# 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 primary areas of focus include HIV/AIDS, liver diseases, serious respiratory and cardiovascular conditions, cancer and inflammation.

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).



#### 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 clinical studies evaluating compounds with the potential to become the next generation of innovative therapies for HIV/AIDS, liver diseases, serious respiratory and cardiovascular 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 (in Europe)

1991 Nucleotides in-licensed from IOCB Rega

1996 Vistide® approved

1999 NeXstar acquired (establishment of European operations); Tamiflu® approved

2001 Viread® approved

2002 Hepsera® approved

**2003** Triangle Pharmaceuticals acquired; Emtriva® approved

2004 Truvada® approved; Macugen® approved

2006 Atripla® approved; Ranexa® approved; Corus, Raylo, Myogen acquired

2007 Letairis® approved; Cork, Ireland, manufacturing facility acquired from Nycomed

**2008** Viread for hepatitis B approved; Lexiscan® approved

2009 CV Therapeutics acquired

**2010** Cayston® approved; CGI Pharmaceuticals acquired

2011 Arresto BioSciences and Calistoga Pharmaceuticals acquired; Complera® approved

2012 Pharmasset acquired; Truvada for PrEP approved; Stribild® approved

2013 YM BioSciences acquired

Last updated August 2013 www.gilead.com

### Marketed Products

Following is a summary of Gilead's product portfolio. See Gilead.com for full prescribing information, including **BOXED WARNINGS and Important 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 infection in patients 12 years of age and older. Atripla combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Sustiva® (efavirenz), manufactured by Bristol-Myers Squibb Company. (First U.S. approval, 2006; EU approval, 2007.)



Complera (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) is a once-daily complete single tablet regimen for the treatment of HIV infection in treatment-naïve adults. Complera combines three medicines in a single pill: Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine) and Edurant® (rilpivirine), manufactured by Janssen R&D Ireland. (U.S. and EU approval, 2011; marketed as Eviplera® in Europe.)



Emtriva (emtricitabine 200 mg) is a once-daily oral nucleoside reverse transcriptase inhibitor (NRTI) used in combination with other antiretroviral agents for the treatment of HIV infection. An oral solution (10 mg/mL) is available for use in pediatric patients. (U.S. and EU approval, 2003.)



Stribild (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a once-daily complete single tablet regimen for the treatment of HIV infection in adults who are antiretroviral treatment-naïve. Stribild combines four medicines in a single pill: elvitegravir, cobicistat, Emtriva (emtricitabine) and Viread (tenofovir disoproxil fumarate). (U.S. approval, 2012; EU approval, 2013.)



Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a fixed-dose once-daily combination pill containing Emtriva and Viread. It is used in combination with other antiretroviral agents for the treatment of HIV infection in adults and pediatric patients 12 years of age and older. (U.S. approval, 2004; EU approval, 2005.) 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 300 mg) is a once-daily oral nucleotide reverse transcriptase inhibitor (NtRTI) used in combination with other antiretroviral agents for the treatment of HIV infection in patients 2 years of age and older. (First U.S. approval, 2001; first EU approval, 2002.) Viread is also approved as a treatment for chronic hepatitis B virus (HBV) infection in adults and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008.)

### Liver Disease



Hepsera (adefovir dipivoxil 10 mg) is a once-daily oral NtRTI for the treatment of chronic HBV infection in patients 12 years of age and older. (U.S. approval, 2002; EU approval, 2003.)

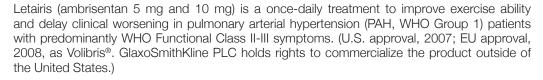


Viread (tenofovir disoproxil fumarate 300 mg) is a once-daily oral NtRTI for the treatment of chronic HBV infection in adults and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008.) As previously noted, Viread is also approved for the treatment of HIV infection in patients 2 years of age and older.

### Cardiovascular







Lexiscan (regadenoson injection 0.4 mg) 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. (U.S. approval, 2008; EU approval, 2010, as Rapiscan®. Astellas Pharma US, Inc. commercializes the product in the United States. Rapidscan Pharma Solutions, Inc. commercializes the product in Europe.)



Ranexa (ranolazine 500 mg and 1000 mg) is an extended-release tablet for the treatment of chronic angina. Ranexa may be used with beta blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors and angiotensin receptor blockers. (U.S. approval, 2006; U.S. indication updated to include first-line treatment for chronic angina, 2008; EU approval, 2008.)

### Respiratory



Cayston (aztreonam for inhalation solution 75 mg/vial) is an inhaled antibiotic indicated to improve respiratory symptoms in cystic fibrosis (CF) patients 7 years of age and older with infection. 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 the first neuraminidase inhibitor tablet for the treatment and prevention of influenza A and B. Developed by Gilead, Tamiflu is commercialized globally by F. Hoffmann-La Roche Ltd. (U.S. approval for influenza treatment, 1999; U.S. indication expanded to include influenza prevention, 2000; EU approval, 2002.)

### Other



AmBisome (amphotericin B liposome for injection 50 mg/vial) is a treatment for life-threatening, systemic fungal infections in adults. (EU approval, 1990; U.S. approval, 1997. Astellas Pharma US, Inc. commercializes the product in the United States and Canada.)



Macugen (pegaptanib sodium injection 0.3 mg) 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. (U.S. approval, 2004; EU approval, 2006. Macugen is marketed in the United States by Eyetech Inc., and by Pfizer Inc. outside the United States.)



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

# 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**

|   | Phase 1     | Phase 2             | Phase 3   |
|---|-------------|---------------------|-----------|
| Cobicistat (CYP3A inhibitor) Potential Indication: HIV/AIDS   | U.S. and EU | Marketing Approvals | Submitted |
| <b>Elvitegravir</b> (integrase inhibitor) Potential Indication: HIV/AIDS  | U.S. and EU | Marketing Approvals | Submitted |
| Single Tablet Regimen (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) Potential Indication: HIV/AIDS    |             | <b>&gt;</b>         |           |
| Single Tablet Regimen<br>(darunavir/cobicistat/emtricitabine/tenofovir alafenamide)<br>Potential Indication: HIV/AIDS |             |                     |           |

### Liver Diseases

|  | Phase 1     | Phase 2               | Phase 3   |
|--|-------------|-----------------------|-----------|
| <b>Sofosbuvir</b> (nucleotide NS5B inhibitor)<br>Potential Indication: Chronic HCV infection   | U.S. and EU | Marketing Approvals ( | Submitted |
| <b>Fixed-dose Combination</b> of sofosbuvir and ledipasvir (nucleotide NS5B inhibitor/NS5A inhibitor) Potential Indication: Chronic HCV infection  |             | <b>&gt;</b>           |           |
| <b>GS-9451</b> (NS3 protease inhibitor) Potential Indication: Chronic HCV infection  |             |                       |           |
| <b>GS-9669</b> (non-nucleoside NS5B inhibitor)<br>Potential Indication: Chronic HCV infection  |             |                       |           |
| <b>GS-5816</b> (pan-genotypic NS5A inhibitor) Potential Indication: Chronic HCV infection  |             |                       |           |
| <b>GS-9620</b> (TLR-7 agonist) Potential Indication: Chronic HCV infection   |             |                       |           |
| <b>GS-9620</b> (TLR-7 agonist) Potential Indication: Chronic HBV infection   |             |                       |           |
| <b>Tenofovir Alafenamide</b> (nucleotide reverse transcriptase inhibitor) Potential Indication: Chronic HBV infection                              |             |                       |           |
| <b>GS-4774</b> (Tarmogen T cell immunity stimulator) Potential Indication: Chronic HBV infection   |             |                       |           |
| <b>Simtuzumab</b> (monoclonal antibody) Potential Indication: Liver Fibrosis Due to Nonalcoholic Steatohepatitis or Primary Sclerosing Cholangitis |             |                       |           |
| <b>GS-5745</b> (MMP9 mAb inhibitor) Potential Indication: Ulcerative colitis   |             |                       |           |

### Cardiovascular

|  | Phase 1 | Phase 2 | Phase 3 |
|--|---------|---------|---------|
| Ranolazine (late sodium current inhibitor) Potential Indication: Incomplete Revascularization Post-PCI |         |         |         |
| Ranolazine (late sodium current inhibitor) Potential Indication: Type 2 Diabetes                       |         |         |         |
| Ranolazine (late sodium current inhibitor) Potential Indication: Paroxysmal Atrial Fibrillation        |         |         |         |
| GS-6615 Potential Indication: Ischemic Heart Disease   |         |         |         |

# Respiratory

|   | Phase 1 | Phase 2 | Phase 3 |
|---|---------|---------|---------|
| <b>Simtuzumab</b> (monoclonal antibody) Potential Indication: Idiopathic Pulmonary Fibrosis |         |         |         |
| <b>GS-5806</b> Potential Indication: Respiratory Syncytial Virus                            |         |         |         |

# Oncology/Inflammation

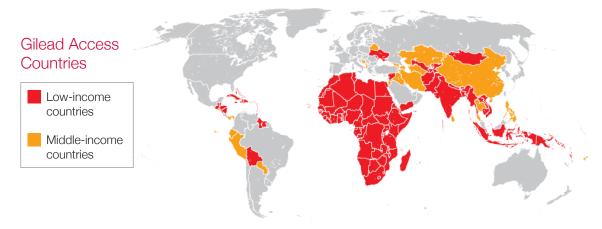
|   | Phase 1 | Phase 2 | Phase 3 |
|---|---------|---------|---------|
| Idelalisib (PI3K delta inhibitor)<br>Potential Indication: Chronic Lymphocytic Leukemia   |         |         |         |
| <b>Idelalisib</b> (PI3K delta inhibitor)<br>Potential Indication: Indolent non-Hodgkin's Lymphoma   |         |         |         |
| <b>Momelotinib</b> (JAK inhibitor) Potential Indication: Myelofibrosis  |         |         |         |
| Simtuzumab (monoclonal antibody) Potential Indication: Myelofibrosis  |         |         |         |
| Simtuzumab (monoclonal antibody) Potential Indication: Pancreatic Cancer  |         |         |         |
| <b>Simtuzumab</b> (monoclonal antibody) Potential Indication: Colorectal Cancer   |         |         |         |
| <b>GS-9973*</b> (Syk inhibitor) Potential Indication: Hematological Malignancies *Being developed as a single agent and in combination with idelalisib. |         |         |         |
| <b>GS-9820</b> (PI3K delta inhibitor)<br>Potential Indication: Lymphoid Malignancies  |         |         |         |
| <b>GS-5745</b> (MMP9 mAb inhibitor)<br>Potential Indication: Solid Tumors   |         |         |         |

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

### Global Access Programs

Gilead recognizes 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 programs 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 3.9 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 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. Partners have also been granted rights to produce generic versions of new Gilead HIV 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 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 programs for eligible patients in the United States who do not have insurance, are underinsured or who otherwise need financial assistance. These programs include U.S. Advancing Access<sup>®</sup>, 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 programs, 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 program (HIV on the Frontlines Of Communities in the United States), which partners with healthcare providers, government agencies and community organizations across the United States to implement routine HIV screening and linkages to care. 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 where significant stigma and misconceptions about the disease persist.

#### The Gilead Foundation

Established in 2005, the Gilead Foundation supports domestic and international programs, many of which are focused on building local capacity and improving health infrastructure in the developing world. Our 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 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
- Japan
- Korea

#### **Europe**

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

### 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.

Follow Gilead on Twitter (@GileadSciences).

Cobicistat, elvitegravir, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, darunavir/cobicistat/emtricitabine/tenofovir alafenamide, idelalisib, ledipasvir, momelotinib, ranolazine for incomplete revascularization post-PCI, ranolazine for type 2 diabetes, ranolazine for PAF, simtuzumab, sofosbuvir, sofosbuvir/ledispavir, tenofovir alafenamide, GS-4774, GS-5745, GS-5806, GS-5816, GS-6615, GS-9451, GS-9620, GS-9669, GS-9820, GS-9973 and GS-9973/idelalisib are investigational treatments and have not yet been determined safe or efficacious in humans.