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Nonalcoholic Steatohepatitis (NASH): KOL Insight [2018]

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Abstracts

Are novel therapies set to revolutionise NASH?

No drug therapies have been approved for patients with nonalcoholic steatohepatitis (NASH) but this could all change in the next 3-5 years. Four late-stage pipeline programmes are advancing through development, and 16 mid-stage pipeline programmes are also making progress. Which ones will pass muster? And which ones do leading key opinion leaders (KOLs) believe will have the biggest impact on the future treatment paradigm for NASH? Will it be cenicriviroc (Allergan), selonsertib (Gilead), obeticholic acid (Intercept Pharmaceuticals), or elafibranor (Genfit)?

Learn how 12 of the world's leading KOLs from Europe and the US see the NASH treatment landscape evolving, and how they expect developers to differentiate their pipeline therapies in KOL Insight: Nonalcoholic Steatohepatitis (NASH).

Take a tour of the report now

The table of contents

The key business questions answered

The key KOL quotes

See the therapies covered

Find out who the 6 EU & 6 US KOLs are

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Review an extract from the report - 1 drug profile

Top takeaways

Will Intercept's obeticholic acid be the first-to-market? The US FDA has issued a boxed warning for Ocaliva in PBC patients regarding liver damage. Is this likely to affect its chances in NASH?

How do KOLs rate the next-generation of FXR agonists? Enanta, Gilead and Novartis are developing agents in this space but which one stands out and can they challenge obeticholic acid?

How clinically attractive is Genfit's elafibranor? The REGENERATE trial is in progress but what advantages do KOL think elafibranor has over its competitors?

How do KOLs view the progress of Allergan's cenicriviroc? The Phase III AURORA study has been initiated based on the data from the CENTAUR Phase IIb study, but how do KOLs rate this data?

How do KOLs rate the potential of Gilead's STELLAR 3/4 studies for NASH? Do KOLs believe selonsertib monotherapy has a future or should the company focus on its parallel combination strategy?

How do KOLs rate saroglitazar's chances? Phase III studies are underway in India, but with saroglitazar only in Phase II trials in the US, is it too early for KOLs to have a view?

Can Inventiva's pan-PPAR agonist, lanifibranor, challenge Genfit's elafibranor and Zydus' saroglitazar? What potential do KOLs think PPARs have in NASH?

How is the Phase II data for Conatus' emricasan perceived by KOLs? What do they say about the designs of ENCORE-PH and ENCORE-NF Phase II studies for the agent?

Will Galmed's Aramchol find a place in NASH? What do experts think about the Phase II ARRIVE study data and will it affect its NASH development?

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Will Novo Nordisk's GLP-1 agonist semaglutide find a place in NASH? The antidiabetic agent is useful for treating insulin resistance but will it show anti-fibrotic effects? KOLs provide their views.

What do KOLs expect from FGFR inhibitors in NASH? MGL-3196 (Madrigal), BMS-986036 (BMS) and NGM282 (NGM Biopharma) are competing in this space but which candidate stands out?

How do KOLs view other novel agents/MOAs such as volixibat (Shire) and Boehringer Ingelheim's BI 1467335 and Can-Fite's namodenoson? Will they have an impact in NASH?

Quotes

"Clearly, there's a persistent unmet need for treatments and to refine the populations who need treatment. An even more urgent unmet need is to have better, non-invasive diagnostics and strategies for screening of patients who either have NASH, or are at risk for NASH." US Key Opinion Leader

Sample of therapies covered

Late-stage Pipeline Therapies

Obeticholic acid (Ocaliva; Intercept Pharmaceuticals)

Elafibranor (Genfit Pharmaceuticals)

Selonsertib (Gilead)

Cenicriviroc (Allergan)

Mid-stage Pipeline Therapies

Aramchol (Galmed Medical Research)

BI 1467335 (Boehringer Ingelheim)

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BMS 986036 (Bristol-Myers Squibb)

EDP 305 (Enanta Pharmaceuticals)

Emricasan (Conatus/Idun/Novartis)

GS 0976 (Gilead Sciences)

GS 9674 (Gilead Sciences)

IMM 124E (Immuron)

Lanifibranor (Inventiva Pharma)

MGL 3196 (Roche/Madrigal Pharmaceuticals)

Namodenoson (Can-Fite BioPharma/Chong Kun Dang)

NGM 282 (NGM Biopharmaceuticals)

Saroglitazar (Zydus Cadila)

Semaglutide (Novo Nordisk)

Tropifexor (Novartis/Allergan)

Volixibat (Shire/Sanofi)

KOLs interviewed

KOLs from North America

Dr. Naim Alkhouri, MD; Staff Physician, Digestive Disease Institute and Cleveland Clinic's Children Hospital, Cleveland, Ohio

Prof Scott L. Friedman, MD; Dean for Therapeutic Discovery and Chief of Division of Liver Diseases, The Icahn School of Medicine, Mount Sinai Hospital, New York City

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Prof Philip Rosenthal, MD; Director of Pediatric Hepatology, University of California, San Francisco (UCSF)

Dr. Robert Wong, MD, MS; Assistant Clinical Professor at UCSF, Gastroenterology and Hepatology Faculty, California

KOLs from Europe

Dr. Stefano Bellentani, MD, PhD; Gastroenterologist at Azienda USL di Modena, Italy

Dr. Pinelopi Manousou, MD, PhD; Consultant Hepatologist at St Mary's Hospital, Imperial College London, UK

Dr. Stuart McPherson, MD, FRCP; Consultant Liver Specialist, Newcastle upon Tyne Hospital, UK

Prof Phillip Newsome, MD; Professor of Experimental Hepatology, Director of the Centre for Liver Research and Clinical Director of the Birmingham University Stem Cell Centre, UK

Dr. Valerio Nobili, MD; Consultant Hepatologist at Bambino Gesu Children's Hospital, Rome, Italy

Prof Vlad Ratziu, MD, PhD; Professor of Hepatology, Université Pierre et Marie Curie and the Hôpital Pitié-Salpêtrière Medical School, Paris, France

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