Gilead to Present New Data on HIV Prevention, Treatment and Cure Research at IAS 2019

July 18, 2019

FOSTER CITY, Calif. -- (BUSINESS WIRE) -- Jul. 18, 2019 -- Gilead Sciences, Inc. (NASDAQ: GILD) today announced that new data from the company’s HIV research and development programs will be presented at the 10th International AIDS Society Conference on HIV Science (IAS 2019) being held in Mexico City from July 21-24. Fifteen abstracts, along with community-focused symposia and workshops, reflect Gilead’s ongoing commitment to scientific innovation, a key pillar to addressing unmet and evolving medical needs in HIV.

“Gilead’s scientific discovery has helped transform both HIV treatment and prevention and we are committed to advancing the next generation of therapies to improve the care of people and communities impacted by this disease,” said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research & Development, Gilead Sciences. “Our data at this year’s meeting include exciting progress in our HIV prevention, treatment and cure programs, which together are helping to advance the field of HIV toward the ultimate goal of ending the epidemic.”

Data from Gilead’s HIV research and development program to be presented at the meeting include two late-breaking presentations. The first late-breaker presentation will share additional results from the DISCOVER trial, evaluating Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets; F/TAF) for HIV pre-exposure prophylaxis (PrEP). Descovy was approved for the treatment of HIV infection in combination with other agents in 2016. The use of Descovy for HIV prevention is investigational, Gilead submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) in early April for once-daily Descovy for PrEP™, with a target FDA action date anticipated six months thereafter.

The second late-breaking presentation includes the latest findings on the potential role of GS-6207, a novel, investigational HIV-1 capsid inhibitor. In late May, FDA granted Breakthrough Therapy Designation for the development of GS-6207 for the treatment of HIV-1 infection in heavily treatment experienced patients with multi-drug resistance.

In addition, new safety and efficacy data on Biktarvy® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg; B/F/TAF) in virologically suppressed patients and women will be presented, along with ongoing research on agents that may one day play a role in an HIV cure strategy. On June 20, FDA approved labeling revisions to Biktarvy to expand the patient population to include HIV-1 infected pediatric patients weighing at least 25 kg.

Select Gilead HIV clinical development program data to be presented at IAS 2019:

**HIV prevention**

- **DISCOVER STUDY for HIV Pre-Exposure Prophylaxis (PrEP): F/TAF has a More Rapid Onset and Longer Sustained Duration of HIV Protection Compared with F/TDF** [TUAC0403LB; Oral Presentation – Hot off the press: What’s new in HIV prevention; Tuesday, July 23, 16:30 – 18:00; Palacio de Valparaíso 2]
- **A Pooled Analysis of the Effect of Adherence on the Renal Safety of FTC/TDF (Truvada) for PrEP: 7 International Demonstration Projects** [TUPEC393; Poster Exhibition – Track C; Sala B]

**Investigational long-acting therapy**

- **Safety and Antiviral Activity Over 10 Days Following a Single Dose of Subcutaneous GS-6207, a First-in-Class, Long-Acting HIV Capsid Inhibitor in People Living with HIV** [LBPEB13; Poster Exhibition – Track B; Sala B]
- **In Vitro Resistance Profile of GS-6207, a First-in-Class Picomolar HIV Capsid Inhibitor in Clinical Development as a Novel Long-Acting Antiretroviral Agent** [TUPEA075; Poster Exhibition – Track A; Sala B]

**HIV treatment**

- **Switching to a Single-Tablet Regimen Bictegravir, Emtricitabine, and Tenofovir Alafenamide (B/F/TAF) from Dolutegravir (DTG) Plus Emtricitabine and Either Tenofovir Alafenamide or Tenofovir Disoproxil Fumarate (F/TAF or F/TDF)** [MOAB0105; Oral Presentation – ART: Trials and tribulations; Monday, July 22, 11:00 – 12:30; Sala A]
- **Longer-Term (96-week) Efficacy and Safety of Switching to Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Women** [MOAB0106; Oral Presentation – ART: Trials and tribulations; Monday, July 22, 11:00 – 12:30; Sala A]

**HIV cure strategy research**

- **Vesatolimod (GS-9620) is Safe and Pharmacodynamically Active in HIV-Infected Individuals** [WEAA0304; Oral Presentation – Mission remission: Challenge accepted; Wednesday, July 24, 16:30 – 18:00; Palacio de Valparaíso 1]
- **Oral TLR7 Agonist Administration Induces an Immunostimulatory Response in SIV-Infected ART-Suppressed Infant Rhesus Macaques** [WEAA0105; Oral Presentation – Paediatric HIV infection: It’s never too early; Wednesday, July 24, 11:00 – 12:30; Palacio de Iturbide 1 y 2]

For more information, including a complete list of abstract titles at the meeting, please visit: [http://programme.ias2019.org/Abstract](http://programme.ias2019.org/Abstract).

The use of Descovy for the prevention of HIV is investigational and has not been determined to be safe or efficacious and is not approved anywhere globally.
Neither Biktarvy nor Descovy cures HIV infection or AIDS.

Gilead’s efforts to address barriers to HIV care

Beyond presenting scientific data from the company’s HIV research and development program, Gilead will convene discussions about the barriers that can influence engagement in HIV care on individual, systemic and community levels. New programs and strategies are needed to assess and address the barriers to care that can prevent people and communities impacted by HIV from accessing care. These Gilead-supported sessions are part of the company’s ongoing efforts to changing the future of the epidemic through supporting the development and delivery of practical solutions towards better care for those people living with or at risk for HIV.

IMPORTANT U.S. SAFETY INFORMATION AND INDICATION FOR DESCOVY

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- Descovy is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Descovy have not been established in patients coinfected with HIV-1 and HBV. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of Descovy. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue Descovy. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Warnings and precautions

- Immune reconstitution syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- New onset or worsening renal impairment: Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of FTC and tenofovir alafenamide with elvitegravir and cobicistat, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate Descovy in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue Descovy in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
- **Renal monitoring:** In all patients, monitor CrCl, urine glucose, and urine protein prior to initiating and during therapy. In patients with chronic kidney disease, additionally monitor serum phosphorus
- Lactic acidosis and severe hepatomegaly with steatosis: Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue Descovy if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- Most common adverse reaction (incidence ≥10%; all grades) in clinical studies was nausea (10%).

Drug interactions

- Prescribing information: Consult the full prescribing information for Descovy for more information on potentially significant drug interactions, including clinical comments.
- Metabolism: Drugs that inhibit P-gp can increase the concentrations of components of Descovy. Drugs that induce P-gp can decrease the concentrations of components of Descovy, which may lead to loss of efficacy and development of resistance.
- Drugs affecting renal function: Coadministration of Descovy with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine and tenofovir and the risk of adverse reactions.

Dosage and administration

- Dosage: Patients who weigh ≥25 kg: 1 tablet taken orally once daily with or without food.
- Renal impairment: Not recommended in patients with CrCl <30 mL/min.
- Testing prior to initiation: Test patients for HBV infection and assess CrCl, urine glucose and urine protein.
- Pediatrics: The safety and effectiveness of Descovy coadministered with an HIV-1 protease inhibitor that is administered with either ritonavir or cobicistat have not been established in pediatric subjects weighing less than 35 kg.

Pregnancy and lactation

- Pregnancy: There is insufficient human data on the use of Descovy during pregnancy. An Antiretroviral Pregnancy Registry
(APR) has been established; available data from the APR for FTC shows no difference in the rates of birth defects compared with a U.S. reference population.

- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

**INDICATION**

Descovy is indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in patients weighing at least 35 kg.

Descovy is also indicated, in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.

**Limitations of Use:**

Descovy is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV-1 infection.

**IMPORTANT U.S. SAFETY INFORMATION AND INDICATION FOR BIKTARVY**

**BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B**

- Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of Biktarvy. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue Biktarvy. If appropriate, anti-hepatitis B therapy may be warranted.

**Contraindications**

- **Coadministration:** Do not use Biktarvy with dofetilide or rifampin.

**Warnings and precautions**

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during Biktarvy therapy and monitor for adverse reactions.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of Biktarvy, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate Biktarvy in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue Biktarvy in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  - **Renal monitoring:** Prior to or when initiating Biktarvy and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue Biktarvy if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

**Adverse reactions**

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 96 were diarrhea (6%), nausea (6%), and headache (5%).

**Drug interactions**

- **Prescribing information:** Consult the full prescribing information for Biktarvy for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of Biktarvy. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of Biktarvy. Biktarvy can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- **Drugs affecting renal function:** Coadministration of Biktarvy with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

**Pregnancy and lactation**
Pregnancy: There is insufficient human data on the use of Biktarvy during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.

Lactation: Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

Dosage and administration

- **Dosage:** 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

INDICATION

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen for ≥3 months with no history of treatment failure and no known resistance to any component of Biktarvy.

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 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 12 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company’s manufacturing partners.

For more information on Gilead Sciences, please visit the company’s website at [www.gilead.com](http://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 the risk that the sNDA for Descovy for PrEP may not get approved by FDA or other regulatory authorities in the currently anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. In addition, there is the possibility of unfavorable results from other ongoing and additional clinical trials involving GS-6207, GS-9620 and GS-968. As a result, Descovy for PrEP, GS-6207, GS-9620 and/or GS-968 may never be successfully commercialized, and Gilead may be unsuccessful in developing an HIV cure strategy. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements.

U.S. full Prescribing Information for Descovy, Truvada and Biktarvy, including **BOXED WARNINGS**, is available at [www.gilead.com](http://www.gilead.com).

For more information on Gilead Sciences, please visit the company’s website at [www.gilead.com](http://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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