Liver Forum 8
Tuesday, April 10th, 2018
Salons de l'Aveyron, Paris, France
Draft Agenda

12:30 PM	**Welcome Reception and Registration**	
2:00 PM	**Session I: Project and Regulatory Updates**	
		Moderator: Veronica Miller, *Forum for Collaborative Research*
2:00 PM	Welcome and Introduction	Katherine Greene, *Forum for Collaborative Research*
2:15 PM	Champion of Collaboration Award	**Awardee:** Cheronda Cherry-France, *U.S. Food and Drug Administration*
2:25 PM	Core Outcomes in NASH Project	Donna Messner, *Center for Medical Technology Policy*
2:35 PM	U.S. Food and Drug Administration Regulatory Update	Lara Dimick-Santos, *U.S. Food and Drug Administration*
2:45 PM	Regulatory Discussion	**Panelists:** Lara Dimick-Santos, *U.S. Food and Drug Administration* Elmer Schabel, *European Medicines Agency*
3:10 PM	**Session II: Parallel Breakout Sessions**	
3:10 PM	European Payer Perspective	***(OPEN SESSION)***
	Health Technology Assessment Perspective on NAFLD/NASH	Francois Maignen, *National Institute for Health and Care Excellence*
	Parallel Consultation with Regulators and Health Technology Assessment Bodies	**Discussants:** Francois Maignen, *National Institute for Health and Care Excellence* Samuel Mettam, *Boehringer Ingelheim* William Rosenberg, *University College London* Elmer Schabel, *European Medicines Agency*
	Discussion	
3:10 PM	NASH Biomarker Overview	***(OPEN SESSION)***
	Overview of NASH Biomarker Needs & Aims	Christopher Leptak, *U.S. Food and Drug Administration**
	Updates from NASH Biomarker Consortia	
	- NIMBLE Updates	Roberto Calle, *FNIH Biomarkers Consortium* Rohit Loomba, *University of California, San Diego*
	- LITMUS Updates	Quentin Anstee, *Newcastle University* Detlef Schuppan, *Mainz University Medical Center*
	Discussion	Sudha Shankar, *NGM Biopharmaceuticals*
3:10 PM	NASH Cirrhosis Working Group	***(WG MEMBERS ONLY)***
	Working Group Overview	**Working Group Chairs:**
	- Mission: Compensated and Decompensated	Arun Sanyal, *Virginia Commonwealth University* Naga Chalasani, *University of Indiana* Jean Chan, *Conatus Pharmaceuticals* Peter Traber, *Galectin Therapeutics*
	Regulatory Needs	
	- Defining Populations	
	- Measuring Endpoints	
	Discussion	
4:30 PM	**Break**	
4:30 PM	**Session III: Reports**	
		Moderator: Katherine Greene, *Forum for Collaborative Research*
5:00 PM	Breakout Session Report	
	- European Payer Perspective	
	- NASH Biomarker Updates	
	- Cirrhosis Working Group	
5:40 PM	Working Group Updates	
	- Standard of Care: Lifestyle	Manal Abdelmalek, *Duke University* Sven Francque, *University Hospital Antwerp* Oliver Glass, *Duke University*
	- Standard of Care: Comorbidities	Morten Hansen, *Novo Nordisk A/S Denmark* Raluca Pais, *Hôpital Pitié Salpêtrière* Vlad Ratziu, *Hôpital Pitié Salpêtrière et Université Pierre et Marie Curie*
	- Case Definitions	Stephen Harrison, *Pinnacle Clinical Research*
6:00 PM	**Session IV: Combination Therapy**	
		Moderator: Veronica Miller, *Forum for Collaborative Research*
6:00 PM	EU Requirements for Fixed Dose Combinations and Lessons Learned from Hypertension and Diabetes: Implications for NASH	Elmer Schabel, *European Medicines Agency*
6:20 PM	FDA Considerations for Fixed-Dose Drug Combinations and Lessons Learned	Stephanie Omokaro, *U.S. Food and Drug Administration*
6:35 PM	Industry Perspectives on Combination Therapy	**Panelists:** Laurent Fischer, *Allergan* Eric Hughes, *Novartis Pharma AG* Rob Myers, *Gilead Sciences*
7:05 PM	Discussion	Steve Rossi, *NGM Biopharmaceuticals*
7:30 PM	**Adjourn and Evening Reception**	

* *Remote Presentation*