Gilead Announces Phase 3 Results for Investigational Fixed-Dose Combination of Bictegravir, Emtricitabine and Tenofovir Alafenamide for Treatment of HIV

July 24, 2017 5:07 AM ET

– Bictegravir-Containing Regimen Found to be Non-Inferior to Dolutegravir-Containing Regimens –

– Investigational Regimen Demonstrated No Treatment-Emergent Resistance through 48 Weeks –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 24, 2017-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced detailed 48-week results from two Phase 3 studies (Studies 1489 and 1490) evaluating the efficacy and safety of a fixed-dose combination of bictegravir (50 mg) (BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25mg) (FTC/TAF), a dual-NRTI backbone, for the treatment of HIV-1 infection in treatment-naïve adults. In the ongoing studies, BIC/FTC/TAF was found to be statistically non-inferior to regimens containing dolutegravir (50mg) (DTG) in combination with a dual-NRTI backbone. The data were presented in two late-breaker sessions [MOAB01 and TUPDB02] at the 9th IAS Conference on HIV Science (IAS 2017) in Paris.

“Physicians continue to look for treatment regimens with simple, convenient dosing that can sustain virologic suppression with a safety profile that is appropriate for most HIV patients,” said Joel Gallant, MD, MPH, Medical Director of Specialty Services at Southwest CARE Center in Santa Fe, N.M. and lead author of Study 1489. “Combinations of an integrase inhibitor plus a dual-NRTI backbone have become a standard of care for initial treatment of HIV. In clinical trials, the investigational regimen of BIC/FTC/TAF has been well tolerated with low rates of discontinuations due to adverse events, a high barrier to resistance and few drug interactions.”

“These data reinforce the safety and efficacy profile consistently seen in other trials evaluating regimens based on the FTC/TAF combination,” said Paul Sax, MD, Clinical Director of the Division of Infectious Diseases at Brigham and Women’s Hospital, Boston, Professor of Medicine at Harvard Medical School and lead author of Study 1490. “These results suggest that the combination of bictegravir with FTC/TAF has the potential to be appropriate for a broad range of HIV patients, including those with mild to moderate renal impairment.”

In Study 1489, a total of 629 treatment-naïve adults with HIV were randomized 1:1 to receive BIC/FTC/TAF or abacavir/dolutegravir/lamivudine (600/50/300mg) (ABC/DTG/3TC). At Week 48, 92.4 percent (n=290/314) of patients taking BIC/FTC/TAF and 93.0 percent (n=293/315) of patients taking ABC/DTG/3TC achieved the primary endpoint of HIV-1 RNA levels less than 50 copies/mL (difference: -0.6 percent, 95 percent CI: -4.8 percent to 3.6 percent, p=0.78).

A separate analysis investigated the effect of the two regimens on changes in bone mineral density (BMD) and measures of renal function. Mean percentage changes in BMD from baseline to Week 48 were -0.83 percent for BIC/FTC/TAF vs. -0.60 percent for ABC/DTG/3TC (p=0.39) in lumbar spine, and -0.78 percent for BIC/FTC/TAF vs. -1.02 percent for ABC/DTG/3TC (p=0.23) in total hip. No differences were noted between the treatments in changes from baseline to Week 48 for estimated glomerular filtration rate (eGFR) or proteinuria. Lipid changes were not significantly different between the two arms. No patients randomized to either arm developed treatment-emergent resistance and discontinuations due to adverse events were low in both groups (0.0 percent (n=0) for BIC/FTC/TAF vs. 1.3 percent (n=4) for ABC/DTG/3TC). The most commonly reported adverse events (all grades) were nausea (10 percent for BIC/FTC/TAF vs. 23 percent for ABC/DTG/3TC), diarrhea (13 percent vs. 13 percent) and headache (11 percent vs. 14 percent).

In Study 1490, a total of 645 treatment-naïve adults with HIV were randomized 1:1 to receive BIC/FTC/TAF or DTG+FTC/TAF. At Week 48, 89.4 percent (n=286/320) of patients taking BIC/FTC/TAF and 92.9 percent (n=302/325) of patients taking DTG+FTC/TAF achieved the primary endpoint of HIV-1 RNA levels less than 50 copies/mL (difference: -3.5 percent, 95 percent CI: -7.9 percent to 1.0 percent, p=0.12). No patients in either treatment arm developed resistance to any of the study drugs. Lipid changes were not significantly different between the two arms, and

there were no renal discontinuations or cases of proximal renal tubulopathy. Discontinuations due to adverse events were low in both treatment arms (1.6 percent (n=5) for BIC/FTC/TAF vs. <1.0 percent (n=1) for DTG+FTC/TAF). The most commonly reported adverse events (all grades) were headache (13 percent for BIC/FTC/TAF vs. 12 percent for DTG+FTC/TAF) and diarrhea (12 percent vs. 12 percent).

“The Phase 3 findings presented at IAS 2017 demonstrate that a single-tablet combination of bictegravir with the FTC/TAF backbone may deliver an important novel triple-therapy HIV treatment,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “These data in treatment-naïve patients, and data from two additional Phase 3 studies in treatment-experienced patients, formed the basis of our regulatory applications in the United States and the European Union.”

In addition to Studies 1489 and 1490, 48-week data from two other ongoing studies evaluating BIC/FTC/TAF among virologically suppressed adult patients (Studies 1844 and 1878) are also part of the regulatory submissions in the U.S. and EU.

Bictegravir in combination with FTC/TAF as a single tablet regimen is an investigational treatment that has not been determined to be safe or efficacious and is not approved anywhere globally.

Further information about the clinical trials can be found at www.clinicaltrials.gov.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company’s mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

For nearly 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, it’s estimated that more than 10 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company’s manufacturing partners.

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 the possibility that regulatory authorities may not approve BIC/FTC/TAF in the currently anticipated timelines, and marketing approvals, if granted, may have significant limitations on their use. As a result, BIC/FTC/TAF 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 March 31, 2017, 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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