

# NASH [2017]: Bulletin #1

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## Abstracts

Gain new key opinion leader (KOL) insights on the latest events that have the potential to shape the treatment landscape of nonalcoholic steatohepatitis (NASH). Topics covered include expert opinions on the recent positive recommendation by a data safety monitoring board (DSMB) for the continuation of the RESOLVE-IT Phase III trial with Genfit Pharmaceuticals' elafibranor without any modifications. KOLs discuss the positive Phase II data presented at the international EASL congress 2017 for two novel fibroblast growth factor (FGF) modulators, Bristol-Myers Squibb's BMS-986036 and NGM Biopharmaceuticals' NGM282. Experts also cover late-breaking data presented at EASL 2017 for Gilead's GS-0976, an oral inhibitor of acetyl-CoA carboxylase (ACC), in patients with NASH.

### Business Questions:

How do KOLs view the positive recommendation issued by the DSMB for continuation of the RESOLVE-IT trial with elafibranor?

Are KOLs satisfied with elafibranor's safety profile in NASH?

What are the likely reasons behind the delay in recruitment of NASH patients with F2/F3 fibrosis in the RESOLVE-IT study?

Are KOLs concerned about the delay in patient recruitment for RESOLVE-IT and other clinical studies in NASH?

What are KOL opinions on the improvement in fat reduction reported for both BMS-986036 and NGM282 compounds at EASL 2017?

Will the improvements in hepatic fat content with FGF therapies correlate with

long-term clinical outcomes?

How do KOLs view the surrogate endpoint of MRI-PDFF adopted in early-stage studies and can it compete with the gold-standard biopsy?

Do KOLs hold any safety concerns with FGF modulation in NASH?

What sort of role do experts envisage for FGF therapies in the NASH treatment space, or is it too early to tell?

How do KOLs view the data reported for Gilead's GS-0976 at EASL 2017, and are they hopeful about the therapy in NASH?

Are the experts optimistic about GS-0976 combined with the MAP kinase inhibitor selonsertib?

If approved, what type of NASH patients would GS-0976 be best positioned in?

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