

# Gilead Sciences

Advancing Therapeutics. Improving Lives.



## Company Overview

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. With each new discovery and investigational drug candidate, we seek to improve the care of patients living with life-threatening diseases around the world. Gilead's therapeutic areas of focus include HIV/AIDS, liver diseases, hematology and oncology, inflammatory and respiratory diseases and cardiovascular conditions.

Our portfolio of 22 marketed products contains a number of category firsts, including complete treatment regimens for HIV and chronic hepatitis C infection available in once-daily single pills. Gilead's portfolio includes Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg) for chronic hepatitis C, which is a complete antiviral treatment regimen in a single tablet that provides high cure rates and a shortened course of therapy for many patients.



Harvoni, Gilead's once-daily single tablet hepatitis C regimen.

### Nearly 30 Years of Growth

Since its founding in Foster City, California, in 1987, Gilead has become a leading biopharmaceutical company with a rapidly expanding product portfolio, a growing pipeline of investigational drugs and over 8,000 employees in offices across six continents. Millions of people around the world are living healthier lives because of innovative therapies developed by Gilead.

Today, our research and development effort includes more than 400 ongoing and planned clinical studies evaluating compounds with the potential to become the next generation of effective medicines.

Gilead's 2015 annual revenues were \$32.6 billion and the company is #1 in the *Barron's* 500 rankings. Recently, Gilead was named one of *Fast Company's* Most Innovative Companies of 2015 and ranked #36 in Business Insider's list of the 50 Best Companies To Work For In America.

### Key Moments in Our History

- 1987** Gilead founded
- 1990** AmBisome® approved (Europe)
- 1991** Nucleotides in-licensed from IOCB Rega
- 1996** Vistide® approved
- 1999** Tamiflu® approved; NeXstar acquired
- 2001** Viread® approved
- 2002** Hepsera® approved
- 2003** Emtriva® approved; Triangle Pharmaceuticals acquired
- 2004** Truvada®, Macugen® approved
- 2006** Ranexa®, Atripla® approved; Corus, Raylo, Myogen acquired
- 2007** Letairis® approved; Cork, Ireland, manufacturing facility acquired from Nycomed
- 2008** Lexiscan®, Viread® for hepatitis B approved
- 2009** CV Therapeutics acquired
- 2010** Cayston® approved; CGI Pharmaceuticals acquired
- 2011** Complera® approved; Arresto BioSciences, Calistoga Pharmaceuticals acquired
- 2012** Truvada® for PrEP, Stribild® approved; Pharmasset acquired
- 2013** Sovaldi® approved; YM BioSciences acquired
- 2014** Zydelig®, Tybost®, Vitekta®, Harvoni® approved
- 2015** Genvoya® approved; EpiTherapeutics acquired
- 2016** Odefsey®, Descovy® approved

# Marketed Products

Following is a summary of Gilead's product portfolio. For safety information on these products see full Prescribing Information, including **BOXED WARNINGS** for certain products, on Gilead.com.

## HIV/AIDS



Atripla (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients 12 years of age and older. Atripla combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), manufactured by Gilead, and Sustiva® (efavirenz), manufactured by Bristol-Myers Squibb Company. (First U.S. approval, 2006; EU approval, 2007. Bristol-Myers Squibb Company commercializes the product in the United States, Western Europe and Canada; Merck & Co., Inc. commercializes the product in the rest of the world.)



Complera (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) is indicated for use as a complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history and with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy, and in certain virologically-suppressed (HIV-1 RNA <50 copies/mL) adult patients on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen. For prescribing considerations, please see the full Prescribing Information for Complera. Complera combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), manufactured by Gilead, and Edurant® (rilpivirine), manufactured by Janssen R&D Ireland. (First U.S. and EU approval, 2011; marketed as Eviplera® in Europe. Janssen R&D Ireland commercializes the product in select markets.)



Descovy (emtricitabine 200 mg/tenofovir alafenamide 25 mg) is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. Descovy is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. (U.S. and EU approval, 2016.)



Emtriva (emtricitabine) 200 mg is a once-daily oral nucleoside analog reverse transcriptase inhibitor (NRTI) used in combination with other antiretroviral agents for the treatment of HIV-1 infection. (U.S. and EU approval, 2003. Japan Tobacco Inc. commercializes the product in Japan.)



Genvoya (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg) is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients 12 years of age and older who are antiretroviral treatment-naïve or to replace the current antiretroviral regimen in those who are virologically-suppressed on a stable antiretroviral regimen for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya. Genvoya combines four medicines in a single pill: Vitekta (elvitegravir), Tybost (cobicistat), Emtriva (emtricitabine) and tenofovir alafenamide. (U.S. and EU approval, 2015. Japan Tobacco Inc. will commercialize the product in Japan.)



Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg) is indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years and older who have no antiretroviral (ARV) treatment history with HIV-1 RNA ≤100,000 copies/mL; or to replace a stable ARV regimen in patients who are virologically-suppressed (HIV-1 RNA <50 copies/mL) for ≥6 months with no history of treatment failure and no known resistance to any component of Odefsey. Odefsey combines three medicines in a single pill: Emtriva (emtricitabine), tenofovir alafenamide and Edurant (rilpivirine) (Janssen Sciences Ireland UC). Odefsey is the smallest pill of any single tablet regimen for the treatment of HIV.



Stribild (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen for ≥6 months with no history of treatment failure and no known resistance to any component of Stribild. Stribild combines four medicines in a single pill: Vitekta (elvitegravir), Tybost (cobicistat), Emtriva (emtricitabine) and Viread (tenofovir disoproxil fumarate). (U.S. approval, 2012; EU approval, 2013. Japan Tobacco Inc. commercializes the product in Japan.)

## HIV/AIDS (continued)

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Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), a combination of Emtriva (emtricitabine) and Viread (tenofovir disoproxil fumarate), is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients 12 years of age and older. (U.S. approval, 2004; EU approval, 2005. Japan Tobacco Inc. commercializes the product in Japan.) Once-daily Truvada is also indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. (U.S. approval, 2012.) For prescribing considerations, please see the full Prescribing Information for Truvada.



Tybost (cobicistat) 150 mg is a CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection. (U.S. approval, 2014; EU approval, 2013.)



Viread (tenofovir disoproxil fumarate) 300 mg is a once-daily oral nucleotide reverse transcriptase inhibitor (NtRTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients 2 years of age and older. (First U.S. approval, 2001; first EU approval, 2002. Japan Tobacco Inc. commercializes the product in Japan.) Viread is also indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008.)



Vitekta (elvitegravir) 85 mg and 150 mg is an integrase strand transfer inhibitor indicated as part of combination antiretroviral therapy for the treatment of HIV-1 infection in treatment-experienced adults. Vitekta should be coadministered with an HIV protease inhibitor and ritonavir and in combination with other antiretroviral drugs. (U.S. approval, 2014; EU approval, 2013.)

## Liver Diseases

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Harvoni (ledipasvir 90 mg/sofosbuvir 400 mg) is indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 4, 5 and 6 infection in adults and in patients co-infected with HIV. Harvoni efficacy has been established in patients with hepatitis C virus (HCV) genotypes 1, 4, 5 and 6, with a treatment duration of 12 or 24 weeks depending on prior treatment history, cirrhosis status and baseline viral load. Eight weeks of treatment with Harvoni can be considered for treatment-naïve genotype 1 patients without cirrhosis who have baseline HCV viral loads below 6 million IU/mL. Harvoni combines the NS5A inhibitor ledipasvir with Sovaldi (sofosbuvir). (First U.S. and EU approval, 2014.)



Sovaldi (sofosbuvir) 400 mg is an HCV nucleotide analog NS5B polymerase inhibitor indicated for the treatment of CHC infection as a component of a combination antiviral treatment regimen. Sovaldi efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. (U.S. approval, 2013; EU approval, 2014.)



Hepsera (adefovir dipivoxil) 10 mg is indicated for the treatment of chronic HBV infection in patients 12 years of age and older. (U.S. approval, 2002; EU approval, 2003. GlaxoSmithKline Inc. commercializes the product in China, Japan and Saudi Arabia.)



Viread (tenofovir disoproxil fumarate) 300 mg is indicated for the treatment of chronic HBV infection in adults and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008. Japan Tobacco Inc. commercializes the product in Japan.) As previously mentioned, Viread is also indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 2 years of age and older.

## Hematology/Oncology

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Zydelig (idelalisib) 150 mg is indicated in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. Zydelig is also indicated for the treatment of relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies and for the treatment of relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. (U.S. and EU approval, 2014.)

## Cardiovascular

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Letairis (ambrisentan) 5 mg and 10 mg is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability and delay clinical worsening; and in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (64%) or PAH associated with connective tissue diseases (32%). (First U.S. approval, 2007; EU approval, 2008. GlaxoSmithKline Inc. commercializes the product as Volibris® outside the United States.)



Lexiscan (regadenoson injection) 0.4 mg is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. (U.S. approval, 2008; EU approval, 2010, as Rapiscan®. Astellas Pharma, Inc. commercializes the product in the United States and Canada. Rapidscan Pharma Solutions, Inc. commercializes the product in Europe and select other markets.)



Ranexa (ranolazine extended-release tablets) 500 mg and 1000 mg is indicated for the treatment of chronic angina. (First U.S. approval, 2006; EU approval, 2008. Menarini Group commercializes the product in Europe and select other markets.)

## Inflammation/Respiratory

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Cayston (aztreonam for inhalation solution) 75 mg/vial is indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV<sub>1</sub> <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*. Cayston is administered with the Altera® Nebulizer System, a portable, drug-specific delivery device using the eFlow® Technology Platform developed by PARI Pharma GmbH. (EU approval, 2009; U.S. approval, 2010.)



Tamiflu (oseltamivir phosphate) 75 mg is an influenza neuraminidase inhibitor indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. Tamiflu is also indicated for the prophylaxis of influenza in patients 1 year and older. (First U.S. approval, 1999; EU approval, 2002. Developed by Gilead, Tamiflu is commercialized worldwide by F. Hoffmann-La Roche Ltd.)

## Other

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AmBisome (amphotericin B) liposome for injection 50 mg/vial is indicated for empirical therapy for presumed fungal infection in febrile neutropenic patients; for the treatment of Cryptococcal Meningitis in HIV-infected patients; treatment of patients with Aspergillus, Candida, and/or Cryptococcus species refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate; and visceral leishmaniasis. For leishmaniasis, relapse rates were high in immunocompromised patients. (EU approval, 1990; U.S. approval, 1997. Astellas Pharma, Inc. commercializes the product in the United States and Canada. Dainippon Sumitomo Pharma Co., Ltd. commercializes the product in Japan.)

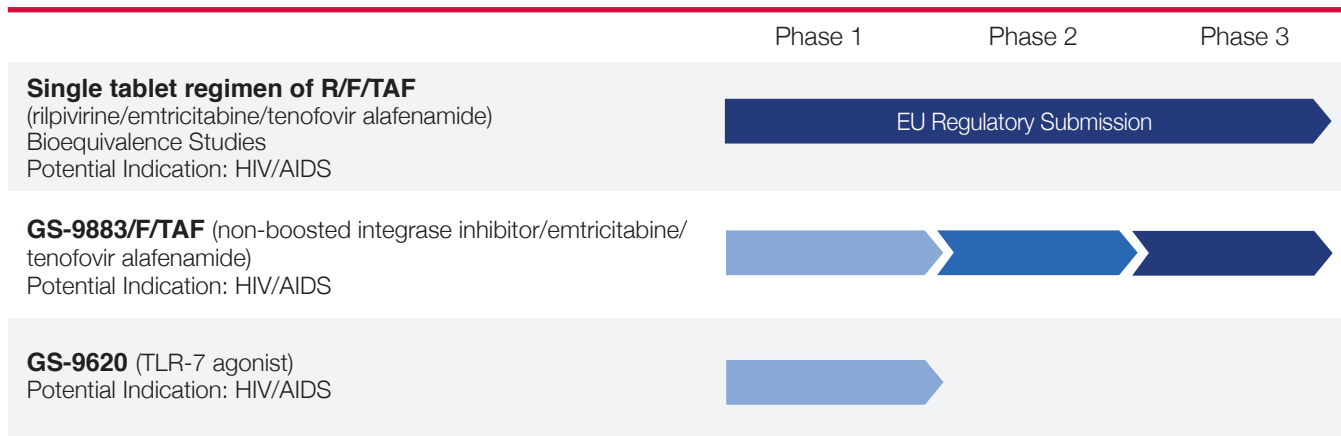


Macugen (pegaptanib sodium injection) 0.3 mg is indicated for the treatment of neovascular (wet) age-related macular degeneration. (U.S. approval, 2004; EU approval, 2006. The product is commercialized in the United States by Valeant Pharmaceuticals International, and outside the United States by Pfizer Inc.)

# Research

Gilead's research and development program identifies and evaluates investigational compounds that show potential to advance the treatment of life-threatening diseases in areas of unmet medical need. Safety and efficacy of the following compounds have not been established.

## HIV/AIDS



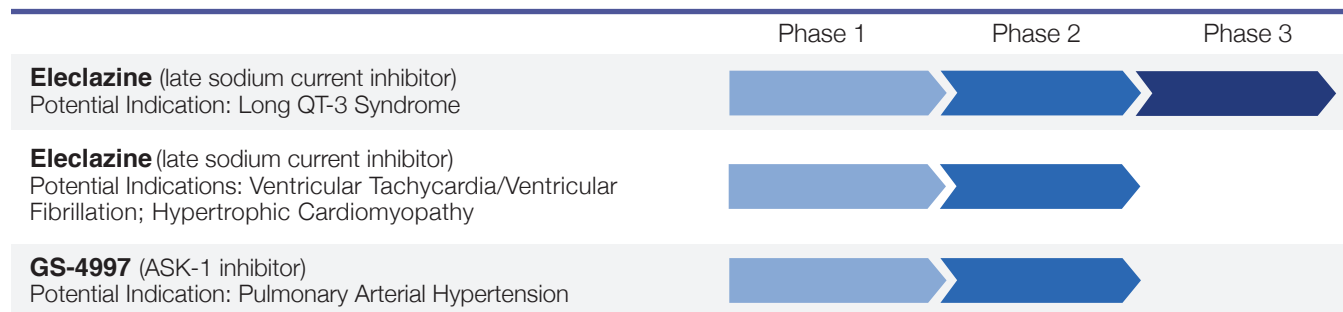
## Liver Diseases



## Hematology/Oncology

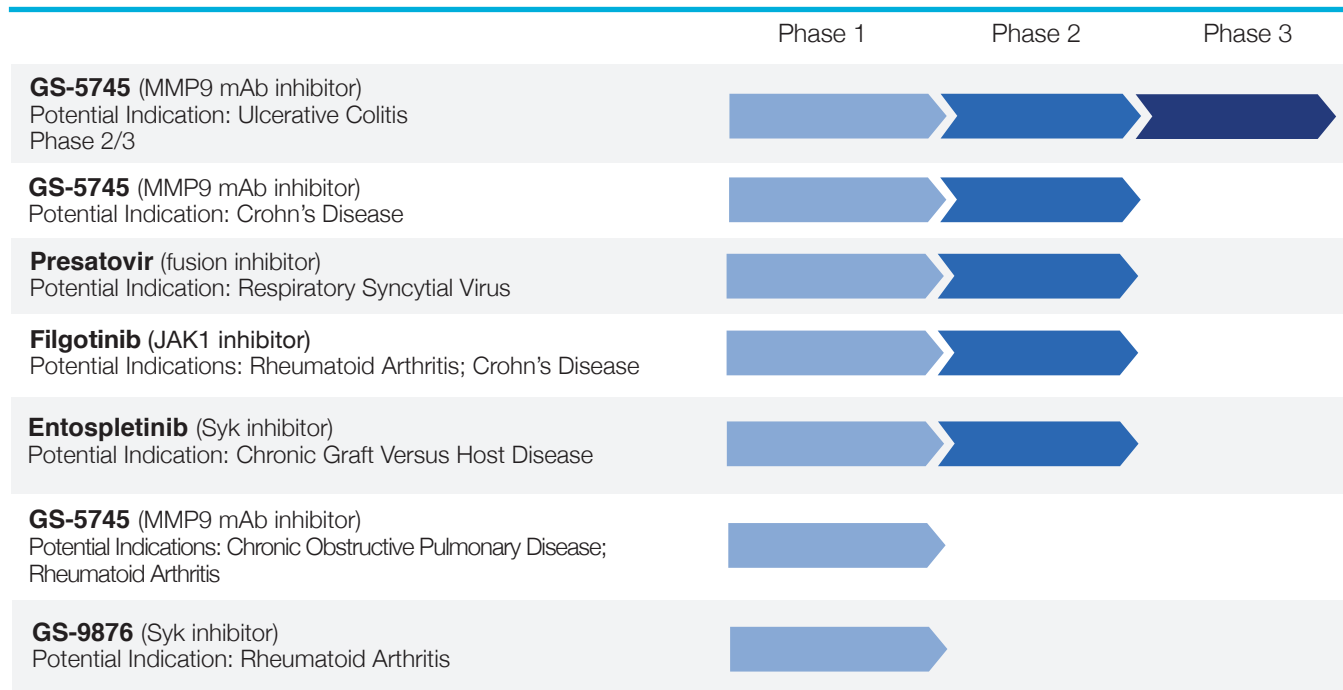


## Cardiovascular Disease

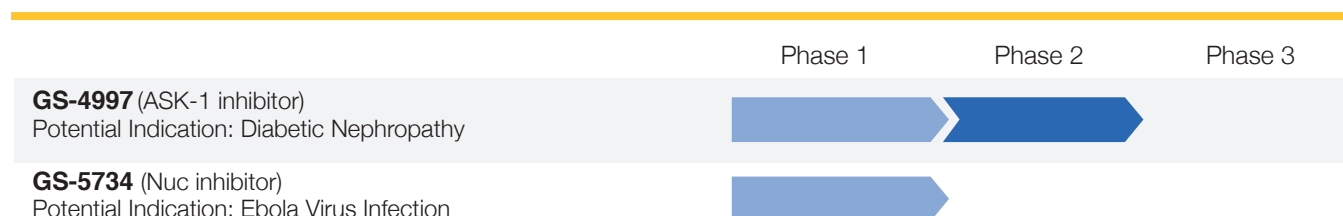




## Inflammation/Respiratory



## Other



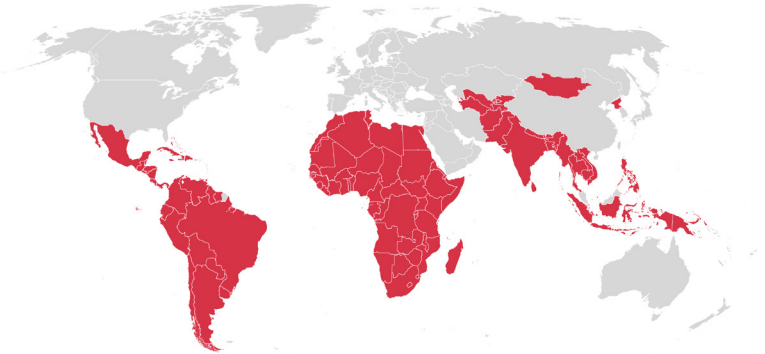
# Responsibility

As Gilead grows as a company, we strive to play our part in expanding global access to our medications and to provide support to the communities in which we operate.

## Global Access Programs

Gilead recognizes the urgent need for access to our medications worldwide, particularly in developing countries where the AIDS epidemic and other health challenges are devastating communities. We operate access programs to provide our HIV and viral hepatitis medications at substantially reduced prices in 130 low- and middle-income countries. We also coordinate and support educational activities for medical and clinical workers to ensure proper use of our medicines. As a result, approximately 8.7 million patients in the developing world now receive Gilead's therapies for HIV/AIDS, representing over 60 percent of all patients on antiretroviral therapy in resource-limited countries. Gilead is also working with regional partners and generic manufacturers to scale up distribution of discounted hepatitis C medicines in low- and middle-income countries, adopting a systematic country-by-country approach that initially prioritizes those with the highest disease burden.

Access Operations & Emerging Markets Geography



## Partnerships with Generic Manufacturers and Medicines Patent Pool

Gilead has signed non-exclusive licenses with multiple generic manufacturers, granting them rights to produce high-quality, low-cost generic versions of certain Gilead medicines for HIV/AIDS and chronic hepatitis B and C. Partners have also been granted rights to produce generic versions of new Gilead therapies once they receive U.S. regulatory approval. Gilead was the first pharmaceutical company to sign an agreement with the Medicines Patent Pool, which is working to increase global access to high-quality, low-cost antiretroviral therapy through the sharing of patents. The Patent Pool has been granted similar licensing terms for Gilead HIV medicines as our generic manufacturing partners.

## Fighting Visceral Leishmaniasis in the Developing World

We work closely with the World Health Organization (WHO) and non-governmental organizations to provide AmBisome at a preferential price for the treatment of visceral leishmaniasis (VL) in resource-limited settings. VL is the second-largest parasitic killer in the world after malaria, responsible for approximately 40,000 deaths each year. In December 2011, Gilead signed a partnership agreement with WHO to donate 445,000 vials of AmBisome over five years. This donation is being used to treat more than 50,000 patients in resource-limited countries.

## Patient Access in the United States

In the United States, Gilead has put in place comprehensive patient access programs, reflecting feedback from community groups and patient advocates, to help people who are uninsured or underinsured access our medicines. This includes providing our medicines to eligible patients at no charge and offering a co-pay coupon program for patients with private insurance, regardless of income.

## Screening, Diagnosis and Linkages to Care

Gilead is actively involved in several community partnerships that focus on expanding screening programs, encouraging patients to take an active role in their treatment and linking them to prompt, appropriate medical care. In 2010, Gilead launched the FOCUS Program, which partners with healthcare providers, government agencies and community organizations across the United States to develop replicable model programs to routinize HIV screening and linkage to care. Gilead is now supporting partner organizations to apply the FOCUS model to screening and linkage to care for hepatitis C, with the goal of identifying replicable programs that can be applied broadly. Gilead is also helping to strengthen community-level public health efforts to expand screening programs for hepatitis B. In the United States, this work focuses on Asian American communities, where hepatitis B hits the hardest and significant stigma and misconceptions about the disease persist.



## The Gilead Foundation

The Gilead Foundation, a non-profit organization established in 2005, seeks to improve the health and well-being of underserved communities in the United States and internationally. The Foundation's giving focuses on expanding access to HIV and hepatitis education, outreach, prevention and health services.

## Strength Through Partnership

Collaborations with partners in science, academia, business and local communities are central to our work. Partnerships enhance our ability to develop innovative medicines and deliver them to people as efficiently as possible.

# Leadership

The following individuals comprise Gilead's Senior Management Team. See Gilead.com for biographies and a listing of members of the company's Board of Directors.

- **John F. Milligan, PhD**  
President and Chief Executive Officer
- **John C. Martin, PhD**  
Executive Chairman
- **Gregg H. Alton**  
Executive Vice President, Corporate and Medical Affairs
- **Norbert W. Bischofberger, PhD**  
Executive Vice President, Research and Development and Chief Scientific Officer
- **Paul R. Carter**  
Executive Vice President, Commercial Operations
- **Andrew Cheng, MD, PhD**  
Executive Vice President, Clinical Research and Development Operations
- **William A. Lee, PhD**  
Executive Vice President, Research
- **John McHutchison, MD**  
Executive Vice President, Clinical Research
- **Brett Pletcher**  
Executive Vice President and General Counsel
- **Robin L. Washington**  
Executive Vice President and Chief Financial Officer
- **Katie L. Watson**  
Executive Vice President, Human Resources
- **Taiyin Yang, PhD**  
Executive Vice President, Pharmaceutical Development and Manufacturing

## Growing Worldwide Footprint

We have operations in the following locations:

### North America

- Foster City, CA  
(Corporate Headquarters)
- Fremont, CA
- Oceanside, CA
- San Dimas, CA
- Branford, CT
- Seattle, WA
- Alberta, Canada
- Ontario, Canada
- Mexico City, Mexico

### South America

- Argentina
- Brazil

### Asia

- China
- Hong Kong
- India
- Japan
- Korea
- Singapore
- Taiwan

### Africa

- South Africa

### Australia

- Australia/New Zealand

### Europe

- Stockley Park, UK
- Cambridge, UK
- London, UK
- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Ireland
- Israel
- Italy
- Netherlands
- Norway
- Poland
- Portugal
- Russia
- Slovakia
- Spain
- Sweden
- Switzerland
- Turkey

### Middle East

- United Arab Emirates

## More Information

For more information about Gilead, its products or community involvement, please contact Gilead at +1 (650) 574-3000 or [public\\_affairs@gilead.com](mailto:public_affairs@gilead.com).

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