



Gilead Announces Topline Data From Phase 3 STELLAR-4 Study of Selonsertib in Compensated Cirrhosis (F4) Due to Nonalcoholic Steatohepatitis (NASH)

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 11, 2019-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that STELLAR-4, a Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of selonsertib, an investigational, once-daily, oral inhibitor of apoptosis signal-regulating kinase 1 (ASK1), in patients with compensated cirrhosis (F4) due to nonalcoholic steatohepatitis (NASH), did not meet the pre-specified week 48 primary endpoint of a ≥ 1 -stage histologic improvement in fibrosis without worsening of NASH.

In the study of 877 enrolled patients who received study drug, 14.4 percent of patients treated with selonsertib 18 mg ($p=0.56$ vs. placebo) and 12.5 percent of patients treated with selonsertib 6 mg ($p=1.00$) achieved a ≥ 1 -stage improvement in fibrosis according to the NASH Clinical Research Network (CRN) classification without worsening of NASH after 48 weeks of treatment, compared with 12.8 percent of patients who received placebo. Selonsertib was generally well-tolerated and safety results were consistent with prior studies.

"While we are disappointed that the STELLAR-4 study did not achieve its primary endpoint, we remain committed to advancing therapies for patients with advanced fibrosis due to NASH, where there is a significant unmet need for effective and well-tolerated treatments. Gilead has a long-term commitment and proven track record of addressing significant challenges in the field of liver diseases. Data from this large study of patients with compensated cirrhosis due to NASH, including the extensive set of biomarkers collected, will further advance our understanding of the disease and inform our broader NASH development programs," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead. "We are grateful to the patients and investigators who participated in the STELLAR-4 study, and we now await the upcoming results from the Phase 3 STELLAR-3 trial of selonsertib in patients with bridging fibrosis (F3) due to NASH and the Phase 2 ATLAS combination trial of selonsertib, cilofexor (GS-9674) and firsocostat (GS-0976) in patients with advanced fibrosis due to NASH later this year."

Further in-depth analysis of the findings is ongoing and the data will be submitted to an upcoming scientific conference. Gilead will work with the Data Monitoring Committee and investigators to conclude the STELLAR-4 study in a manner consistent with the best interests of each patient.

Selonsertib, cilofexor and firsocostat, alone or in combination, are investigational compounds and are not approved by the U.S. Food & Drug Administration (FDA) or any other regulatory authority. Safety and efficacy have not been established for these agents.

About Selonsertib and the STELLAR-4 Study

Selonsertib is an investigational small molecule inhibitor of ASK1, a protein that promotes inflammation, apoptosis (cell death) and fibrosis in settings of oxidative stress. Oxidative stress can be increased in many pathological conditions including liver diseases such as NASH.

The STELLAR-4 study is a Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of selonsertib in patients with compensated cirrhosis (F4) due to NASH. Eligible adults ages 18 to 70 years were randomized and received selonsertib 18 mg ($n=354$), selonsertib 6 mg ($n=351$) or placebo ($n=172$) for up to 240 weeks. Either selonsertib or placebo is being administered orally once daily. The primary endpoints of the study are a composite of the proportion of patients who achieve a ≥ 1 -stage improvement in fibrosis according to the NASH CRN classification without worsening of NASH at week 48 and event-free survival at week 240 as assessed by time to the first clinical event. Further information about the clinical study can be found at www.clinicaltrials.gov.

About Gilead's Clinical Programs in NASH

NASH is a chronic and progressive liver disease characterized by fat accumulation and inflammation in the liver, which can lead to scarring, or fibrosis, that impairs liver function. Individuals with advanced fibrosis, including bridging fibrosis (F3) or compensated cirrhosis (F4), are at a significantly higher risk of liver-related mortality and all-cause mortality.

Gilead is advancing multiple novel investigational compounds for the treatment of advanced fibrosis due to NASH, evaluating single-agent and combination therapy approaches against the core pathways associated with NASH – hepatocyte lipotoxicity, inflammation and fibrosis. Investigational compounds in development include the ASK1 inhibitor selonsertib, the selective, non-steroidal FXR agonist cilofexor (GS-9674) and the ACC inhibitor firsocostat (GS-0976). The STELLAR-3 Phase 3 trial evaluating selonsertib among NASH patients with bridging fibrosis (F3) is ongoing. Cilofexor and firsocostat are currently in Phase 2 studies in NASH, including the ATLAS Phase 2 trial evaluating combinations of selonsertib, cilofexor and firsocostat in advanced fibrosis (F3 and F4) due to NASH.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead's ability to complete its clinical trial programs evaluating single-agent and combination therapy approaches, including selonsertib, cilofexor and/or firsocostat, in patients with NASH in the currently anticipated timelines or at all. In addition, there is the possibility of unfavorable results from further clinical trials involving these compounds. Further, it is possible that Gilead may make a strategic decision to discontinue development of selonsertib, cilofexor and/or firsocostat if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, the compounds may never be successfully commercialized. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely

on these forward-looking statements.

These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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Source: Gilead Sciences, Inc.

Sung Lee, Investors
(650) 524-7792

Arran Attridge, Media
(650) 425-8975