2018 NASH Biomarker Program

FRIDAY 18 MAY 2018 - DAY 1

8:30 Workshop opening
8:40 Pathways and priorities for biomarker assessment
Peter Stein, MD  |  U.S. Food and Drug Administration

9:00 Integrating science, logistics and cost in approval of hierarchical testing strategies for NASH: The payer's perspective
Robert LoNigro, MD  |  Heritage Provider Network

9:20 Panel discussion
10:00 Coffee break

Session 2: Milestones and road map for biomarker development
10:30 Linking "intended use" to evidence needed for bringing a biomarker to market
John Sninsky, PhD  |  CareDx

11:00 Repeatability, reproducibility and analytic standards for biomarker development
Abbas Bandukwala  |  U.S. Food and Drug Administration

11:20 What is needed to link device approval to clinical application approval
David Litwack, PhD  |  U.S. Food and Drug Administration

11:40 Reporting standards: STARD & TRIPOD
Patrick Bossuyt, PhD  |  AMC-UvA

12:00 Quality standards for imaging studies
Claude Sirlin, MD  |  UC San Diego

12:20 Panel discussion
13:05 Lunch & Poster viewing

Session 3: Context of use - Diagnosis of "at risk" pre-cirrhotic NASH
14:05 Case definitions for use as reference standards
Mohammed Siddiqui, MD  |  Virginia Commonwealth University

14:25 Contexts of use and implications for study design
Quentin Anstee, BSc, MB BS, PhD, MRCP(UK), FRCP  |  Newcastle University

14:45 Population heterogeneity, sample size and analytic considerations in biomarker development
Lulu Wang, PhD  |  Gilead Sciences

15:05 Oral abstract presentations:
Validation of NIS4 algorithm for detection of NASH at risk of cirrhosis in 467 NAFLD patients prospectively screened for inclusion in the RESOLVE-IT trial
Rémy Harf  |  Genfit

A sequential circulating Fibroblast Activation Protein (cFAP) based model is superior to Hepascore alone in excluding significant fibrosis in non-alcoholic fatty liver disease
Mark Gorrell  |  The University of Sydney

15:35 Discussion
16:15 Coffee break

Session 4: Context of use - Diagnosis of cirrhosis
16:45 Defining the reference standard for biomarker development - Histology versus clinical outcomes
Kathleen Donohue, MD  |  U.S. Food and Drug Administration

17:05 Oral abstract presentations:
A Context of Use Framework for Bioanalytical Validation of the CK18 Apoptosis Biomarker for NASH Drug Development
Sumit Kar  |  Ceterion

Serum markers of collagen formation are associated with the severity of Liver fibrosis and Non-Alcoholic Steatohepatitis (NASH) histological features and to impaired renal function (IRF) in a NAFLD cohort
Samuel Daniels  |  Nordic Bioscience AS

Algorithm to identify non-alcoholic steatohepatitis (NASH) patients with a NAS≥4 and F≥2: algorithm derived in an American screening cohort and validation in a British non-alcoholic fatty liver disease (NAFLD) cohort
Céline Fournier  |  Echosens

17:50 Round Table Discussion: Redefining cirrhosis for the 21st century

18:30 Welcome Reception & Poster viewing

International Workshop on NASH Biomarkers 2018
18-19 May 2018, Washington, D.C.

SATURDAY 19 MAY 2018 - DAY 2

8:30 Defining therapeutic response in pre-cirrhotic and cirrhotic NASH
Manal Abdelmalek, MD  |  Duke University

8:50 Study design to validate biomarkers of therapeutic response for pre-cirrhotic NASH
Brent Tetri, MD  |  Saint Louis University

9:10 Study design to validate biomarkers of therapeutic response in cirrhosis due to NASH
Detlef Schuppan, MD, PhD  |  University of Mainz

9:30 Oral abstract presentations:
Use of plasma PRO-C3, PRO-C5, and PRO-C6 for the diagnosis and follow-up of fibrosis stage in patients with nonalcoholic fatty liver disease (NAFLD)
Diana Leeming  |  Nordic Bioscience A/S

NGM282 Rapidly Decreases PRO-C3 Levels in Biopsy-Confirmed NASH Patients Correlating with changes in MRI-PDFF, ALT and Liver Histology: Results from a Phase 2 Dose-Finding Study
Stephen Ross

10:00 Panel discussion
10:20 Coffee break

Session 5: Context of use - Assessment of therapeutic response

10:50 The clinical need for integrated assessment of NASH diabetes and heart disease
Arun Sanyal MD, MBBS  |  Virginia Commonwealth University

11:10 Neoepitope fragments of extracellular matrix as markers of pulmonary fibrosis: Insights into clinical and preclinical utilization for unfolding disease pathogenesis
Diana Leeming, PhD  |  Nordic Biosciences A/S

11:30 Oral abstract presentations:
Repeatability and Reproducibility of Multiparametric Magnetic Resonance Imaging of the Liver
Andrea Dennis
Feasibility of Using Deep-learning-based Techniques for Liver Couinaud Segmentation and Proton Density Fat Fraction (PDFF) Estimation
Hashem Almahmoud  |  University of California, San Diego

12:00 Special Lecture: Generating evidence to meet regulatory and third party payer needs for approval - Lessons learned from cologuard
Arul Sanyal MD, MBBS  |  Virginia Commonwealth University

12:40 Discussion
13:00 Closure of the workshop

Visit the conference website for more information:
http://expertmedicalevents.com/event/upcoming/nash-biomarkers-workshop-2018