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# OUR MISSION



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Gilead Lab

## SCIENTIFIC INNOVATION & ADDRESSING UNMET NEEDS

Gilead uses its scientific expertise to help transform and simplify care for people with life-threatening illnesses around the world. With a portfolio of more than 25 products and hundreds of ongoing and planned clinical studies, we are focused on solving some of the biggest health challenges today. For more than 30 years, Gilead's products have targeted therapeutic areas of unmet medical need, which today include HIV/AIDS, liver diseases, hematology and oncology, inflammatory diseases and respiratory diseases.

### HIV

Gilead has been a leading innovator in the field of HIV for nearly 30 years, driving advances in treatment, prevention and cure research. In 2017, we saw growing uptake of our tenofovir alafenamide (TAF)-containing medicines. Our first TAF-containing products for HIV — Genvoya®, Odefsey® and Descovy® — came out in 2015 and 2016, and in the past year, we've seen them achieve more than 50 percent of the market share of our tenofovir-containing regimens.

In 2017, we released Phase 3 study data for Biktarvy®, a daily single tablet regimen combining bictegravir, emtricitabine and TAF, which was found to be effective and tolerable for both patients new to treatment and stably suppressed patients transitioning from other medicines. Biktarvy received FDA approval in February 2018.

In addition, we are continuing to develop new treatment options that will offer alternatives to daily regimens. Gilead is developing GS-CA1, an investigational small molecule capsid inhibitor designed to disrupt the protein shell that protects the viral genome, interfering with two stages of the virus's replication cycle. GS-CA1 is being formulated as a long-acting injectable that could be administered monthly or quarterly, providing potential treatment alternatives for patients who find it difficult to maintain a daily medication regimen.

Despite tremendous advances in treatment, HIV is still an epidemic, and it continues to have a heavy impact among the most marginalized populations. Through the advancement of pre-exposure prophylaxis (PrEP), Gilead is helping HIV-negative individuals who are at-risk reduce their chances of acquiring HIV infection through sex. In 2017, more than 153,000 people in the United States who are at-risk of



contracting HIV sexually were prescribed Truvada® to help protect themselves from HIV infection when used in combination with safer sex practices.

In the past decade, the epicenter of the HIV/AIDS epidemic in the United States has moved to the South, which now experiences the greatest burden of infection, illness and deaths of any region in the nation. In 2017, Gilead launched the Gilead COMPASS (COMmitment to Partnership in Addressing HIV/AIDS in Southern States) Initiative™ to increase the reach of groups working to address the HIV/AIDS epidemic and improve the lives of those affected by the disease in the region.

Treatment and prevention are vital, but Gilead is also actively working to

## 153,000

people in the United States prescribed Truvada for preventing HIV infection when used in combination with safer sex practices.

cure HIV. We have several medicines in development that are intended to eliminate the HIV viral reservoirs that form in a patient's body while protecting uninfected cells. Our goal is to reverse the latency that enables the virus to lurk undetected by the immune system; eliminate the infected cells through activation of a number of immune mechanisms including natural killer cells and macrophages; and engage antibodies that provide ongoing resistance to HIV exposure. The complexity of HIV infection requires a multifaceted

approach, and we are collaborating with a number of research organizations on Phase 1 studies of specific aspects of this potential cure research strategy.

We are also pursuing an HIV cure by supporting the efforts of other researchers in the field. The HIV cure grants program, initially announced in February 2016, provides funding to top academic institutions focused on HIV translational research and efficacy studies in preclinical models. The first set of HIV cure grants, totaling more than \$22 million, were awarded to 12 projects in January 2017. In October 2017, Gilead announced the second round of grants totaling \$7.5 million to support five additional HIV cure research initiatives.

## Oncology

To advance and accelerate research and development efforts in cancer immunotherapy and other cell-based therapies, Gilead completed acquisitions of Kite Pharma and Cell Design Labs in 2017. These acquisitions place Gilead at the forefront of cell therapy, among oncology's most exciting fields of research and development.

Just a few weeks after the Kite acquisition was completed in October, the FDA granted approval for Yescarta® (axicabtagene ciloleucel, or axi-cel™), the first chimeric antigen receptor T (CAR T) cell therapy for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy. CAR T cell therapy re-engineers a patient's own T cells to detect and kill cancer cells. Yescarta, which is individually manufactured for each patient, has the potential to become one of the most powerful agents for certain types and lines of therapies for hematologic cancers. By the end of 2017, 16 United States treatment centers were certified to administer Yescarta and were starting to enroll patients. Certification is being rolled out gradually, as centers must be carefully trained to manage the complex administrative process and understand how to address the risk of potentially serious side effects, including cytokine response syndrome and neurotoxicity. Kite expects to have Yescarta accessible to 80 percent of eligible patients during the second half of 2018.

Kite continues to research additional uses for CAR T cell therapy, including treatments for refractory acute lymphoblastic leukemia and other blood cancers, solid tumors, and other complex diseases such as autoimmune and degenerative disorders.

In December, Gilead acquired Cell Design Labs, a company with significant expertise in custom cell engineering that is currently developing two proprietary technology platforms: synNotch™, a synthetic gene expression system that can be used to engineer customized therapeutic responses in



Kite employees in Santa Monica, CA

*Today, we are a leader in engineered T cell therapy, transforming cancer treatment with what is potentially the biggest breakthrough since the introduction of combination chemotherapy more than 60 years ago.*

CAR T cells, and Throttle™, an “on switch” that can control CAR T activity in response to small molecules. SynNotch and Throttle are designed to improve the precision and control of immunotherapy treatment, potentially improving safety and efficacy across a broad range of diseases such as prostate cancer, liver cancer and multiple myeloma.

## Liver Disease

Gilead is at the forefront of advancing care for people living with liver disease, including the approximately 400 million people living with hepatitis worldwide. We have developed breakthrough medicines for the treatment of chronic hepatitis C virus (HCV) infection and are developing innovative treatments to manage or potentially cure chronic hepatitis B virus (HBV) infection. In addition, we seek to remove barriers to testing and treatment for at-risk individuals and expand access to our therapies worldwide. We are also developing medicines for nonalcoholic steatohepatitis (NASH), a fatty liver disease that is expected to become the leading cause of liver transplantation by 2020.

### Hepatitis C Virus

Currently, no vaccine exists for HCV and, until recently, treatment could take six to 12 months, often with debilitating side effects and low cure rates. Gilead has helped transform the treatment of liver disease by providing medicine options that offer cure rates as high as 95 to 99 percent for all genotypes (1-6) of HCV infection in less time and with fewer side effects than prior interferon-containing treatment regimens.

Gilead is actively supporting worldwide efforts to eliminate HCV by 2030. With approximately 71 million people infected with HCV worldwide, Gilead’s highly effective and tolerated single tablet regimens (STRs) have helped significantly reduce the total HCV burden worldwide.

In 2017, Gilead launched Sovaldi® in China, for use with certain other medicines, bringing new treatment for certain genotypes of chronic HCV to the approximately 10 million people there infected with the virus. In addition, the FDA and European Commission granted marketing authorization for Vosevi® as a once-daily STR for the treatment of certain adults with genotype 1-6 chronic HCV infection.

***Gilead is actively supporting worldwide efforts to eliminate HCV by 2030.***



#### **Single tablet regimen**

Gilead’s highly effective and tolerated STRs have helped significantly reduce the total HCV burden worldwide.

#### **95%-99% cure rates**

Medicine options provided by Gilead offer cure rates as high as 95 to 99 percent for all genotypes (1-6) of HCV infection.

#### **71 million**

People infected with HCV worldwide.

### **Nonalcoholic steatohepatitis**

Another focus of Gilead’s efforts in liver disease is NASH, a progressive fatty liver disease associated with obesity that leads to inflammation and fibrosis (scarring), which further impair liver function. NASH patients whose fibrosis progresses to cirrhosis have a median time to death of just five years. There currently are no treatments approved for people living with NASH.

Gilead is researching three molecules targeting different biological pathways associated with NASH. This includes two ongoing Phase 3 studies of the ASK-1 inhibitor selonsertib, an investigational first-in-class molecule targeting apoptosis signal-regulating kinase 1 (ASK-1), a protein that’s activated in NASH and other metabolic disorders, helping to lead to fibrosis. Gilead is also conducting Phase 2 studies with investigational therapies targeting farnesoid X receptor and acetyl-CoA carboxylase and will begin Phase 2 combination studies this year.

### Hepatitis B Virus

For two decades, Gilead has worked to improve care for people living with chronic HBV. While a vaccine exists for HBV, developing a cure is a more complex challenge than it is for HCV. Gilead scientists believe a cure will need to combine multiple drugs that inhibit viral replication while simultaneously eliminating HBV DNA from all infected liver cells. Gilead continues to conduct research and clinical trials on novel therapies aimed at enabling the immune system to suppress HBV infection. Gilead offers medicines including Viread® and Vemlidy® that help patients treat chronic infection.

### Additional Focus Areas

Gilead is bringing scientific expertise and determination to the fight against other challenging diseases, including inflammatory diseases and emerging viruses. Clinical trials are underway for filgotinib, an investigational once-daily, highly selective Janus kinase-1 inhibitor that shows promise for inflammatory diseases such as rheumatoid arthritis (RA) and Crohn's disease. Filgotinib has shown a promising efficacy and safety profile in Phase 2 trials for RA and Crohn's disease; we are currently enrolling patients for Phase 3 trials for RA, Crohn's disease and ulcerative colitis and expect to start sharing data from these studies beginning in 2018. Gilead is partnering with a variety of organizations to conduct clinical trials of investigational agent remdesivir as a potential treatment for Ebola and other emerging viruses, including Dengue and Marburg, in the countries and regions where the viruses pose the greatest threat.

## ACCESS TO OUR MEDICINES

To be effective at treating, curing or preventing diseases, medicines must be available to the patients who need them. Through our Access to Medicines programs, Gilead is working to expand access to treatment wherever possible by helping patients overcome barriers to get the medicines they need. Gilead is expanding disease awareness, addressing stigma and supporting front-line services and care in more than 130 low- and middle-income countries.

### Access to Our Medicines in the United States

The United States healthcare landscape is complex and can be difficult for patients to navigate. To ease the burden this can place on patients and their families, Gilead's Patient Support Programs help provide patients with access to medicines, copay assistance and counseling across our therapeutic areas.



**>40,000**

Patients received treatment at no cost using Gilead's Patient Assistance Program.



**50%**

Of all individuals taking Gilead HIV medicines in the United States receive them through federal and state programs at substantially discounted prices.

### Gilead Patient Support Programs

#### Patient Counseling

We offer support in navigating access and coverage for patients who have insurance but are unsure whether their plan provides coverage or affordable copays for our medicines. Our case managers help patients understand what their insurance will cover and provide research on potential alternative coverage and copay support.

#### Patient Assistance Programs

Patients without insurance can apply to our Patient Assistance Program to receive treatment at no cost; patients who qualify can receive their Gilead products free, directly from Gilead. In 2017, more than 40,000 patients received treatment at no cost.

To see the full list of programs through which we offer Patient Support, please visit the [United States Patient Access](#) page of our website.

### Assistance for Individuals Living with HIV

Approximately half of all individuals taking Gilead HIV medicines in the United States receive them through federal and state programs at substantially discounted prices. We have a long history of working with state AIDS Drug Assistance Programs to provide lower pricing for our HIV medicines.

Gilead's Truvada for PrEP Medication Assistance Program helps eligible HIV-negative adults in the United States who do not have insurance to obtain access to Truvada for PrEP. Gilead also offers a copay assistance program to help eligible patients with insurance offset out-of-pocket costs. Gilead recently enhanced these programs to ensure the assistance provided for Truvada is consistent, regardless of whether an individual needs access for prevention or treatment. The number of people prescribed Truvada for PrEP has increased to more than 153,000 in the United States.

### Access to Our Medicines in Low- and Middle-Income Countries

In 2018, Gilead will mark the 15th anniversary of pioneering programs that provide access to our medicines in low- and middle-income countries. During that time we have learned that there is no one-size-fits-all solution to treatment access challenges. That's why we work with public health officials, community advocates, researchers, doctors and patients to understand barriers and opportunities, with a focus on communities impacted by HIV, viral hepatitis and visceral leishmaniasis.

To increase education and disease awareness, engage partners strategically and deliver medicines efficiently, we offer:

- Tiered pricing, with discounts on medicines based on disease burden and national per-capita income.
- Responsible generic licensing of our products to enable high-quality, low-cost versions of Gilead's HIV and viral hepatitis medicines for patients in low- and middle-income countries.
- Advocacy for public health initiatives and policies that maximize patient reach and prevent new infections.



## >11 million

In 2017, more than 11 million people benefited from Gilead medicines in low- and middle-income countries.



## 130 countries

Low- and middle-income countries supported by Gilead through our access to medicines programs.

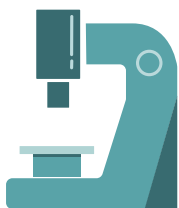
## Strengthening Health Systems

Strengthening public health systems is at the core of our strategy to expand treatment access. All too often, inadequate infrastructure creates barriers for patients, so we work with partners worldwide to improve infrastructure from the ground up.



### Educating communities

We support community organizations in their efforts to develop public health education programs.



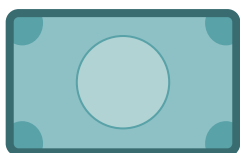
### Supporting collaborative research

We work with investigators in low- and middle-income nations to demonstrate the efficacy of our medicines, evaluate new drugs and identify optimal strategies that connect patients from screening to care. In addition, we invest in high-quality research facilities that attract and support talented young researchers from low- and middle-income countries.



### Preparing the healthcare workforce

Many low- and middle-income countries have too few qualified front-line healthcare workers and lack access to the latest training and resources. We help provide trainings, continuing education and long-distance learning to share the latest standards of care.



### Providing technical assistance

We provide financial support and technical assistance to help low- and middle-income countries' health systems obtain urgently needed medical equipment and basic necessities.



### Securing the supply chain

We help ensure communities have uninterrupted supplies of medicines by investing in proprietary tools that our partners can use to forecast demand and prevent supply disruptions.

### Fostering Global Support Through Advocacy

We work with partners around the world to make an evidence-based case for policies that will improve access to health services in low- and middle-income countries. The prevention, screening and treatment standards established by the World Health Organization, International AIDS Society and other organizations play a critical role in driving progress against disease. To help ensure their guidelines are informed by the latest evidence, we regularly share scientific and cost-effectiveness data. We also work with national governments to develop research and organize events that demonstrate the benefits of health investment and enable policymakers from around the world to share best practices and make new commitments.

In 2017, we reaffirmed our commitment to the London Declaration, a global pledge to combat 10 key neglected tropical diseases by 2020. Cases of visceral leishmaniasis have dropped significantly in endemic regions. We also co-organized a Wilton Park symposium in Swakopmund, Namibia, which brought together government officials, scientists, patient advocates and program implementers to identify ways to strengthen the HIV prevention movement in sub-Saharan Africa.

### Compassionate Use: Expanded Access Program

Gilead's expanded access program, also known as "compassionate use," provides the opportunity for individual patients with serious or life-threatening conditions to access our investigational medicinal products.

Our Expanded Access Program varies regionally as a result of the unique regulatory mechanisms in different countries worldwide. Since investigational medicinal products have not yet received regulatory approval, their potential risks and benefits are not yet established. It is important for physicians and patients to consider all possible benefits and risks when seeking access to an investigational medicinal product.



Gilead evaluates standard criteria when considering requests from individual patients to participate in our expanded access program. These criteria include:

- A strong biological rationale or clinical data show that the potential patient benefits of the investigational medicine outweigh the potential risks.
- The patient's physician has determined that treatment with the investigational medicine is in the patient's best interests.
- The investigational medicine will be administered in accordance with applicable laws and regulatory requirements.
- The patient is not eligible or able to participate in a clinical trial or similar sponsored access program.
- No therapeutic alternative is available.

Visit Gilead's [Expanded Access](#) webpage for more information on individual access to investigational medicines intended to treat serious diseases.