The Industry Definitive Forum for Actionable Insights

22-24 October, 2018 | Frankfurt, Germany

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2nd Annual NASH Summit 2018 EUROPE

Accelerate the Development of Successful NASH Therapeutics

Hear from 25 experts including:

Nikolai Naoumov
Executive Director, Hepatology Science & Innovation
Novartis

Stephen Rossi
Senior Director, Clinical Development & Medical Affairs
NGM Biopharmaceuticals

Meena Jain
Director, Clinical Development, Cardiovascular & Metabolic Disease
MedImmune

Andreas Geier
Head of Hepatology
University of Wurzburg

Donna Cryer
President & Chief Executive Officer
Global Liver Institute

"If 150 people leave here, go out talk to their companies, their colleagues, their peers, talk about what they learnt here and make corrections: **the amplification effect begins to move the field**"

Jason Campagna, Senior Vice President, Global NASH Lead, Intercept Pharmaceuticals
Conference Chair: 2nd Annual NASH Summit, Boston

Partners

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Welcome to the 2nd Annual NASH Summit Europe

Harnessing Understanding to Advance NASH Pipeline Development

Built from research with the **FDA, EMA** and **Gilead**, the **2nd Annual NASH Summit Europe** will once again elevate industry-to-industry dialogue and reveal leading insights in overcoming the hurdles limiting NASH therapeutic success.

Join the NASH community as they collectively address the biggest challenges in NASH through a tighter lens including the potential for **stand alone versus combination therapeutics**, **the genetic drivers** influencing disease heterogeneity and the **future payer and reimbursement** landscape.

Hear from 22 stakeholders including **Pfizer**, **Novartis** and **MedImmune** as this exclusively drug development driven forum equips you with the connections and actionable takeaways you need to capture one of many market opportunities for a successful NASH candidate.

What attendees of the 2nd Annual NASH Summit Boston had to say:

"Excellent opportunity to catch up with the field and hear other industry speakers present their work"
Genentech

"Brilliant conference for knowledge exchange"
Fresenius Kabi Deutschland GmbH

"I very much enjoyed the atmosphere, quality of presentations and the productive discussions with colleagues"
Medicis Capital

Gain Leading Insights in All Areas of NASH Drug Development

1. Analyse NASH as a Component of Systemic Cardiometabolic Disease

Draw conclusions from the pathophysiological mechanisms linking NASH to metabolic and cardiovascular disease with **Sanofi** to understand patient phenotype outside the hepatology clinic and optimise clinical trial design

2. Address the NASH Diagnostic Conundrum

Evaluate laboratory markers of steatosis, inflammation and fibrosis associated with NASH therapeutic efficacy with **NGM Biopharmaceuticals** and **Genfit**; and review the capacity for available biomarkers to benefit recruitment enrichment or be optimised as primary or secondary endpoints

3. Understand the Lessons Learnt from Trial Failures & Hear Mechanisms of Action of Emerging Therapeutics

Inform your own pipeline decisions with actionable insights from **Pfizer** and **Genfit;** and benchmark your candidate against novel targets and mechanisms of action

4. Hear the NASH Patient's Perspective & the Practical Reality of Clinical Diagnostics & Treatment

Harness understanding of NASH epidemiology and advanced fibrosis in Western countries and collectively review what gaps exist in the R&D to commericalisation landscape with the **Global Liver Institute**

5. Share Countering Perspectives on Challenges Lying Ahead with Leading Drug Developers

Gain a comprehensive outlook on the combination therapy landscape from **Metabolys** and **Novartis**; as well as takeaways on the road to payers and reimbursement in anticipation of your own candidate's success

"Very good conference both editorial and fertile comprising overall knowledge on novel drugs in the area"
Can-Fite Biopharma

25 Expert Speakers

Adil Mardinoglu
Assistant Professor of Systems Biology
Royal Institute of Technology (KTH)

Aditya Venugopal
Senior Director
Intercept Pharmaceuticals

Aimo Kannt
Cluster Head Comorbidities & Complications of Diabetes
Sanofi

Andreas Geier
Head of Hepatology
University of Wurzburg

Bill Esler
Senior Director
Pfizer

Claus Kremoser
Chief Executive Officer
Phenex Pharmaceuticals

David Fraser
Chief Scientific Officer
NorthSea Therapeutics

Dimitar Tonev
Honorary Consultant
HCV Research UK

Donna Cryer
President & Chief Executive Officer
Global Liver Institute

Donny Wong
Global Analytics & Insight Lead, CVRM Early Assets
AstraZeneca

Elias Papatheodorou
Chief Executive Officer
Genkyotex

Eric Hughes
Head of Global Development Franchise, Immunology, Hepatology & Dermatology
Novartis

Gabriel Baverel
President & Chief Executive Officer
Metabolys

Henning Grønbæk
Professor Internal Medicine & Hepatology
Aarhus University

Marcin Krawczyk
Saarland University Medical Center

Meena Jain
Director, Clinical Development, Cardiovascular & Metabolic Disease
MedImmune

Nikolai Naoumov
Executive Director, Hepatology Science & Innovation
Novartis

Peter Traber
Partner
Alarita Consulting

Pnina Fishman
Chief Executive Officer
Can-Fite BioPharma

Pietro Scalfaro
Chief Medical Officer
Enyo Pharmaceuticals

Rebecca Taub
Chief Medical Officer, Executive Vice President Research & Development
Madrigal Pharmaceuticals

Richard Lee
Director
Ionis Pharmaceuticals

Sebastien Bolze
Chief Scientific Officer
Poxel Pharmaceuticals

Sophie Mégnien
Chief Medical Officer
Genfit

Stephen Rossi
Senior Director, Clinical Development & Medical Affairs
NGM Biopharmaceuticals

Suneil Hosmane
Executive Vice President – Strategic Development
Genfit

Conference Day One | Tuesday, October 23, 2018

Sophie Mégnien
Chief Medical Officer
Genfit

8.50 **Chair's Opening Remarks**

NASH, Now - Reviewing Clinical Success & Failure

Sophie Mégnien
Chief Medical Officer
Genfit

9.00 **Regulatory Landscape in NASH**
- Outlining the regulatory approaches for new drug registration in NAS
- Updating on clinical endpoints strategies
- Updating on the Elafibranor clinical program

Bill Esler
Senior Director
Pfizer

9.30 **Acetyl-CoA Carboxylase Inhibitors from Bench to Bedside & Back Again**
- Outlining the potential of ACC inhibitors to address multiple pathogenic drivers in NASH by exerting direct benefits on steatosis, hepatic inflammation and fibrosis
- Evaluating how Pfizer progressed a systemically acting ACC inhibitor into clinical development in 2010, but this compound was terminated due to an unexpected safety finding
- Reviewing learnings from this first inhibitor, as well as detailed studies informing the mechanism of the unexpected safety findings, and how these were used to shape the design of Pfizer's second generation ACC inhibitor which is presently in phase 2 clinical development
- Discussing the learnings from the first generation ACC inhibitor, how these influenced the design of the second generation ACC inhibitor, and clinical experience to date with this 2nd generation compound

10.00 **Speed Networking**
This session is the ideal opportunity to get face-to-face time with many of the brightest minds driving scientific and clinical research in NASH and establish meaningful business relationships

10.45 **Morning Break**

Addressing Challenges to Inform Future Pipeline Decisions

Aimo Kannt
Cluster Head
Comorbidities & Complications of Diabetes
Sanofi

11.15 **NASH as a Component of Systemic Cardiometabolic Disease**
- Demonstrating the association of NASH with metabolic disorders and cardiovascular morbidity and mortality
- Outlining NAFLD and extrahepatic malignancies in the context of NASH
- Analysing pathophysiological mechanisms linking NASH to metabolic and cardiovascular disease

11.45 **Roundtable Discussions**
Practical and highly interactive breakout roundtables where attendees can crowd-source solutions and share opinions around pre-assigned topic areas. A valuable chance for attendees to unite around hot topics and collectively debate how to advance drug development.

1. Preclinical modeling of key aspects of NASH pathology

Richard Lee
Director
Ionis Pharmaceuticals

2. How long and large should a phase 3 NASH trial be?

Meena Jain
Director, Clinical Development, Cardiovascular & Metabolic Disease
MedImmune

3. What do we know/ can we understand about the pricing and reimbursement landscape?

Donny Wong
Global Analytics & Insight Lead, CVRM Early Assets
AstraZeneca

4. Assessing the application of biomarkers in NASH drug development so far

Stephen Rossi
Senior Director, Clinical Development & Medical Affairs
NGM Biopharmaceuticals

12.15 Moderator Feedback Panel
Following roundtables, moderators will share key themes discussed and conclusions reached with the wider audience and open the floor for Q&As, allowing full delegation discussions on each topic area.

12.45 Session Reserved for Metabolon

1.00 Lunch & Networking

Robustly Understanding NASH Pathophysiology for More Precise Candidate Development

Marcin Krawczyk
Saarland University Medical Center

2.00 Addressing Heterogeneity & the Role of Genetics in NASH Patient Populations
- Highlighting potential differences in predispositions and drivers that lead to population heterogeneity
- Outlining the latest understanding of genes modulating risk for NASH drug development
- Addressing NASH non-responders in the context of limited understanding of disease progression

Beyond the Biopsy: Biomarker Predictability to Support Drug Development

Henning Grønbæk
Professor Internal Medicine & Hepatology
Aarhus University

2.30 The Role of Macrophages in Non-Alcoholic Fatty Liver Disease - From Biomarkers to Treatment Targets
- Outlining the role of macrophages in NAFLD to NASH transition
- Proving macrophage activation markers as biomarkers for prediction of NASH severity and treatment effects
- Showcasing macrophages as targets for NASH prevention and inhibition

3.00 Afternoon Break & Networking

Stephen Rossi
Senior Director, Clinical Development & Medical Affairs
NGM Biopharmaceuticals

3.30 Targeting the FGF19 Pathway for the Treatment of NASH: From Benchside to Biopsy
- Discussing the structure activity development and pre-clinical models establishing the biologic activity of an engineered FGF19 analogue
- Evaluating the non-invasive imaging and laboratory markers of steatosis, inflammation and fibrosis associated with the treatment of NASH with NGM282
- Reviewing the translation of activity on non-invasive markers to histologic-response for NGM282

Suneil Hosmane
Executive Vice President – Strategic Development
Genfit

4.00 Developing an In Vitro Diagnostic Test (IVD) In Parallel to Advancing a Drug Candidate
- Primer on different types of diagnostic tests
- Overview of NASH diagnostic landscape
- Identifying biomarkers to aide in the diagnosis of NASH patients

Aditya Venugopal
Senior Director
Intercept Pharmaceuticals

4.30 Non-Invasive Learnings From Clinical Studies of Therapeutic Agents
- Session details to follow

5.00 Chair's Closing Remarks

5.10 Poster Session
After the formal presentations have finished, the learning and networking carries on. The poster session is an informal part of the conference agenda, allowing you to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships.

Whether you're presenting or not, this is the session to hear your peers' progress and learn more about emerging candidates, novel *in vitro* and *in vivo* modalities, and the validation of non-invasive diagnostics alongside drug development.

Conference Day Two | Wednesday, October 24, 2018

Eric Hughes
Head of Global Development Franchise, Immunology, Hepatology & Dermatology
Novartis

8.50 **Chair's Opening Remarks**

Successful Therapeutic Approaches in NASH: Countering Perspectives on Combinations

Gabriel Baverel
President & Chief Executive Officer
Metabolys

9.00 **MTBL0036, a New Anti-NASH & Anti-Fibrotic Compound with a Mitochondrial Molecular Target**
- Rationalising the potential of a stand-alone drug for NASH fibrosis
- Demonstrating MTBL0036 as the most efficacious of all the orally active anti-NASH candidates in development
- Showcasing how action on a key mitochondrial target drastically reduces inflammation and ballooning as well as ameliorating hepatic fibrosis

Elias Papatheodorou
Chief Executive Officer
Genkyotex

9.30 **Targeting Multiple Fibrogenic Pathways with the NOX1/4 Inhibitor GKT831**
- Explore GKT831's mechanism of action - targeting multiple fibrogenic pathways
- Gain a comprehensive understanding of clinical efficacy and safety profiles in liver, lung and kidney fibrosis

Nikolai Naoumov
Executive Director, Hepatology Science & Innovation
Novartis

10.00 **Targeting Multiple Pathways in NASH – Clinical Perspectives for Combination Therapies**
- Exploring pathogenesis of liver injury in NASH
- Evaluating recent advances with monotherapies directed at metabolic pathways, liver inflammation and fibrosis
- Understanding the rationale for combination regimes in NASH and exploring combination options in clinical studies

10.30 **Morning Break & Networking**

Candidate Showcase: Emerging Therapeutic Mechanism of Action & Results to Date

Pnina Fishman
Chief Executive Officer
Can-Fite BioPharma

11.00 **The Polypharmacological Anti-NASH Effects of Namodenoson Are Mediated via De-Regulation of the Wnt/β-catenin Pathway**
- Namodenoson is a small molecule, agonist at the A3 adenosine receptor with excellent safety profile tested in >200 patients
- Definitive molecular mechanism of action including de-regulation of Wnt/b-catenin
- Current Phase 2 in NAFLD/NASH patients is ongoing

David Fraser
Chief Scientific Officer
NorthSea Therapeutics

11.30 **Anti-Inflammatory & Anti-Fibrotic Effects of Icosabutate, a Structurally Engineered Fatty Acid, in Differentiated Rodent NASH Models**
- Outlining the rationale behind structural engineering of fatty acids for the treatment of liver disease
- Showcasing ADME properties of icosabutate
- Demonstrating the effects of icosabutate on inflammation and fibrosis in diverse rodent NASH models
- Sharing insights into mechanism/s of action

Sebastien Bolze
Chief Scientific Officer
Poxel Pharmaceuticals

12.00 **PXL770, a Direct AMP Kinase Activator, for the Treatment of NASH**
- Why is direct AMPK activation a good target for the treatment of NASH?
- Exploring how PXL770 is a direct AMPK activator with beneficial effects on liver steatosis, inflammation and fibrosis in animal models
- Analysing the clinical profile of PXL770

	12.30	**Lunch & Networking**
 **Peter Traber** Partner **Alarita Consulting**	1.30	**Therapeutic Approaches to Cirrhotic Versus Non-Cirrhotic NASH** • More details to follow

Including the Patient's Perspective to Address NASH in the Clinic

 **Donna Cryer** President & Chief Executive Officer **Global Liver Institute**	2.00	**Harnessing Patient Advocacy to Advance NASH Drug Development** • Outlining the key initiatives of the Global Liver Institute and NASH Council • What does the landscape look like from an advocacy perspective? • What gaps still exist and how can we bridge the gaps from R&D to commercialisation– what do we need to start thinking about now?
 **Andreas Geier** Head of Hepatology **University of Wurzburg**	2.30	**The Reality of Clinical Diagnostics & Treatment** • Understanding the epidemiology of NAFLD, NASH and advanced fibrosis in Western countries • Discussing non-invasive diagnostic approaches and patient journey in clinical reality • Assessing current access to treatment and clinical studies
	3.00	**Afternoon Break & Networking**

Reviewing Clinical Development & the Regulatory Guidelines

 **Claus Kremoser** Chief Executive Officer **Phenex Pharmaceuticals**	3.30	**How to Develop a Differentiated FXR Agonist that Avoids the Side Effects of 1st Generation FXR Drugs** • Reviewing the NASH clinical "icebreaker" as the FXR agonist OCA • How to avoid OCA showing HDL lowering and pruritus • Explaining how the 2nd generation FXR agonist GS-9674 differs from OCA to avoid these liabilities
 **Rebecca Taub** Chief Medical Officer, Executive Vice President Research & Development **Madrigal Pharmaceuticals**	4.00	**Showcasing the Clinical Development of MGL3196** • Reviewing Madrigal's clinical development of MGL3196 • Advancing understanding surrounding thyroid hormone receptor beta agonist reducing lipotoxicity in the NASH liver • Critically analysing MGL-3196 as the first truly beta selective THR-beta agonist
 **Pietro Scalfaro** Chief Medical Officer **Enyo Pharmaceuticals**	4.30	**Adhering to Regulatory Guidelines & Overcoming Clinical Challenges Related to NASH PoC Studies** • Filling the gap between non-invasive assessment of NASH PoC endpoints and the clinically relevant endpoints • Robustly applying non-invasive MRI imaging in addition to liver fat quantification • Reviewing *in silico* trial simulations using 10'000 virtual NASH patients to explore and support diverse study designs • Are there more relevant and helpful approaches in the European vs. North American current thinking in the moving target NASH development field?
	5.00	**Chair's Closing Remarks**

"Great event exceptional networking opportunities. High quality of presentations. Very efficient way to spend my time"
Synexus

Pre-Conference Workshop Day | Monday, October 22, 2018

Workshop A | Systems biology in NASH: Approaches & Applications

10:00am – 1:00pm

Systems biology is an interdisciplinary field that studies the complex interactions within the liver, other tissues and gut microbiota using a holistic approach. Detailed insights into the biological functions of the liver and its crosstalk with the gut microbiota can be used to develop novel strategies for the prevention and treatment of NASH, and facilitate more efficient drug development decisions.

This in-depth session focuses on:

- Comprehensively analysing the biological functions in healthy and NASH diseased states using biological network models as an integration of multiomics data
- Successfully employing systems biology in hepatology to identify biomarkers and liver specific drug targets to treat NASH
- Detailing how to use systems biology for simulation of liver tissue functions and its crosstalk with other tissues for prediction of therapeutic and side effects
- Successfully employing systems biology in elucidating how carbohydrate-restricted diets improve metabolism in subjects with NAFLD

Workshop Leader

Adil Mardinoglu
Assistant Professor of Systems Biology
Royal Institute of Technology (KTH)

Dr. Adil Mardinoglu is an expert in the field of Systems Biology and Bioinformatics. His recent research activities include the generation of the context specific genome-scale metabolic models for healthy human cell-types as well as certain types of cancer e.g. liver cancer. He employed the reconstructed comprehensive models for revealing the molecular mechanisms of obesity associated diseases as well as for discovery of the novel biomarkers and drug targets. He's also reconstructed personalized and population based models for liver cancer patients in order to identify anticancer drug targets that can inhibit the growth of, or kill tumors.

Workshop B | Addressing Challenges Relating to Non-Invasive Technology Used for the Identification of NASFLD/NASH

2:00pm – 5:00pm

Despite an arsenal of compounds ranging from early preclinical to late clinical development in NASH, challenges in diagnosing and stratifying patient populations hinder the ability to recruit and enrich patient cohorts in line with clinical trial demands.

From risk stratification, recruitment enrichment, treatment effect validation to how these come together as potential primary or secondary endpoints, be part of this constructive discussion around the main pillars of the NASH diagnostic conundrum.

Join your peers to discuss:

- Addressing the questions: non-invasive diagnostics, where are we now? What diagnostics, for what mechanism of action, when and for what purpose?
- Comparison of the practical application and value of non-invasive technology in clinical trials so far

Workshop Leader

Dimitar Tonev
Honorary Consultant
HCV Research UK

Dimitar is a pharmaceutical physician with 20 years of drug and diagnostics development across the universe of chronic liver diseases. He acts as Medical Director for Humedics, Perspectum Diagnostics and has previously held the role of Medical Director at Promethera Biosciences and Regional Medical Director at Intercept Pharmaceuticals.

Partnership Opportunities

Why Partner?

Partnering with the 2nd Annual NASH Summit Europe is an opportunity to elevate your company's standing and influence industry thinking in the NASH community.

Your brand, your message, your reputation, showcased in front of industry's most active NASH drug developers.

This could involve presenting on the agenda, hosting networking sessions or exhibiting. We'll ensure full exposure for your company from wide reaching brand awareness in the lead up to the meeting with our multi-channel global communication strategy to arranging targeted introductions with key individuals you'd like to meet

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InfiCure Bio has developed a new and unique pre-clinical mouse model, the N-IF mouse, which spontaneously develops fibrosis in multiple organs. We offer expert led, tailored, high-quality drug validation services for R&D companies and CRO's. Our unique whole organism model offers extraordinary research advantages; is 100 percent reproducible, has a pathological progress similar to humans and displays a fibrosis preceded by inflammation. Inficure Bio is ready to break the status quo in anti-fibrotic drug development.

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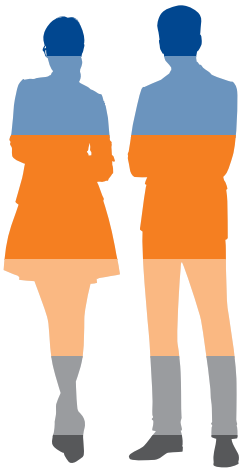
Seniority of Attendees



- C—Level 11%
- President/Vice President 17%
- Global Head/Head of 33%
- Director/Associate Director 21%
- Scientist 15%
- Professor 3%

Snapshot of Companies Who Have Attended the NASH Summit

abbvie · Allergan · AstraZeneca · Bristol-Myers Squibb · Celgene · CohBar · ConSynance · Esperion The Lipid Management Company · Genentech A Member of the Roche Group · MedImmune · MERCK · NOVARTIS · novo nordisk · Pfizer · Roche · Takeda

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*Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

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Package Details	Register & Pay by **Friday 14 September, 2018**	Standard Prices
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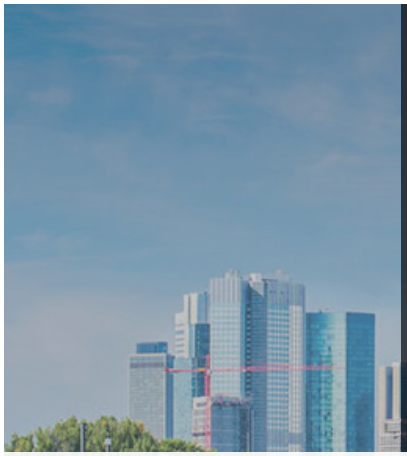

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