Liver Forum 12

Disease Assessment Strategies to Accelerate Drug Development

Friday, April 22, 2022

DRAFT AGENDA: Day 1

8:00 AM	**Opening Remarks**	
8:00 AM	Introductory Remarks: Liver Forum Co-Chairs	*Veronica Miller, Forum for Collaborative Research* *Arun Sanyal, Virginia Commonwealth University* *Judith Ertle, Boehringer Ingelheim*
8:05 AM	Setting the Stage	*Veronica Miller, Forum for Collaborative Research*
8:15 AM	**Session I: Improving the Reference Standard**	
	Moderator: *Michelle Berrey, Intercept Pharmaceuticals*	
8:15 AM	Challenges with Histological System: Clinician Perspective	*Stephen Harrison, Pinnacle Clinical Research*
8:30 AM	Challenges with Histological System: Pathologist Perspective	*Karoline Lackner, Medical University of Graz*
8:45 AM	Challenges with Histological System: Statistician Perspective	*Amrik Shah, Karma Statistics*
9:00 AM	Panel Discussion	**Panelists:** *Speakers &* *Peter Mesenbrink, Novartis Pharmaceuticals Corporation* *Massimo Siciliano, EMA External Expert* *Ruby Mehta, U.S. Food and Drug Administration*
10:00 AM	**Break**	
10:30 AM	**Session II: Improving the Reference Standard**	
	Moderators: *Naga Chalasani, Indiana University School of Medicine &* ***Melissa Palmer, Liver Consulting LLC***	
10:30 AM	Assessment of Ballooning: Implications of Recent Data	*Elizabeth Brunt, Washington University*
10:45 AM	Assessment of Fibrosis: Experiences from Longitudinal Studies and Novel Approaches	*Nikolai Naoumov, Independent Expert, London, UK*
11:00 AM	Assessment of Inflammation: Portal/ Septal Inflammation vs. Lobular	*David Kleiner, National Cancer Institute*
11:15 AM	Application of Digital Pathology Tools in Drug Development	*Arun Sanyal, Virginia Commonwealth University*
11:30 AM	Panel Discussion	**Panelists:** *Speakers &* *Prakash Jha, U.S. Food and Drug Administration* *Ruby Mehta, U.S. Food and Drug Administration*
12:20 PM	**Lunch**	
1:20 PM	**Session III: Opportunities and Challenges for NIT**	
	Moderators: *Rebecca Taub, Madrigal Pharmaceuticals &* ***Mary Rinella, University of Chicago***	
1:20 PM	A Meta-analytic Summary of NIT Applications in NASH Development	*Quentin Anstee, Newcastle University*
1:40 PM	Integrating NIT Development within a Drug Development Program	*John Sninsky, Advisor to the Forum*
1:55 PM	Validating Surrogate Endpoints Using Existing Data and Collaborative Analyses: Lessons from Virology	*Jeffrey Murray, Advisor to the Forum*
2:10 PM	Panel Discussion	**Panelists:** *Speakers &* *Preston Dunnmon, Janssen Research and Development*
3:00 PM	**Break**	

3:30 PM	**Session IV: Diagnostic Context of Use**	
	Moderator: *Erin Quirk, Terns Pharmaceuticals*	
3:30 PM	Update on Current Literature on Diagnostic COU for Circulating Biomarkers	*Sudha Shankar, Co-chair NIMBLE Consortium*
3:45 PM	QIBA and Imaging Biomarkers for Fat Quantification	*Anthony Samir, Harvard Medical School*
4:00 PM	MRI and Diagnostic Application of cT1 and Elastography Through the Lens of Regulatory Science	*Claude Sirlin, University of California, San Diego*
4:15 PM	Regulatory Perspectives on Qualification of NITs for Diagnostic COU	*Abbas Bandukwala, U.S. Food and Drug Administration*
4:30 PM	Panel Discussion	**Panelists:** *Speakers &* *Wayne Eskridge, Fatty Liver Foundation*
5:15 PM	**Adjourn and Reception**	
7:00 PM	Reception End	

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Saturday, April 23, 2022

DRAFT AGENDA: Day 2

8:00 AM	**Session Open**	
8:00 AM	**Session V: Prognostic NITs and Their Application in Clinical Trials for NASH**	
	Moderators: *Brent Tetri, Saint Louis University School of Medicine & Carla Yunis, Pfizer , Inc.*	
8:00 AM	The NASH-TARGET Approach for Non-invasive Diagnosis and Risk Stratification	*Sidney Barritt, University of North Carolina- Chapel Hill*
8:15 AM	Application of MRI and Other Imaging Approaches for Prognostic COU	*Alina Allen, Mayo Clinic*
8:30 AM	Circulating Biomarkers and Their Application for Prognostic COU	*Matthew Gee, Siemens Healthineers*
8:45 AM	Panel Discussion	**Panelists:** *Speakers*
9:30 AM	**Break**	
10:00 AM	**Session VI: Status of NITs for Predictive Disease Monitoring/ Treatment Response COU**	
	Moderators: *Philip Newsome, University of Birmingham & Michael Cooreman, Inventiva Pharma*	
10:00 AM	Integrated NIT Analysis in Drug Development	*Anne Minnich, Bristol Myers Squibb*
10:15 AM	Update on NAIL NIT Concept	*Sophie Jeannin, Summit Clinical Research*
10:30 AM	Placebo Arm Studies and Can NITs Be Used to Reduce Variance in Placebo Arm Responses in NASH Trials	*Veronica Miller, Forum for Collaborative Research*
10:45 AM	Making the Case for a NIT-based Recruitment and Assessment of Progression to Cirrhosis in NASH Trials	*Arun Sanyal, Virginia Commonwealth University*
11:00 AM	Needs for NIT Development to Reduce Misclassification of Non-Responders in Clinical Trials	*Judith Ertle, Boehringer Ingelheim*
11:15 AM	Panel Discussion	**Panelists:** *Speakers &* *Elizabeth Brown, Bristol Myers Squibb* *Nicholas Di Prospero, Janssen Pharmaceuticals* *Dominic Labriola, Madrigal Pharmaceuticals*
12:15 PM	**Session VII: Where does that leave us?**	
	Moderators: *Arun Sanyal, Virginia Commonwealth University & Veronica Miller, Forum for Collaborative Research*	
12:15 PM	Panel Discussion	**Panelists:** *Ruby Mehta, U.S. Food and Drug Administration* *Eirum Chaudhri, Merck, Inc.* *Roberto Calle, Regeneron Pharmaceuticals* *Quentin Anstee, Newcastle University*
12:55 PM	**Closing Remarks**	
12:55 PM	Wrap Up	*Arun Sanyal, Virginia Commonwealth University* *Veronica Miller, Forum for Collaborative Research*
1:00 PM	**Adjourn**	
1:00 PM	Lunch	