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NEW NASH READOUTS FOR NGM, BRISTOL

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New data showed that **fibroblast growth factor (FGF)** analogs from **NGM Biopharmaceuticals Inc.** (South San Francisco, Calif.) and **Bristol-Myers Squibb Co.** (NYSE:BMY) each reduced liver fat in separate Phase II studies to treat non-alcoholic steatohepatitis. The data appeared in abstracts released ahead of the European Association for the Study of the Liver meeting, slated for April 19-23 in Amsterdam.

Each of two tested doses of **NGM282**, NGM's engineered form of **FGF19**, significantly reduced absolute liver fat content vs. placebo after 12 weeks. A 6 mg dose led to an 11.9% reduction and a 3 mg dose led to a 9.7% reduction, vs. 0.1% for placebo ($p<0.001$ for both). The primary endpoint was achieving a liver fat reduction of at least 5%.

The 82-patient study included patients with stage 1-3 liver fibrosis and at least 8% liver fat content. Among them, 42% of those receiving the high dose achieved fat content below 5%, as did 26% of those receiving the low dose. The trial assessed fat content by MRI-proton density fat fraction (MRI-PDFF).

Spokesperson Pam Lord said NGM is evaluating next steps for development of NGM282 in NASH, its lead indication. In 2015, the product met the primary endpoint in a Phase II trial to treat primary biliary cirrhosis (PBC) **(see BioCentury Extra, March 24, 2015)**.

In a separate study, each of two doses of BMS-986036 (**PEG-FGF21**) significantly reduced absolute hepatic fat fraction vs. placebo, as measured by MRI-PDFF. The study's 10 mg dose led to a 6.8% reduction ($p=0.0004$) and a 20 mg dose led to a 5.2% reduction ($p=0.008$), vs. 1.3% for placebo. Based on those measurements, BMS spokesperson Christina Trank told BioCentury that the pegylated analog of FGF21 met its primary efficacy endpoint.

BMS's study evaluated 68 evaluable patients with at least 10% hepatic fat fraction receiving either dose or placebo for 16 weeks. Data presented last year at the American Association for the Study of Liver Diseases meeting in Boston showed that BMS-986036 failed to significantly change HbA1c or weight in a Phase II trial to treat Type II diabetes, but reduced levels of a liver fibrosis marker. BMS obtained rights to the **FGF21**-like protein in 2011 from **Ambrx Inc.** (San Diego, Calif.).