Intellectual Property and Access to HIV Medicines in the Developing World

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About Gilead Sciences

♦ Worldwide presence
  – More than 4,500 employees
  – 31 offices in 24 countries

♦ 14 marketed drugs; active R&D program
  – Primary therapeutic areas: HIV/AIDS, liver disease, serious cardiovascular and respiratory conditions, oncology
  – 10 successful acquisitions, growing company reach

♦ Committed to ensuring global access
  – Believe our responsibility to patients extends beyond the lab, and beyond developed-world markets
## Our HIV Products and Pipeline

<table>
<thead>
<tr>
<th>Single Agents</th>
<th>Fixed-Dose Combinations</th>
<th>Single-Tablet Regimens</th>
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</thead>
<tbody>
<tr>
<td><strong>Current Medications</strong></td>
<td></td>
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<tr>
<td><strong>Viread</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
<td><strong>Emtriva</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
<td><strong>Truvada</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
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<tr>
<td>Tenofovir (TDF)</td>
<td>Emtricitabine (FTC)</td>
<td>TDF+FTC</td>
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<tr>
<td>Approved 2001</td>
<td>2003</td>
<td>2004</td>
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<tr>
<td><strong>In the Pipeline</strong></td>
<td></td>
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<tr>
<td>Elvitegravir (EVG)</td>
<td>Cobicistat (COBI)</td>
<td>Other Fixed-Dose Combinations</td>
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<td>Approval expected 2013</td>
<td></td>
<td>E.g., COBI+DRV</td>
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<td>GS 7340</td>
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Global HIV Treatment Scale-Up

- Significant progress on global treatment access
  - More than 7 million people on HIV treatment worldwide

- Yet tremendous unmet need
  - 34 million people living with HIV; more than 7 million people need treatment now and do not receive it
  - WHO guidelines: Begin treatment at CD4 count of 350 cells/mm³. (HHS guidelines recently revised to CD4 500)
  - Early treatment may reduce transmission risk up to 96% (HPTN 052 study)

Source: World Health Organization
Gilead’s Access Programs

- Gilead’s Access Program was launched in 2003 as a **sustainable**, **market-based** approach for facilitating global access to our medicines.

- **Regional distributors** distribute steeply discounted branded Viread and Truvada to more than 130 low- and middle-income countries.

- Branded products have a **tiered pricing system** that reflects each country’s ability to pay and are based primarily on a country's gross national income per capita and HIV prevalence.

- Gilead has **voluntarily extended licenses** to 14 Indian manufacturers and one South African company to produce generic Viread and Truvada for low- and middle-income countries.

- Licensing partners receive a **full technology transfer** of the manufacturing process and set their own product prices, using their expertise in making large quantities of high-quality medicines at low cost.
Recent Program Innovations

- Gilead extended generic licenses to Indian partners in 2011 to produce three pipeline medicines for HIV once they receive U.S. regulatory approval: elvitegravir, cobicistat and the Quad single tablet regimen.

- In July 2011, Gilead signed agreement with the Medicines Patent Pool (MPP), established by UNITAID in 2009 to facilitate access to essential medicines through patent sharing/licensing.
  - Gilead is the first and only innovator company to sign with MPP.
  - MPP was granted similar terms as Indian partners: TDF license plus future rights to pipeline products.
  - MPP can sub-license Indian manufacturers to produce these medicines for developing countries.
Results

Access to Gilead HIV Medicines

A proven model reaching 2.4 million HIV patients, more than a third of all those on treatment in developing countries
Looking Ahead: IP and Access Policies

The framework we hope to work toward:

♦ Patents should be issued and enforced based on the merits of the science and innovation

♦ There have been and will continue to be situations in which compulsory licenses are the right course of action
  – At the same time, essential that due process is in place to assess merits of compulsory licenses on a case-by-case basis

Gilead remains strongly committed to its access programs:

♦ A proven model reaching 2.4 million HIV patients

♦ Financially self-sustaining, market-based, scalable and replicable

♦ Lessons still to be learned – and we remain open to program evolution and innovation
Thank You