

# Nonalcoholic Steatohepatitis: KOL Insight

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## Abstracts

### Why This Report is Essential

Expect a revolution in the treatment of nonalcoholic steatohepatitis (NASH) as a number of new therapies compete to become the first approved treatment for a disease that has high unmet clinical need. Nonalcoholic Steatohepatitis: KOL Insight reveals the critical views of US and European KOLs whose insights hold key lessons for pharma. Gain insights on products in the pipeline and how they could revolutionise the treatment algorithm.

Among the pipeline products analysed in this report is Intercept's/Dainippon Sumitomo Pharm's FXR agonist, obeticholic acid, Genfit's PPAR alpha/delta agonist, GFT505 and Gilead's Simutuzumab. Others vying for market voice include Tobira Therapeutics's dual CCR2/CCR5 antagonist, cenicriviroc (TBR-652) and in the paediatric sector, Raptor Pharmaceuticals' delayed-release cysteamine bitartrate.

The upcoming products vary in their effectiveness in resolving the steatohepatitis and controlling fibrosis associated with NASH. Combination therapy is likely to shape the treatment paradigm in the future, as none offer a single solution.

Nonalcoholic Steatohepatitis: KOL Insight gives exclusive insights on what leading NASH specialists think about the emerging clinical benefits and disadvantages of key pipeline programmes and what will influence prescribing decisions. In addition, specialists voice their opinions on optimal clinical trial designs, including endpoint selection, which could help clarify future treatment decisions.

### Key Benefits

Understand the clinical insights of current treatment strategies and formulate

effective strategies for new product positioning and clinician communication.

Map new treatment options to the NASH spectrum, including patient sub groups, in preparation for market planning activities.

Identify what emerging product attributes and patient characteristics KOLs think will be most important in terms of influencing prescribing decisions.

Discover which clinical trials, including designs and endpoints, the KOLs believe will have a significant impact on future treatment decisions and their likely outcomes.

Evaluate the evolving NASH competitive landscape to get an edge on potential licensing opportunities in the future.

## Answers to Critical Questions

Intercept's/Dainippon Sumitomo Pharma's obeticholic acid addresses NASH on many levels but how will adverse reactions impact its approval and the future use of the drug?

What key clinical differentiators could Genfit exploit for GFT505, its PPAR alpha/delta agonist?

What pricing strategy should Gilead consider for anti- lysyl oxidase-like-2 (LOXL2) mAb, simtuzumab?

Preliminary results for Tobira's dual CCR2/CCR5 antagonist, cenicriviroc, are seen as encouraging by KOLs, but what do KOLs think are the best combination approaches with this product?

Raptor Pharmaceuticals' RP103 is expected to be first-to-market for paediatric NASH, but cost and competition from other therapies which gain the same indication remain challenges for the future; how might the company best meet these?

What role will biomarkers play in shaping the NASH treatment landscape?

The use of combination therapy looks set to deliver the best outcomes for patients with NASH, but which products and MOAs are looking compatible at this stage?

## Top Takeaways

Hear the detailed opinions of leading front line clinicians on current and future treatments for NASH, and what they see as the critical advantages/disadvantages affecting their decision to use.

Understand important clinical and market factors that will shape the NASH sector and identify key areas for strategic and tactical action.

Benchmark current thinking on how the new therapies will fit into the treatment paradigm.

Review KOL attitudes to important clinical trials such as FLINT, GOLDEN, CENTAUR, ORION, CyNCH, and LEAN.

## Key Opinion Leaders

### North America

Scott L. Friedman, Professor, Icahn School of Medicine at Mount Sinai

Brent A. Neuschwander-Tetri, Professor, Saint Louis University School of Medicine

Stephen A. Harrison, University of Texas Health Science Center in San Antonio and Brooke Army Medical Center, Fort Sam Houston, Texas

Philip Rosenthal, Professor, University of California, San Francisco

Mary Rinella, Northwestern University Feinberg School of Medicine

Joel Lavine, Morgan Stanley Children's Hospital and Columbia University

Medical Center

## Europe

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Fabio Marra, University of Florence

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Anonymous German KOL

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