CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210251Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY REVIEW(S)

CLINICAL VIROLGY REVIEW OF NGS DATA

Application Type	NDA
Application Number(s)	210251
Priority or Standard	Priority
Submit Date(s)	June 10, 2017
Received Date(s)	June 12, 2017
PDUFA Goal Date	February 12, 2018
Division/Office	DAVP/OAP
Review Completion Date	11/09/2017
Established Name	Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) Fixed-Dose Combination
(Proposed) Trade Name	BIKTARVY™
Pharmacologic Class	Bictegravir is an integrase strand-transfer inhibitor (INSTI), emtricitabine and tenofovir alafenamide are nucleos(t)ide reverse transcriptase inhibitors (N[t]RTI)
Applicant	Gilead Sciences
Formulation(s)	FDC Tablet
Dosing Regimen	bictegravir 50 mg/emtricitabine 200 mg/TAF 25 mg
Applicant Proposed Indication(s)/Population(s)	Treatment of HIV-1 infection in adults who are HIV-1 treatment-[redacted] (b) (4) associated with resistance to the individual components of BIKTARVY
Recommendation on Regulatory Action	Approval

SUMMARY AND RECOMMENDATIONS

The Clinical Virology Review of the next generation sequencing data submitted in support of this NDA is complete, and has been added to the NDA/BLA Multi-Disciplinary Review and Evaluation for BIKTARVY™ (B/F/TAF) fixed dose combination tablet. My recommendation, based on my review of the NGS data, is for approval.

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/s/

ERIC F DONALDSON
11/09/2017

JULIAN J O REAR
11/13/2017

CLINICAL VIROLOGY REVIEW

Application Type	NDA
Application Number(s)	210251
Priority or Standard	Priority
Submit Date(s)	June 10, 2017
Received Date(s)	June 12, 2017
PDUFA Goal Date	February 12, 2018
Division/Office	DAVP/OAP
Review Complete Date	October 25, 2017
Established Name	Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) Fixed-Dose Combination
(Proposed) Trade Name	BIKTARVY™
Pharmacologic Class	Bictegravir is an integrase strand-transfer inhibitor (INSTI); emtricitabine and tenofovir alafenamide are nucleos(t)ide reverse transcriptase inhibitors (NRTI).
Applicant	Gilead Sciences
Formulation(s)	FDC Tablet
Dosing Regimen	Bictegravir 50 mg/Emtricitabine 200 mg/TAF 25 mg
Applicant Proposed Indication(s)/Population(s)	Treatment of HIV-1 infection in adults who are HIV-1 treatment-naïve or virologically suppressed with no known substitutions associated with resistance to the individual components of BIKTARVY
Recommendation on Regulatory Action	Approval

SUMMARY AND RECOMMENDATIONS

Virology review is complete, and has been added to the NDA Multi-disciplinary Review and Evaluation for BIKTARVY™ (B/F/TAF) fixed-dose combination tablet.

With respect to Clinical Virology, approval of this original NDA for BIKTARVY tablet is recommended, based on Week-48 data from 2 Phase 3 trials conducted in ART-naïve adult subjects (Trials GS-US-380-1489 and GS-US-380-1490) and from 2 Phase 3 trials conducted in virologically suppressed adult subjects (Trials GS-US-380-1844 and GS-US-380-1878).

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/s/

SUNG S RHEE
11/08/2017

JULIAN J O REAR
11/08/2017
I concur with Dr. Sung's recommendation for approval