Combined Clinical, Clinical Pharmacology, and Cross-Discipline Team Leader Review

Date	December 16, 2021
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Subject	Combined Clinical, Clinical Pharmacology, and Cross-Discipline Team Leader Review
NDA/BLA # and Supplement#	208215 S-20
Applicant	Gilead Sciences, Inc
Date of Submission	March 29, 2021
PDUFA Goal Date	December 29, 2021
Proprietary Name	DESCOVY
Established or Proper Name	Fixed Dose Combination of emtricitabine (FTC) and tenofovir (TAF)
Dosage Form(s)	Tablet
Applicant Proposed Indication(s)/Population(s)	Indication: For the treatment of HIV-1 infection in combination with other antiretroviral agents. Population: Pediatric patients not receiving a protease inhibitor administered with ritonavir or cobicistat, and weighing at least 14 to less than 25 kg
Applicant Proposed Dosing Regimen(s)	One low dose tablet (FTC 120 mg and TAF 15 mg) once daily
Recommendation on Regulatory Action	Approval

1. Benefit-Risk Assessment

Benefit-Risk Assessment Framework

Benefit-Risk Integrated Assessment

The safety, efficacy, and pharmacokinetic data submitted in this efficacy supplement support approval of Descovy with a low dose fixed dose formulation of emtrictabine (120 mg) and tenofovir alafenamide (15 mg) for the treatment of HIV-1 infection in children weighing ≥ 14 to < 25 kg and also support the addition of 48-week safety and efficacy data in HIV-1 infected patients weighing at least 25 kg. The two drugs contained in Descovy are also included in the single dose tablets of Genvoya (elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide) and Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide). The exposures of emtricitabine and tenofovir alafenamide have been shown to be similar in adults who received Descovy to those in adults who received Genvoya or Biktarvy. The exposures of emtricitabine and tenofovir alafenamide are similar in pediatric subjects who receive low dose Genvoya and low dose Biktarvy and are expected to be similar in pediatric patients who receive low dose Descovy. Therefore, the safety and efficacy of Descovy in patients who weigh ≥ 14 to < 25 kg is based on pharmacokinetic bridging to the results of a single, open-label study of Biktarvy in HIV-1 infected pediatric patients weighing ≥ 14 to < 25 kg. The results of a single, open-label study of Genvoya in subjects weighing ≥ 25 kg support the addition of 48-week safety and efficacy data weighing ≥ 25 kg to the Descovy package insert; Descovy is already approved for this population based on data through Week 24 of the same study and the follow-up data are intended to demonsrate the durability of virologic response.

The safety and efficacy of Descovy in HIV-1 infected pediatric patients weighing ≥ 14 to < 25 kg was based on PK bridging to a single study of Biktarvy in that population. Biktarvy was studied in a multicenter, open-label, non-comparative trial (Study GS-US-380-1474) in which 22 children > 2 years of age, and weighing > 14 to < 25 kg), were enrolled and followed for > 24 weeks of study treatment. The trial design comprised two phases: a PK lead-in phase and a treatment phase in which the safety and efficacy of Biktarvy were evaluated. Biktarvy was administered as a low dose tablet (B/F/TAF: 30 mg/120 mg/15 mg). Exposures of Biktarvy components and tenofovir trial subjects were considered acceptable and supported the conclusion that the exposures observed in this weight (age) group are comparable to the exposure observed in adults who received the recommended dose.The virologic efficacy outcome, as measured by the proportion of subjects with plasma HIV-1 RNA < 50 copies/mL at Week 24, was 90.9% (20/22; 95% confidence interval (CI) 70.8% to 98.9%.). Two subjects (9.1%, 2/22) were on study drug but did not have virologic data collected at the Week 24 visit because of COVID-19 pandemic-related travel disruption. There was no evidence of virologic failure and among the 20 subjects with available HIV-1 RNA viral load, 20/20 (100%) achieved the efficacy outcome. There was a slight decrease in CD4 cell counts through Week 24. The mean CD4 cell count at baseline was 1104 (cells/µL, and the mean CD4 count at Week 24 was 931 cells/µL; the mean change from baseline in CD4 cell count was -126 cells/µL. The mean CD4% was the same at baseline and Week 24 (33.4%). The most commonly observed drug-related adverse events (AE) in the Biktarvy study were similar to those seen in adults and were mild in nature (neutropenia, abdominal pain, constipation, irritability, nausea and social avoidant behavior). There were no Grade 3 or higher AEs, no serious adverse events (SAE) and no deaths reported. There were no discontinuations due to an AE. All the laboratory AEs were Grade 1 or 2, except for one Grade 3 elevated alkaline phosphatase at Week 48 that resolved by Week 60. There were no relevant changes from baseline in vital sign parameters and no changes from baseline in height and height Z-scores. The body weight and body weight Z-scores increased (as expected) during the study.

Descovy was approved for treatment of HIV-1 infected patients weighing at least 25 kg in 2017 based on the 24-week results of a Genvoya study (GS-US-292-0106). The 48-week safety and efficacy data for Genvoya were submitted to support the durability of the safety and efficacy of Descovy. At Week 48, 51 of the 52 subjects (98%) in GS-US-292-0106 weighing ≥ 25 kg had HIV-1 RNA < 50 copies/mL. The mean change from baseline in CD4 count was -66 cells/µL; the mean change in CD4 percentage from baseline was -0.6%. This mean decrease in CD4 count was also observed at Week 24. There were no

deaths, no premature discontinuations due to an adverse event, and no serious adverse events. Adverse reactions were primarily observed in the gastrointestinal organ system, which is consistent with AEs observed in adolescents and adults. Although tenofovir can negatively affect renal function, there were no renal AEs and no Grade 1 or higher laboratory values for creatinine, serum phosphorous, or urine glucose. Because tenofovir use can result in loss of bone mineral density, subjects were followed with DXA scans at Week 24 and Week 48. The mean BMD increased from baseline to Week 48, +3.9% at the lumbar spine and +4.2% for TBLH. However, 6 Genvoya subjects had significant (at least 4%) lumbar spine BMD loss at Week 48; 2 of these subjects also had at least 4% TBLH BMD loss at Week 48. After review of these data from Cohort 2, we have determined that the efficacy and safety are similar at Weeks 24 and 48, showing a durable efficacy response with no increase in risk. Therefore, the efficacy and safety data from this group will be included in the Descovy package insert.

The reason for the decrease in CD4 counts in both the Biktarvy and Genvoya studies is unclear. It may be that small changes in CD4 count appear larger with a high baseline value, as evidenced by the lack of change in CD4 percentage. In the Biktarvy study, the mean change from baseline to Week 24 was -126 cells/µL, and there was no change in CD4 percentage. In the Genvoya study, the mean change from baseline in CD4 count was -66 cells/µL at Week 48; the mean change in CD4 percentage from baseline to Week 48 was -0.6%. A mean decrease in CD4 count was also observed at Week 24 in the Genvoya study. . In other studies of HIV-infected adults with high baseline CD4 counts ≥ 500 who switched to Genvoya, minimal increases or decreases in CD4 counts were observed in subjects, but there was little change in CD4 percentage. It may be that small changes in CD4 count appear larger with a high baseline value, as evidenced by the lack of change in CD4 percentage. The possibility that the declines are directly related to exposure to one of the components of Genvoya or Biktarvy has not been definitively excluded but a mechanism by which ARVs are causing the observed decrease in CD4 count has not been identified. Despite the declines in CD4 count, there were no opportunistic infections or increased incidence of infections observed in subjects in either study. The possibility of a more clinically significant decrease in CD4 count in patients with a low baseline CD4 count cannot be ruled out; this situation could result in a higher risk of opportunistic infections. Therefore, the change in CD4 counts is described in the package insert for Descovy.

In conclusion, after review of the data from the study, we have determined that the benefit of Descovy for the treatment of HIV infection outweighs the risks and recommend approval of Descovy and of the low dose Descovy tablet (emtrictabine 120 mg and tenofovir alafenamide 15 mg) for the treatment of HIV-1 infection in children weighing > 14 kg.

Benefit-Risk Dimensions

Dimension	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition	• HIV-1 infection is a life-threatening and serious disease of major public health significance. • Approximately 38 million people infected worldwide, including an estimated 1.7 million children (range 1.3 to 2.2 million) under 15 years of age. • Globally, approximately 160,000 children under 14 years of age acquired HIV in 2018. • There is no vaccine and no post-exposure immunoprophylaxis available for HIV.	HIV-1 remains a major cause of morbidity and mortality worldwide. If untreated, HIV-1 is a life-threatening condition, one that affects a large population. HIV-1 infection is a significant public health concern.

Dimension	Evidence and Uncertainties	Conclusions and Reasons
Current Treatment Options	• Currently available HIV treatment includes six different antiretroviral drug classes and at least 25 individual antiretroviral drugs, not including fixed drug combinations. ○ The drug classes include nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors, CCR5 receptor antagonists, and integrase strand transfer inhibitors (INSTIs). • While there are approved ARVs in multiple classes available for the treatment of HIV infection in children, there continue to be challenges. For example, poor adherence, and short and long term toxicities may contribute to the development of drug resistance and failed therapy. • The Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection recommend that the initial treatment regimen for pediatric patients include FTC and TAF in HIV-1 infected children ≥ 6 years of age. • Descovy provides nucleoside reverse transcriptase inhibitor and a nucleotide reverse transcriptase inhibitor in a single tablet. Descovy is administered once daily. While Descovy has to be taken with a third ARV, the inclusion of a two-drug combination in Descovy simplifies the ARV regimen.	Use of Descovy allows for a relatively simple, once daily regimen. Use of once daily regimens increases adherence and improves virologic outcomes for people living with HIV. Moreover, a TAF-containing regimen would be a better choice than a TDF-based regimen in this population due to a more favorable bone and renal toxicity profile.
Benefit	• To support an efficacy claim for the use of Descovy for the treatment of HIV infection in children ≥ 2 years of age and ≥ 14 kg and < 25 kg, the applicant submitted the 24-week efficacy and safety results from a single study (Study Trial GS-US-380-1474), which is a Phase 2/3, open-label, multicenter, multicohort, non-comparator trial evaluating a pediatric formulation of Biktarvy, a fixed dose combination tablet containing 30mg bictegravir, 120 mg emtricitabine, and 15 mg tenofovir alafenamide fumarate (B/F/TAF). • The same dose of FTC (120 mg) and TAF (15 mg) are included in the lower dose formulations of both drugs Descovy and Biktarvy. Therefore, It is appropriate to use the safety and efficacy data from the study of Biktarvy to support the safety and efficacy of Descovy by pharmacokinetic bridging. • Exposures of B/F/TAF components and tenofovir, of the active form of TAF, in trial subjects were considered acceptable and supported the conclusion that the exposures observed in this weight (age) group are comparable to the exposure observed in adults who received the recommended dose. • In this study, 22 children weighing ≥ 14 to 25 kg (age range 3 to 9 years old) with	The results of a Biktarvy study were used to support the efficacy of Descovy in children ≥ 2 years of age and ≥ 14 kg and < 25 kg. Both Biktarvy and Descovy contain the same dose of FTC and TAF; therefore, it is appropriate to use Biktrary data to support the efficacy of Descovy. In HIV-1 infected pediatric patients weighing ≥ 14 kg, the exposures matched those determined to be efficacious in adults, thereby supporting the extrapolation of efficacy. Efficacy is supported by clinical data demonstrating that Biktarvy provided durable virologic suppression. It is well known that long-term viral suppression in children will prevent or lead to fewer complications over time. The results of a study of Genvoya in HIV-1 infected

Dimension	Evidence and Uncertainties	Conclusions and Reasons

	virologically suppressed HIV infection, were treated with B/F/TAF once daily for 24 weeks.
	• The study demonstrated a high efficacy among those who received treatment:
	  ○ Twenty of 22 subjects (90%) achieved the efficacy outcome of plasma HIV-1 RNA <50 copies/mL at Week 24; the two without documentation of HIV suppression did not have HIV RNA testing at Week 24 because of the COVID-19 pandemic. No subjects experienced failure, and among the 20 subjects with available HIV-1 RNA viral load, all (100%) achieved the efficacy outcome.
	• To demonstrate durable efficacy and safety of Descovy for the treatment of HIV infection in children ≥ 6 years of age and weighing at least 25 kg, the applicant submitted the 48-week efficacy and safety results from a single study (Study Trial GS-US-292-1016), which is an open-label, multicenter, multicohort, non-comparator trial evaluating Genvoya, a fixed dose combination tablet containing 150 mg elvitegravir, 150 mg cobicistat, 200 mg emtricitabine, and 10 mg tenofovir alafenadmide. The full dose tablets of Descovy and Genvoya both contain the same dosage of FTC and an equilvalent dose of TAF (10 mg of TAF administered with cobicistat, a pharmacoenhancer, is equivalent to 25 mg of TAF administered without a pharmacoenhancer). Pharmacokinetic studies of Descovy and Genvoya demonstrated similar exposures of FTC and TAF in adults who received Descovy and in those who received Genvoya in a previously reviewed efficacy supplement which supported labeling for children weighing at least 25 mg.
	  ○ In the 48-week results, 52 children weighing > 25 kg (age range 7 to 11 years) with virologically suppressed HIV infection were switched to Genvoya and received one tablet daily.
	  ○ The study demonstrated durable efficacy: 51 of 52 subjects achieved the efficacy outcome of plasma HIV-1 RNA <50 copies/mL at Week 48.
	  ○ One subject withdrew consent and discontinued the study, but no subjects experienced virologic failure.
	• The CD4 count decreased in both the Biktarvy study and the Genvoya study from baseline to Weeks 24 and 48, respectively. In the Biktarvy study, the mean change from baseline to Week 24 was -126 cells/µL, and there was no
		pediatric patients were used to support the efficacy of Descovy in pediatric patients ≥ 25 kg. FTC and TAF exposures have been demonstrated to be similar in adults who received Descovy and Genvoya. Therefore, it is appropriate to use the results of a study of Genvoya to support the efficacy of Descovy. Genvoya provided durable virologic suppression in the pediatric population of subjects ≥ 6 years of age and weighing ≥ 25 kg as demonstrated by plasma HIV RNA levels at Week 48.
		
		CD4 counts decreased over time in both cohorts in the pediatric study. The reason for the drop was unclear. However, there was no correlation of decreased CD4 count and increased incidence of infections.

Dimension	Evidence and Uncertainties	Conclusions and Reasons
	change in CD4 percentage. In the Genvoya study, the mean change in CD4 count from baseline to Week 48 was -66 cells/µL. The mean change in CD4 percentage was -0.6%.	
Risk and Risk Management	• Safety in pediatric patients ≥ 14 kg to < 25 kg was supported by the safety in a study of Biktarvy, and the 48-week safety in subjects ≥ 25 kg was supported by a study of Genvoya. • Subjects administered Biktarvy reported few mild side-effects (neutropenia, abdominal pain, constipation, irritability, nausea and social avoidant behavior), all of which were considered mild (Grade 1 or 2 AEs). There were no deaths or drug-related SAEs. • There were no premature discontinuations of treatment due to an AE. All the laboratory AEs were Grade 1 or 2, except for one Grade 3 laboratory abnormality of an elevated alkaline phosphatase at Week 48 that resolved by Week 60. • There were no notable effects of treatment on development or growth (baseline to Week 24) in Tanner stage, bone age, height, weight and Body Mass Index (BMI) percentiles, and vital signs. • In the 48-week study of Genvoya, there were no Grade 3 or 4 adverse events, no adverse events leading to premature discontinuations, no serious adverse events, and no new CDC Class C AIDS defining events. • The most commonly reported adverse reactions were vomiting, abdominal pain, and headache. All were Grade 1 or Grade 2. • The majority of laboratory abnormalities were Grade 1 or 2 in intensity. There were two Grade 4 laboratory values: neutropenia and hyperkalemia. Neither laboratory abnormality led to an adverse event and both improved over time. • Five subjects had a clinically meaningful decrease in BMD as measured by Z-score. Three of the 5 subjects had the change in adjusted z-score by Week 48 (one subject with decreased BMD in TBLH and 2 with decreased BMD in the spine). Two subjects with decreased BMD in both the TBLH and spine did not have a change in z-score until Week 96.	The frequency of adverse events observed in these studies were generally mild and similar to those noted in adolescents and adults. Decreases in bone mineral density were observed in a minority of subjects. The clinical relevance of this finding is unclear. These changes were not associated with pathological fractures. The information will be included in the package insert. Based on the available safety profile for Biktarvy and Genvoya, no Risk Evaluation and Mitigation Strategy (REMS) is recommended at this time for Descovy.

2. Background

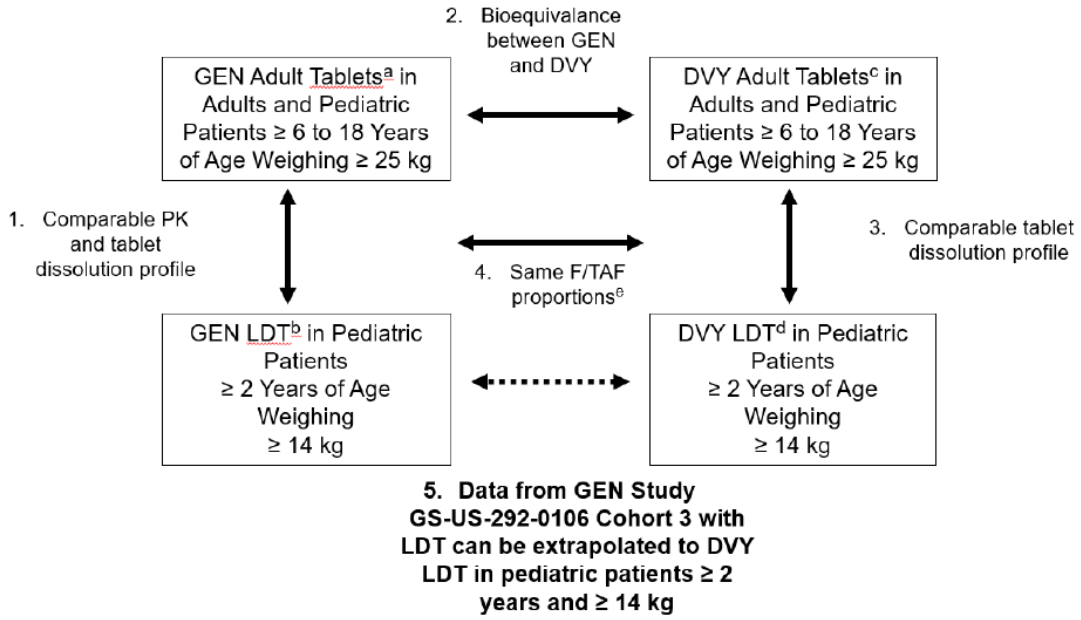
Descovy is a combination of emtricitabine (FTC or F) and tenofovir alafenamide (TAF), both HIV nucleos[t]ide analog reverse transcriptase inhibitors (NRTIs). Descovy is indicated in combination with other antiretroviral agents (ARVs) for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg. Descovy is also indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg. The Applicant submitted this supplemental NDA to extend the latter indication (HIV treatment with ARVs other than protease inhibitors that require a CYP3A inhibitor) to pediatric patients at least 2 years of age and weighing at least 14 kg.

Descovy is also indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. The current supplemental NDA does not propose any changes related to the PrEP indication.

The original approval of Descovy was based on a bridge of efficacy and safety data by demonstrating comparable exposures of F/TAF between Descovy (F/TAF 200 mg/25 mg) and Genvoya [Elvitegravir (EVG) 150 mg/F 200 mg/TAF 10 mg/Cobicistat (COBI) 150 mg]. Of note, due to P-gp inhibition by COBI, comparable exposures were observed between 25 mg TAF in Descovy and 10 mg TAF in Genvoya; therefore, no efficacy studies of Descovy were conducted. Because of the demonstration of similar exposures of F/TAF in Descovy as compared to Genvoya in adults, the 24-week results of a pediatric study of Genvoya were used to support the safety and antiviral activity of Descovy in pediatric patients 6 years of age and older weighing at least 25 kg.

In this supplemental NDA, the Applicant took a similar approach to support efficacy and safety for low dose Descovy (i.e., relying on the safety and efficacy findings with low dose Genvoya) in pediatric patients at least 2 years of age and weighing 14 to less than 25 kg. The Applicant's proposed approach is described in Fig 1.

Fig 1. Extrapolation Approach for Descovy Low-Dose Tablets



a GEN adult tablets containing F/TAF 200/10 mg
b GEN LDTs containing F/TAF 120/6 mg
c DVY adult tablets – F/TAF 200/25 mg
d DVY LDTs – F/TAF 120/15 mg
e F/TAF LDT proportions are 60% of adult tablets

Although the proposed approach is consistent with the approach taken for the approval of Descovy in adults and pediatric patients weighing at least 25 kg, the review team has concluded that the data supporting the recent approval of low dose Biktarvy (Bictegravir 30 mg/F 200 mg/ TAF 15 mg) are more suitable to support the approval of low dose Descovy instead of data with low dose Genvoya (EVG 90 mg/FTC 120 mg/TAF 6 mg/COBI 90 mg). The proposed low dose of Descovy is the same with low dose Biktarvy (FTC 200 mg/TAF 15 mg). The indication is also consistent, use of F/TAF with ARVs that are not a boosted protease inhibitor. The review team also concluded that low dose Genvoya cannot be approved at this time due to signifncanly low EVG Ctau. Therefore, approving low dose DESCOVY based on data with low dose Genvoya, which is not available in the US market, may potentially confuse healthcare providers. The Applicant agreed to this approach and submitted a letter of authorization to the Biktarvy NDA (210251).

3. Discipline-Specific Considerations

The Chemistry, Manufacturing, and Control review team determined that the information submitted by the Applicant support the approval of low dose DESCOVY. The request for a

biowaiver has been granted. Refer to the review of Chemistry, Manufacturing and Control for full details

All pertinent information pertaining to the clinical pharmacology, clinical efficacy, clinical microbiology, and safety assessments can be found in the respective discipline reviews of the data supporting approval of Biktarvy and Genvoya for the corresponding pediatric population.

For information regarding pediatric subjects with a body weight of at least 14 kg to less than 25 kg, please refer to the reviews of the Biktarvy pediatric efficacy supplement (NDA 210251 S-014, DAARTS date:10/7/2021).

For information regarding data from subjects who weighed at least 25 kg, please refer to the reviews of Genvoya pediatric efficacy supplements (NDA 207561 S-014, DAARTS date, 9/11/2017 and NDA 207561 S-029, DARRTS date 11/19/2021).

4. Pediatric Studies

Currently, there are four outstanding PREA PMRs as follows. (b) (4)

PMR 3531-1 Conduct a study to evaluate the pharmacokinetics (PK), safety and antiviral activity of DESCOVY (emtricitabine and tenofovir alafenamide) administered in combination with atazanavir and TYBOST (cobicistat), and in combination with darunavir and TYBOST in HIV-1 infected pediatric subjects weighing less than 25 kg. The safety and activity of the treatment regimen must be assessed for a minimum of 24 weeks. The minimum age criteria for the treatment regimen being evaluated are specified below.

- DESCOVY administered in combination with atazanavir coadministered with TYBOST must be evaluated in pediatric patients 3 months of age and older
- DESCOVY administered in combination with darunavir coadministered with TYBOST must be evaluated in pediatric patients 3 years of age and older

Study Completion: 09/2022
Final Report Submission: 03/2023

PMR 3531-2 Conduct a study to evaluate the PK, safety and antiviral activity of DESCOVY administered in combination with atazanavir and TYBOST, and in combination with darunavir and TYBOST in HIV-1 infected pediatric subjects 6 to less than 12 years of age (weighing 25 kg to less than 35 kg). The safety and activity of the treatment regimen must be assessed for a minimum of 24 weeks.

Study Completion: 12/2021

Final Report Submission: 06/2022

PMR 3531-3 Conduct a study to evaluate the pharmacokinetics (PK), safety and antiviral activity of DESCOVY administered in combination with regimens that do not contain cobicistat or other PI/CYP3A inhibitor in HIV-1 infected pediatric subjects 4 weeks of age and older and weighing less than 25 kg. The safety and activity of DESCOVY must be assessed for a minimum of 24 weeks. Clinical trials evaluating DESCOVY administered in combination with regimens that do not contain cobicistat or a PI/CYP3A inhibitor are not required if data from other ongoing or completed pediatric studies can be leveraged to provide the requested PK, safety, and antiviral activity data for DESCOVY.

Study Completion: 02/2022
Final Report Submission: 06/2022

PMR 3531-4 Conduct a study to evaluate the PK, safety and antiviral activity of DESCOVY administered in combination with lopinavir/ritonavir in HIV-1 infected pediatric subjects 4 weeks to less than 3 months of age. The safety and activity of DESCOVY must be assessed for a minimum of 24 weeks.

Study Completion: 09/2022
Final Report Submission: 03/2023

5. Other Relevant Regulatory Issues

The Applicant requested orphan drug exclusivity for a seven-year period from the date of approval of NDA 208215/S-019. Orphan drug designation was granted on June 6, 2017 (designation request # 16-5697) for the treatment of HIV infection in pediatric patients under 12 years of age.

An Advisory Committee meeting was not convened for this application. No postmarketing requirements will be issued and no additional comments will be conveyed to the Applicant.

6. Labeling

The labeling has been updated to reflect changes in the indication (Sections 1 and 2) and description of the low dose tablet (Section 3). The clinical safety,efficacy, PK data supporting the extension of the indication, based on GS-US-292-0106 (Genvoya pediatric study, Cohort 2, Week 48 data) and GS-US-380-1474 (Biktarvy pediatric study, cohort 3, Week 24 data), have been added in Sections 6, 8, 12, and 14.

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/s/

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