Global Health, IP & TRIPS at 20
Twin Challenges of Innovation and Access: Leveraging IP to Achieve Both

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Gilead's Commitment to Innovation and Access

Mission: Discover, develop and deliver innovative medicines in areas of unmet medical need

- Active ingredient in Gilead's HIV medicines is the most widely prescribed molecule (TDF) for HIV therapy worldwide.

- New hepatitis C (HCV) regimens provide a simple, safe and highly effective cure; an all-oral regimen to treat all HCV patients (pan-genotypic) is in development.

Focus on patient needs

- Guiding principle: All people should have access to our medicines, regardless of where they live or their economic status.

- As part of a comprehensive access approach, Gilead has entered into licensing agreements with generic pharmaceutical manufacturers to create a sustainable, market-based model for broadening access to HIV, hepatitis B (HBV) and HCV medicines in the developing world.

- Our partnership model for HIV now reaches 8 million patients in developing countries.
More Than a Decade of Progress

Gilead launches its HIV Access Program

Gilead becomes the first HIV manufacturer to sign a licensing agreement with the Medicines Patent Pool

Gilead’s first hepatitis C medicine becomes available in Egypt, the highest-burden country in the world, less than a year after its U.S. approval

Gilead HIV medicines reach 8 million patients in the developing world

2003
Gilead expands HIV Access Program through licensing agreements with Indian generic manufacturers

2006
Gilead is ranked #1 by the Access to Medicine Index for patents/licensing and equitable pricing

2011
Gilead licenses its hepatitis C medicines to India-based generic manufacturers

2012
Gilead expands its hepatitis C licensing agreements to include more countries and products

2013
Gilead makes its branded hepatitis C medicines available at their lowest prices in all countries in its expanded generic-eligible territory

2014

2015
Our Model of Treatment Expansion

**Tiered Pricing**
Branded drugs available at deeply discounted prices

**Generic Licensing**
Partnerships with generic manufacturers to produce high-quality, low-cost medicines

**Drug Registration**
Working with network of business partners to submit regulatory dossiers on a country by country basis

**Relevant Data**
Broad clinical trials across broad patient populations; local clinical trials where appropriate; key demonstration projects

**Partnerships & Health Systems Strengthening**
Agreements with non-profit service providers and on the ground medical education and training

**Product Donations**
Targeted donations enabling treatment initiation for key underserved populations
HIV Treatment Access
Supporting the global movement for universal access

1996 2006 2015
A total of 21 HIV licensees (direct with Gilead or through the MPP)

* Licensed by the MPP
Generic Competition + Innovative Financing = ↓ Prices & ↑ Access

Driven by competition among licensed generic manufacturers and supported by global funding, the cost of Gilead HIV medicines has fallen by 80%. More than half of HIV patients on ARVs in the developing world are now receiving Gilead medicines.
Accelerating Access to New HIV Treatments

• Even before new HIV treatments are approved, Gilead is working to expedite access to them.

• Tenofovir alafenamide (TAF) represents Gilead’s latest treatment innovation.
  – High efficacy at a dose <1/10 that of Viread® (TDF)
  – Improved kidney and bone safety parameters

• In July 2014, Gilead expanded its MPP agreement to increase access to TAF for HIV and hepatitis B, contingent on U.S. regulatory approval.
  – U.S. PDUFA date November 5, 2015
  – EU MAA submitted in December 2014

• MPP can sub-license TAF to generic drug companies in India and China, who may manufacture and distribute it in 112 developing countries.

“The MPP announcement reflects the importance of ensuring rapid access to new lower-dose HIV medicines for people living with HIV/AIDS worldwide and accelerating efforts to control the HIV/AIDS epidemic.”

- Ambassador Deborah Birx, U.S. Global AIDS Coordinator (July 24, 2014)
### TAF Regulatory and Research Updates

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<tr>
<th>Quarter</th>
<th>Events</th>
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<tbody>
<tr>
<td><strong>Q1 2015</strong></td>
<td>Initiated Phase 2 study of <strong>new integrase inhibitor (GS-9883)</strong> with F/TAF</td>
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<td><strong>Q2 2015</strong></td>
<td>Submitted applications for <strong>F/TAF</strong> in the U.S. and EU</td>
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<tr>
<td><strong>Q3 2015</strong></td>
<td>Submitted applications for <strong>rilpivirine/F/TAF</strong> in the U.S. and EU</td>
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<td><strong>Q4 2015</strong></td>
<td>Anticipated approval of <strong>E/C/F/TAF</strong> in the U.S. and EU</td>
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### HIV Eradication Research Updates

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<tr>
<td><strong>Q1 2015</strong></td>
<td>Presented promising pre-clinical data on <strong>GS-9620</strong></td>
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<tr>
<td><strong>Q2 2015</strong></td>
<td>Initiated <strong>Phase 1 study</strong> to show proof-of-concept in humans</td>
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Hepatitis C Treatment Access
Rapid scale-up for global impact

2011-2013  2014
More than 150 million people worldwide are infected with the hepatitis C virus (HCV), and HCV-related complications cause up to 500,000 deaths each year.
New Opportunities for HCV Treatment Expansion

- **First cure**: For the first time, HCV cures are available in short, well-tolerated regimens with high cure rates – provides potential path to hepatitis C elimination.

- **Speed of access**: Gilead is working quickly to enable developing world access to its medicines.
  - Within 10 months of U.S. FDA approval, made Sovaldi® available in Egypt at significantly reduced price
  - Since Oct. 2014, >125,000 Egyptians have begun treatment with Sovaldi; nearly 500 new patients initiate therapy every day

- **Continued research**: Gilead continues to develop treatment options and conduct critical research that can benefit developing world patients.
  - Investigational pan-genotypic therapy (velpatasvir) currently in Phase 3 clinical trials; key to expanding developing world access – would eliminate need for expensive, often unavailable genotypic testing
  - Conducting demonstration projects in several countries (e.g., Rwanda, Georgia, Ukraine) to quantify burden of disease, identify risk factors for transmission, guide future prevention efforts and develop baseline data needed to gauge progress
Addressing Challenges to HCV Access

- Toxic, lengthy, ineffective treatments
  - Highly effective once-daily, all-oral regimen w/ significantly reduced treatment duration
- Pricing Barriers
  - Differential pricing for low- and middle-income countries; generic licensing; national agreements
  - Variety of HCV genotypes and challenges of genotypic testing
  - Promising investigational pan-genotypic regimen (velpatasvir)
  - Country-specific regulatory approvals/delays
  - Regional business partners facilitate global registration of medicines
- Frail healthcare infrastructures
  - Clinical and provider education, health systems strengthening
Further Challenges to Tackle

- No Dedicated Global Financing for HCV Mono-infection
- Lack of Awareness of HCV as a Public Health Threat
- Limited Global HCV Advocacy
- HCV Testing Not Readily Available in Many Countries
- Limited National Resources for HCV
- Policy and Stigma that Make It Difficult to Reach Some High-Risk Groups (e.g., IDU)
Hepatitis C Generic Licensing Partners

Eleven International Partners
Produce generic hepatitis C medicines for 101 resource poor countries

India

Gurgaon,
RiPharma
Laboratories
Ahmedabad,
Cadila Healthcare
Mumbai,
Cipla
Hyderabad,
Aurobindo Pharma
Laurus Labs
Mylan Laboratories
Nelco Pharma
Bangalore,
Broon Ltd.
SeQuent Scientific
Shines Arcalab

Three In-Country Partners
Produce generic hepatitis C medicines for their home countries

Egypt
Cairo,
Magic Pharma
Pharmed Healthcare

Pakistan
Raiwind,
Ferozsons
Reach of HCV Generic Licensing

1. Afghanistan
2. Algeria
3. Angola
4. Antigua and Barbuda
5. Bangladesh
6. Benin
7. Bhutan
8. Bolivia
9. Botswana
10. Burkina Faso
11. Burundi
12. Cambodia
13. Cameroon
14. Cape Verde
15. Central African Republic
16. Chad
17. Comoros
20. Cook Islands
21. Côte d’Ivoire
22. Cuba
23. Djibouti
24. Dominica
25. Egypt
26. El Salvador
27. Eritrea
28. Ethiopia
29. Equatorial Guinea
30. Fiji
31. Gabon
32. Gambia
33. Ghana
34. Guatemala
35. Guinea
36. Guinea-Bissau
37. Guyana
38. Haiti
39. Honduras
40. India
41. Indonesia
42. Kenya
43. Kiribati
44. Kyrgyzstan
46. Lesotho
47. Liberia
48. Libya
49. Madagascar
50. Malawi
51. Maldives
52. Mali
53. Marshall Islands
54. Mauritania
55. Mauritius
56. Micronesia
57. Mongolia
58. Morocco
59. Mozambique
60. Myanmar
61. Namibia
62. Nauru
63. Nepal
64. Nicaragua
65. Niger
66. Nigeria
67. North Korea
68. Pakistan
69. Palau
70. Papua New Guinea
71. Paraguay
72. Philippines
73. Rwanda
74. Samoa
75. São Tomé and Príncipe
76. Senegal
77. Seychelles
78. Sierra Leone
79. Solomon Islands
80. Somalia
81. South Africa
82. South Sudan
83. Sri Lanka
84. St. Vincent and the Grenadines
85. Sudan
86. Suriname
87. Swaziland
88. Tajikistan
89. Tanzania, U. Rep. of
90. Timor-Leste
91. Togo
92. Tonga
93. Tunisia
94. Turkmenistan
95. Tuvalu
96. Uganda
97. Uzbekistan
98. Vanuatu
99. Vietnam
100. Zambia
101. Zimbabwe

• The **101 countries** in Gilead’s generic-eligible territory are home to **more than half** of all people worldwide living with HCV (**103 million** people).

• Territory covers all low-income and nearly all lower-middle-income countries (**65 MICs**).

• Gilead’s branded hepatitis C medicines are **available at their lowest prices in all countries** in the expanded generic-eligible territory.
Egypt has the highest HCV prevalence in the world – nearly 15%, by some estimates

The partnership:

• Ministry of Health implementing ambitious national HCV treatment program; providing care through government clinics and hospitals.
• Gilead provides branded Sovaldi to Egyptian Ministry of Health at a significantly reduced price.
• Gilead supports MoH-led HCV medical education and prevention efforts.
• As of June 2015, more than 125,000 patients have initiated treatment with Sovaldi.
• Will also begin providing Harvoni in November 2015.

Launch of Egypt’s national hepatitis C treatment initiative, October 2014
Egypt has the highest HCV prevalence in the world – nearly 15%, by some estimates.

Access in Action: Georgia

Approximately 7% of Georgians are infected with HCV – the third-highest prevalence in the world

The partnership:

- Ministry of Health, U.S. Centers for Disease Control and Prevention and Gilead collaborating to eliminate hepatitis C in Georgia
- Goal is to demonstrate the impact of widespread HCV screening and universal treatment on a national scale
- Ministry of Health leading and implementing the program
- U.S. CDC providing technical support and guidance
- Gilead providing branded Sovaldi and Harvoni at no cost to program; goal of initially treating 5,000 patients in the first year and eventually up to 20,000 patients each year
An estimated 3 million people in Brazil are chronically infected with HCV – but only 10% are currently diagnosed

The partnership:

• Reached an agreement with the Brazilian Ministry of Health to enable availability of branded Sovaldi through the national public health system

• Ministry of Health has committed to scaling up treatment nearly threefold

• Sovaldi also an integral component of Brazil's new HCV treatment guidelines

• Gilead also implementing medical education programs to familiarize Brazilian healthcare providers with the latest HCV treatment options

Brazilian Ministry of Health press conference launching new treatment guidelines, July 2015
The partnership:

- In July 2015, Spain’s health ministry published a **national strategic plan** to combat hepatitis C.
- Includes three DAAs (Harvoni and Viekirax+Exviera), with a cap of €786 million to treat 51,900 patients over three years.
  - After cap is reached, health ministry will resume negotiation with drug makers.
- Spain’s finance ministry has established **innovative regional loans** to fund HCV treatment:
  - Very low interest rates
  - 10 years to repay loans, with two-year grace period
  - HCV treatment loans do not count toward regional debts.
- Regions will report monthly number of patients treated to national health ministry.

Recent reports indicate that Spain has an HCV prevalence of 1.2% – about 472,000 Spaniards.