Gilead Sciences

Advancing Therapeutics. Improving Lives.

GILEAD

Company Overview

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercialises 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 primary areas of focus include HIV/AIDS, liver disease and serious cardiovascular and respiratory conditions.

Our portfolio of 15 marketed products includes a number of category firsts, including the only complete treatment regimens for HIV infection available in a once-daily single pill. Gilead's portfolio also includes Truvada® (emtricitabine/tenofovir disoproxil fumarate), the first drug approved for HIV prevention in uninfected adults at high risk, a strategy known as pre-exposure prophylaxis (PrEP; U.S. approval, 2012).

Stribild®, Gilead's newest once-daily single tablet HIV regimen.

25 Years of Growth

Gilead was founded in 1987 in Foster City, California. In 25 years, Gilead has become a leading biopharmaceutical company with a rapidly expanding product portfolio, a growing pipeline of investigational drugs and approximately 5,000 employees in offices across four continents. Millions of people around the world are living healthier, more fulfilling lives because of innovative therapies developed by Gilead.

Today, our research and development effort is the largest it has ever been, with more than 130 Phase 2 and 3 clinical studies evaluating compounds with the potential to become the next generation of innovative therapies for HIV/AIDS, liver disease, serious respiratory, cardiovascular and metabolic conditions, cancer and inflammation.

In 2012, Gilead's annual revenues were $9.7 billion and the company was ranked #2 in *Fortune* magazine's list of fastest-growing corporations by 10-year profits. Also in 2012, the *Harvard Business Review* ranked Gilead's chief executive officer, John C. Martin, #5 on its list of the 100 best-performing CEOs in the world, as well as the top-ranked health care CEO.

Key Moments in Our History

1987	Gilead founded
1990	AmBisome® approved
1991	Nucleotides in-licensed from IOCB/Rega
1997	Vistide® approved
1999	NeXstar acquired (establishment of European operations)
2002	Tamiflu® approved; Viread® approved
2003	Triangle acquired; Emtriva® approved; Hepsera® approved
2005	Truvada approved
2006	Corus, Raylo, Myogen acquired; Macugen® approved
2007	Atripla® approved; Cork, Ireland, manufacturing facility acquired from Nycomed
2008	Ambrisentan approved as Volibris®; Viread for hepatitis B approved; Ranexa® approved
2009	CV Therapeutics acquired; Cayston® approved
2010	CGI Pharmaceuticals acquired; Regadenoson approved as Rapiscan®
2011	Arresto BioSciences and Calistoga Pharmaceuticals acquired; Eviplera® approved
2012	Pharmasset acquired
2013	YM BioSciences acquired; Stribild approved

Drug approval dates shown here are EU approval dates; U.S. approval dates may differ.

Marketed Products

Following is a summary of Gilead's product portfolio. Please contact Gilead for full prescribing information on any of these products, including efficacy and safety information.

HIV/AIDS

Atripla (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a once-daily complete single tablet regimen for the treatment of HIV-1 infection in patients 12 years of age and older with virologic suppression to HIV-1 RNA levels of less than 50 copies/mL on their current combination antiretroviral therapy for more than three months. Atripla combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Sustiva® (efavirenz), marketed by Bristol-Myers Squibb Company (BMS) and Merck & Co., Inc. (EU approval, 2007; first U.S. approval, 2006. Atripla is commercialised in Europe through a partnership between Gilead, BMS and Merck.)

Emtriva (emtricitabine) is a once-daily oral nucleoside reverse transcriptase inhibitor (NRTI) used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children. An oral solution is available for use in paediatric patients. (EU and U.S. approval, 2003.)

Stribild (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil (as fumarate) 245 mg) is a once-daily complete single tablet regimen for the treatment of HIV infection in adults who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to any of Stribild's three antiretroviral component agents. (EU approval, 2013; U.S. approval, 2012.)

Eviplera (emtricitabine/rilpivirine/tenofovir disoproxil) is a once-daily complete single tablet regimen for the treatment of HIV-1 infection in treatment-naïve adults with a viral load less than or equal to 100,000 HIV-1 RNA copies/mL. Eviplera combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Edurant® (rilpivirine), manufactured by Janssen R&D Ireland. (EU and U.S. approval, 2011; marketed as Complera® in the United States.)

Truvada (emtricitabine/tenofovir disoproxil fumarate) is a fixed-dose once-daily combination pill containing Viread and Emtriva. It is used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and paediatric patients 12 years of age and older. (EU approval, 2005; U.S. approval, 2004.) In the United States, once-daily Truvada is also approved, in combination with safer sex practices, to reduce the risk of sexually acquired HIV infection in adults at high risk. (U.S. approval, 2012.)

Viread (tenofovir disoproxil fumarate) is a once-daily oral nucleotide reverse transcriptase inhibitor (NtRTI) used in combination with other antiretroviral agents for the treatment of HIV-1 infection in patients 2 years of age and older. (First EU approval, 2002; first U.S. approval, 2001.) Viread is also approved as a treatment for chronic hepatitis B virus (HBV) infection in patients 12 years of age and older. (First EU and U.S. approval, 2008.)

Liver Disease

Hepsera (adefovir dipivoxil) is a once-daily oral NtRTI for the treatment of chronic HBV infection in adults with compensated and decompensated liver disease. (EU approval, 2003; U.S. approval, 2002.)

Viread (tenofovir disoproxil fumarate) is a once-daily oral NtRTI for the treatment of chronic HBV infection in patients 12 years of age and older with compensated liver disease and in adults with decompensated liver disease. (First EU and U.S. approval, 2008; EU indication expanded to included decompensated liver disease, 2010.) As previously noted, Viread is also approved for the treatment of HIV infection in patients 2 years of age and older.

Cardiovascular

Letairis® (ambrisentan), marketed as Volibris in Europe, is a once-daily treatment to improve exercise ability and delay clinical worsening in pulmonary arterial hypertension (PAH, WHO Group 1) patients with predominantly WHO Functional Class II-III symptoms. (EU approval, 2008; U.S. approval, 2007. GlaxoSmithKline PLC holds rights to commercialise the product outside of the United States.)

Lexiscan® (regadenoson) injection, marketed as Rapiscan in Europe, is the first A_{2A} adenosine receptor agonist approved for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging studies. The product has been designed to target the A_{2A} adenosine receptor, which is the adenosine receptor subtype responsible for coronary vasodilation. (EU approval, 2010; U.S. approval, 2008. Rapidscan Pharma Solutions, Inc. commercialises the product in Europe. Astellas Pharma US, Inc. commercialises the product in the United States.)

Ranexa (ranolazine) is an extended-release tablet indicated as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta blockers and/or calcium antagonists). (EU approval, 2008; U.S. approval, 2006. In Europe, the product is commercialised by the Menarini Group.)

Respiratory

Cayston (aztreonam lysine) is an inhaled antibiotic indicated for the suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* infection in patients with cystic fibrosis (CF) 6 years of age and older. (EU approval, 2009; U.S. approval, 2010.)

Tamiflu (oseltamivir phosphate) is the first neuraminidase inhibitor tablet for the treatment and prevention of influenza A and B. Developed by Gilead, Tamiflu is commercialised globally by F. Hoffmann-La Roche Ltd. (EU approval, 2002; U.S. approval for influenza treatment, 1999; U.S. indication expanded to include influenza prevention, 2000.)

Other

AmBisome (amphotericin B liposome for injection) is a treatment for severe systemic and/or deep mycoses where toxicity (particularly nephrotoxicity) precludes the use of conventional systemic amphotericin B in effective dosages, visceral leishmaniasis in immunocompetent patients and the empirical treatment of presumed fungal infections in febrile neutropenic patients, where the fever has failed to respond to broad spectrum antibiotics and appropriate investigations have failed to define a bacterial or viral cause in adults and children (above 1 month). (EU approval, 1990; U.S. approval, 1997. Astellas Pharma US, Inc. commercialises the product in the United States and Canada.)

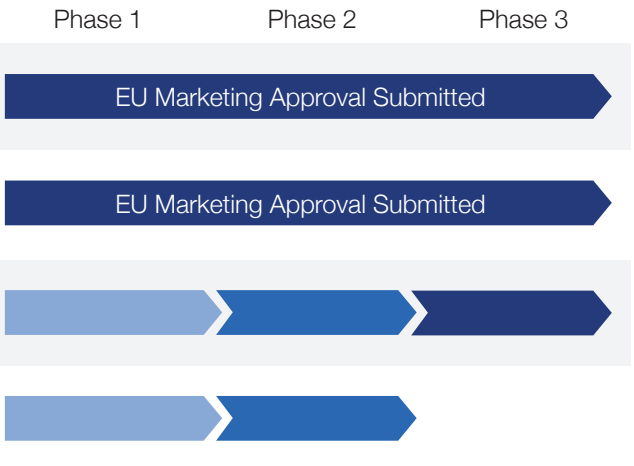
Macugen (pegaptanib sodium injection) is an injection for the treatment of neovascular age-related macular degeneration (also known as “wet” AMD), an eye disease that destroys central vision in elderly patients. (EU approval, 2006; U.S. approval, 2004. Pfizer Inc. commercialises Macugen globally, with the exception of the United States, where Eyetech Inc. markets the product.)

Vistide (cidofovir injection) is an antiviral injection for the treatment of cytomegalovirus retinitis in adult patients with AIDS. (EU approval, 1997; U.S. approval, 1996.)

Research

Gilead's research and development program identifies and evaluates compounds that show potential to advance the treatment of life-threatening diseases in areas of unmet medical need.

HIV/AIDS



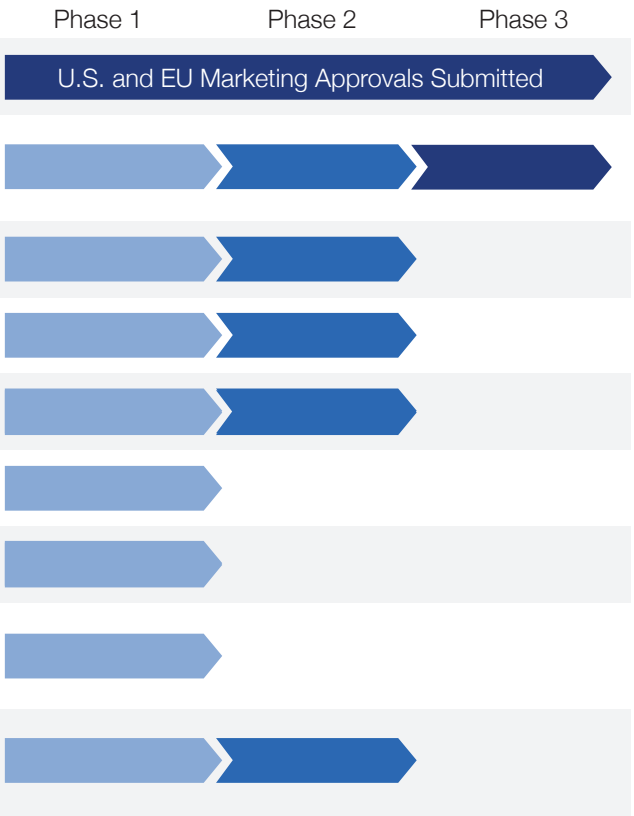
Cobicistat (pharmacokinetic enhancer)
Potential Indication: HIV/AIDS
Approved as Tybost™ in the United States in 2013.

Elvitegravir (integrase inhibitor)
Potential Indication: HIV/AIDS
Approved as Vitekta™ in the United States in 2013.

Single Tablet Regimen (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)
Potential Indication: HIV/AIDS

Single Tablet Regimen
(darunavir/cobicistat/emtricitabine/tenofovir alafenamide)
Potential Indication: HIV/AIDS

Liver Diseases



Sofosbuvir (nucleotide NS5B inhibitor)
Potential Indication: Chronic HCV infection

Single Tablet Regimen of sofosbuvir and ledipasvir (nucleotide NS5B inhibitor/NS5A inhibitor)
Potential Indication: Chronic HCV infection

GS-9451 (NS3 protease inhibitor)
Potential Indication: Chronic HCV infection

GS-9669 (non-nucleoside NS5B inhibitor)
Potential Indication: Chronic HCV infection

GS-5816 (pan-genotypic NS5A inhibitor)
Potential Indication: Chronic HCV infection

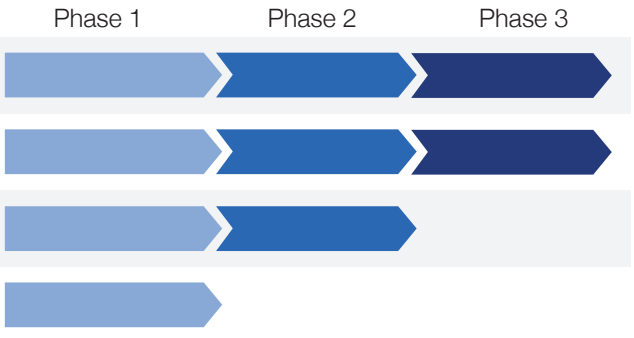
GS-9620 (TLR-7 agonist)
Potential Indication: Chronic HCV infection

GS-9620 (TLR-7 agonist)
Potential Indication: Chronic HBV infection

Tenofovir Alafenamide (nucleotide reverse transcriptase inhibitor)
Potential Indication: Chronic HBV infection

Simtuzumab (monoclonal antibody)
Potential Indication: Liver Fibrosis Due to Nonalcoholic Steatohepatitis or Primary Sclerosing Cholangitis

Cardiovascular



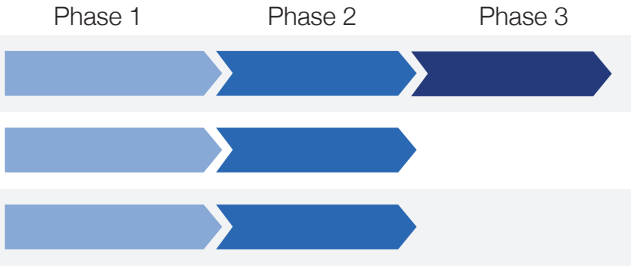
Ranolazine (late sodium current inhibitor)
Potential Indication: Incomplete Revascularization Post-PCI

Ranolazine (late sodium current inhibitor)
Potential Indication: Type 2 Diabetes

Ranolazine/Dronedarone Fixed-Dose Combination
Potential Indication: Paroxysmal Atrial Fibrillation

GS-6615
Potential Indication: Ischemic Heart Disease and Arrhythmias

Respiratory

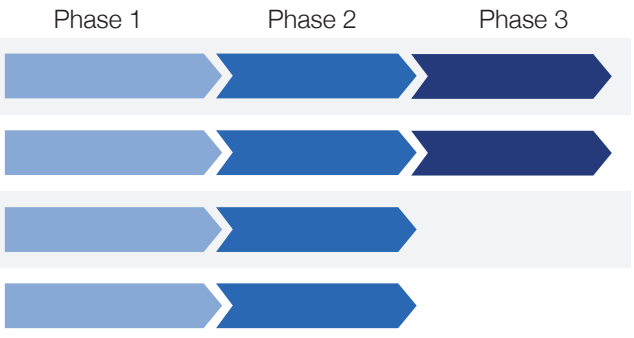


Aztreonam for Inhalation Solution
Potential Indication: Non-CF Bronchiectasis

Simtuzumab (monoclonal antibody)
Potential Indication: Idiopathic Pulmonary Fibrosis

GS-5806
Potential Indication: Respiratory Syncytial Virus

Oncology/Inflammation



Idelalisib (P13K delta inhibitor)
Potential Indication: Chronic Lymphocytic Leukemia

Idelalisib (P13K delta inhibitor)
Potential Indication: Indolent non-Hodgkin's Lymphoma

Momelotinib (JAK inhibitor)
Potential Indication: Myelofibrosis

Simtuzumab (monoclonal antibody)
Potential Indication: Myelofibrosis

Simtuzumab (monoclonal antibody)
Potential Indication: Pancreatic Cancer

Simtuzumab (monoclonal antibody)
Potential Indication: Colorectal Cancer

GS-9820 (P13K delta inhibitor)
Potential Indication: Lymphoid Malignancies

GS-9973* (Syk inhibitor)
Potential Indication: B-Cell Malignancies

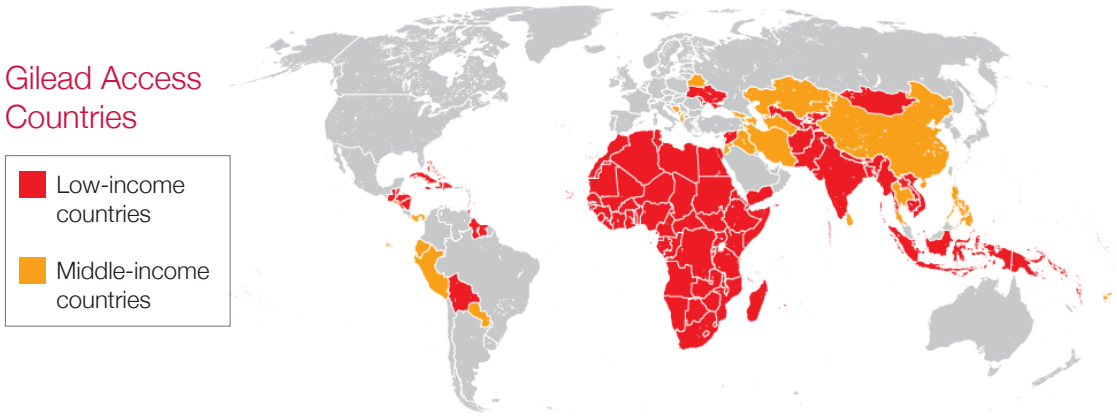
*Being developed as a single agent and in combination with idealisib.

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 operate. To this end, we undertake the following initiatives:

Global Access Programmes

Gilead recognises the urgent need for access to our medications worldwide, particularly in developing world countries where the AIDS epidemic and other health challenges are devastating communities. We operate access programmes to provide our HIV medications at substantially reduced prices in more than 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 3.5 million patients in the developing world now receive Gilead's therapies for HIV/AIDS.



Partnerships with Generic Manufacturers and Medicines Patent Pool

Gilead has signed non-exclusive licences 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. Partners have also been granted rights to produce generic versions of new Gilead HIV therapies once they receive U.S. regulatory approval. Gilead is 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 organisations 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 more than 50,000 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 will be used to treat more than 50,000 patients in resource-limited countries.

Patient Access in the United States

Gilead supports a number of programmes for eligible patients in the United States who do not have insurance, are underinsured or who otherwise need financial assistance. These programmes include U.S. Advancing Access®, Atripla Patient Access Program, Truvada for PrEP Medication Assistance Program, Gilead™Solutions, Cayston Access Program and Ranexa Connect™.

Screening, Diagnosis and Linkages to Care

Gilead is actively involved in several community partnerships at the grassroots level that focus on expanding HIV screening programmes, encouraging patients to take an active role in their treatment and linking them to prompt, appropriate medical care. In 2010, Gilead launched the HIV FOCUS programme (HIV on the Frontlines Of Communities in the United States), which partners with healthcare providers, government agencies and community organisations across the United States to implement routine HIV screening and linkages to care. In the EAME region, Gilead has introduced a grants scheme called the Fellowship Programme. This programme has launched in France, Germany, Italy, Ireland and the UK and awards financial grants to encourage the development, exploration and dissemination of new ideas to promote best practices in patient-centred care such as testing and linkages to care. Gilead is also helping to strengthen community-level public health efforts to expand screening programmes for hepatitis B. In the United States, this work focuses on Asian American communities, where hepatitis B hits the hardest and where significant stigma and misconceptions about the disease persist.

The Gilead Foundation

Established in 2005, the Gilead Foundation supports U.S. and international programmes, many of which are focused on building local capacity and improving health infrastructure in the developing world.

Ongoing Research Collaborations

We work with academic, government and private sector partners to better understand the profile of our products in important areas such as paediatric HIV care, prevention of mother-to-child HIV transmission, PrEP, and co-infection with HIV and tuberculosis or hepatitis B. Gilead actively supports clinical studies in more than 55 countries by providing product donations.

Leadership

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

- **John C. Martin, PhD**
  Chairman and Chief Executive Officer
- **John F. Milligan, PhD**
  President and Chief Operating Officer
- **Norbert W. Bischofberger, PhD**
  Executive Vice President, Research and Development, and Chief Scientific Officer
- **Gregg H. Alton**
  Executive Vice President, Corporate and Medical Affairs
- **Kevin Young CBE**
  Executive Vice President, Commercial Operations
- **Robin L. Washington**
  Senior Vice President and Chief Financial Officer
- **Katie L. Watson**
  Senior Vice President, Human Resources

Growing Worldwide Footprint

We have approximately 5,000 employees around the world. Gilead's corporate headquarters are located in Foster City, California. We have additional operations in the following locations:

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

Asia-Pacific
- Australia/New Zealand
- China
- Hong Kong
- Korea

Europe
- Stockley Park, UK (EAME Headquarters)
- Austria
- Benelux (offices in Belgium and the Netherlands)
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Ireland
- Italy
- Norway
- Poland
- Portugal
- Spain
- Sweden
- Switzerland
- Turkey
- Cambridge, UK

More Information

For more information about Gilead, its products or community involvement, please contact Gilead at +1 (650) 574-3000 (U.S.) / +44 208 587 2323 (EU) or public_affairs@gilead.com.

Follow Gilead on Twitter (@GileadSciences).

Aztreonam for inhalation solution for bronchiectasis, cobicistat, elvitegravir, idelalisib (formerly GS-1101), GS-5806, GS-5816, ledipasvir(formerly GS-5885), momelotinib, simtuzumab (formerly GS-6624), GS-6615, tenofovir alafenamide (formerly GS-7340), sofosbuvir (formerly GS-7977), GS-9451, GS-9620, GS-9669, ranolazine for incomplete revascularization post-PCI and type 2 diabetes, ranolazine/dronedarone for PAF, GS-9973 and GS-9820 are investigational treatments and have not yet been determined safe or efficacious in humans.

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