

November 8, 2019

## FORMA's FASN Inhibitor FT-4101 Significantly Reduced Hepatic De Novo Lipogenesis In Healthy Adult Subjects

– Phase 1 data presented in a poster session at AASLD's The Liver Meeting® 2019 –

**WATERTOWN, Mass.** – November 8, 2019 – FORMA Therapeutics Inc., a clinical stage biopharmaceutical company focused on hematologic, oncologic and metabolic diseases, today announced the presentation of Phase 1 data for FT-4101, the company's potent, selective fatty acid synthase (FASN) inhibitor in clinical development for the treatment of nonalcoholic steatohepatitis (NASH), at The Liver Meeting® 2019, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), taking place November 8-12, 2019 in Boston, MA. The Phase 1 study in healthy adult subjects showed that administration of ascending single doses of FT-4101 was safe and well tolerated, and that inhibition of FASN with a single dose of FT-4101 reduced hepatic de novo lipogenesis (DNL) in a dose-dependent manner relative to placebo, with statistical significance achieved in two of the three doses evaluated.

“With the rising prevalence of obesity and type 2 diabetes, hepatologists deem NASH to be a growing global epidemic,” said Patrick Kelly, M.D., CMO of FORMA Therapeutics. “We are very pleased with the favorable DNL inhibition activity and safety data from this study, which support further investigation of FT-4101 for this significant unmet need.”

### About the Study

The Phase 1, three-cohort study was conducted to evaluate the effect of three single dose levels, 3 mg, 6 mg and 9 mg, of FT-4101 on hepatic DNL in healthy adult subjects. FT-4101 reduced DNL compared to placebo as follows:

Dose	DNL AUC <sub>0-12HR</sub>	Statistical Significance	DNL AUC <sub>0-24HR</sub>	Statistical Significance
3 mg	17.6 ± 17.7%	NS vs placebo	24.4 ± 15.3%	NS vs placebo
6 mg	41.8 ± 21.9%	P=0.011	42.6 ± 20.6%	P=0.010
9 mg	68.4 ± 18.2%	P<0.0001	81.8 ± 31.4%	P<0.0001

In this early study, FT-4101 also showed DNL inhibition without changes in fasting cholesterol, triglycerides, LDL and HDL levels, some of which have been observed with other investigational DNL inhibitors. Further, the long half-life of FT-4101, prolonged DNL inhibition and the safety profile observed in the study support once daily, chronic dosing. The administration of ascending single doses of FT-4101 (3 mg, 6 mg, and 9mg) in healthy adult subjects was safe and well tolerated. There were no deaths, serious adverse events (AEs) or laboratory AEs, or discontinuations due to AEs.

## **FT-4101 Presentation**

**Poster Number:** 2151

**Poster Title:** Inhibition of fatty acid synthase (FASN) with FT-4101 reduces hepatic de novo lipogenesis (DNL) in healthy adult subjects

**Location:** Hynes Convention Center, Hall B

## **About FT-4101**

FT-4101 is a potent, selective, oral small molecule inhibitor of fatty acid synthase (FASN), a key enzyme in the de novo lipogenesis (DNL) pathway responsible for hepatic lipid composition. Through FASN inhibition, FT-4101 is expected to reduce the rate of new fat production, thereby systemically affecting lipid accumulation in the liver and potentially mitigating the cellular damage, inflammation, and fibrosis that characterizes the pathology of nonalcoholic steatohepatitis (NASH). FT-4101 is being evaluated in a randomized, double-blind, placebo-controlled [Phase 2 study](#) to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics (PK/PD) and efficacy of FT-4101 in adult patients with NASH.

## **About NASH**

Nonalcoholic steatohepatitis (NASH), a form of hepatitis (liver inflammation), is caused by the buildup of fat in the liver. Patients with NASH can develop liver fibrosis, cirrhosis and/or liver cancer. The Global Liver Institute estimates that up to 12% of adults, or 115 million people worldwide, have NASH. Despite the large patient population, there are no approved medications to treat the disease. While many pharmaco-therapeutic agents in development for NASH mechanistically act on fatty acid oxidation, inflammation and fibrosis, all downstream consequences of steatosis, FORMA is targeting the enzyme involved in the pathway driving steatosis with FT-4101.

## **About FORMA**

FORMA Therapeutics is focused on the discovery, development and commercialization of transformative medicines that will make a difference for patients with rare hematologic diseases and cancers. A fully integrated biopharmaceutical company, FORMA's validated, proprietary R&D engine combines deep biology insight, chemistry expertise and clinical development capabilities to create differentiated drug candidates with best-in-class or first-in-class potential. FORMA has delivered high-value clinical candidates to its partners and generated a broad proprietary portfolio of programs, ranging from pre-clinical to pivotal-stage, with the potential to provide profound patient benefit. For more information, please visit the company website at [www.formatherapeutics.com](http://www.formatherapeutics.com).

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