

Biktarvy, the booming blockbuster, drives HIV market - Cortellis

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From gene therapies and vaccines, to combination therapies and antibodies, treatments in the Cortellis Drugs to Watch 2018 report were varied both in action and target. The [Cortellis](#) team featured 12 potential blockbusters last year which had forecasted sales of more than \$1 billion by 2022.

One treatment stood out, due to its achievement of blockbuster status within less than 12 months of market entry. Biktarvy, Gilead Sciences's complete regimen for the treatment of HIV, was launched in the U.S. and EU in February and July of last year, respectively.^{1, 2} With actual sales available for 2018, the year's most successful launch amongst the 12 transformative therapies can be evaluated, including a deeper insight into its competitors.

Entering the market as a daily, fixed-dose combination of the integrase inhibitor bictegravir (BIC) plus two nucleoside reverse transcriptase inhibitors (NRTIs), emtricitabine (FTC) and tenofovir alafenamide fumarate (TAF), initial sales were strong, growing quarter on quarter.³ Total reported 2018 sales were \$1.184 billion, with forecasts for 2023 now predicted at \$7.369 billion (Source: Refinitiv I/B/E/S).

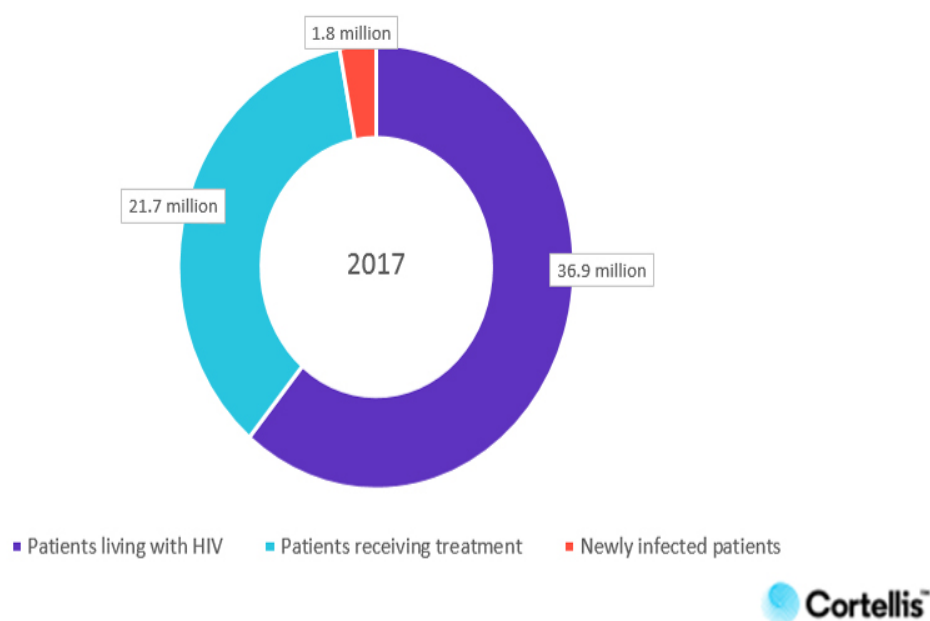


Figure 1. HIV incidence and current treatment status; data taken from the World Health Organization.

The HIV market continues to expand

The World Health Organization estimated that in 2017, 36.9 million people were living with HIV, 21.7 million were receiving treatment and 1.8 million were newly infected.⁴ Retrovir was the first drug approved, in 1987, for the treatment of HIV-1 infection, and advancements over the past 30+ years have led to once-daily, oral, fixed-dose combinations, with limited adverse effects and strong efficacy data supporting their now widespread use.⁵ Although unable to cure HIV, current treatments suppress a patient’s viral load, allowing their immune system to strengthen, and also act to prevent further damage; however, treatment is required throughout a patient’s lifetime. HIV cases are currently rising at around 15% per decade due to infected people living longer, sustained infections and increasing populations.^{6,7} With a projected value of \$22.5 billion in 2024, the worldwide HIV market makes for a lucrative investment opportunity.⁸

The battle of the best

Gilead and GlaxoSmithKline (GSK), as well as Viiv Healthcare as a joint venture formed between GSK and Pfizer, have been key players in the HIV arena for over two decades. In August 2004, two dual NRTI combination pills, Gilead's Truvada and GSK's Epzicom, were approved in the U.S., battling for market share. Gilead's triple NRTI/non-NRTI combination Atripla launched in July 2006.⁵ Gilead still favors triple combinations, a tried and tested approach that will have contributed to Biktarvy's early success.⁹

In just over two years from 2012, three new products came to market: Gilead's quadruple-component pill Stribild (dual NRTI + boosted integrase inhibitor) in August 2012; Viiv's integrase inhibitor Tivicay in August 2013; and Viiv's three-component pill Triumeq (dual NRTI + integrase inhibitor) in September 2014.¹⁰ Triumeq achieved sales of \$1.115 billion in the first full year following market entry, and with 2018 reported sales of \$3.535 billion, Viiv's has a significant contender in the HIV battle. Gilead launched its quadruple-drug tablet, Genvoya (dual NRTI + boosted integrase inhibitor), in December 2015, grossing an impressive \$1.5 billion in its first year.¹⁰ Genvoya sales of \$4.624 billion in 2018 enabled Gilead to cement its strong position, and in June 2019, it was reported that Gilead held an HIV market share of 53%, versus GSK's 23%.¹¹

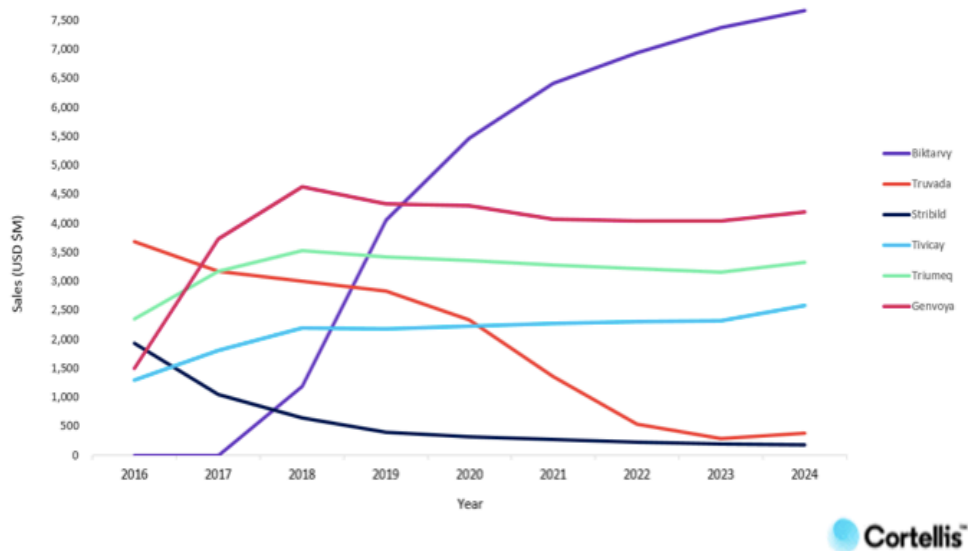


Figure 2. Forecasted sales of Biktarvy and other HIV therapy showing Biktarvy’s predicted success. Data obtained from [Cortellis Competitive Intelligence](#), accessed July 9, 2019. **Source:** Refinitiv I/B/E/S.

GSK’s next challenger, Juluca, the first two-component, complete regimen, gained U.S. approval in November 2017.¹² However, its launch has been overshadowed by Biktarvy’s early 2018 launch, with three-drug regimens continuing to be favored.¹³

Trend of upwards growth

Given its efficacy and safety data, combined with minimal adverse events, prescribers are likely to favor Biktarvy over established regimens. Recently updated U.S. HIV treatment guidelines recommend the combination for initial use in “most people with HIV,” providing crucial support for a key position in the market and continued strong sales.¹⁴

In the first quarter of 2019, Biktarvy was the number one prescribed regimen for both treatment-naïve and switch patients, with 80% of Biktarvy prescriptions resulting from switches.¹⁵ Further regional

launches are expected in 2019, leading to a predicted trend of upwards growth for Gilead’s latest triple-combination.¹⁵

Future forecasts

With the release last March of the Drugs to Watch 2018, Biktarvy was forecast to achieve sales of \$2.282 billion in 2019 and \$3.716 billion in 2022. Over a year later, these predictions have risen to \$4.050 and \$6.836 billion, respectively. Gilead’s robust history, Biktarvy’s compelling efficacy data, and long-standing infiltration in key markets have all contributed to its early triumph. With forecast sales of \$7.674 billion in 2024, Biktarvy may allow Gilead to secure its leading position in the HIV arena for years to come.

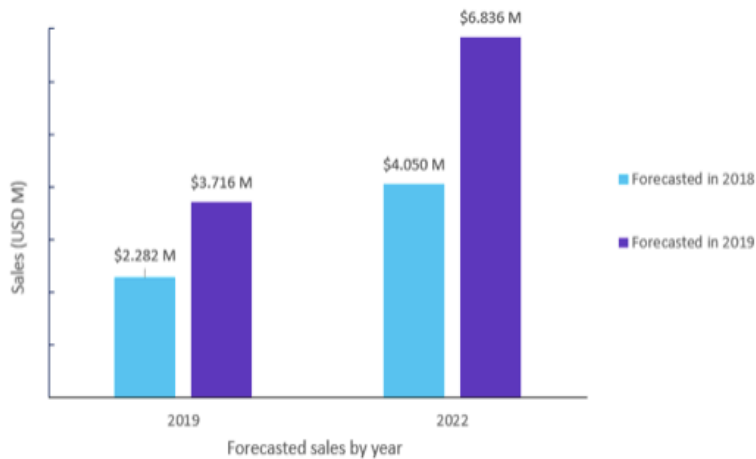


Figure 3. Forecasted 2019 and 2022 Biktarvy sales as of the Cortellis Drugs to Watch 2018 report, in March 2018, and as of July 2019. Data obtained from [Cortellis Competitive Intelligence](#), accessed July 9, 2019. **Source:** Refinitiv I/B/E/S.

This year’s edition of our annual report, [Cortellis Drugs to Watch 2019](#),

identified seven drugs expected to launch this year with sales forecasts of \$1 billion or more by 2023. Click here to see the full report: [Cortellis Drugs to Watch 2019](#).