Gilead Announces Topline Data From Phase 3 STELLAR-3 Study of Selonsertib in Bridging Fibrosis (F3) Due to Nonalcoholic Steatohepatitis (NASH)

April 25, 2019

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 25, 2019--Gilead Sciences, Inc. (Nasdaq: GILD) today announced that STELLAR-3, 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), for patients with bridging fibrosis (F3) 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 802 enrolled and dosed patients, 9.3 percent of patients treated with selonsertib 18 mg (p=0.42 versus placebo) and 12.1 percent of patients treated with selonsertib 6 mg (p=0.93) 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, versus 13.2 percent with placebo. Selonsertib was generally well tolerated and safety results were consistent with prior studies.

“While we had hoped for different outcomes from the STELLAR program, we remain focused and committed to developing highly effective treatments for patients living with advanced fibrosis due to NASH. We are actively exploring the STELLAR data and will work with external collaborators like PathAI and insitro, to further our understanding of this complex disease and advance our development programs. We thank the patients and their physicians who participated in the STELLAR program for contributing to these efforts,” said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development, Gilead Sciences. “We believe that effective therapy for NASH will ultimately require a combination approach that targets distinct pathways involved in the pathogenesis of this disease. In this regard, we look forward to data from the Phase 2 ATLAS combination trial of selonsertib, cilofexor and firsocostat in patients with advanced fibrosis due to NASH, which will be available later this year.”

Gilead will now work with the Data Monitoring Committee and investigators to conclude the STELLAR-3 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-3 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-3 study is a Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of selonsertib in patients with bridging fibrosis (F3) due to NASH. Eligible adults ages 18 to 70 years were randomized to receive selonsertib 18 mg (n=322), selonsertib 6 mg (n=321) or placebo (n=159) for up to 240 weeks, 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 as defined by the NAFLD activity score (NAS) at week 48 and event-free survival at week 240 as assessed by time to the first clinical event. Secondary endpoints include the proportion of patients who have a ≥ 1-stage improvement in fibrosis without worsening of NASH at week 240, and the proportion of patients who have NASH resolution without worsening of fibrosis at week 48 and week 240. 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 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, and the ACC inhibitor, firsocostat, which are being studied in the Phase 2 ATLAS trial as single agents and combinations 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-K for the year ended December 31, 2018, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently

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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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