

FDA-IASLC Workshop on Neoadjuvant Therapy in Lung Cancers (Draft Agenda)

**Bethesda North Marriott Hotel and Conference Center
Rockville, MD 20852
March 1-2, 2018**

**Chairs: Gideon Blumenthal, Mark G. Kris, Paul A. Bunn, Jr.,
Rolf Stahel, Rafael Rosell**

Thursday, March 1, 2018		
3:30 – 5:45 p.m.	Session I: Current State of Neoadjuvant Treatment in Lung Cancers Chair: Mark Kris, David Carbone	
3:30 – 3:45 p.m.	Surgery After Induction Therapy	Stephen Swisher
3:45 – 4:00 p.m.	Pre-Op Chemotherapy	Enriqueta Felip
4:00 – 4:15 p.m.	Pre-Op Immunotherapy	Naiyer Rizvi
4:15 – 4:30 p.m.	Pre-Op Radiation	Dirk de Ruyscher
4:30 – 4:50 p.m.	Neoadjuvant Trials in Progress in EU and ROW – end points	Rolf Stahel
4:50 – 5:10 p.m.	Neoadjuvant Trials in Progress in US – end points	Robert. Doebele
5:10 – 5:40 p.m.	Questions and Answers	
5:40 – 6:00 p.m. Coffee Break		
6:00 – 7:30 p.m.	Session II: Neoadjuvant Opportunities Chair: Paul A. Bunn, Jr., Caroline McCoach	
6:00 – 6:30 p.m.	Use of Pathological Response After Neoadjuvant Therapies in Breast Cancers: Lessons the Lung Cancers Community Can Learn	Luca Gianni
6:30 – 7:00 p.m.	Biological Considerations for Neoadjuvant Therapies in Lung Cancers	Rafael Rosell
7:00 – 7:30 p.m.	Questions and Answers	
7:30 p.m. Dinner		

Friday, March 2, 2018

7:30 – 10:25 a.m.	Session III: How to Measure the Activity of Neoadjuvant Therapies	
	Imaging:	
	Chairs: Jamie Chaft, Fred R. Hirsch	
7:30 – 7:45 a.m.	CT	Larry Schwartz
7:45 – 8:00 a.m.	PET	Wilfried Eberhardt
8:00 – 8:15 a.m.	Radiogenomics: Using Radiology to Assess Biology	Hugo Aerts
	Resection Specimens	
	Pathology:	
8:15 – 8:35 a.m.	Current Policies/Procedures to Measure Pathological Response	Bill Travis
8:35 – 8:55 a.m.	pCR vs mPR vs Continuous	Janis Marie Taube
8:55 – 9:15 a.m.	Standardizing Techniques	Ignacio Wistuba
9:15 – 9:35 a.m.	Molecular Characterization	Dara Aisner
	Blood-Based Testing	
9:35 – 9:55 a.m.	cfDNA, CTCs	Max Diehn
9:55 – 10:25 p.m.	Discussion	

10:25 – 10:40 a.m.	Coffee Break
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10:40 – 11:45 am	Session IV: Using Data from Neoadjuvant Trials in Drug Development	
	Chair: Edith Perez, Giorgio Scagliotti	
10:40 – 10:55 a.m.	Trials of Immunotherapeutics	Nicholas Botwood
10:55 – 11:10 a.m.	Trials of Targeted Therapies	Nabil Chehab
11:10 – 11:25 a.m.	Combination Trials	Steven Keller
11:5 – 11:45 am	Discussion	

11:45 – 12:45 p.m.	Lunch
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Friday, March 2, 2018		
12:45 – 3:25 p.m.	Session V: Statistical Considerations, Trial Designs and Evidence Generation Using Neoadjuvant Data	
	Chair: Gideon Blumenthal	
12:45 – 1:05 p.m.	Benchmarks of Surrogacy	Don Berry
1:05 – 1:25 p.m.	Strength of Evidence/Conclusions of Current Data	Raji Sridhara
1:25 – 1:45 p.m.	Special Issues Evaluating Blood-Based Biomarkers	TBD
1:45 – 2:05 p.m.	Potential use of neoadjuvant data in future efficacy supplements and endpoint considerations: pCR, mPR, EFS	Nicole Drezner
2:05 – 2:25 p.m.	Validated Endpoints vs Endpoints Reasonably Likely to Predict Clinical Benefit as a Basis for Approvals	Tatiana Prowell
2:25 – 2:45 p.m.	International Regulatory Landscape	Jonas Bergh
2:45 – 3:05 p.m.	Overcoming Obstacles to Enrollment in Neoadjuvant Trials	Valerie Rusch Laurie Fenton Ambrose
3:05 – 3:25 p.m.	Discussion	
3:25 – 4:00 p.m.	Consensus, Conclusions and Open Items	
	Session Leaders: Bunn, Kris, Chaft, Perez, Blumenthal	