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NASH: KOL Insight [2017]

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Abstracts

Will novel therapies revolutionise the treatment of NASH?

No drug therapies have been approved for patients with nonalcoholic steatohepatitis (NASH) but how is this set to change within the next five years? Allergan/Tobira's cenicriviroc and Gilead's selonsertib have entered the Phase III pipeline but how do they compare with other agents, Intercept's obeticholic acid and Genfit's elafibranor. How important are improvements in fibrosis and what do key opinion leaders (KOLs) believe will impact drug approval prospects? Experts discuss current study designs and endpoints and the challenges facing novel therapies such as long-term safety, cost and diagnosis.

Learn how KOLs see the market evolving, and how they expect developers to differentiate their pipeline therapies in KOL Insight: Nonalcoholic steatohepatitis (NASH). 6 US and 6 European KOLs give their insight on two off-label marketed products and 12 pipeline programmes. KOLs also provide their candid views on the potential for novel mechanisms of action.

Take a tour of the report now

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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

Obeticholic acid approved for primary biliary cirrhosis (PBC) but what are its prospects in NASH? Find out how KOLs view the modifications of the pivotal Phase III REGENERATE study and whether they are concerned about long-term safety and cost?

Cenicriviroc and selonsertib have entered Phase III development but what are KOL expectations? Both drugs have demonstrated improvements in fibrosis in Phase II studies but what do the experts think about potential future outcomes?

Does elafibranor have potential for broad use in NASH? The Phase III RESOLVE-IT Phase III study is ongoing with Genfit's elafibranor but how do KOLs view the study design?

Emricasan and Aramchol are targeting different stages of NASH but which strategies are most appealing? Find out KOL opinions on different approaches targeting the multifaceted disease.

Which early-stage mechanisms of action (MOAs) show the most promise? Pipeline drugs with diverse mechanisms are in Phase II. Given the complexities of NASH pathogenesis, which MOAs are the most appealing to KOLs?

Which clinical endpoints are key to securing drug approval in NASH? Are improvements in fibrosis crucial or are KOLs satisfied with other endpoints such as resolution of NASH, NAFLD activity score (NAS) and hepatic venous pressure gradient (HVPG)?

Clinical trial enrolment and design an issue going forward? Companies have announced reductions in patient enrolment numbers in NASH clinical trials due to challenges encountered. Do KOLs have concerns about trial enrolment?

Non-invasive biomarkers a critical unmet need in NASH? Liver biopsy remains the gold standard for NASH diagnosis. Are KOLs concerned about the requirement of liver biopsies to monitor drug response and disease progression

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in clinical trials?

Are combination approaches the key to successfully treating NASH? Given the multitude of pathways involved in the pathogenesis of NASH, do KOLs agree that future treatment is most likely going to involve combination therapy?

Will cost and reimbursement restraints impact NASH? Cost-effectiveness of novel agents approved in NASH is likely to become an important consideration. Explore the concerns voiced by KOLs about the potential restrictions facing novel therapies.

Quotes

“Combinations ensure [that] you're not just targeting one pathway. Fibrosis is important but so are the inflammatory cascade, insulin resistance and metabolic syndrome. I think that the most promising will be combinations of a primarily antifibrotic agent with an agent that specifically targets the metabolic pathway and insulin resistance.” US Key Opinion Leader

“This is very developing field, a lot of labs around the world are looking for the ideal non-invasive biomarker for NASH, and I am quite confident that in the next five years we will discover the best one.” EU Key Opinion Leader

Sample of therapies covered

Marketed Therapies (off-label)

pioglitazone (Actos/Glustin; Takeda/Eli Lilly)

vitamin E

Pipeline Therapies

obeticholic acid (Ocaliva; Intercept Pharmaceuticals)

elafibranor (Genfit Pharmaceuticals)

cenicriviroc (Allergan/Tobira Therapeutics)

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selonsertib (Gilead)

emricasan (Novartis/Conatus Pharmaceuticals)

Aramchol (Galmed Pharmaceuticals)

semaglutide (Novo Nordisk)

GR-MD-02 (Galectin Therapeutics)

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Sample of KOLs interviewed

KOLs from North America

Professor 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

Professor Joel E. Lavine, MD, PhD, Chief of the Division of Pediatric Gastroenterology, Hepatology and Nutrition, Morgan Stanley Children's Hospital and Columbia University Medical Center New York

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

KOLs from Europe

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

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

Professor 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

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