Atripla Key Metrics in the Nine Major Pharmaceutical Markets

<table>
<thead>
<tr>
<th>2012 Market Sales</th>
<th>2022 Market Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>$2397.8m</td>
<td>$117.6m</td>
</tr>
<tr>
<td>5EU - Atripla</td>
<td>5EU - Atripla</td>
</tr>
<tr>
<td>$789.1m</td>
<td>$4.8m</td>
</tr>
<tr>
<td>Brazil and China - Atripla</td>
<td>Brazil and China - Atripla</td>
</tr>
<tr>
<td>$23.7m</td>
<td>$2.4m</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>$3210.6m</strong></td>
<td><strong>$124.7m</strong></td>
</tr>
</tbody>
</table>

Key Events (2012–2022)

<table>
<thead>
<tr>
<th>Event</th>
<th>Level of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off patent of Atripla’s components (efavirenz) in 2013</td>
<td>↓↓</td>
</tr>
<tr>
<td>Patent expiry of Atripla in the EU in 2018</td>
<td>↓↓↓</td>
</tr>
</tbody>
</table>

Sales of Atripla in the Global HIV Market

Sales of Atripla are expected to decrease from $3210.6 million in 2012 to $124.7 million in 2022 at a negative compound annual growth rate (CAGR) of 27.7%.

Major drivers of Atripla sales over this forecast period will include:

- Ease of administration and increased compliance
- Likelihood to provide another revenue stream for Atripla for gaining approval for pre-exposure prophylactic (PrEP) therapy

Major barriers of Atripla sales over this forecast period will include:

- Deleterious side-effect profile, including gastrointestinal disorder, fatigue, and nervous system disorders
- Increased risk of drug resistance – can only be prescribed to people with good adherence
- More single-tablet regimen (STRs) emerging in the market is expected to increase the competition in the drug class
- The patent expiry of BMS’s Sustiva (efavirenz), one of Atriplas components, will affect its sales, especially in the 5EU

Source: GlobalData
Key Opinion Leaders Interested in New and Efficacious Therapies that Improve the Treatment Algorithm for HIV Treatment

The Key Opinion Leaders (KOLs) interviewed for this report highlighted that the primary concerns for this market still remain disease awareness and patient compliance with existing treatment regimens. They also embrace the adoption of aggressive efforts to diagnose new infections and start people on antiretrovirals. In terms of treatment choice, these KOLs indicated that integrase inhibitor-based regimens are likely to be the wave of the future of the market due to the emergence of viral resistance through the use of other treatments. KOLs also show a preference to simplified regimens and fixed dose combinations and would like to see more treatment choices as STRs.

“The most of what I would like to see is not related to drug so much as it is to the healthcare system, getting more people diagnosed and retained in care.”

Key Opinion Leader, January 2013

“The major hurdles which prevent patients from getting diagnosed are lack of awareness on the part of physicians [they should be testing] and lack of access to healthcare for many patients.”

Key Opinion Leader, January 2013

“Yes, we do perform screening for all high-risk patients. General hospitals also perform routine screening for all patients who are admitted. So, 70% to 80% of the new HIV-positive patients come from general hospitals. More and more patients are tested for HIV and they are forced into diagnosis.”

Key Opinion Leader, November 2012
Executive Summary

“We have the test-and-treat policy. If we identify a positive patient we immediately start therapy, and it helps preventing opportunistic infections and malignancies.”

Key Opinion Leader, November 2012

“When you talk to patients they are quite keen on injectable drugs once a month.”

Key Opinion Leader, November 2012

“My personal advice to the companies would be to conduct many more studies with people who are likely to be less adherent; poorly adherent patients, patients with high viral loads and low CD4+ counts.”

Key Opinion Leader, November 2012
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2 Introduction

2.1 Catalyst

The Atripla market is a $3,210.6 million market with intense corporate competition between pharmaceutical giants.

- The decrease in the CD4 count threshold required of asymptomatic patients prior to the administration of antiretroviral therapy, and the test-and-treat approach adopted by many countries, is likely to increase the market size.

- The 2012 approval of Gilead’s new single-tablet regimen (STR), Stribild, introduces a new fixed-dose combinatorial drug onto the market and underscores the patient and physician preference for STRs for HIV treatment.

- Gilead’s “cash-cow”, Truvada, received approval as the first-ever treatment to be used as a pre-exposure prophylactic treatment in HIV-negative patients who are in high risk of exposure to HIV infection.

- The movement towards compulsory licensing in emerging markets, such as Brazil and China, in favor of providing affordable treatments to infected individuals, has a ripple effect on the size of these markets and the attractiveness of the market as a whole.

- The impending patent expiries of high-grossing drugs, such as BMS’s Sustiva (a component of Atripla), Gilead’s Atripla and Truvada, ViV’s Epzicom, and AbbVie’s Norvir and Kaletra are expected to dramatically change the face of the market in favor of generic drugs and pushing manufacturers to develop more efficacious products in order to retain their market share in the long term.

2.2 Related Reports


• GlobalData (2013). HIV – Italy Drug Forecast and Market Analysis to 2022. GDHC1032CFR
• GlobalData (2013). HIV – China Drug Forecast and Market Analysis to 2022. GDHC1037CFR
• GlobalData (2013). HIV – Brazil Drug Forecast and Market Analysis to 2022. GDHC1036CFR
• GlobalData (2013). Complera (HIV) – Forecast and Market Analysis to 2022. GDHC1115DFR
• GlobalData (2013). Stribild (HIV) – Forecast and Market Analysis to 2022. GDHC1114DFR
• GlobalData (2013). Truvada (HIV) – Forecast and Market Analysis to 2022. GDHC1112DFR
• GlobalData (2013). Epzicom (HIV) – Forecast and Market Analysis to 2022. GDHC1113DFR
• GlobalData (2013). Kaletra (HIV) – Forecast and Market Analysis to 2022. GDHC1051DFR
• GlobalData (2013). Reyataz (HIV) – Forecast and Market Analysis to 2022. GDHC1052DFR
• GlobalData (2013). Prezista (HIV) – Forecast and Market Analysis to 2022. GDHC1053DFR
• GlobalData (2013). Norvir (HIV) – Forecast and Market Analysis to 2022. GDHC1054DFR
• GlobalData (2013). Isentress (HIV) – Forecast and Market Analysis to 2022. GDHC1055DFR
• GlobalData (2013). Cobicistat (HIV) – Forecast and Market Analysis to 2022. GDHC1056DFR
• GlobalData (2013). Dolutegravir (HIV) – Forecast and Market Analysis to 2022. GDHC1058DFR
• GlobalData (2013). 572-Trii (HIV) – Forecast and Market Analysis to 2022. GDHC1059DFR
• GlobalData (2013). Quad 2 (HIV) – Forecast and Market Analysis to 2022. GDHC1060DFR
• GlobalData (2013). Elvitegravir (HIV) – Forecast and Market Analysis to 2022. GDHC1057DFR
• GlobalData (2013). HIV – Current and Future Players. GDHC1004FPR
7.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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