

Liver Forum 16

Friday, March 22 -- Saturday, March 23, 2024

Marriott Bethesda Downtown at Marriott HQ

7707 Woodmont Avenue, Bethesda, MD 20814

DAY 1 AGENDA (9:00AM - 6:00PM)

8:00 AM	Registration and Breakfast	
9:00 AM	Introductory Remarks and Program Overview	
9:05 AM	Welcome, Introduction, Forum Updates, Program Overview, and Acknowledgment	
9:20 AM	Session I: Clinical Trials for MASH: Anticipating Marketing Approval(s)	
	Moderators: Michelle Long, Novo Nordisk & Veronica Miller, Forum	
9:20 AM	Updates from regulators	<i>Joachim Musaus, EMA*</i>
9:30 AM	Overview of clinical trials once therapeutics are approved for marketing	<i>Veronica Miller, Forum</i>
9:45 AM	Panel- Open discussion	<i>Michelle Long, Novo Nordisk; Veronica Miller, Forum; Joe Toerner, FDA DHN</i>
9:55 AM	Session II: Lessons Learned	
	Moderators: Pam Danagher, Terns Pharmaceuticals & Veronica Miller, Forum	
9:55 AM	OCA Month 48 (histology, efficacy and safety) from the NASH / MASH program	<i>Michelle Berrey, Intercept Pharmaceuticals</i>
10:15 AM	Challenges in continuing long-term randomization with drugs approved for marketing: COBALT	<i>Michelle Berrey, Intercept Pharmaceuticals</i>
10:35 AM	Challenges with RWD-RWE in the liver disease space: HEROES STUDY	<i>Paul Nitschmann, Intercept Pharmaceuticals</i>
10:55 AM	Open discussion: Q&A	<i>All attendees</i>
11:15 AM	Break	
11:45 AM	Resmetirom program updates	<i>Becky Taub, Madrigal Pharmaceuticals</i>
12:15 PM	Panel- Open discussion	<i>Manal Abdelmalek, Mayo Clinic; Michelle Berrey, Intercept Pharmaceuticals; Henry Chang, Fatty Liver Foundation; Judith Ertle, Boehringer Ingelheim*; Paul Nitschmann, Intercept Pharmaceuticals; Lorraine Stiehl, American Liver Foundation, Becky Taub, Madrigal Pharmaceuticals; Terry Wright, GSK</i>

12:45 PM	Lunch	
1:45 PM	Session III: Collaboration for Greater Efficiency	
	Moderator: Richard Haubrich, Forum & Michelle Long, Novo Nordisk	
1:45 PM	Updates: Placebo Arm Database (PDB) Project	<i>Chris Hoffman & Veronica Miller, Forum</i>
2:05 PM	Introduction to Clinical Research Data Sharing Alliance: Avenues for Collaboration with LF	<i>Aaron Mann, Clinical Research Data Sharing Alliance (CRDSA)</i>
2:35 PM	Foundation for the National Institute of Health (FNIH)- NIMBLE	<i>Alex Pasek, Foundation for the National Institutes of Health (FNIH)</i>
2:55 PM	Radiology Liver Diseases (RLD) Program	<i>Michael Middleton & Claude Sirlin, UCSD</i>
3:15 PM	Panel- Open discussion	<i>Speakers & Michael Betel, Fatty Liver Alliance; Andrew Billin, Gilead; Samuel Engel, Merck; Céline Fournier, Echosens*; Aiguo Han, Virginia Tech; Mark Hartman, Eli Lilly and Company; Jeffrey Siegel, FDA</i>
4:15 PM	Break	
4:45 PM	Session IV: Standardizing for Greater Efficiency	
	Moderator: Manal Abdelmalek, Mayo Clinic	
4:45 PM	Standardizing MASH NITs	<i>Veronica Miller, Forum; Michelle Long, Novo Nordisk</i>
5:00 PM	Standardizing clinical outcomes assessments	<i>Manal Abdelmalek, Mayo Clinic</i>
5:15 PM	Panel discussion	<i>Donna Cryer, Global Liver Institute; Libette Luce, Akeru Therapeutics; Wenyan Wang, 89bio; Julia Wattacheril, Columbia University</i>
5:45 PM	Day 1 Recap	
5:45 PM	Wrap Up	<i>Michelle Long, Novo Nordisk; Veronica Miller, Forum</i>
6:00 PM	Networking Reception	

*Remote participation

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DAY 2 AGENDA (9:00AM - 1:00PM)

8:00 AM	Registration and Breakfast	
9:00 AM	Session V: Working Groups (WG) Updates	
	Moderator: Veronica Miller, Forum & Arun Sanyal, VCU	
9:00 AM	Combination Therapy	<i>Michelle Long, Novo Nordisk</i>
9:15 AM	Pooling of Endpoints Across Trials	<i>Michelle Long, Novo Nordisk</i>
9:30 AM	MetALD Program	<i>Maja Thiele, Odense University; Nikhil Vergis, GSK</i>
10:00 AM	Panel- Open discussion	<i>Claudia Filozof, Fortrea; Jenn Jones, Sober Livers; Michelle Long, Novo Nordisk; Timothy Morgan, VA Long Beach Healthcare System*; Charmaine Stewart, FDA; Maja Thiele, Odense University; Nikhil Vergis, GSK; Pam Young, Pfizer</i>
11:00 AM	Break	
11:30 AM	Session VI: Where Do We Go from Here?	
	Moderators: Michelle Long, Novo Nordisk; Veronica Miller, Forum; Arun Sanyal, VCU	
11:30 AM	Open discussion	<i>All attendees</i>
12:30 PM	Wrap-Up & Next Steps	
12:45 PM	Adjourn and Lunch	

*Remote participation

Feedback Survey QR Code

