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

Generic Name	Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate	**Innovator**	Gilead
Dosage	50 mg/200 mg/ 25 mg ; Tablets	**Branded US Sales**	More Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	Less Than 5
Final Approvals	None	**Generic Launches**	None
Indication	BIKTARVY is a three-drug combination of bictegravir (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.		
Complexities	Yes		

Chronology Of Events

Please Contact contact@researchdelta.com to get Detailed Information.

Executive Summary

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Patent Status

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Launch Timelines and Competition

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Chronology Of Events

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

Generic Name	Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate	**Innovator**	Gilead
Dosage	30 mg / 120 mg / 15 mg ; Tablet	**Branded US Sales**	More Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	More Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	BIKTARVY is a three-drug combination of bictegravir (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.		
Complexities	Yes		

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