

## Biktarvy - (50 mg/200 mg/ 25 mg ; Tablets)

|                              |  |                             |                     |
|------------------------------|--|-----------------------------|---------------------|
| <b>Generic Name</b>          | Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate   | <b>Innovator</b>            | Gilead              |
| <b>Dosage</b>                | 50 mg/200 mg/ 25 mg ; Tablets  | <b>Branded US Sales</b>     | More Than \$1000 mn |
| <b>Probable FTF</b>          | Less Than 5  | <b>Known Para IV Filers</b> | Less Than 5         |
| <b>Other ANDA developers</b> | More Than 5  | <b>Tentative Approvals</b>  | Less Than 5         |
| <b>Final Approvals</b>       | None   | <b>Generic Launches</b>     | None                |
| <b>Indication</b>            | BIKTARVY is a three-drug combination of bicittegravir (BIC), a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors (NRTIs), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY. |                             |                     |
| <b>Complexities</b>          | Yes  |                             |                     |

### Chronology Of Events

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Executive Summary

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Patent Status

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Launch Timelines and Competition

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### Chronology Of Events



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## Biktarvy - (30 mg / 120 mg / 15 mg ; Tablet)

|                              |   |                             |                     |
|------------------------------|---|-----------------------------|---------------------|
| <b>Generic Name</b>          | Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate  | <b>Innovator</b>            | Gilead              |
| <b>Dosage</b>                | 30 mg / 120 mg / 15 mg ; Tablet   | <b>Branded US Sales</b>     | More Than \$1000 mn |
| <b>Probable FTF</b>          | None  | <b>Known Para IV Filers</b> | None                |
| <b>Other ANDA developers</b> | More Than 5   | <b>Tentative Approvals</b>  | None                |
| <b>Final Approvals</b>       | None  | <b>Generic Launches</b>     | None                |
| <b>Indication</b>            | BIKTARVY is a three-drug combination of bicittegravir (BIC), a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors (NRTIs), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY. |                             |                     |
| <b>Complexities</b>          | Yes   |                             |                     |

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