	**C. Norman Coleman, MD, & Kaye J. Williams, PhD** **Session I speakers and the following additional panelist:** **Özlem Ataman, MD, PhD,** SOTIO **Melinda Merchant, MD, PhD,** AstraZeneca
11:45 PM	**LUNCH BREAK (ON YOUR OWN)**
SESSION II: CLINICAL CONSIDERATIONS **SESSION COCHAIRS: FEI-FEI LIU, MD, & RICKY SHARMA, MD, PHD**	
12:45 PM	**Novel Clinical Trial Designs in the Era of Precision Radiation Medicine** **Andrew B. Sharabi, MD, PhD,** UCSD Moores Cancer Center
1:10 PM	**Radiation Therapy Quality Assurance in Clinical Trials: Why and How** **Jessica Lowenstein, MS,** IROC Houston, MD Anderson
1:35 PM	**Clinically Relevant End-points for RT Combination Trials** **Fei-Fei Liu, MD,** Ontario Institute for Cancer Research
2:00 PM	**The Road to Registration: FDA Perspective on Defining Clinical Benefit** **Tatiana M. Prowell, MD,** U.S. Food and Drug Administration
2:25 PM	**PANEL DISCUSSION and AUDIENCE Q&A**
Moderators	**Fei-Fei Liu, MD, & Ricky Sharma, MD, PhD** **Session II speakers and the following additional panelists:** **Helen Bulbeck, PhD,** brainstrust **Zelanna Goldberg, MD, MA,** Pfizer **Geoffrey Kim, MD,** AstraZeneca

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2:55 PM	**BREAK**
3:10 PM	**Patient Reported Outcomes – FDA Perspective** **Paul G. Kluetz, MD,** U.S. Food and Drug Administration
3:35 PM	**The Patient's Perspective on PROs: Measuring What Matters to Patients** **Patty Spears,** UNC Lineberger Comprehensive Cancer Center
4:00 PM	**Incorporation of Wearables and Novel PROs Into Clinical Trials** **Adam P. Dicker, MD, PhD,** Thomas Jefferson University Kimmel Cancer Center
4:25 PM	**PANEL DISCUSSION and AUDIENCE Q&A**
Moderator	**Fei-Fei Liu, MD, & Ricky Sharma, MD, PhD** **Session II speakers and the following additional panelist:** **Zelanna Goldberg, MD, MA,** Pfizer
4:55 PM	**Wrap up: Summary & Future Directions** **Stephen M. Hahn, MD,** UT MD Anderson Cancer Center
5:00 PM	**ADJOURN**

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AGENDA: FEBRUARY 23, 2018	
INTRODUCTION	
8:00 AM	**Introduction** **Phuoc T. Tran, MD, PhD,** Johns Hopkins University
8:05 AM	**Which Molecular Pathways are Worth Targeting in Radiation-Drug Combination Studies?** **David G. Kirsch, MD, PhD,** Duke University Medical Center
SESSION III: IMMUNOTHERAPY **SESSION COCHAIRS: MARKA CRITTENDEN, MD, PHD, & ANDREW B. SHARABI, MD, PHD**	
8:30 AM	**Demystifying Abscopal Effect – Opportunities and Challenges** **Marka Crittenden, MD, PhD,** Earle A. Chiles Research Institute, The Oregon Clinic
8:50 AM	**Mechanisms of Response and Resistance to Radiation and Immune Checkpoint Blockade** **Andy J. Minn, MD,** Abramson Family Cancer Research Institute
9:10 AM	**SBRT Combined with Anti-PD-1 as a Platform: Results of the Initial Phase I/II Trial** **Steven J. Chmura, MD, PhD,** University of Chicago
9:30 AM	**Toxicities of Radiation-Immunotherapy Combinations** **Jonathan D. Schoenfeld, MD, MPhil, MPH,** Dana-Farber Cancer Institute
9:50 AM	**PANEL DISCUSSION and AUDIENCE Q&A**
Moderator	**Marka Crittenden, MD, PhD, & Andrew B. Sharabi, MD, PhD** **Session III speakers and the following additional panelist:** **David M. Berman, MD, PhD,** MedImmune **Michael Yellin, MD,** Celldex Therapeutics **Margaret K. Yu, MD,** Janssen Research & Development
10:20 AM	**BREAK**
SESSION IV: OTHER TARGETED THERAPIES **SESSION COCHAIRS: THEODORE S. LAWRENCE, MD, PHD, & ESTER M. HAMMOND, PHD**	
10:35AM	**Chemoradiation and Novel Kinase Inhibitors** **Kyle Cuneo, MD,** University of Michigan
10:55 AM	**The Potential of DNA Damage Response Inhibitors in Combination with Radiation Treatment** **Meredith A. Morgan, PhD,** University of Michigan
11:15 AM	**Hypoxia – Success and Failure** **Ester M. Hammond, PhD,** University of Oxford

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11:35 AM	**Nanotherapeutics and Radiotherapy** **Andrew Wang, MD,** University of North Carolina at Chapel Hill
11:55 AM	**PANEL DISCUSSION and AUDIENCE Q&A**
Moderator	**Theodore S. Lawrence, MD, PhD, & Ester M. Hammond, PhD** **Session IV speakers and the following additional panelist:** **Gideon M. Blumenthal, MD**, U.S. Food and Drug Administration **Özlem Ataman, MD, PhD,** SOTIO
12:25 PM	**LUNCH BREAK (ON YOUR OWN)**
1:20 PM	**Prognostic and Predictive Biomarkers in Radiation Oncology** **Daniel E. Spratt, MD,** University of Michigan
1:45 PM	**Debate: The Next Drug Approved in Combination With Radiation Will Be…**
Moderator:	**Amanda Walker, MD,** U.S. Food and Drug Administration
	Debater 1 – "An IO Agent" **James W. Welsh, MD,** UT MD Anderson Cancer Center
	Debater 2 – "Something Else (not IO!)" **Theodore S. Lawrence, MD, PhD,** University of Michigan
2:15 PM	**AUDIENCE Q&A**
2:25 PM	**PANEL DISCUSSION**
Moderator	**Amanda Walker, MD,** U.S. Food and Drug Administration **Panelists:** **Paul G. Kluetz, MD,** U.S. Food and Drug Administration **Helen Bulbeck, PhD,** brainstrust **Robert Iannone, MD,** AstraZeneca **Quynh-Thu Le, MD, FACR, FASTRO,** Stanford Cancer Institute **Ricky Sharma, MD, PhD,** University College London
2:55 PM	**Wrap up: Summary & Future Directions** **Amanda Walker, MD,** U.S. Food and Drug Administration
3:00 PM	**ADJOURN**

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