Global Engage

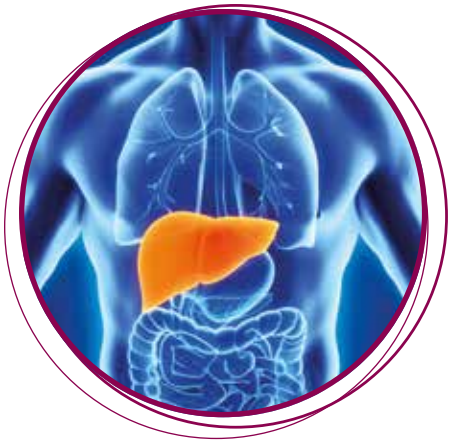
3RD GLOBAL NASH CONGRESS 2020

co-located

METABOLIC SYNDROME / DIABETES & NAFLD SYMPOSIUM

— LONDON UK —

10-11 February 2020



#NASHCongress

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Global Engage

Global Engage is pleased to announce the **3rd Global NASH Congress 2020**, and co-located **Metabolic Syndrome, Diabetes** and **NAFLD Symposium** which will be taking place 10-11 February 2020 at the London Heathrow Marriott.

This established meeting featuring over 60 individual talks, panels and roundtable discussions has been purposely designed to facilitate collaboration and attract attendance from the multiple communities working on NASH, NAFLD, obesity, diabetes and metabolic syndrome. It has the USP of attracting multiple stakeholders including KOL, investigators, academia, pharma, providers and regulators, whose aim is to tackle the often overlooked NASH epidemic as well as overlapping areas and develop ground breaking and impactful treatments for patients.

The meeting will focus on several key themes:

- Regulatory Updates, Commercialization and Payor Perspective
- Optimising Preclinical & Translational Strategy / Models
- Non Invasive Biomarkers and Diagnostic Tools
- New targets for the treatment of NASH/ Fibrosis / NAFLD
- Recent updates in NASH Pathogenesis
- Emerging research and treatment areas - Novel targets and pathways, GLP-1 etc
- Clinical Development & Trial results / design / optimization
- Prevention and control / Nutrition and lifestyle
- Ties between obesity, diabetes and NAFLD
- Role of liver and NAFLD in insulin resistance and metabolic syndrome
- Organ communication between diseases

We look forward to welcoming you to the event.

Novel Biomarkers and Diagnostic Tools

- Advancing biomarkers for improved diagnosis, staging, changes and prognosis
  - Review of current and potential biomarkers for each stage
- Evaluation of diagnostic tools
  - Improving diagnostic accuracy for identification and clinical outcome
  - Patient identification
  - Selection of treatment
  - Where are new biomarkers coming from?
  - Liver biopsies
- Technology Focus - Imaging and other non invasive technologies – overview, developments and methods
  - Quantitative analysis of samples
  - Improved disease measurement, tracking and monitoring

Preclinical & Translational Strategy and New targets for treatment of NASH/ Fibrosis

- Pre-clinical development of NASH targets
- Target discovery and validation - New targets for treatment of NASH/ Fibrosis
- Preclinical & translational models – Predictive value
- Model consistency
- Marrying model identification with disease stage
- Integration of clinical data to validate existing and identify novel mechanisms and targets
- Successful compounds in the clinic – How did they perform in preclinical models

Recent updates in NASH Pathogenesis

Exploring factors for advances in treatment - such as:

- Genetic susceptibility
- Metabolic syndrome
- Mitochondrial dysfunction and apoptosis
- Insulin resistance
- Gut microbiome
- Combination therapies
- Gut immune system
- Prevention and treatment – Tackling the root cause by improving awareness
- Utilizing nutrition and lifestyle factors

Regulatory Updates, Commercialization and Payor Perspective

- EMA / FDA – Current regulatory guidance, interaction and expectations for the future
- Regulatory pathways for approval of products
- Harmonizing clinical development and the regulatory landscape
- Nash submission experiences in the EU and US
- Payor perspective – Cost of treatment; Reimbursement; How will this work?;Demonstration of patient benefit
- Overcoming commercialisation challenges

Clinical Development & Clinical Trial Data

- Current NASH Drug Development case studies
- Improving patient recruitment and retention for clinical trials
- Novel clinical trial design – Uniformity and harmonization of trials
- Determining clinical endpoints
- Population screening
- Identifying correct treatment for stage
- What we learned from phase 3 clinical trials in 2019

Metabolic Syndrome, Diabetes and NAFLD Symposium

- Links between obesity, diabetes and NAFLD
- Role of liver, & NAFLD in insulin resistance and metabolic syndrome
- Organ communication between diseases
- Non-invasive biomarkers, technology and diagnostic tools
- Emerging research and treatment areas - Novel targets and pathways, GLP-1 etc
- Mechanistics underlying the association between NAFLD, other diseases and CVD
- Effect of anti-diabetic drugs
- Diabetes management with end stage liver disease
- Prevention and control / Nutrition and lifestyle
- Clinical & Regulatory updates & pathways in NAFLD
- Clinical development & trial results / Design / Optimization

Cross event roundtable discussions – Including:-

1. Clinical Trial Design
2. Regulation of Inflammation and fibrosis
3. Collaborative projects: academia, healthcare providers, industry
4. Determining clinical endpoints
5. Prevention and control – influence of nutrition and lifestyle
6. Liver biopsy; the gold standard
7. Translational value of preclinical models of NAFLD
8. NAFLD & Liver Transplants
9. Optimizing Preclinical models
10. Ties between obesity, diabetes, NAFLD & NASH
11. Invasive and non invasive biomarkers
12. The influence of genetics
13. Pros and cons of population screening strategies
14. Imaging methods, analysis and technology updates
15. Regulatory guidance Q&A

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Vice President, Clinical Development, Allergan

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Professor of Hepatology, University of Paris-VII, Department of Hepatology, Hôpital Beaujon, Clichy

WILLIAM ROSENBERG
Peter Scheuer Chair in Liver Diseases, Deputy Director, UCL Institute for Liver and Digestive Health

ANDREW BILLIN
Director Biomarker Sciences, Gilead Sciences

HENNING GRØNBÆK
Professor, Department Hepatology & Gastroenterology, Aarhus University Hospital

HANNES HAGSTRÖM
Consultant in Hepatology, Unit of Hepatology, karolinska University hospital, Sweden

MICHAEL PAVLIDES
Head of Liver Imaging, Oxford Centre for Clinical Magnetic Resonance Research (OCMR)

GURU AITHAL
Professor of Hepatology and the Head of the Division for the Nottingham Digestive Diseases Centre, University of Nottingham

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

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Chief of Gastrenterology and Hepatology, Clinica Santa Chiara, Switzerland

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Chief Medical Officer, Executive Vice President, Late Development & Medical Affairs, Poxel

HAROLD H. SHLEVIN
Chief Executive Officer, Galectin Therapeutics Inc.

HUBERT CHEN
Chief Medical Officer, Metacrine

DAVID BAKER
Senior Director, Head of Metabolism, AstraZeneca

PATRICK VRILLANDT
Principal Clinical Assessor, Medicines Evaluation Board, The Netherlands

CONFIRMED SPEAKERS

JERRY COLCA
CSO Cirius Therapeutics (Kalamazoo MI and San Diego CA, USA)

BERTRAND CARIOU
Professor of Endocrinology, Nantes University Hospital, France

AMALIA GASTALDELLI
Head of Cardiometabolic Risk Lab, Italian National Research Council, Italy

CAREL LE ROUX
Professor of Experimental Pathology, Conway Institute, Diabetes Complications Research Centre, University College Dublin, Ireland

RICHARD TORSTENSON
Regulatory Advisor, Allergan

MICHAEL FUCHS
Professor of Medicine, Virginia Commonwealth University and Chief of Hepatology & Liver Transplantation, McGuire VA Medical Center, USA

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

ANDREW FOWELL
Consultant Hepatologist, Queen Alexandra Hospital

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

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Associate Professor in clinical nutrition, Head of Clinical Research Unit, Uppsala University, Sweden

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Professor, Department Hepatology & Gastroenterology, Aarhus University Hospital

ANGELA SLITT
Professor, Department of Biomedical and Pharmaceutical Sciences, University of Rhode Island, USA

ALEX MIRAS
Senior Clinical Lecturer in Endocrinology, Department of Metabolism, Digestion and Reproduction, Imperial College, UK

VENUE INFORMATION

London Heathrow Marriott Hotel
Bath Road, Heathrow Airport Hayes,
UB3 5AN, United Kingdom

Located less than half a mile away from the Heathrow Airport, this four-star deluxe hotel offers comfortable, noise-free accommodations and is near attractions such as Legoland and Windsor Castle. Modern and vibrant, discover the culinary delights and more in the London Heathrow Marriott.

08:00-08:55 Registration & Refreshments

08:55-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks:**

09:00-09:35

KEYNOTE PRESENTATION:
EDUARDO MARTINS
Vice President, Clinical Development, Allergan

Can we cure NASH with pharmacotherapy

09:35-10:10

KEYNOTE PRESENTATION:
LAURENT CASTERA
Professor of Hepatology, University of Paris-VII (Department of Hepatology, Hôpital Beaujon, Clichy, France

Elastography and serum biomarkers as noninvasive tools for NAFLD

- Noninvasive tools are widely used in NAFLD
- They are useful to detect NAFLD and advanced fibrosis
- Their utility for monitoring treatment response remains to be demonstrated

10:10-10:40

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

NOVEL BIOMARKERS AND DIAGNOSTIC TOOLS

11:40-12:05

WILLIAM ROSENBERG
Peter Scheuer Chair in Liver Diseases, Deputy Director, UCL Institute for Liver and Digestive Health

Application of non-invasive tests for liver fibrosis

REGULATORY UPDATES, COMMERCIALIZATION AND PAYOR PERSPECTIVE

11:40-12:05

SENIOR REPRESENTATION (Reserved)
FDA

FDA regulatory considerations for NASH - TBC

The talk will briefly touch upon NICE's purpose, methods and decision-making. The talk will focus on the design of clinical trials and outcome measures to generate evidence that will facilitate a NICE appraisal. This will include patient-relevant outcomes, health-related quality of life measures and long-term outcomes. A HTA perspective on issues relating to the development of diagnostics and the use of surrogate outcomes in trials will be outlines

METABOLIC SYNDROME, DIABETES AND NAFLD SYMPOSIUM

11:40-12:05

JERRY COLCA
CSO Cirius Therapeutics (Kalamazoo MI and San Diego CA, USA)

A new insulin sensitizing agent- an approach to treating the overlapping pathology of NASH and diabetes

- Metabolic dysfunction, including insulin resistance, is a common pathology in NASH and type 2 diabetes. There is a significant overlap between type 2 diabetes and NASH.
- An unbiased approach discovered the mitochondrial pyruvate carrier (MPC) as an unappreciated target of first generation insulin sensitizers. The MPC appears to be the connection between overnutrition and the metabolic dysfunction of NASH and diabetes. MSDC-0602K was developed as a second generation insulin sensitizer selective for this activity.
- Clinical studies confirm that MSDC-0602K has effects similar to the first generation insulin sensitizer pioglitazone in subjects with both NASH and type 2 diabetes but without dose-limiting side effects

12:05-12:30

ANDREW BILLIN

Director Biomarker Sciences, Gilead Sciences

Utility of currently available non-invasive tests (NITs) for disease staging and prognosis in patients with NASH

- NITs are a critical tool for evaluating patients and for enrolling clinical trials. The talk will discuss:
- NITs as useful tools to identify patients with advanced fibrosis due to NASH
- Prognostic value of NITs and histology
- Utility of NITs for monitoring treatment response

12:30-12:55

HENNING GRØNBÆK

Professor, Department Hepatology & Gastroenterology, Aarhus University Hospital

From single to multiomic blood biomarkers for diagnosis and staging of non-alcoholic fatty liver disease

- Non-alcoholic fatty liver disease (NAFLD), has been recognized as a clinical challenge for more than 20 years. However, there is still an unmet need for better biomarkers for diagnosis of NAFLD severity and treatment response.
- Due to the complexity of NASH pathogenesis, it is unlikely that a single biomarker will suffice to diagnose NASH with inflammation and fibrosis.
- The evidence of diagnostic blood biomarkers from single markers, clinical scores to multilomics for diagnosis of NAFLD liver disease severity will be presented.

12:55-13:20

HANNES HAGSTRÖM

Consultant in Hepatology, Unit of Hepatology, karolinska University hospital, Sweden

Identifying patients with risk of adverse outcomes – where should we look more closely?

Progression of fibrosis is slow in NAFLD, and only a minority of patients develop clinically significant liver disease. The talk will focus on how to identify those with the highest risk of fibrosis progression, development of cirrhosis and liver-related death.

12:05-12:30

MARK A. AINSWORTH

Chief Medical Officer, Danish Medicines Agency, Denmark

Regulatory aspects of NASH – The EMA reflection paper

12:30-12:55

ELI GAJRAJ

Principal Technical Adviser, NICE Scientific Advice

HTA perspective on evidence generation

The talk will briefly touch upon NICE's purpose, methods and decision-making. The talk will focus on the design of clinical trials and outcome measures to generate evidence that will facilitate a NICE appraisal. This will include patient-relevant outcomes, health-related quality of life measures and long-term outcomes. A HTA perspective on issues relating to the development of diagnostics and the use of surrogate outcomes in trials will be outlines

12:55-13:20

PATRICK VRILLANDT

Principal Clinical Assessor, Medicines Evaluation Board, The Netherlands

A regulatory perspective on the developments in NASH - TBC

12:05-12:30

BERTRAND CARIOU

Professor of Endocrinology, Nantes University Hospital, France

Effects of anti-diabetic drugs on NASH (GLP-1, SGLT2i, glitazones, etc..).

12:30-12:55

AMALIA GASTALDELLI

Head of Cardiometabolic Risk Lab, Italian National Research Council, Italy

Pancreas liver cross talk in diabetes and NAFLD

- Insulin glucagon
- Insulin clearance

12:55-13:20

CAREL LE ROUX

Professor of Experimental Pathology, Conway Institute, Diabetes Complications Research Centre, University College Dublin, Ireland

How the gut talks to the brain to impact the liver

- Obesity is a disease of the subcortical areas of the brain.
- The best way to reduce the symptoms of obesity is to enhance satiety signals from the gut to the brain.
- At least 10% weight loss is required to impact complications of obesity such as NAFLD and NASH

13:20-14:20 Lunch

14:20-14:50

14:50-15:15

MICHAEL PAVLIDES

Head of Liver Imaging, Oxford Centre for Clinical Magnetic Resonance Research (OCMR)

Multiparametric MRI for the evaluation of NAFLD

With the increasing prevalence of NAFLD worldwide, there is an urgent clinical need for reliable methods to diagnose and stage liver pathology. Liver biopsy, the current gold standard, is invasive and limited by sampling and observer dependent variability. Magnetic resonance protocols for liver tissue characterisation have been developed and evaluated in a variety of clinical settings. Multiparametric MRI has shown excellent diagnostic performance against liver biopsy for the staging of liver fibrosis and quantification fat and iron, and good prognostic performance for the prediction of adverse clinical outcomes. Furthermore, MR based techniques show promise as tools for monitoring the effects of therapy picking up early improvements. Lastly, MRI techniques have shown superior reproducibility compared to alternatives and have been used to study liver fat and liver iron in population level studies. Collectively, the emerging evidence suggests that liver multiparametric MR techniques can be powerful tools for the assessment of patients with NAFLD, as they allow for the quantification of multiple parameters and can be applied in a variety of contexts of use.

15:15-15:40

GURU AITHAL

Professor of Hepatology and the Head of the Division for the Nottingham Digestive Diseases Centre, University of Nottingham

Biomarkers in Non-Alcoholic Fatty Liver Diseases

- Use of imaging biomarkers to stratify patients with NAFLD
- Novel methods in MRI
- Application of metabolic imaging in NAFLD

14:50-15:40

50 MINUTE ROUNDTABLE DISCUSSIONS:

TABLE 1: Clinical Trial Design

SVEN FRANCQUE

Chairman, Division of Gastroenterology and Hepatology, Antwerp University Hospital, Belgium

TABLE 2: Liver biopsy; the gold standard

ANDREW FOWELL

Consultant Hepatologist, Queen Alexandra Hospital

- 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.

TABLE 3: Collaborative projects: academia, healthcare providers, industry

JULIA BROSNAN

Senior Director, External Collaborations and Scientific Alliances, Pfizer, USA

TABLE 4: Determining clinical endpoints

STEFANO BELLENTANI

Chief of Gastrenterology and Hepatology, Clinica Santa Chiara, Switzerland

TABLE 5: Insulin resistance and hyperinsulinemia

AMALIA GASTALDELLI

Head of Cardiometabolic Risk Lab, Italian National Research Council, Italy

JERRY COLCA

CSO, Cirius Therapeutics

14:50-15:15

RICHARD TORSTENSON

Regulatory Advisor, Allergan

Clinical and regulatory pathways in NAFLD - TBC

15:15-15:40

MICHAEL FUCHS

Professor of Medicine, Virginia Commonwealth University and Chief of Hepatology & Liver Transplantation, McGuire VA Medical Center, USA

Screening for NAFLD in special populations

- NAFLD screening is not recommended for the general population, but can it be justified for T2DM and/or obesity?
- What screening tools can be effectively utilized for these populations and how should they be applied?

15:40-16:25 Afternoon Refreshments / One-to-One Meetings / Even Numbered Poster Presentations

16:25-16:50

ANDREAS GEIER

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

Integrating NAFLD Screening into secondary and tertiary care

- NAFLD screening is currently not recommended in the general population, though 20-30% are affected
- NAFLD diagnostic algorithms include non-invasive scores and elastometry as primary and advanced tools
- Automated screening tools in primary care as well as platforms for secondary NAFLD diagnostics are urgently needed

NOVEL BIOMARKERS AND DIAGNOSTIC TOOLS

16:55-17:10

POSTER COMPETITION WINNER TALKS

17:10-17:35

RUI CASTRO

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

miRNAs as novel biomarkers and diagnostic tools

Recent evidences have highlighted the role of microRNAs as key molecular triggers of NAFLD, by participating in the development of adipose tissue dysfunction and insulin resistance, up to their pathological role on the different liver cell types, during disease progression. Several current basic and clinical investigations have pinpointed the capacity of miRNAs to act as accurate non-invasive diagnostic and prognostic biomarkers for NAFLD, particularly those circulating within extracellular vesicles, as an alternative to the limitations posed by liver biopsy-based findings. Finally, different molecules targeting key miRNAs participating in NAFLD pathogenesis have shown promise in preclinical development, inspiring new efforts in achieving its safe, successful translation into the clinic.

16:25-16:50

WEILIN XIE

Senior Principal Scientist, Celgene

Targeting fibrotic component of NASH

PRECLINICAL & TRANSLATIONAL STRATEGY AND NEW TARGETS FOR TREATMENT OF NASH/ FIBROSIS

16:55-17:10

POSTER COMPETITION WINNER TALKS

17:10-17:35

FATEMEH AKHLAGHI

Professor & Ernest Mario Distinguished Chair in Pharmaceutics, The University of Rhode Island, USA

Pharmacokinetics challenges associated with drug development in NAFLD/NASH

A significant effort is underway to develop effective therapeutic options to treat NAFLD, NASH, or fibrosis. Expression and activity of drug-metabolizing enzymes and xenobiotic transporters are believed to be affected by these disease state. This project aims to develop a physiologically based pharmacokinetic (PBPK) model to allow prediction of drug disposition in patients with NAFLD. We have established a unique and comprehensively-characterized repository of human livers, histologically graded for NASH and fibrosis. Utilizing an innovative non-targeted mass spectrometry-based proteomics technique, we have quantified the relative expression of hepatic DME and xenobiotic transporters. The PBPK modeling approach using protein expression data from diseased tissue will be helpful for the ongoing drug development in the area of NAFLD and diabetes.

16:25-16:50

ALEX MIRAS

Senior Clinical Lecturer in Endocrinology, Department of Metabolism, Digestion and Reproduction, Imperial College, UK

The impact of medical devices on diabetes and fatty liver disease

- Presentation of the most commonly used medical devices
- Effects of the devices on glucose and weight
- Effects of the devices on fatty liver disease

METABOLIC S CLINICAL DEVELOPMENT SYNDROME, DIABETES AND NAFLD SYMPOSIUM

16:55-17:10

POSTER COMPETITION WINNER TALKS

17:10-17:35

ROYCE VINCENT

Consultant Chemical Pathologist and Honorary Senior Lecturer, Department of Clinical Biochemistry, King's College Hospital NHS Foundation Trust, UK

Metabolic/bariatric surgery and NAFLD - TBC

How bile acids can impact NAFLD and how the alerted BA metabolism after surgery may be a potential mechanism for improvement in NAFLD

17:35-18:00

BEVIN GANGADHARAN

Research Associate, Oxford University

Novel serum biomarkers for NAFLD Identified using proteomics

Several biomarkers identified using proteomics which successfully track disease progression including ones which can discriminate healthy individuals from NAFL, NAFL from NASH and the stages of lobular inflammation. We have developed the first antibody-free serum protein biomarker assay and are currently looking into developing a rapid point-of-care test (POCT) which would work with a single drop of finger pricked capillary blood. We are the first to publish a novel method which uses a universal calibration mix which can be used for any protein biomarker and up to six different biomarkers in a single acquisition. We are the only group who have been successful in using this novel method which has the potential to improve biomarker detection and quantitation in the clinic.

17:35-18:00

HENNING GRØNBÆK

Professor, Department Hepatology & Gastroenterology, Aarhus University Hospital

Crosstalk between adipose tissue insulin resistance and liver macrophages in non alcoholic fatty liver disease - TBC

17:35-18:00

ANJA GEERTS

Professor, Department of Gastroenterology and Hepatology, University of Ghent, Belgium

The pitfalls of bariatric surgery in NAFLD patients

Bariatric surgery is often presented as a therapy for NAFLD. However, the risk of alcohol addiction is a major problem in this population. Development of rapid progressive liver failure is the danger that we will be increasingly confronted with.

18:00-18:25

DEVANAND SARKAR

Professor, Virginia Commonwealth University, USA

RNAi strategy for the treatment of NASH: focus on astrocyte elevated Gene-1 (AEG-1)

AEG-1 is overexpressed in NASH patients. A hepatocyte-specific AEG-1 transgenic mouse develops spontaneous NASH and a hepatocyte-specific conditional AEG-1 knockout mouse shows resistance to high fat diet (HFD)-induced NASH.

- AEG-1 induces NASH by inhibiting PPARα, thus fatty acid β-oxidation, by increasing translation of fatty acid synthesizing enzymes, and by activating NF-κB, a master regulator of pro-inflammatory cytokines.
- Treatment with hepatocyte-targeted nanoparticles delivering AEG-1 siRNA prevented development of NASH in mice fed HFD.

18:00-18:25

TONI VIDAL-PUIG

Professor of Molecular Nutrition and Metabolism, University of Cambridge; Associate Director MRC Metabolic Disease Unit; Honorary Consultant in Metabolic Medicine Addenbrooke's Hospital; Scientific Director Cambridge Phenomics Centre;Associate Faculty Sanger Institute

Adipose tissue expandability, lipotoxicity and fatty liver

Our main hypothesis is that the link between obesity and metabolic complications such as NAFLD is the ectopic accumulation of lipids. Based on this the intellectual framework of our approaches include strategies to improve adipose tissue storage capacity, promote energy dissipation and modulation of lipid networks to prevent toxic lipid formation. More specifically we will focus on the early stages of NAFLD and the transition to NASH. Also I will provide information about current efforts to identify preclinical models to study NAFLD/NASH suitable for translation.

17:35-18:00

SVEN FRANCQUE

Chairman, Division of Gastroenterology and Hepatology, Antwerp University Hospital, Belgium

The adipose tissue-liver axis in NAFLD: implications for therapy

Adipose tissue dysfunction and inflammation is considered an important aetiological factor in the pathogenesis of NAFLD. Not only substrates released or insufficiently buffered by the adipose tissue, but also adipokines, inflammatory cytokines and immune cells originating from the adipose tissue impact on the liver. Hepatokines exert reciprocal influences. The adipose tissue-liver crosstalk is not only important in understanding NAFLD pathophysiology, but also in understanding the extra-hepatic consequences associated with NAFLD. This concept is also relevant in the treatment of NAFLD, which requires a systemic approach. Several drugs that impact on adiposity or adipocyte function, such as glucagon-like peptide 1 receptor agonists or peroxisome proliferator-activated receptor gamma agonists used for the treatment of obesity and/or diabetes, could therefore also be considered for the treatment of NAFLD. Liraglutide and pioglitazone have already been tested in that context. Interestingly, several of the new drugs in the pipeline for NAFLD build further on this concept and hold promise. The presentation will summarize current data on the adipose tissue-liver axis in NAFLD and discuss its potential therapeutic relevance.

18:25	Chair's Closing Remarks / End of Day One
1825-19:25	Networking Drinks Reception

08:00-08:55 Registration & Refreshments

08:55-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks:**

09:00-09:35

KEYNOTE ADDRESS:

ROGER WILLIAMS (Reserved)

Director of Research, Lancet Commission for Liver Disease in the UK

The synergy of alcohol and obesity in NASH

09:35-10:10

NIKOLAI NAOUMOV

Executive Director, Hepatology Science and Innovation, Novartis, Switzerland

Progress in developing combination therapies – Novartis' approach

- 2019 is an important milestone in NASH drug development with results and learnings from the first Phase 3 trials and several large Phase 2 trials becoming available.
- Recognizing the complex pathophysiology of NASH and patients' heterogeneity, Novartis' approach has been focused on developing Tropifexor - a highly potent, multi-modal, non-steroid FXR agonist - as monotherapy, as well as a therapy-backbone of several combinations, with both internal compounds and through inter-company collaborations to optimally serve the spectrum of NASH patients.
- Accumulating results from clinical studies with compounds targeting different molecular pathways along with biomarker development provide the evidence-base for tailoring combination therapies according to the disease stage and existing co-morbidities.

10:10-10:40

SVEN FRANCQUE

Chairman, Division of Gastroenterology and Hepatology, Antwerp University Hospital, Belgium

NAFLD as a risk factor for cardiovascular disease

The primary cause of death in patients with NAFLD is cardiovascular disease (CVD) and NAFLD patients seem to be at increased risk compared to a matched control population, pointing towards an independent contribution of NAFLD to the development of cardiovascular morbidity and mortality. The close intertanglement of NAFLD and the metabolic syndrome make it difficult to compile hard clinical evidence to substantiate the latter statement, although a lot of clinical data are supportive and many pre-clinical and clinical data give insight into the potential mechanistics underlying the association between NAFLD and CVD. With the emerging treatments for NAFLD, some of which also impact on metabolic factors that also impact CVD, the issue becomes particularly relevant, as NAFLD pharmacotherapy must not only be safe, but some might have a beneficial effect on CVD outcomes, which might represent an additional benefit beyond the hepatological endpoints and play a role in their indication and positioning. The presentation will summarize the current knowledge and its potential implications for the overall clinical care of patients with NAFLD.

10:40-11:25 Morning Refreshments / One-to-One Meetings / Odd Numbered Poster Presentations

11:25-11:55

RECENT UPDATES IN NASH PATHOGENESIS

11:55-12:20

YARON ILAN

Professor of Medicine, Gastroenterology & Liver Units, Director, Department of Medicine, Hebrew University-Hadassah Medical Center

Oral immune therapy for NASH: Methods for targeting the gut

- The gut immune system and the gut microbiome are attractive new targets for the treatment of NASH
- Oral immunotherapy is a novel method for targeting the gut for alleviating the systemic inflammatory response associated with NASH
- This method enables immune modulation without immune suppression and had a high safety profile.
- It can be combined with additional drugs for improving efficacy.

12:20-12:45

ALEXANDER WREE

Professor, Department of Hepatology and Gastroenterology, Charité Berlin, Germany

Inflammasome activation in NASH - basic principle and therapeutic target

- Chronic hepatic inflammation is a hallmark in the progression of non-alcoholic steatohepatitis (NASH)
- Inflammasome cascades are over-activated in a group of NASH-patients
- NLRP3 inflammasome signaling explains key mechanisms in murine models of NASH
- Targeting the inflammasome complex using a range of novel drugs

12:45-13:10

STEFANO GINANNI CORRADINI

Associate Professor,Division of Gastroenterology, Department of Translational and Precision Medicine, University "Sapienza" of Rome Italy

The role of PNPLA3 variants and lysosomal acid lipase activity in NASH pathogenesis

NASH pathogenesis is multifactorial and not completely clear. The human patatin-like phospholipase domain-containing 3 (PNPLA3) is a key regulator of lipid droplets in hepatocytes and hepatic stellate cells. The I148M (rs738409) and the more recently discovered E434K (rs2294918) PNPLA3 sequence variants increase the risk of progressing into the entire spectrum of non-alcoholic fatty liver disease and NASH. The mechanisms underlying this effect seem to be due to direct changes in hepatocyte and hepatic stellate cells lipid droplet

CLINICAL DEVELOPMENT

11:55-12:20

STEFANO BELLENTANI

Chief of Gastrenterology and Hepatology, Clinica Santa Chiara, Switzerland

Global epidemiology of NAFLD/NASH: the new emergency epidemic?

- Update on the global epidemiology of NAFLD/NASH;
- The natural history of NAFLD/NASH: towards cardiovascular diseases or cirrhosis and HCC ?
- The incidence and the future global burden of NASH/NAFLD

12:20-12:45

WOLF PETER HOFMANN

Professor, Gastroenterologie am Bayerischen Platz (GBP) Germany

Establishing a NAFLD real world cohort: Experience from Germany

Real life cohorts may help to better understand the natural history of NAFLD and to identify individuals who may benefit from future therapies. Here we present the first data from a german NAFLD real world cohort and discuss how follow up data can be used to capture clinical end points and pharmacovigilance.

12:45-13:10

KARIN CONDE-KNAPE

CVP Cardiovascular and Liver Disease Research, Novo Nordisk, Denmark

Anti-inflammatory/anti-fibrotic mechanisms for the treatment of NASH

- Brief overview of anti-inflammatory/ antifibrotic MOA for the treatment of NASH
- Clinical vs preclinical data
- Are preclinical models predictive at all for these MOA?

METABOLIC S CLINICAL DEVELOPMENT YNDROME, DIABETES AND NAFLD SYMPOSIUM

11:55-12:20

LUCA VALENTI

Associate Professor of Internal Medicine, University of Milan, Italy

Genetics of NAFLD

12:20-13:10

50 MINUTE ROUNDTABLE DISCUSSIONS:

TABLE 1: **Regulation of Inflammation and fibrosis**

VINOOD PATEL

Reader, University of Westminster, UK

TABLE 2: **Translational value of preclinical models of NAFLD**

RUI CASTRO

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

TONI VIDAL-PUIG

Professor of Molecular Nutrition and Metabolism, University of Cambridge, UK

TABLE 3: **NAFLD & liver transplants**

MICHAEL FUCHS

Professor of Medicine, Virginia Commonwealth University and Chief of Hepatology & Liver Transplantation, McGuire VA Medical Center, USA

TABLE 4: **Prevention and control – influence of nutrition and lifestyle**

JOANNA DOWMAN

Consultant Hepatologist, Queen Alexandra Hospital, UK

12:45-13:10

biology. Lysosomal acid lipase (LAL) is an enzyme that hydrolyzes triglycerides and cholesteryl esters in several cells including hepatocytes, Kupffer cells, bone marrow-derived monocyte-macrophages and platelets. Recent data suggest that transcriptional or post-transcriptional reductions of LAL activity in blood have relevance for the pathogenesis of NASH.

12:45-13:10

Continued

12:20-13:10

Continued

13:10-14:10 Lunch

14:10-15:00

PANEL DISCUSSIONS:

Combination Therapies

NIKOLAI NAOUMOV (Moderator)
Executive Director, Hepatology Science and Innovation, Novartis, Switzerland

ELIAS PAPATHEODOROU
CEO, Genkyotex, Switzerland

MICHAEL FUCHS
Professor of Medicine, Virginia Commonwealth University and Chief of Hepatology & Liver Transplantation, McGuire VA Medical Center, USA

SVEN FRANCQUE
Chairman, Division of Gastroenterology and Hepatology, Antwerp University Hospital, Belgium

EDUARDO MARTINS
Vice President, Clinical Development, Allergan

SENIOR REPRESENTATIVE (Reserved)
FDA

14:10-14:35

CHRISTOPHE ARBET-ENGELS
Chief Medical Officer, Executive Vice President, Late Development & Medical Affairs, Poxel
The Poxel NASH portfolio (PXL770 and PXL065), their programs and available results

14:35-15:00

REBECCA TAUB
Chief Medical Officer and President, Research & Development, Madrigal Pharmaceuticals, USA
Phase 3 Clinical Development of Resmetirom

14:10-14:35

WILLIAM ALAZAWI
Reader in Hepatology, Consultant Hepatologist, Barts Liver Centre, Queen Mary University of London
Case Study: Study of 18 million healthcare records from European adults from the UK, Netherlands, Italy and Spain for Diabetes, NAFLD, liver cirrhosis and liver cancer - TBC

14:35-15:00

ULF RISÉRUS
Associate Professor in clinical nutrition, Head of Clinical Research Unit, Uppsala University, Sweden
Role of diet in the treatment of NAFLD

- The influence of modulating the amount of fat and carbohydrates in the diet
- The influence of type dietary fatty acids on liver fat content – new lessons from trials
- Optimal diet for prevention of NAFLD and NASH?

15:00-15:25

MICHAEL FUCHS

Professor of Medicine, Virginia Commonwealth University and Chief of Hepatology & Liver Transplantation, McGuire VA Medical Center, USA

Novel serum biomarkers mirroring the transition from steatosis to steatohepatitis

- Linking oxysterols to insulin resistance and inflammasome activation
- Identification of new NASH serum biomarkers and Cyp7b1 as new target for NASH drug development

15:00-15:25

HAROLD H. SHLEVIN

Chief Executive Officer, Galectin Therapeutics Inc.

Phase 3 trial in compensated NASH cirrhotics - TBC

- Novel endpoint and special considerations made to be able to minimize the invasive testing of patients as a means to help both with enrollment and with retention over the 2 year duration of treatment.
- How our Phase 2 results served to inform about this endpoint.

15:00-15:25

ANGELA SLITT

Professor, Department of Biomedical and Pharmaceutical Sciences, University of Rhode Island, USA

Topic: How environmental exposures are linked to liver disease

15:25-15:50

SENIOR REPRESENTATIVE

Invitation Out

15:25-15:50

HUBERT CHEN

Chief Medical Officer, Metacrine

Sustained FXR agonist as optimized, best-in-class treatment for NASH

Activating farnesoid X receptor (FXR) has been clinically validated to improve non-alcoholic steatohepatitis (NASH) and fibrosis, although common drawbacks include increased low-density lipoprotein cholesterol (LDL-C) and moderate-severe pruritus within the therapeutic dose range. Recently, transient non-bile acid FXR agonists have shown limited efficacy with once-daily dosing, likely due to suboptimal target engagement. Sustained FXR agonist with a novel non-bile acid structure and enhanced potency, such as Metacrine's MET409, has demonstrated prolonged FXR engagement and an encouraging safety and tolerability profile – including a lack of adverse impact on LDL-C levels – in early clinical trials. These results demonstrate the potential of sustained FXR agonism to deliver a differentiated, best-in-class profile.

15:25-15:50

RUI CASTRO

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

Inter-organ crosstalk in NAFLD

NAFLD highly associates with components of the metabolic syndrome, such as obesity and type II diabetes, two of the best characterized NAFLD risk factors. In fact, NAFLD is a complex and multifactorial disease, and its pathogenesis also involves the adipose tissue, skeletal muscle and gut, in a bilateral crosstalk. As such, NAFLD triggering and progression remains incompletely understood, particularly regarding the signaling mechanisms responsible for disruption of extra-hepatic homeostasis.

15:50-16:15

SENIOR REPRESENTATIVE

Invitation Out

15:50-16:15

DAVID BAKER

Senior Director, Head of Metabolism, AstraZeneca

AstraZeneca Programs and available results - TBC

- AstraZeneca's ambition in discovering new therapies in NASH
- Challenges with pre-clinical models of NASH
- Understanding genetic drivers of NASH to develop novel approaches to treating the disease.

15:50-16:15

CHRIS BYRNE

Professor Endocrinology & Metabolism, Human Development and Health Academic Unit, Faculty of Medicine, The \Institute of Developmental Sciences (IDS), University of Southampton, UK

Diabetes and NAFLD: a vicious spiral affecting both diseases

- Risk of diabetes with NAFLD
- Worsening insulin resistance and glycaemic control with NAFLD affecting diabetes treatments
- Diabetes management with end stage liver disease.

16:15 Conference Close

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