Introduction

Introducing the first edition of CHAI’s HIV Mid-Year Market Memo, an informational brief that covers the latest trends in the HIV space in low- and middle-income countries (LMICs) since the publication of CHAI’s annual ARV Market Report in October 2016. For further background on these topics, please see the above report.

Data Sources For The Memo:
1. CHAI’s Annual Data Request to 20+ LMICs
2. Articles from journals and news outlets
3. Supplier and partner market intelligence
4. Major conferences and meetings

Adult ARV Market

First-Line (1L) Adult Products

<table>
<thead>
<tr>
<th>1L ARV Pricing</th>
<th>USD, Pppy</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLE600</td>
<td>$83.40*</td>
</tr>
<tr>
<td>TLE400</td>
<td>$81.00*</td>
</tr>
<tr>
<td>TBD**</td>
<td></td>
</tr>
</tbody>
</table>

Benefits of DTG Relative to EFV
1. Higher genetic barrier to resistance
2. Fewer side effects
3. Lower expected costs
4. Faster time to viral suppression

Inclusion of DTG Guidance

2L ARV Trends

ATV/r | LPV/r
Pre-2017

Preliminary analysis shows ATV/r continued to increase its 2L adult market share from 2015 to 2016

Reference Pricing (PPPY)

ATV/r: $186*
LPV/r: $221*

Pipeline Adult Products

FDC DRV/r
2L PI shown to be superior, or non-inferior, to ATV/r and LPV/r in clinical trials

TAF
Tenofovir pro-drug that may reduce costs due to lower amounts of API needed

Expected SRA approval of two generic suppliers

Mid-2018

CHAI-Unitaid Catalytic Procurement of DTG Singles

Under the leadership of Ministries of Health (MoHs) in Kenya, Nigeria and Uganda, CHAI and Unitaid have supported a catalytic procurement of DTG singles to help key requirements for national roll-out and to provide a platform for TLD FDC introduction.

Key Goals:
- Understand patient preferences
- Set standards for monitoring toxicity
- Inform areas of potential future trainings
- Identify prescriber knowledge gaps

“Treat All” Guidance

Surveyed LMICs have adopted WHO-recommended “Treat All” policies

Sample Adopters

India
Lesotho
Malawi

*Global Fund PPM Reference Pricing, March 1, 2017; **TLD pricing being negotiated
Pediatric ARV Market

LPV/r Oral Pellet Adoption Profile

12+ LMICs have already placed or will be placing orders for LPV/r oral pellets

Key Product Information
Formulation: LPV/r (40/10mg) oral pellets – 120 caps
Reference Price: $19.20/pack* Supplier: Cipla

Four Pellet Recommendations
1. Prioritize patient populations for adoption (e.g., < 3yrs)
2. Establish adoption and implementation plan
3. Anticipate 6-9 month lead times
4. Monitor adoption in coordination with ARV Procurement Working Group

ABC/3TC (120/60mg) Uptake

Sample Adopters
- Kenya
- Uganda
- Vietnam

Generic Suppliers of ABC/3TC (120/60mg)
- Mylan
- Cipla

Pipeline Pediatric Products

LPV/r (40/10mg) Granules
Another solid formulation alternative to oral solution
Expected first generic SRA approval H1 2018

ABC/3TC/LPV/r “4-in-1”
Provides WHO-preferred regimen for patients <3 yrs in one pill
Expected first generic SRA approval H2 2018

ABC/3TC (120/60mg) Uptake
50% decrease in pill burden, compared to ABC/3TC (60/30mg) tablets

The Global Accelerator for Pediatric Formulations (GAPf) and its member organizations continue to play a pivotal role in identifying innovative approaches for fast-track development and introduction of priority formulations

Prevention

Updates On Oral PrEP
10+ countries have included oral PrEP guidance in national guidelines since South Africa became the first LMIC to introduce oral PrEP in national program in mid-2016

Sample LMICs That Have Introduced Oral PrEP Guidance
- Botswana
- Kenya
- Myanmar
- South Africa
- Zambia

Prevention Research Developments
Long-acting Injectables (LAI)
In Dec 2016, HPTN 083, the first phase III trial testing the efficacy of LAI cabotegravir, in doses once every 8 weeks, began with results expected in 2021

Implants
In late 2016, the Bill & Melinda Gates Foundation committed up to $140 million in funding to Intarcia Therapeutics for development of a subdermal implant that will dispense PrEP over the course of 6-12 months

HIV Vaccine
In Nov 2016, HVTN 702, the first HIV vaccine trial since 2009, launched in South Africa with results expected in 2021

Diagnostics

Viral Load Scale-Up
Nearly all LMICs have adopted routine viral load (VL) testing. Testing volumes in LMICs increased by >20% between 2015 and 2016

Shift To Dried Blood Spot (DBS) Testing
LMICs implemented VL using plasma but are scaling up using DBS. In countries that have significantly scaled-up, DBS assumes an average of 60% of total volumes

Piloting Point-of-Care (POC) VL
Cameroon, Ethiopia, Kenya, Malawi, Tanzania, and Zimbabwe are piloting POC VL

Trends In Early Infant Diagnosis (EID)
5+ LMICs have adopted testing at or near birth*; most are expected to adopt by 2019

12+ LMICs recommend alternative entry points* for case finding

11+ LMICs are piloting or scaling-up point-of-care EID*

The Future of CD4 Testing
Although CD4 testing remains necessary, volumes are expected to decrease with significant adoption of “Treat All” (see ‘Adult ARV Market’ section) and VL testing for routine monitoring

2017 CHAI HIV Mid-Year Market Memo | Clinton Health Access Initiative, Inc.