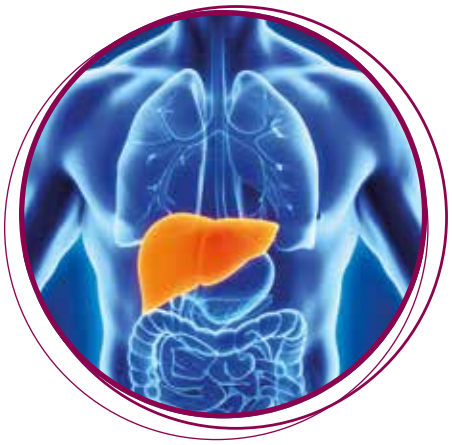
Global Engage

2ND GLOBAL NASH CONGRESS 2019

— LONDON UK —

25-26 February 2019



#NASHCongress

www.global-engage.com

WARM WELCOME

Global Engage

Global Engage is pleased to announce the **2nd Global NASH Congress 2019**, which will be taking place 25-26 February 2019 in London.

An increasing number of people are being diagnosed with nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) each year, and the primary method of treatment is weight loss. With no approved medicines on the market, the drug development race is intensifying. The pathogenesis of NASH is still not fully understood, and definitive diagnostic methods are invasive, so development has been slow.

However, promising developments in research will hopefully bolster drug development and other methods of treatment. Examples of such developments include improved in vivo liver models, non-invasive diagnostic biomarkers and better understanding of the disease's mechanisms. This year's congress will focus on these exciting advancements, as well as on the challenges of preclinical and clinical research in NASH. There will also be sessions covering regulation and business development, as well as a showcase of the most promising therapeutics in development.

Attracting experts working in all areas of nonalcoholic steatohepatitis, the conference will examine the latest research and development in pathogenesis, diagnosis and treatment of the disease. Featuring small group roundtable discussions and ample networking time, the event provides an excellent opportunity to meet and collaborate with senior representatives from industry, hospitals and universities. During the two-day conference, there will be 40 expert-led presentations, interactive roundtable discussions exploring key issues, and a dynamic exhibition room filled with technology providers showcasing their technologies.

EXPERT SPEAKERS Include:

KARINE CLÉMENT
Director of INSERM/Sorbonne University, NutriOmics team, France

NIKOLAI NAOUMOV
Executive Director, Hepatology Science and Innovation, Novartis, Switzerland

SOPHIE MÉGNIEN
Chief Medical Officer (CMO) GENFIT SA, USA

ANDREAS GEIER
Professor of Internal Medicine and Hepatology, Head Division of Hepatology, University of Würzburg, Germany

DAY 1 - TRACK 1

Current Approaches to NASH and Preclinical Strategy

- Guidance on clinical endpoints
- Improving patient recruitment for clinical trials
- Regulatory pathways
- Target discovery and validation
- Preclinical models
- Off-label drugs and drug repurposing
- Novel therapeutic methods
- Lifestyle intervention strategies
- Liver transplants
- Combination therapy

DAY 1 - TRACK 2

Non-invasive Biomarkers and Diagnostic Tools

- Non-invasive biomarkers
- Blood-based biomarkers
- MRI/MRE-based assessments
- Non-invasive cirrhosis assessment
- Liver biopsies; the gold standard
- Developments in liver biopsy imaging analysis
- Improving experimental models

DAY 2 - TRACK 1

The Pathogenesis of NASH and Related Health Conditions

- Genetics and epigenetics
- Epidemiology
- Metabolic syndrome
- Lipotoxicity
- Mitochondrial dysfunction and apoptosis
- Insulin resistance
- The gut microbiome
- Diabetes
- Cardiovascular disease
- Hepatocellular carcinoma

DAY 2 - TRACK 2

Therapeutics in Development

- Presentations from the most exciting companies in NASH drug development
- Targeting the gut
- Targeting metabolic pathways
- Targeting oxidative stress and inflammation
- Targeting progressive fibrosis (antifibrotics)

ROUNDTABLE DISCUSSIONS

1. Regulatory Challenges for FDA Approval Facing NASH Treatments
2. NAFLD and liver transplantation: current burden and expected changes
3. Liver biopsy: the gold standard
4. Collaborative projects: academia, healthcare providers, industry
5. Regulation of Inflammation and Fibrosis in NASH
6. From triglycerides to toxic lipids in NASH
7. NASH and CVD
8. Invasive and non-invasive Biomarkers for NASH/NAFLD
9. NAFLD related hepatocellular carcinoma (HCC)
10. NASH in the paediatric population

2019 EVENT SPONSORS

Gold Sponsors

Other Exhibitors & Sponsors

2018 PAST SPONSORS

Gold Sponsors

Silver Sponsors

Other Exhibitors & Content Sponsors

SPONSORSHIP AND EXHIBITION OPPORTUNITIES AVAILABLE

For more details contact Faizel Ismail at faizel@globalengage.co.uk or call +44 (0) 7415 228 053

CHRISTIAN TRAUTWEIN
Director of the Department of Internal Medicine III, University Hospital Aachen, Germany

CYNTHIA MOYLAN
Associate Professor of Medicine, Duke University, USA

THOMAS JENSEN
Assistant Professor of Medicine Colorado University Denver School of Medicine in Division of Endocrinology, Diabetes, and Metabolism. Co-Director of NAFLD Multidisciplinary Clinic, USA

GIULIO MARCHESINI
Professor of Diabetes, "Alma Mater" University, Department of Medical and Surgical Sciences, Italy

RUI CASTRO
Assistant Professor, Department of Biochemistry and Human Biology, Faculty of Pharmacy, University of Lisbon, Portugal

BRYAN FUCHS
Assistant Professor of Surgery, Harvard Medical School, Massachusetts General Hospital Cancer Center, USA

ANDREAS GEIER
Professor of Internal Medicine and Hepatology, Head Division of Hepatology, University of Würzburg, Germany

BRIAN HARVEY
EVP Scientific and Regulatory Affairs, Global Liver Institute, USA

RALUCA PAIS
Pitié Salpetriere Hospital, Institute of Cardiometabolism and Nutrition (ICAN), France

ANDREW FOWELL
Consultant Hepatologist, Portsmouth Hospitals NHS Trust

JULIA BROSNAN
Senior Director, External Alliances, Internal Medicine Research Unit, Pfizer

WAJAHAT MEHAL
Professor of Medicine (Digestive Diseases), Yale School of Medicine, USA - Regulation of Inflammation and Fibrosis in NASH

ELMER SCHABEL
Clinical Assessor, Licensing Division 2, Federal Institute for Drugs and Medical Devices (BfArM), Germany

JOYCE KORVICK
Deputy Director for Safety, Division of Gastroenterology and Inborn Errors Products (DGIEP), CDER, FDA, USA

RICHARD TORSTENSON
Senior Regulatory Affairs Specialist, Novo Nordisk, Denmark

JEREMY W TOMLINSON
Professor of Metabolic Endocrinology, University of Oxford, UK

YI LUO
Director Clinical Biomarkers in Innovative Medicine Development, Bristol-Myers Squibb, USA

NIKOLAI NAOUMOV
Executive Director, Hepatology Science and Innovation, Novartis, Switzerland

KARINE CLÉMENT
MD, PhD, Director of INSERM/ Sorbonne University, NutriOmics team, France

LUCA VALENTI
Associate Professor of Internal Medicine, University of Milan, Italy

KARIN CONDE-KNAPE
CVP Cardiovascular and Liver Disease Research, Novo Nordisk, UK

OREN TIROSH
Institute of Biochemistry, Food Science and Nutrition, Faculty of Agriculture, Food and Environment, The Hebrew University of Jerusalem, Israel

FADY NTANIOS
Senior Director, Global Medical Affairs, Pfizer, USA

VINOOD PATEL
Reader in Clinical Biochemistry, University of Westminster, UK

CLAUS HELLERBRAND
Professor for Biochemistry and Molecular Pathobiology, Institute of Biochemistry, Friedrich-Alexander University of Erlangen-Nüremberg, Germany

DAVID FRASER
CSO, NorthSea Therapeutics, Norway

HANNS-ULRICH MARSCHALL
Professor of Clinical Hepatology, University Hospital Consultant, University of Gothenburg, Sweden

SOPHIE MÉGNIEN
Chief Medical Officer (CMO), GENFIT SA, USA

RONIT SHIRI-SVERDLOV
Professor of Hepatic Inflammation and Metabolic Health, Maastricht University, The Netherlands

ELIAS PAPATHEODOROU
CEO, Genkyotex, Switzerland

SUSANNE KASER
Associate Professor, Department of Internal Medicine I, Medical University Innsbruck, Austria

PIERRE BROQUA
CSO/COO, Inventiva, France

ADIL MARDINOGLU
Professor of Systems Biology, King's College London, UK-

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks:**

09:00-09:35

KEYNOTE ADDRESS:
CHRISTIAN TRAUTWEIN

Director of the Department of Internal Medicine III, University Hospital Aachen, Germany

Factors influencing initiation and progression of NASH

- Alpha1-anti-tryspin
- Genetic factors
- Animal models

09:35-10:10

CYNTHIA MOYLAN

Associate Professor of Medicine, Duke University, USA

Epigenetics and development and progression of nonalcoholic fatty liver disease

- Summarize data on key epigenetic mechanisms of NAFLD development and progression.
- Update current research on DNA methylation, NAFLD and liver fibrosis
- Discuss the role and future application of DNA methylation as an emerging non-invasive indicator of NAFLD and its progression

10:10-10:40

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / **+44 (0) 1865 849841**

10:40-11:50 Morning Refreshments / One-to-One Meetings / Poster Presentations

CURRENT APPROACHES TO NASH AND PRECLINICAL STRATEGY

11:50-12:15

Invitation Out

NON-INVASIVE BIOMARKERS AND DIAGNOSTIC TOOLS

11:50-12:15

THOMAS JENSEN

Assistant Professor of Medicine Colorado University Denver School of Medicine in Division of Endocrinology, Diabetes, and Metabolism. Co-Director of NAFLD Multidisciplinary Clinic, USA

The role of a Multidisciplinary Clinic in the Management of NAFLD

- Screening and workup of patients at high risk for advanced NAFLD
- Comprehensive management and monitoring of patients with NAFLD
- Learning cases, and if time, discussions on fructose, uric acid and copeptin

12:15-12:45

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / **+44 (0) 1865 849841**

12:15-12:45

SOLUTION PROVIDER PRESENTATION:
SAMUEL BECKETT

Commercialisation Coordinator, Helena Biosciences Europe

Glycomics, a powerful new method in the detection, diagnosis and monitoring of chronic liver disease

Glycomics is the study of glycans – polysaccharide structures found on secreted and membrane bound glycoproteins, with roles including cell structure maintenance, signalling, protein folding and cellular recognition. The Glyco Liver Profile is a simple, non-invasive, serum test and has been shown to provide a highly sensitive and specific method for the detection of liver diseases such as NASH as well as an essential tool for the diagnosis and monitoring of chronic liver disease, and predicting the development of HCC. This presentation provides an overview of liver glycomics and the diagnostic capabilities of glycans, discussing how the test is conducted, its role in the detection of NASH, fibrosis and cirrhosis and its potential in providing risk analysis for the development of HCC.

12:45-13:10

GIULIO MARCHESINI

Professor of Diabetes, "Alma Mater" University, Department of Medical and Surgical Sciences, Italy

A web-based intervention to support lifestyle changes in NAFLD

- Lifestyle changes are mandatory in NAFD, but are scarcely implemented by busy liver units. Lifestyle programs may be jeopardized by job- and time-constraints of patients, unable to regularly attend programmed meetings.
- A web-based program was set–up to facilitate patients education to healthy diet and habitual physical activity, thus promoting and weight loss. The contact with the center was maintained through mails, food diaries exchange, physical activity monitoring.
- The web program compares favorably with face-to-face education, and is better suited for young, busy patients, and for cases living far from Liver units who cannot regularly attend educational programs.

12:45-13:10

Invitation Out

13:10-14:10 Lunch / One-to-One Meetings / Poster Presentations

14:10-14:40

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / +44 (0) 1865 849841

14:10-14:40

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / +44 (0) 1865 849841

14:40-15:05

RUI CASTRO

Assistant Professor, Department of Biochemistry and Human Biology, Faculty of Pharmacy, University of Lisbon, Portugal

NASH preclinical models for the study of microRNAs as biomarkers and therapeutic targets

- At the moment, no single animal model recapitulates all features of human NASH. As such, investigators should carefully choose the dietary or genetic model that best suits their research goals and expected outputs.
- Dietary models have proven particularly useful to test hypotheses on NASH molecular triggers and drivers of progression, as well as to identify therapeutic targets or test putative pharmacological agents. In this regard, microRNAs are being increasingly recognized as potential biomarkers and therapeutic targets in NASH.
- In particular, circulating miRNAs embody novel means of disease diagnosis and monitoring, while modulation of metabolism-related miRNAs delays disease triggering and halts NASH progression.

14:40-15:05

BRYAN FUCHS

Assistant Professor of Surgery, Harvard Medical School, Massachusetts General Hospital Cancer Center, USA

Molecular MR Imaging of Liver Fibrosis

- A major obstacle to the development of anti-fibrotic therapies is the lack of non-invasive technologies to both select for patients with active disease for clinical trial enrollment and monitor their response to treatment in these trials
- We have developed MR probes for the detection of Type I Collagen and Allysine for measuring fibrosis and fibrogenesis, respectively
- Here, we will describe the pre-clinical validation of these probes

15:05-15:30

ANDREAS GEIER

Professor of Internal Medicine and Hepatology, Head Division of Hepatology, University of Würzburg, Germany

Improving patient recruitment for clinical trials

- Patient recruitment for NASH trials is often difficult despite the fact that NAFLD is the most frequent chronic liver disease in Western countries affecting 25-30% of the population.
- Awareness of the disease and its natural course is limited in both the general public and medical doctors.
- Screening algorithms to identify NAFLD subjects at risk (NASH or present fibrosis) are recommended by international guidelines but infrequently followed in primary care.
- Specialized secondary diagnostic platforms for elastography and or advanced "direct" fibrosis testing are not widely available in some countries.
- Programs to foster the disease awareness, utilization of screening measures and second line diagnostics are key to improve patient recruitment for clinical trials.

50 MINUTE ROUNDTABLE DISCUSSIONS

15:05-15:55

ROUNDTABLE DISCUSSIONS SESSION:

1) Regulatory Challenges for FDA Approval Facing NASH Treatments

BRIAN HARVEY

EVP Scientific and Regulatory Affairs, Global Liver Institute, USA

2) NAFLD and liver transplantation: current burden and expected changes

RALUCA PAIS

Pitié Salpetriere Hospital, Institute of Cardiometabolism and Nutrition (ICAN), France

3) Liver biopsy: the gold standard

ANDREW FOWELL

Consultant Hepatologist, Portsmouth Hospitals NHS Trust

4) Collaborative projects: academia, healthcare providers, industry

JULIA BROSNAN

Senior Director, External Alliances, Internal Medicine Research Unit, Pfizer

15:30-15:55

ELMER SCHABEL
Clinical Assessor, Licensing Division 2, Federal Institute for Drugs and Medical Devices (BfArM), Germany
The EMA reflection paper on chronic liver disease and its implications for drug development in NASH

The European Medicines Agency is expecting to publish a "Reflection paper on chronic liver diseases (PBC, PSC, and NASH)" in autumn 2018, and will conduct a stakeholder meeting at the beginning of December 2018. A detailed display of the contents of this first regulatory guidance with regard to NASH, as well as a preliminary evaluation of the initial feedback and input received by stakeholders is planned to be given in this talk. Both, the reflection paper as well as the feedback received are expected to foster further discussions, including problems of patient selection and endpoints, and on reflections on potential future approval pathways, in a situation when the current unmet medical has already been met.

15:05-15:55

5) Regulation of Inflammation and Fibrosis in NASH

WAJAHAT MEHAL
Professor of Medicine (Digestive Diseases), Yale School of Medicine, USA - Regulation of Inflammation and Fibrosis in NASH

15:55-16:45 Afternoon Refreshments / One-to-One Partnering Meetings / Poster Presentations

16:45-17:10

JOYCE KORVICK
Deputy Director for Safety, Division of Gastroenterology and Inborn Errors Products (DGIEP), CDER, FDA, USA
Topic: Regulatory Pathways for NASH Drug Development

16:45-17:10

INDUSTRY PRESENTATION:
Reserved for FDA Representative

17:10-18:00

PANEL DISCUSSION:
Clinical Endpoints for NASH Trials

RICHARD TORSTENSON
Senior Regulatory Affairs Specialist, Novo Nordisk, Denmark

GIULIO MARCHESINI
Professor of Diabetes, "Alma Mater" University, Department of Medical and Surgical Sciences, Italy

CYNTHIA MOYLAN
Associate Professor of Medicine, Duke University, USA

ELMER SCHABEL
Clinical Assessor, Licensing Division 2, Federal Institute for Drugs and Medical Devices (BfArM), Germany

17:10-17:35

JEREMY W TOMLINSON
Professor of Metabolic Endocrinology, University of Oxford, UK
Dissecting the urinary steroid metabolome to stage NAFLD

Dysregulated steroid hormone metabolism has been implicated in the pathogenesis of non-alcoholic fatty liver disease (NAFLD). The liver represents the major site of steroid hormone metabolism and therefore we have hypothesised that the pattern of steroid hormone metabolites excreted in the urine may have potential as a novel non-invasive biomarker to stage NAFLD. We have analysed steroid metabolites in urine samples from cohorts of patients with biopsy-proven NASH across all stages of disease. Adopting machine learning-based analysis using generalised matrix learning vector quantisation, we have achieved excellent separation of controls and NASH groups with area under curve analysis of receiver operating characteristic curves out-performing many established non-invasive markers of NAFLD stage, suggesting that this strategy may have significant clinical utility.

17:35-18:00

YI LUO
Director Clinical Biomarkers in Innovative Medicine Development, Bristol-Myers Squibb, USA
Circulating biomarkers for fibrosis in NASH: collagen biomarkers and beyond

Fibrosis is a key readout of disease progression in NASH and reflects mortality risk. Non-invasive biomarkers capable of diagnosing fibrosis stages and monitoring fibrosis changes in NASH patients are needed. Fibrosis results from the imbalance of fibrogenesis and fibolysis due to sustained tissue injury. We have evaluated serum collagen biomarkers in an observational cohort of patients with biopsy proven NASH and demonstrated that elevated PRO-C3 levels are associated with advanced fibrosis stages in NASH. We further explored novel biomarkers that are correlated with fibrosis stages in this cohort using metabolomics and proteomics analysis.

18:00 Chair's Closing Remarks / End of Day One

18:00-19:00 Networking Drinks Reception

DAY 1 (15:05-15:55)

50 MINUTE ROUNDTABLE DISCUSSIONS:

1) Regulatory Challenges for FDA Approval Facing NASH Treatments

BRIAN HARVEY

EVP Scientific and Regulatory Affairs, Global Liver Institute, USA

- NonAlcoholic Steatohepatitis (NASH) is a common cause of chronic liver disease and can progress to liver fibrosis and cirrhosis.
- The natural history of NASH is unclear (e.g., percentage of progression to cirrhosis).
- Mechanisms underlying NASH include accumulation of fat in liver, inflammation and progress to cirrhosis. How will treatments be judged by regulators if they only treat one aspect of disease.
- Liver biopsy is the only generally acceptable method for diagnosis of NASH and to accurately assess progression to cirrhosis. Increased screening (e.g., FibroScan, MRI, Biomarkers) for liver disease in populations at increased risk for NASH, such as Type II Diabetes, Obesity, Hyperlipidemia and abnormal LFTs, could identify patients to be referred for liver biopsy and increase number of patients available for NASH trials.

2) NAFLD and liver transplantation: current burden and expected changes

RALUCA PAIS

Pitié Salpetriere Hospital, Institute of Cardiometabolism and Nutrition (ICAN), France

- The prevalence of NAFLD and NAFLD related cirrhosis is expected to increase in the years to come.
- NAFLD is becoming the leading cause of liver transplantation (LT) for both hepatocellular carcinoma (HCC) and end-stage liver disease (ESLD).
- Impact of NAFLD on the pool of potential donors
- Outcomes of patients with NAFLD while on the waiting list for LT
- Long-term outcomes of patients with NAFLD following LT:
  - Cardiovascular morbidity and mortality
  - Post-transplant metabolic syndrome
  - Recurrent and de novo NAFLD

3) Liver biopsy: the gold standard

ANDREW FOWELL

Consultant Hepatologist, Portsmouth Hospitals NHS

- Liver biopsy; still the 'gold standard'?
- What are the best non-invasive alternatives for diagnosing NASH and related fibrosis?
- Monitoring fibrosis progression and regression in NAFLD.

4) Collaborative projects: academia, healthcare providers, industry

JULIA BROSNAN

Senior Director, External Alliances, Internal Medicine Research Unit, Pfizer

5) Regulation of Inflammation and Fibrosis in NASH

WAJAHAT MEHAL

Professor of Medicine (Digestive Diseases), Yale School of Medicine, USA - Regulation of Inflammation and Fibrosis in NASH

- Inflammation and fibrosis provides many points of regulation.
- Pattern recognition receptor and inflammasome pathways are attractive for regulation of inflammation.
- Hepatic stellate cell activation and matrix degradation are attractive site for regulation of fibrosis.

08:00-08:55 Refreshments

08:55-09:00 **Morning Chair:**

09:00-09:35

KEYNOTE ADDRESS:
NIKOLAI NAOUMOV

Executive Director, Hepatology Science and Innovation, Novartis, Switzerland

Combination therapies – a personalised approach for effective NASH treatment

- NASH is a multifaceted progressive disease involving metabolic processes, chronic inflammation and liver fibrosis. Patients with NASH are heterogenous with respect to key drivers, predominant mechanisms of liver injury, stage of NASH disease, associated comorbidities, etc.
- Multiple compounds are currently in clinical development targeting different pathways involved in NASH pathogenesis
- Combination regimens involving compounds directed at different pathophysiological processes would allow tailoring therapy for different disease stages and are expected to be more successful with a larger proportion of treatment responders, as well as greater efficacy.

09:35-10:00

KARINE CLÉMENT

Director of INSERM/Sorbonne University, NutriOmics team, France

Gut Microbiome signature of NAFLD/NASH ; can we disentangle from metabolic signals

This talk will address the current knowledge on microbiota composition/ signatures in NAFLD/NASH and liver fibrosis taking advantage of current research activities of European consortia (EU-ePos and Litmus) and existing literature background. Some published literature has addressed the potential mechanistic relationships between gut microbiota and human NAFLD physiopathology. However, there is still a need to address the question whether it exists peculiar signatures of liver diseases being independent of metabolic disorders such as obesity and Type 2 diabetes, common diseases increasing the risk of liver injury. There is indeed a need to disentangle these conditions in the context of gut microbiota studies and in the future the challenge will be to identify gut microbiota and microbiota-derived metabolites that could predict the disease stage of progression.

10:00-10:30

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / **+44 (0) 1865 849841**

10:30-11:40 Morning Refreshments / One-to-One Meetings / Poster Presentations

THE PATHOGENESIS OF NASH & RELATED HEALTH CONDITIONS

11:40-12:05

LUCA VALENTI

Associate Professor of Internal Medicine, University of Milan, Italy

Genetics of progressive nonalcoholic fatty liver disease

- Hepatic fat accumulation and nonalcoholic fatty liver disease (NAFLD), especially the progressive form of the disease, have a strong heritable component
- The I148M variant of PNPLA3 is the main common genetic determinant of NAFLD, and is associated with the whole spectrum of liver damage, ranging from simple steatosis to cirrhosis and hepatocellular carcinoma development. However, variation in TM6SF2, MBOAT7, GCKR, PPP1R3B and HSD17B13 also contribute to disease risk, and rare mutations in genes involved in lipid metabolism, liver disease and cancer predisposition contribute as well
- We are now starting to translate these new discoveries into the clinics, to improve stratification of the risk of progressive NAFLD and identify new therapeutic approaches

12:05-12:35

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / **+44 (0) 1865 849841**

12:35-13:25

50 MINUTE ROUNDTABLE DISCUSSIONS:

1) From triglycerides to toxic lipids in NASH

OREN TIROSH

Institute of Biochemistry, Food Science and Nutrition, Faculty of Agriculture, Food and Environment, The Hebrew University of Jerusalem, Israel

2) NASH and CVD

FADY NTANIOS

Senior Director, Global Medical Affairs, Pfizer, USA

THERAPEUTICS IN DEVELOPMENT

11:40-12:05

KARIN CONDE-KNAPE

CVP Cardiovascular and Liver Disease Research, Novo Nordisk, UK

Metabolic Mechanisms in the Treatment of NASH

- Metabolic dysregulation as a driver for NASH
- Metabolic mechanisms for NASH treatment
- GLP1 in the treatment for NASH

12:05-12:35

SOLUTION PROVIDER PRESENTATION

For sponsorship opportunities contact Faizel Ismail:
faizel@globalengage.co.uk / +44 (0) 1865 849841

12:35-13:00

CHRIS PRIOR

CEO, Innovate Biopharmaceuticals, Inc., USA

Restoration of intestinal barrier function and the Gut-Liver axis: preventing immunogenic bacterial and antigen translocation as a potential therapy for the treatment of NASH

- Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) are associated with increased intestinal barrier permeability resulting from translocation of bacterial and other sensitizing antigens via the Gut-Liver axis. Larazotide acetate (LA), an oral peptide, already safely tested in nearly 600 patients, restores structural integrity of the epithelial barrier and decreases permeability by renormalizing tight junctions. This

12:35-13:25

3) Invasive and non-invasive Biomarkers for NASH/NAFLD

VINOOD PATEL

Reader in Clinical Biochemistry, University of Westminster, UK

4) NAFLD related hepatocellular carcinoma (HCC)

CLAUS HELLERBRAND

Professor for Biochemistry and Molecular Pathobiology, Institute of Biochemistry, Friedrich-Alexander University of Erlangen-Nüremberg, Germany

5) NASH in the paediatric population

*Full talk details can be found at the end of Day 2

12:35-13:00

broad mechanism of action of blocking "antigen trafficking" has a therapeutic benefit in celiac disease (CeD) by preventing the uptake of gliadin peptides and significantly reducing symptoms.

- Since LA significantly reduces translocation of lipopolysaccharide (LPS) in an ex-vivo model of the 'leaky gut' and LPS, via the hepatic portal system is known to inflame hepatocytes, reducing LPS load and other sensitizing antigens may offer clinical benefit.

13:00-13:25

DAVID FRASER

CSO, NorthSea Therapeutics, Norway

Targeting inflammatory and fibrotic pathways in NASH via a structurally engineered fatty acid, icosabutate

- Fatty-acid responsive pathways play a pivotal role in regulating hepatic inflammation and fibrogenesis/fibrolysis
- A liver-targeted structurally engineered fatty acid, icosabutate, effectively targets these pathways and exhibits potent anti-inflammatory and anti-fibrotic effects in multiple, differentiated, rodent NASH models
- Normalisation of elevated liver enzymes in dyslipidemic humans supports rodent data and, in addition to insulin sensitising and hypolipidemic effects, suggests that icosabutate could offer a potent oral treatment for NASH and its associated comorbiditiesDAVID FRASER – NorthSea Therapeutics (SEFAs – Structurally Engineered Fatty Acid)

13:25-14:25 Lunch

14:25-14:50

RONIT SHIRI-SVERDLOV

Professor of Hepatic Inflammation and Metabolic Health, Maastricht University, The Netherlands

Role of lysosomes in NASH

- Disturbed lipid metabolism during NASH contributes to lysosomal dysfunction
- Circulating (plasma) lysosomal enzymes can be used as biomarkers for NASH
- Reducing the activity of circulating lysosomal enzymes is a novel approach to treat NASH

14:25-14:50

SOPHIE MÉGNIEN

Chief Medical Officer (CMO) GENFIT SA, USA

Elafibranor as a potential first-line therapeutic in NASH

Elafibranor is a novel PPARα/α agonist and the first NASH drug candidate to demonstrate NASH resolution without the worsening of fibrosis while concurrently improving cardio-metabolic risk factors. Furthermore, NASH resolution was correlated with fibrosis improvement in patients of the GOLDEN505 study. Elafibranor is safe, with good tolerability and is now being investigated in a large phase 3 trial, RESOLVE-IT. Given the favorable profile of Elafibranor, GENFIT has explored therapeutic combinations to identify synergistic mechanisms of action. Here, we provide an overview of Elafibranor including disease model data from our combination program.

14:50-15:15

HANNS-ULRICH MARSCHALL

Professor of Clinical Hepatology, University Hospital Consultant, University of Gothenburg, Sweden

Receptor-mediated cross-talk between bile acids and microbiota and its impact on NAFLD

- Bile acids regulate numerous metabolic processes via the nuclear farnesoid X receptor (FXR) and the G protein-coupled membrane protein 5 (TGR5).
- Gut microbiota bioconversions modulate the signaling properties of bile acids.
- Altered bile acid and microbiota profiles contribute to the pathogenesis of NAFLD

14:50-15:15

ELIAS PAPATHEODOROU

CEO, Genkyotex, Switzerland

GKT831 a novel anti-fibrotic oral small molecule in PII clinical trials

15:15-15:40

SUSANNE KASER

Associate Professor, Department of Internal Medicine I, Medical University Innsbruck, Austria

Specific effects of antidiabetic therapies on fatty liver disease

- Significant weight reduction has been proven to improve steatosis, inflammation and fibrosis in patients with NASH
- Some antidiabetic therapies that are commonly associated with weight, reduction are currently under evaluation as treatment strategies for NAFLD.
- Common treatment targets include GLP-1 signaling and PPARgamma in diabetes and NASH.

15:15-15:40

PIERRE BROQUA

CSO/COO, Inventiva, France

Lanifibranor a moderate and well-balanced panPPAR agonist for the treatment of NASH

- Evidence that PPARα, δ and g regulate multiple pathways involved in the physiopathology of NASH
- Lanifibranor panPPAR profile
- Data supporting lanifibranor therapeutic potential in NASH

15:40-16:05

ADIL MARDINOGLU

Professor of Systems Biology, King's College London, UK

Employment of systems biology in treatment of liver diseases

To develop novel strategies for prevention and treatment as well as to gain detailed insights about the underlying molecular mechanisms of liver diseases, it is vital to study the biological functions of liver and its interactions with other tissues and gut microbiota. Biological networks can provide a scaffold for studying biological pathways operating in the liver in connection with disease development in a systematic manner. In my presentation, I will present our recent work where biological networks have been employed to identify the reprogramming in liver physiology in response to NASH/NAFLD. I will further discuss how this mechanistic modelling approach can contribute to the discovery of biomarkers and identification of drug targets which may lead to design of targeted and effective treatment strategies.

16:05 Conference Close

DAY 2 (12:35-13:25)

50 MINUTE ROUNDTABLE DISCUSSIONS:

1) From triglycerides to toxic lipids in NASH

OREN TIROSH

Institute of Biochemistry, Food Science and Nutrition, Faculty of Agriculture, Food and Environment, The Hebrew University of Jerusalem, Israel

Treatment of NASH will require the development of novel anti-lipotoxic treatments. The progression of NASH and development of fibrosis is a multifactorial process that comprise metabolic, inflammatory and cell death related events. Some of the lipid involved in disease progression are pro-inflammatory and some are toxic. The session will discuss the following topics in NASH and lipotoxicity: 1) Insulin resistance, metabolism and lipotoxicity: are they connected and what are the clinical evidences in lean and obese NAFLD patients? 2) toxic lipids leading to liver toxicity compared to pro-inflammatory lipids and mediators, 3) Drugs and dietary treatments to ameliorate lipotoxicity and to protect the liver: are we there?

2) NASH and CVD

FADY NTANIOS

Senior Director, Global Medical Affairs, Pfizer, USA

3) Invasive and non-invasive Biomarkers for NASH/NAFLD

VINOOD PATEL

Reader in Clinical Biochemistry, University of Westminster, UK

- Whilst liver biopsy is the gold standard for diagnosing NASH and determining the stage the procedure, lacks the ability to be high throughput, is invasive and has associated risks, and can result from sampling variation.
- Biomarkers both invasive and non-invasive provide a real solution for both diagnosing, staging and prognosis of NASH/NALFD. A number of blood-based markers or when combined with clinical variables have shown good clinical diagnostic outcomes. In addition, several non-invasive algorithms have shown excellent diagnostic accuracy for determining advanced fibrosis.
- The challenge is to obtain clinical validation of current and new markers and assessing best practice in terms of their application in diagnosing, staging or prognosis of NASH/NAFLD.

4) NAFLD related hepatocellular carcinoma (HCC)

CLAUS HELLERBRAND

Professor for Biochemistry and Molecular Pathobiology, Institute of Biochemistry, Friedrich-Alexander University of Erlangen-Nüremberg, Germany

- Hepatocellular carcinoma (HCC) is the fastest growing cause of cancer-related death. At least in part, this is attributable to the rising prevalence of non-alcoholic fatty liver disease (NAFLD). Due to the increasing prevalence of obesity, it can be expected that (the contribution of) NAFLD to HCC's incidence will further grow. Importantly, HCC is increasingly recognized to develop also in non-cirrhotic NAFLD livers.
- Present studies indicate that molecular mechanism of HCC development in NAFLD are complex. Beyond hepatocellular lipid accumulation and injury, e.g. inflammatory cytokines, ER stress and insulin resistance have been identified as drivers of malignant transformation
- The roundtable discussion will provide an overview on the epidemiology, risk factors and molecular pathogenesis of NAFLD related HCC, and potential conclusions regarding (individualized) surveillance, prevention and therapy.

5) NASH in the paediatric population

FREE **POSTER** PRESENTATIONS

PRESENTING A FREE POSTER

Poster presentation sessions will take place in breaks and alongside the other breakout sessions of the conference. Your presentation will be displayed in a dedicated area, with the other accepted posters from industry and academic presenters. We also issue a poster eBook to all attendees with your full abstract in and can share your poster as a PDF after the meeting if you desire (optional). Whether looking for funding, employment opportunities or simply wanting to share your work with a like-minded and focused group, these are an excellent way to join the heart of this congress.

In order to present a poster at the congress you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration).