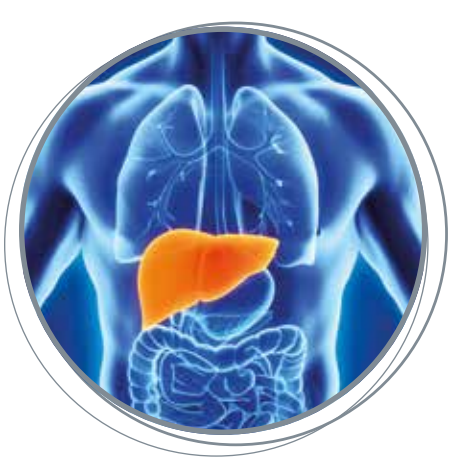
Global Engage

GLOBAL NASH CONGRESS 2018

— LONDON UK —

26-27 February 2018



#NASHGE18

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WARM WELCOME

Global Engage

Global Engage is pleased to announce the **Global NASH Congress 2018**, which will be taking place 26-27 February 2018 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:

ANNA MAE DIEHL
Professor of Medicine, Duke University USA

STEPHANIE O. OMOKARO
Lead Medical Officer, DGIEP Liver Team IV, Center for Drug Evaluation and Research, Food and Drug Administration, USA

DEAN HUM
Chief Operating Officer and Chief Scientific Officer (CSO/COO), Member of the Executive Board, Genfit SA, France

QUENTIN ANSTEE
Professor of Experimental Hepatology & Consultant Hepatologist, Institute of Cellular Medicine, Newcastle University, UK

DAY 1 - TRACK 1

Pathogenesis of NASH

Exploring factors such as:

- Genetic susceptibility
- Metabolic syndrome
- Mitochondrial dysfunction and apoptosis
- Insulin resistance
- The gut microbiome

NASH & Related Health Conditions

- Diabetes
- Cardiovascular disease
- Hepatocellular carcinoma

DAY 1 - TRACK 2

Regulation & Preclinical Strategy

- Guidance on clinical endpoints
- Business development strategy
- Regulatory pathways for metabolic vs antifibrotic treatment
- Target discovery and validation

Treating NASH

- When pharmaceutical intervention is necessary
- The potential for repurposing drugs or combination therapy
- Novel treatment methods

DAY 2 - TRACK 1

Non-Invasive Biomarkers

- Update from the LITMUS Consortium
- Review of current and potential biomarkers for each stage

Tools for Research & Diagnosis

- Non-invasive cirrhosis assessment
- Liver biopsies – the gold standard
- Developments in liver biopsy image analysis
- Improving experimental models

DAY 2 - TRACK 2

Showcase of Therapeutics in Development

- Presentations from some of the most exciting companies in NASH drug development

ROUNDTABLE DISCUSSIONS

- Table 1 – The road to drug approval for NASH – What does it take to make new treatments available to patients
- Table 2 – Gut-liver axis & inflamation: From pathogenesis to potential therapy targets
- Table 3 – NASH and diabetes

ROUNDTABLE DISCUSSIONS

- Table 1 – Different in vitro models for studying liver function and disease
- Table 2 – Determining clinical endpoints
- Table 3 – Collaboration betwen academia, healthcare providers and industry

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ELLEGAARD GÖTTINGEN MINIPIGS

STEFANO BELLENTANI
Chief of Gastroenterology and Hepatology, Clinica Santa Chiara, Locarno, Switzerland

HANNELE YKI-JÄRVINEN
Professor of Medicine, University of Helsinki, Finland

ANNA MAE DIEHL
Professor of Medicine, Duke University USA

INA BERGHEIM
Professor of Molecular Nutritional Science, Department of Nutritional Sciences, University of Vienna, Austria

JÖRN SCHATTENBERG
Attending Physician, Department of Medicine, University Medical Center Mainz, Germany

RICHARD TORSTENSON
Senior Regulatory Affairs Specialist, Novo Nordisk, Denmark

MANUEL BAADER
Principal Scientist, CardioMetabolic Diseases Research, Boehringer Ingelheim Pharma, Germany

MANU CHAKRAVARTHY
Chief Medical Officer and SVP Clinical Development, Axcella Health, USA

YARON ILAN
Director Department of Medicine, Hebrew University-Hadassah Medical Center, Jerusalem, Israel

CHRISTOPHER BYRNE
Professor of Endocrinology & Metabolism, Faculty of Medicine, University of Southampton, UK

JEAN-FRANÇOIS DUFOUR
Director UVCM Hepatology, University of Bern, Switzerland

ERIC HUGHES
Global Development Unit Head, Immunology & Dermatology, Novartis

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Professor of Experimental Hepatology & Consultant Hepatologist, Institute of Cellular Medicine, Newcastle University, UK

JULIA BROSNAN
Senior Director, External Collaborations and Scientific Alliances, Internal Medicine Research Unit, Pfizer Inc., US

VICTOR DE LÉDINGHEN
Professor, Investigation Center of Liver Fibrosis, Bordeaux University Hospital, France

MORRIS BIRNBAUM
Senior Vice President and Chief Scientific Officer, Internal Medicine Research Unit, Pfizer, USA

MAGNUS INGELMAN-SUNDBERG
Professor, Section Head, Vice Chairman, Department of Physiology and Pharmacology, Karolinska Institutet, Sweden

MORTEN HANSEN
Senior International Medical Manager, Novo Nordisk, Denmark

MAGDA GUNN
Scientific Project Manager Responsible Strategic Area Diabetes & Metabolic Disorders, Innovative Medicines Initiative, Belgium

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Lead Medical Officer, DGIEP Liver Team IV, Center for Drug Evaluation and Research, Food and Drug Administration, USA

EMMANUEL TSOCHATZIS
Senior Clinical Lecturer and Honorary Consultant in Hepatology, UCL Institute for Liver and Digestive Health, Royal Free Hospital, UK

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

DEAN HUM
Chief Operating Officer and Chief Scientific Officer (CSO/COO), Member of the Executive Board, Genfit SA, France

SHARON COLLINS PRESNELL
Chief Scientific Officer, Organovo & President, Samsara

DIANA JULIE LEEMING
Head of Fibrosis department, Nordic Bioscience, Denmark

PIERRE BEDOSSA
President of the European Society of Pathology, Director of the Department of Pathology, Physiology and Imaging, Hôpital Beaujon, Université Paris Diderot, France

JERRY COLCA
Vice President for Research and Development, Cirius Therapeutics, USA

ROBERT GOLDIN
Professor of Liver & GI Pathology, Imperial College London, UK

REBECCA TAUB
Chief Medical Officer and Executive Vice President, Research & Development, Madrigal Pharmaceuticals, USA

NATALIA ROSSO
Senior Researcher, Italian Liver Foundation, Italy

GYONGYI SZABO
Professor and Vice Chair for Research, Department of Medicine, University of Massachusetts, USA

ISABELLE LECLERCQ
Professor, Laboratory of Hepato-Gastroenterology, School of Medicine, Université Catholique de Louvain, Belgium

ROBERT WALCZAK
EVP and Head of Research, Genfit SA, France

PETER MOL
Principal Clinical Assessor, Medicines Evaluation Board; Vice-Chair, EMA Scientific Advice Working Party; Assistant Professor, University Medical Center Groningen, The Netherlands

EDGAR CHARLES
Clinical Development Lead, Fibrosis R&D, Bristol-Myers Squibb, USA

DAVID SHERIDAN
(Track Chair)
Associate Professor and Honorary Consultant Hepatologist, Plymouth Hospitals NHS Trust, UK

CONFIRMED SPEAKERS

JEAN-LOUIS ABITBOL
Chief Medical Officer, Inventiva, France

RAJARSHI BANERJEE
CEO, Perspectum Diagnostics

JON RIEK
Vice President of Musculoskeletal & Metabolic Imaging, BioTelemetry Research

OLOF DAHLQVIST LEINHARD
Chief Scientific Officer, AMRA

SENIOR REPRESENTATIVE
Cellular Dynamics International, a FUJIFILM company

ALDO TRYLESINSKI
Executive Medical Director, Non Viral Liver Disease, Intercept Pharmaceuticals, France

NIKOLAOS PYRSOPOULOS
Professor and Chief, Division of Gastroenterology and Hepatology; Medical Director Liver Transplantation, Rutgers New Jersey Medical School, USA

SENIOR REPRESENTATIVE
Resonance Health

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks:**
David Sheridan Associate Professor and Honorary Consultant Hepatologist, Plymouth Hospitals NHS Trust, UK

09:00-09:35

KEYNOTE ADDRESS:
STEFANO BELLENTANI
Chief of Gastroenterology and Hepatology, Clinica Santa Chiara, Locarno, Switzerland

NAFLD and NASH global epidemiology

The burning of Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH) (in U.S.A. it is already the second cause of liver transplantation), the development of novel diagnostic tools and new treatments (more than 130 clinical trials testing new drugs for NASH are ongoing around the world) put NASH to the center of the attention of all the hepatologists worldwide. NASH is not only the hepatic manifestation of the metabolic syndrome, but it is also a chronic disease, that could evolve to cirrhosis, hepatocellular carcinoma, or cardiovascular disease and in other types of cancer. It is time to put NAFLD at the center of the attention of all the practitioners and specialists involved in the management of this very common chronic disease that affects 25% of the general population. My speech would try to offer to the family doctors, the general practitioners, all the internists, and all the industries involved the opportunity to have an update on the epidemiology and natural history of this very common disease. It is also probably time to change the nomenclature and to change the strategies of management and treatment for NASH: move from a negative to a positive definition of this disease and from a single doctor approach to a multidisciplinary team (MDT) approach.

09:35-10:00

HANNELE YKI-JÄRVINEN
Professor of Medicine, University of Helsinki, Finland

Molecular heterogeneity of NAFLDs in humans

10:00-10:30

SOLUTION PROVIDER PRESENTATION:
JON RIEK
Vice President, Musculoskeletal & Metabolic Imaging, BioTel Research

OLOF DAHLQVIST LEINHARD
Chief Scientific Officer & Co-Founder, AMRA

Body composition in NASH clinical trials

Starting a non-alcoholic steatohepatitis (NASH) clinical trial, but you're still using BMI to track body composition? While BMI provides a rough estimate of how over- or under-weight a person is, it doesn't tell you what portion of the weight is muscle or fat, nor how these different tissue types are affected by treatment. Discover alternative, noninvasive imaging methods to determine body composition, including:

- The advantages of noninvasive imaging methods.
- When to use ultrasound, DXA, CT and MRI to measure body composition and how to successfully implement these modalities in clinical trials.
- Body composition measurements from rapid, highly standardized, whole-body MRI.

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

11:40-12:15

KEYNOTE ADDRESS:
ANNA MAE DIEHL
Professor of Medicine, Duke University USA

NASH now

- Summarize data on NAFLD prevalence & natural history
- Update information on NASH pathogenesis
- Discuss treatments that target therapeutic targets to inhibit/reverse NASH

PATHOGENESIS

12:15-12:40

ISABELLE LECLERCQ
Professor, Laboratory of Hepato-Gastroenterology, School of Medicine, Université Catholique de Louvain, Belgium

Topic: Brown adipose tissue and NASH – Title TBC

TRACK CHAIR: David Sheridan Associate Professor and Honorary Consultant Hepatologist, Plymouth Hospitals NHS Trust, UK

REGULATORY ASPECTS & PRECLINICAL STRATEGY

12:15-12:40

PETER MOL
Principal Clinical Assessor, Medicines Evaluation Board; Vice-Chair, EMA Scientific Advice Working Party; Assistant Professor, University Medical Center Groningen, The Netherlands

Targeting NASH, what is the impact on cardiovascular outcomes?

EMA developed a reflection paper on assessment of cardiovascular risk of 4medicinal products for the treatment of cardiovascular and metabolic diseases (EMA/CHMP/50549/2015). Considering that CV outcomes may be more frequent than liver outcomes in the population with NASH, evaluation of the impact of NASH treatments on CV outcomes requires specific attention in designing clinical trials. The talk will discuss the impact of this thinking on drug development from a regulator's perspective.

TRACK CHAIR:

12:40-13:10

SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
Cellular Dynamics International, a FUJIFILM company

12:40-13:10

SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
Resonance Health

13:10-14:10 Lunch

TRACK CHAIR: Nikolaos Pyrsopoulos Professor and Chief, Division of Gastroenterology and Hepatology; Medical Director Liver Transplantation, Rutgers New Jersey Medical School, USA

TRACK CHAIR:

14:10-14:35

INA BERGHEIM

Professor of Molecular Nutritional Science, Department of Nutritional Sciences, University of Vienna, Austria

Non-alcoholic fatty liver disease and nutrition: Impact of dietary pattern

Non-alcoholic fatty liver disease (NAFLD) is by now one of the most common liver diseases world-wide. Besides genetic predisposition, life-style factors including general over-nutrition and dietary pattern e.g. a diet rich in saturated fats and sugar seem to be critical in the onset but also progression of the disease. Indeed, results of animal and human studies suggest that certain macronutrients not only alter hepatic de novo lipogenesis but also modulate intestinal microbiota and barrier function thereby altering the gut-liver axis and promoting the development of NAFLD. Here, new findings on the interplay of dietary pattern and the development of NAFLD with a specific focus on gut liver axis will be highlighted.

14:10-14:35

STEPHANIE O. OMOKARO

Lead Medical Officer, DGIEP Liver Team IV, Center for Drug Evaluation and Research, Food and Drug Administration, USA

FDA regulatory considerations for NASH clinical trial endpoints

There are currently no drugs approved for the treatment of adult or pediatric NASH in the U.S. This presentation will describe drug approval pathways in the US, including regular approval and accelerated approval under Subpart H or Subpart E, in the context of development of drug products intended to treat NASH.

14:35-15:00

JÖRN SCHATTENBERG

Attending Physician, Department of Medicine, University Medical Center Mainz, Germany

Lifestyle intervention in NASH – Backbone of therapy or ineffective?

Talk will outline dietary and physical activity interventions. Highlights a potential Backbone for pharmacotherapy.

14:35-15:00

ERIC HUGHES

Global Development Unit Head, Immunology & Dermatology, Novartis

Targeting different pathways of NASH pathogenesis using single and combination therapies

- NASH pathogenesis involves multiple pathways of liver injury and disease progression – metabolic dysregulations, inflammatory signaling, hepatocyte ballooning and apoptosis, liver fibrosis;
- Novartis is addressing the unmet needs in NASH with a broad portfolio targeting several pathogenic pathways and focusing on the moderate-severe spectrum of NASH;
- The regulatory path for exploring new molecular entities in combination regimens has become more defined which facilitates optimized therapies based on complementary mechanisms;
- Broad internal programs as well as external collaborations will be important in bringing the best treatment options to patients

15:00-15:25

NATALIA ROSSO

Senior Researcher, Italian Liver Foundation, Italy

Role of Translational Research in NAFL/NASH

- The increasing prevalence of obesity, and thus of NAFL/NASH, at a young age is challenging the future of the global care system. In the next decade, metabolic-related liver disorders will be the most frequent indication for liver transplantation
- Progresses in the understanding of the pathogenesis of NAFL/NASH allowed the identification of some molecular pathways involved in the damage. However, due to its complexity, the full process has not been fully unraveled.
- No effective therapeutic strategies are defined – changes in the lifestyle remain the only alternative.

15:25-15:50

JEAN-FRANÇOIS DUFOUR

Director UVCM Hepatology, University of Bern, Switzerland

Topic: NASH & HCC

15:00-15:25

ROUNDTABLE DISCUSSIONS SESSION 1:

1) The road to drug approval for NASH – What does it take to make new treatments available to patients

ELMER SCHABEL

Clinical Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

PETER MOL

Principal Clinical Assessor, Medicines Evaluation Board; Vice-Chair, EMA Scientific Advice Working Party; Assistant Professor, University Medical Center Groningen, The Netherlands

2) Gut-liver axis & inflammation: from pathogenesis to potential therapy targets

GYONGYI SZABO

Professor and Vice Chair for Research, Department of Medicine, University of Massachusetts, USA

3) NASH and diabetes

MORTEN HANSEN

Senior International Medical Manager, Novo Nordisk, Denmark

*Full details of the roundtable talks can be found at the end of day 1

15:50-16:40 Afternoon Refreshments / Odd Numbered Poster Presentations / One-to-One Partnering Meetings

RELATED DISEASES & COMPLICATIONS OF NASH

16:40-17:05

MANU CHAKRAVARTHY

Chief Medical Officer and SVP Clinical Development, Axcella Health, USA

Intersection of diabetes and NASH – different threads of a common fabric

Given the fragmented natural history of NAFLD, challenges in accurately diagnosing NASH, and lack of efficacious NASH treatments, there is an urgent need for a comprehensive approach to the understanding NAFLD pathogenesis and its management. The urgency is felt especially in the backdrop of the unabated global epidemics of diabetes and obesity. Diabetes is associated with worsening progression and outcomes for NASH, including increased risk for cirrhosis, HCC, and overall mortality. This presentation will discuss intersecting mechanisms between diabetes and NAFLD, positing a single disease continuum with common metabolic underpinnings.

17:05-17:30

CHRISTOPHER BYRNE

Professor of Endocrinology & Metabolism, Faculty of Medicine, University of Southampton, UK

Is NAFLD an independent cardiovascular risk factor?

Non-alcoholic fatty liver disease (NAFLD) is a metabolic liver disease that is strongly associated with type 2 diabetes (T2DM) and other metabolic and vascular risk factors that mediate an increased risk of cardiovascular disease (CVD) in patients with NAFLD. NAFLD encompasses a spectrum of liver disease and in affected individuals NAFLD may progress from simple steatosis to steatohepatitis, liver fibrosis and cirrhosis. This presentation will discuss the theoretical mechanisms linking NAFLD with increased risk of cardiovascular disease, the evidence for NAFLD as an independent CVD risk factor, and NAFLD and CVD risk prediction.

17:30-18:45

ROUNDTABLE DISCUSSIONS SESSION 2:

1) Different in vitro models for studying liver function and disease

MAGNUS INGELMAN-SUNDBERG

Professor, Section Head, Vice Chairman, Department of Physiology and Pharmacology, Karolinska Institutet, Sweden

2) Determining clinical endpoints

MANU CHAKRAVARTHY

Chief Medical Officer and SVP Clinical Development, Axcella Health, USA

3) Collaboration between academia, healthcare providers and industry

MAGDA GUNN

Scientific Project Manager Responsible Strategic Area Diabetes & Metabolic Disorders, Innovative Medicines Initiative, Belgium

4) Title TBC

ALDO TRYLESINSKI

Executive Medical Director, Non Viral Liver Disease, Intercept Pharmaceuticals, France

5) NAFLD and Liver Transplant

NIKOLAOS PYRSOPOULOS

Professor and Chief, Division of Gastroenterology and Hepatology; Medical Director Liver Transplantation, Rutgers New Jersey Medical School, USA

*Full details of the roundtable talks can be found at the bottom of this page

TREATING NASH

16:40-17:05

RICHARD TORSTENSON

Senior Regulatory Affairs Specialist, Novo Nordisk, Denmark

Metabolic vs antifibrotic action for treatment of NASH – impact on clinical and regulatory pathways

Clinical and regulatory pathways are evolving simultaneously as a growing number of pharmacotherapies are being developed for treatment of NASH. The different pharmacodynamics mechanisms/pathways evaluated require specific development strategies and regulatory guidance/requirement are not fully harmonized. Current clinical development approaches and the regulatory landscape will be reviewed and discussed.

17:05-17:30

Invitation Out

17:30-17:55

ROBERT WALCZAK

EVP and Head of Research, Genfit SA, France

Drug repurposing as a strategy to accelerate the identification of new NASH medications

The increasing incidence of NASH is becoming a serious global health issue. Understanding its physiopathology and identifying new drug candidates to treat this condition are formidable challenges taken on by both academia and drug industry, as attested by recent publications and drug candidates in phase 2/3 studies. Repurposing has become a popular method in drug life cycle management, and NASH is no exception. This presentation will discuss recent examples of major drug repositioning studies in NASH. Particular emphasis will be given to programs that aim at potential registration and market access. Emerging trends and technological solutions to improve bench to bedside translatability in NASH will be presented.

17:55-18:20

MANUEL BAADER

Principal Scientist, CardioMetabolic Diseases Research, Boehringer Ingelheim Pharma, Germany

Evaluation of autotaxin as a potential drug target for NASH – a case study

During the last years, non-alcoholic steatohepatitis (NASH) has increasingly attracted the interest of academia and pharmaceutical industry. However, the identification of novel innovative therapeutic concepts and validation of potential drug targets, e.g. autotaxin (ATX) for NASH has proven to be highly challenging. Multiple preclinical studies using knockout animals, lysophosphatidic acid (LPA) receptor antagonists or ATX inhibitors have provided evidence for a potential role of the ATX/LPA axis in liver fibrosis. The aim of this presentation is to illustrate how we have designed an in vitro and in vivo test cascade to evaluate the potential of ATX inhibitors for NASH. Key aspects including human disease link, choice of preclinical models and tools, biomarkers, as well as integration of public and proprietary data will be discussed.

17:55-18:45

Continued

18:20-18:45

YARON ILAN

Director Department of Medicine, Hebrew University-Hadassah Medical Center, Jerusalem, Israel

Oral immunotherapy for NASH: A new class of drugs

Targeting the gut immune system for alleviation of the systemic inflammatory response without immune suppression

- The systemic immune system plays a role in inflammation and fibrogenesis associated with NASH and has become a potential target for drug development.
- Oral immunotherapy is based on targeting components of the gut barrier that serve as a means to alter the immune signals being transported from the gut to the systemic immune system, alleviating the immune-mediated damage in target organs.
- Oral immune therapy-based compounds provide an opportunity for immune modulation without immune suppression, with the advantage of being independent of a single molecular/inflammatory pathway. This method of therapy enables targeting all stages of disease. The high safety profile of these drugs make them ideal for long term use, and for using them in combination with other drugs.

18:45	Chair's Closing Remarks / End of Day One
18:45-19:45	Networking Drinks Reception

DAY 1 (15:00-15:50) ROUNDTABLE DISCUSSIONS SESSION 1:

1) The road to drug approval for NASH – What does it take to make new treatments available to patients

ELMER SCHABEL & PETER MOL

- **DRUG DEVELOPMENT:**
  - Identification of suitable candidates – what sort of "proof of principle" and "proof of concept" is necessary?
  - Clinical studies in NASH:
    - Which sort of patients/population (e.g. suitability of different stages; differences to the "real life" population)
    - Study design (early vs. late, observation time necessary, control treatment (including background), etc.)
- **INTERACTION WITH REGULATORS:**
  - "early access" in the US and EU and its "pre-conditions"
    - Situation for the "first-comers"
    - Need for changes in the "me-too"-situation
  - Interaction with regulatory agencies (Scientific Advice, PIP – and its US equivalences)
  - Development of regulatory guidelines – is it needed?
- **INTERACTION WITH PAYERS/HTAS**
  - What does it need from the side of payer organizations:
    - Appropriate comparators – do they exist?
    - "Demonstration of patient benefit"
    - Joint EMA/HTA advice (equivalent in US or globally?)
- **POST-APPROVAL WORK NEEDED:**
  - Issues to be addressed with regard to efficacy
  - Issues to be addressed with regard to safety
  - Other aspects: Treatment duration (cessation of treatment?)

2) Gut-liver axis & inflammation: from pathogenesis to potential therapy targets

GYONGYI SZABO

4) NASH and diabetes

- Hyperglycemia in NAFLD – the role in disease progression and treatment

MORTEN HANSEN

DAY 1 (17:30-18:45) ROUNDTABLE DISCUSSIONS SESSION 2:

1) Different in vitro models for studying liver function and disease

MAGNUS INGELMAN-SUNDBERG

- Comparison of different models and their properties
- The utility of the models for studying NASH
- Possibilities to mimic drug action in vivo in man and study mechanistic effects of drugs

2) Determining clinical endpoints

MANU CHAKRAVARTHY

3) Collaboration between academia, healthcare providers and industry

MAGDA GUNN

This roundtable offers an opportunity for academics, healthcare providers and industry representatives to come together and discuss their experiences working on collaborative projects, examining both the challenges and the benefits of such arrangements.

4) Title TBC

ALDO TRYLESINSKI

5) NAFLD and liver transplantation: an evolving field

NIKOLAOS PYRSOPOULOS

- The number of patients with NAFLD as an indication on the liver transplant waiting list is increasing both in Europe and the United States
- Challenges encountered with NAFLD patients and their management on the waiting list in regard to metabolic, renal and vascular comorbidities
- The impact of NAFLD on the donor pool
- The prevalence and consequences of post-transplant metabolic syndrome, recurrent and de novo NAFLD
- Managing NAFLD in the post Liver Transplant setting

08:20-09:00 Refreshments

09:00-09:35

KEYNOTE ADDRESS:
QUENTIN ANSTEE

Professor of Experimental Hepatology & Consultant Hepatologist, Institute of Cellular Medicine, Newcastle University, UK

Non-invasive biomarkers for NAFLD in clinical practice and clinical trials

Non-invasive biomarkers for NAFLD in clinical practice and clinical trials

- Currently available non-invasive testing technologies and strategies ("wet" biomarkers and imaging)
- From pragmatic solutions to promising developmental/experimental approaches
- Application in clinical practice and the clinical trial environment

09:35-10:05

SOLUTION PROVIDER PRESENTATION:
RAJARSHI BANERJEE

Perspectum Diagnostics

CEO, Perspectum Diagnostics

Multiparametric MRI and liver disease – finding patients, and measuring drug efficacy

MRI is essential in clinical trials for liver disease to better identify and enrich the patient population under study. Perspectum Diagnostics MR analysis Core Lab provides quantitative MRI metrics that correlate with fat (PDFF), iron (T2*) and fibroinflammatory disease (Liver Inflammation and Fibrosis score). Published research has shown that multiparametric MRI can detect even early liver disease, and predict clinical outcomes. There is a burgeoning interest in using LiverMultiScan™ in clinical practice, as well as in pharmaceutical trials to screen at-risk populations and test efficacy of new treatments in NASH and other liver diseases. In this talk we will examine the data supporting MRI utility in NASH.

10:05-10:30

JULIA BROSNAN

Senior Director, External Collaborations and Scientific Alliances, Internal Medicine Research Unit, Pfizer Inc., US

LITMUS – An industry perspective

- The need for non-invasive biomarkers in NAFLD clinical trials
- The role of Public Private Partnerships in addressing this need
- LITMUS – Liver Investigation: Testing Marker Utility in Steatohepatitis

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

NON-INVASIVE BIOMARKERS CONTD. / ROUNDTABLE DISCUSSIONS

11:40-12:05

DEAN HUM

Chief Operating Officer and Chief Scientific Officer (CSO/COO), Member of the Executive Board, Genfit SA, France

Topic: Genfit's IVD Program

12:05-12:30

VICTOR DE LÉDINGHEN

Professor, Investigation Center of Liver Fibrosis, Bordeaux University Hospital, France

Imaging based technologies for NAFLD in clinical practice

Traditionally, liver biopsy was the investigation to assess the severity of NAFLD and diagnose NASH, but is limited by its invasiveness, poor patient acceptability and sampling variability. Even now, liver biopsy remains the primary assessment in phase 3 NASH trials. This is unsatisfactory as drug development would be very slow, and it is impractical to recommend serial liver biopsies as a standard practice for such a common disorder. There is thus immense interest in developing biomarkers for NAFLD/NASH. In this lecture, we will review current and potential biomarkers for different features of NAFLD. For each biomarker, we will evaluate its accuracy, reproducibility, responsiveness, feasibility and limitations. Finally, while most studies evaluated noninvasive biomarkers against liver histology, we will discuss the prognostic role of these markers.

SHOWCASE OF THERAPEUTICS IN DEVELOPMENT

12:20-12:45

REBECCA TAUB

Chief Medical Officer and Executive Vice President, Research & Development, Madrigal Pharmaceuticals, USA

Title TBC

12:05-12:30

MORRIS BIRNBAUM

Senior Vice President and Chief Scientific Officer, Internal Medicine Research Unit, Pfizer, USA

The etiology and treatment of fatty liver disease

- We understand a lot about the signaling pathways that control fat accumulation
- There are now several promising inhibitors of fat accumulation in the clinic

12:30-12:55

DIANA JULIE LEEMING

Head of Fibrosis department, Nordic Bioscience, Denmark

Neoepitope fragments of extracellular matrix as markers of liver fibrosis: Insights into the clinical and preclinical utilization for unraveling disease pathogenesis

- The extracellular matrix (ECM) is an important player during liver fibrosis, and disease may affect the basement membrane and/or the interstitial matrix of the liver. Thus Nordic Bioscience has developed highly specific neoepitope markers for the evaluation of the structural- and post-translational changes occurring in the liver during liver fibrosis progression.
- These neoepitope ECM markers may be used as markers of disease activity for the evaluation of disease progression, burden of disease as well as drug efficacy in patients with chronic liver disease (CLD).
- Such ECM markers may be utilized as drug development tools when used in combination with in-vitro models such as the Scar-in-a-Jar model, ex-vivo models, and in in-vivo CLD models.

12:30-12:55

DEAN HUM

Chief Operating Officer and Chief Scientific Officer (CSO/COO), Member of the Executive Board, Genfit SA, France

Title TBC

12:55-13:20

EMMANUEL TSOCHATZIS

Senior Clinical Lecturer and Honorary Consultant in Hepatology, UCL Institute for Liver and Digestive Health, Royal Free Hospital, UK

Non-invasive assessment of liver fibrosis in NAFLD

- Established and emerging non-invasive fibrosis markers
- Role of serum markers and elastography
- Screening strategies

12:55-13:20

JERRY COLCA

Vice President for Research and Development, Cirius Therapeutics, USA

Modulation of the mitochondrial pyruvate carrier (MPC) as a treatment for NASH

- Growing evidence demonstrates that the NASH pathology is driven by overnutrition and progressive loss of mitochondrial function resulting in insulin resistance, inflammation, and histological damage to the liver including ballooning and fibrosis.
- MSDC-0602K is a new therapeutic in development directed at the mitochondrial target of TZDs (mTOT), which is also known as the mitochondrial pyruvate carrier (MPC). Modulation of the pyruvate uptake reverses the effects of overnutrition in animal models and protects against and reverses liver damage including fibrosis. MSDC-0602K also reduces insulin resistance in animal models and in man.
- EMMINENCE (NCT02784444) is a Phase 2B clinical trial currently underway evaluating 3 doses of MSDC-0602K in patients with biopsy-proven NASH. This one-year trial will evaluate the potential of this treatment to resolve NASH (by biopsy) and whether histological changes correlate with non-invasive biomarkers.

13:20-14:20 Lunch

14:20-14:50

SOLUTION PROVIDER PRESENTATION: SHARON COLLINS PRESNELL

Chief Scientific Officer, Organovo & President, Samsara

3D Bioprinted Human Liver Tissues for Investigation of Liver Injury and Disease

- General attributes of bioprinted liver tissues
- Achieving disease-relevant phenotypes through multiple strategies
- Chronic drug-induced injury
- Target pathway modulation
- Feeding regimens mimicking the western diet
- Utilizing disease-origin cells
- Comparison of induced & disease-origin models of NASH & fibrosis to clinical specimens

organovo

TOOLS & TECHNIQUES FOR RESEARCH & DIAGNOSIS

14:50-15:15

MAGNUS INGELMAN-SUNDBERG

Professor, Section Head, Vice Chairman, Department of Physiology and Pharmacology, Karolinska Institutet, Sweden

Human 3D liver spheroid models for studies of NASH and other liver diseases

- Phenotypic, transcriptomic, proteomic and metabonomic characterization of the 3D liver spheroids
- Different modes for induction and treatment of steatosis and NASH in the spheroid model
- Tools for mechanistic understanding of the development of NASH

SHOWCASE OF THERAPEUTICS IN DEVELOPMENT CONTD.

14:50-15:15

EDGAR CHARLES

Clinical Development Lead, Fibrosis R&D, Bristol-Myers Squibb, USA

PEG-FGF21: From bench to clinical trials

- Rationale for FGF21-based therapeutics
- Selection of noninvasive biomarkers to establish proof of concept
- Using non-invasive biomarkers to transition from POC to later-stage clinical trials

15:15-15:40

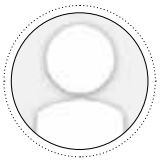
PIERRE BEDOSSA

President of the European Society of Pathology, Director of the Department of Pathology, Physiology and Imaging, Hôpital Beaujon, Université Paris Diderot, France

Liver biopsy as the gold standard for diagnosis

- Histological liver damages in NAFLD are the consequence of a complex association of several pathophysiological mechanisms that can lead to cirrhosis and end-stage liver disease.
- So far, only liver biopsy can evaluate the association and severity of these various lesions, the prognosis of which is highly variable
- Liver biopsy is then recommended when an accurate evaluation of liver tissue damage is needed

15:15-15:40



JEAN-LOUIS ABITBOL

Chief Medical Officer, Inventiva, France

Title TBC

15:40-16:05

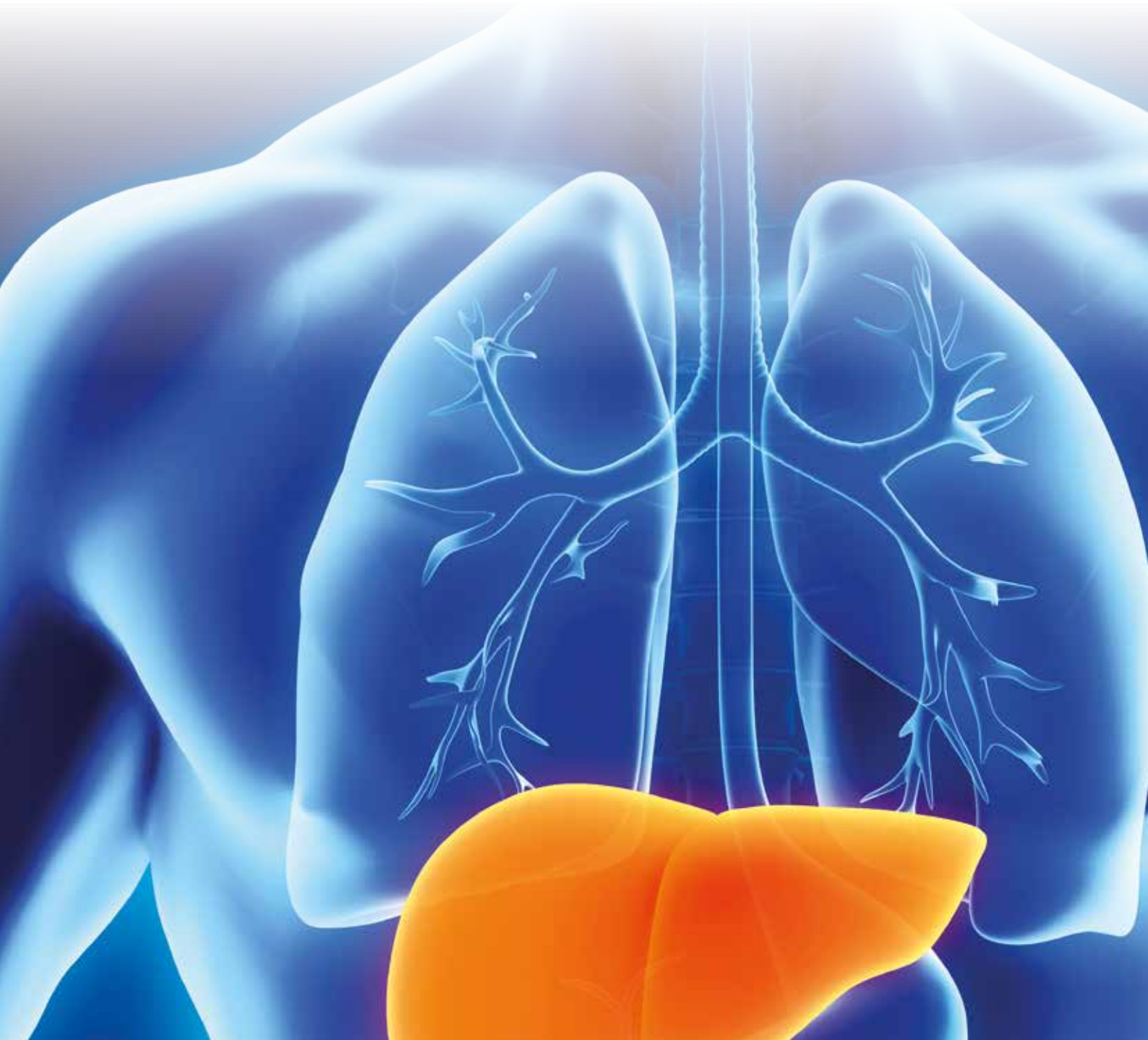
ROBERT GOLDIN

Professor of Liver & GI Pathology, Imperial College London, UK

The role of image analysis in studying liver biopsies from patients with NASH

- There is an increasing trend to digital pathology which facilitates the uptake of image analysis as a routine tool.
- In NASH image analysis has an established role in assessing fat and fibrosis.
- New approaches to assessing ballooning and other key features in NASH are being developed.

16:05 Conference Close



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Poster presentation sessions will take place in breaks and alongside the other bkout 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). We charge an admin fee of £100 to industry delegates to present, that goes towards the shared cost of providing the poster presentation area and display boards, guides etc. This fee is waived for those representing academic institutions and not for profit organisations.

VENUE INFORMATION

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

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