The CLDF NASH Hepatology Leadership Forum is a unique opportunity to convene experts in the field of NASH, clinical trials, advocacy, policy, therapeutics and biomarker development as well as regulatory bodies to discuss challenges and opportunities to identify robust endpoints and trial designs for biomarker and drug development in the field of NASH and NASH-related fibrosis. This meeting will bring world-renowned experts to the table to bridge the knowledge gaps in the field of NASH in order to move the field forward. During the plenary sessions, faculty will lead interactive reviews of emerging NASH clinical data, provide an update on the latest data for non-invasive diagnostic tools (biomarkers and imaging) and review the clinical data related to a select number of promising Phase II and Phase III therapeutics in development for NASH. Additionally, the faculty and the advisors are encouraged to specifically identify the challenges in the field of therapeutics and diagnostics for NASH and provide potential solutions.
AGENDA (CONT.)

4:00 PM – 5:00 PM  Advisor Feedback/Recommendations on Current Challenges in NASH
Discussion Leads: Zobair Younossi, MD and Kenneth Cusi, MD

6:00 PM – 9:00 PM  Reception

SATURDAY, OCTOBER 5, 2019

7:00 AM – 8:00 AM  Breakfast

8:00 AM – 8:05 AM  Opening Remarks
Zobair Younossi, MD

SESSION II: NON-INVASIVE BIOMARKERS IN NASH
Co-Chairs: Quentin Anstee, PhD, FRCP and Michael Middleton, MD, PhD

8:05 AM – 8:30 AM  Serum Biomarkers and Clinical Algorithms in NASH: Utility in Clinical Trials and Clinical Practice
Quentin Anstee, PhD, FRCP

8:30 AM – 8:50 AM  Imaging as an Outcome and Endpoint for Clinical Trials of NASH
Michael Middleton, MD, PhD

8:50 AM – 9:00 AM  An Update from LITMUS
Quentin Anstee, PhD, FRCP

9:00 AM – 9:10 AM  An Update from NIMBLE
Arun Sanyal, MD

9:10 AM – 9:40 AM  Advisor Feedback/Recommendations on Non-invasive Biomarkers in NASH
Discussion Leads: Quentin Anstee, PhD, FRCP and Michael Middleton, MD, PhD

9:40 AM – 9:50 AM  Break

SESSION III: OUTCOMES AND ENDPOINTS
Co-Chairs: Arun Sanyal, MD and Stephen Caldwell, MD

Zachary Goodman, MD

10:10 AM – 10:35 AM  Is Histological Fibrosis Assessment an Appropriate Endpoint for Clinical Trials or a Suitable Reference Standard for Biomarker Development in NASH?
Scott Friedman, MD

10:35 AM – 11:05 AM  Advisor Feedback/Recommendations on Outcomes and Endpoints
Discussion Leads: Arun Sanyal, MD and Stephen Caldwell, MD

SESSION IV: REGULATORY PERSPECTIVE AND IDEAL TRIAL DESIGN
Co-Chairs: Vlad Ratziu, MD and Naga Chalasani, MD

11:05 AM – 11:25 AM  FDA Perspective: Drug Trials & Biomarker Validation
Arun Sanyal, MD
Vlad Ratziu, MD

11:45 AM – 12:05 PM  Ideal Clinical Trial Design for Optimal Outcomes: Monotherapy, Combination Therapy, Maintenance Therapy  
Naga Chalasani, MD

12:05 PM – 12:35 PM  Advisor Feedback/Recommendations on Regulatory Perspective and Ideal Trial Design  
Discussion Leads: Vlad Ratziu, MD and Naga Chalasani, MD

12:35 PM – 1:30 PM  Lunch

SESSION V: NASH AS A PART OF A MULTI-SYSTEM DISEASE  
Co-Chairs: Naim Alkhouri, MD and Ashwani Singal, MD

1:30 PM – 1:50 PM  NASH and Diabetes Linkage  
Kenneth Cusi, MD

1:50 PM – 2:10 PM  NASH and Cardiovascular Linkage  
Laurence Sperling, MD

2:10 PM – 2:30 PM  Patient Perspectives and Advocacy  
Donna Cryer, MD

2:30 PM – 2:50 PM  NASH and Primary Care Setting  
Manal Abdelmalek, MD

2:50 PM – 3:15 PM  Advisor Feedback/Recommendations on NASH as Part of a Multi-System Disease  
Discussion Leads: Naim Alkhouri, MD and Ashwani Singal, MD

SESSION VI: CLINICAL PRACTICE MANAGEMENT  
Co-Chairs: Zobair Younossi, MD and Kenneth Cusi, MD

3:15 PM – 3:35 PM  Clinical Management of NASH: Diet and Nutrition  
Shira Zelber-Sagi, BSc, RD, PhD

3:35 PM – 3:55 PM  Clinical Management of NASH: Exercise and Function  
Lynn Gerber, MD

3:55 PM – 4:15 PM  Weight Loss in NASH: The Role of Surgery and Weight Loss Medications  
Samuel Klein, MD

4:15 PM – 4:35 PM  Which Drug Regimens Do We Currently Have to Treat NASH?  
Kris Kowdley, MD

4:35 PM – 4:55 PM  Challenges in Management and Clinical Trials of NASH in Children  
Joel Lavine, MD

4:55 PM – 5:10 PM  Advisor Feedback/Recommendations on Clinical Practice Management  
Discussion Leads: Zobair Younossi, MD and Kenneth Cusi, MD

5:10 PM  Adjourn
Manal Abdelmalek, MD, MPH  
Duke University  
Durham, North Carolina

Aijaz Ahmed, MD  
Stanford University  
Stanford, California

Naim Alkhouri, MD  
Texas Liver Institute  
San Antonio, Texas

Quentin Anstee, BSc(Hons), MBBS, PhD, MRCP(UK), FRCP  
Institute of Cellular Medicine, Newcastle University  
Newcastle-Upon-Tyne, England

Rita Basu, MD  
University of Virginia  
Charlottesville, Virginia

David Bernstein, MD  
Zucker School of Medicine at Hofstra/Northwell  
Manhasset, New York

Terry Box, MD  
University of Utah  
Salt Lake City, Utah

Stephen Caldwell, MD  
University of Virginia  
Charlottesville, Virginia

Naga Chalasani, MD, FACP, FAASLD  
Indiana University School of Medicine  
Indianapolis, Indiana

Stephen Clement, MD  
Inova Health System  
Falls Church, Virginia

Kathleen Corey, MD, MPH, MMSc  
Harvard Medical School  
Boston, Massachusetts

Donna Cryer, JD  
Global Liver Institute  
Washington, District of Columbia

Kenneth Cusi, MD, FACP, FACE  
University of Florida  
Gainesville, Florida

Steve Flamm, MD  
Northwestern Medicine  
Chicago, Illinois

Scott Friedman, MD  
Icahn School of Medicine at Mount Sinai  
New York, New York

Michael Fuchs, MD, PhD  
McGuire VA Medical Center  
Richmond, Virginia

Lynn Gerber, MD  
George Mason University  
Fairfax, Virginia

Zachary Goodman, MD, PhD  
Inova Health System  
Falls Church, Virginia

Stuart Gordon, MD  
Henry Ford Health System  
Detroit, Michigan

Ira Jacobson, MD  
NYU Langone Health  
New York, New York

Mandana Khalili, MD  
University of California, San Francisco  
San Francisco, California

Samuel Klein, MD  
Washington University School of Medicine  
St. Louis, Missouri

Kris Kowlody, MD  
Liver Institute Northwest  
Seattle, Washington

Paul Kwo, MD  
Stanford University  
Stanford, California

Joel Lavine, MD, PhD  
Columbia University  
New York, New York

Eric Lawitz, MD  
Texas Liver Institute  
San Antonio, Texas

Rohit Loomba, MD  
University of California, San Diego  
San Diego, California

Michael Middleton, MD, PhD  
University of California, San Diego  
San Diego, California

Mazen Noureddin, MD, MHSc  
Cedars Sinai Medical Center  
Los Angeles, California

Puneet Puri, MD  
Virginia Commonwealth University School of Medicine  
Richmond, Virginia

Nikolaos Pyrsopoulos, MD, PhD, MBA  
Rutgers New Jersey Medical School  
Newark, New Jersey

Vlad Ratziu, MD  
Hôpital Pitié Salpêtrière  
Paris, France

Natarajan Ravendran, MD, FACP, AGAF, FAASLD  
Johns Hopkins School of Medicine, Digestive Disease Associates  
Catonsville, Maryland

Arun Sanyal, MD  
Virginia Commonwealth University School of Medicine  
Richmond, Virginia

Muhammad Sheikh, MD, FACP, FACC, AGAF  
Fresno Gastroenterology & Fresno Clinical Research Center  
Fresno, California

Ashwani Singal, MD, MS  
University of South Dakota Sanford School of Medicine and Avera Transplant Institute  
Sioux Falls, South Dakota

Laurence Sperling, MD  
Emory University School of Medicine  
Atlanta, Georgia

Ziad Younes, MD  
Gastro One  
Germantown, Tennessee

Zobair Younossi, MD, MPH, FACP, FACC, AGAF, FAASLD  
Inova Health System  
Falls Church, Virginia

Shira Zelber-Sagi, BSc, RD, PhD  
School of Public Health, University of Haifa  
Mount Carmel, Haifa, Israel

This activity is supported by an educational grant from Intercept Pharmaceuticals, Inc.

Provided by

Chronic Liver Disease Foundation
This activity is sponsored by Echosens and Novartis.