

Written Testimony: Oregon Medicaid – Updated data, *Cabenuva*

This document is a written testimony intended to summarize the key points below required for the Idaho Department of Medicaid Pharmacy & Therapeutics Committee's review of *Cabenuva* (cabotegravir (CAB)/rilpivirine (RPV)).

Indication, dosage and Administration

CABENUVA, a 2-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 with no known or suspected resistance to either cabotegravir or rilpivirine. (1)

Updated Flair 96 weeks results (2)

Background:

FLAIR was a randomized, multicenter, international, open-label non-inferiority study which evaluated *Cabenuva* in virologically suppressed patients.

- Subjects came into the trial without prior ART experience and were started on an initial regimen of DTG/ABC/3TC (*Triumeq*) for 20 weeks to attain virologic suppression.
- Virologically suppressed subjects were randomized to continue on their current regimen (CAR) or switch to *Cabenuva*.
- 48-week data established non-inferiority of *Cabenuva* vs. current regimen

Results – Week 96

- For virologic non-response, identical results for the *Cabenuva* and *Triumeq* arms, with 3.2% in each arm with VL> 50 copies/mL.
- For virologic success, 87% of participants in the *Cabenuva* arm vs. 89% in the *Triumeq* arm had VL<50 copies/mL
- No new confirmed virologic failures since week 48 timepoint in the *Cabenuva* arm

Safety Overview

- The most common drug-related AEs were pyrexia and headache
- Majority (96%) of Drug-related AEs were maximum of Grade 1 or 2
- Four additional subjects discontinued due to AEs since week 48 timepoint.

ISR

- ISRs were generally with the 1st dose, and the rate drops over time and remains low at week 96.
- Approximately 25% of injections are associated with an ISR, the majority being mild or Grade 1 with a median duration of 3 days, and majority resolving within 7 days
- Through 96 weeks, 2% of subjects discontinued due to an ISR, with an additional 2 subjects since week 48.
- Subjects on *Cabenuva* demonstrated a statistically significant improvement from baseline in treatment satisfaction compared with *Triumeq* at Week 96, consistent to findings at week 48.

Summary:

- Monthly *Cabenuva* was noninferior to continued oral CAR at Week 96 for maintaining suppression and was consistent with results at Week 48
- No new CVFs occurred in the *Cabenuva* arm between Week 48 and Week 96
- *Cabenuva* was generally safe and well-tolerated, with few new AEs beyond week 48.
- Injections well tolerated, with 2 new discontinuations since week 48.
- Overall treatment satisfaction was higher with *Cabenuva* vs. oral CAR as measured by HIVTSQs.

References

- (1) ViiV Healthcare Local Label.
- (2) Orkin C, et al. Long-acting cabotegravir plus rilpivirine for treatment in adults with HIV-1 infection: 96-week results of the randomised, open-label, phase 3 FLAIR study. **The Lancet** 2021
[Long-acting cabotegravir plus rilpivirine for treatment in adults with HIV-1 infection: 96-week results of the randomised, open-label, phase 3 FLAIR study](#)

Important safety information is found in the attached Prescribing Information. The Prescribing Information for this product contains a boxed warning. Please consult the WARNING section of the attached Prescribing Information for further details and for important safety information. The information is provided as professional service in response to your unsolicited request. ViiV Healthcare requests that the recipient of this information only share the contents with the Pharmacy and Therapeutics Committee members for the purposes of making evidence-based decisions regarding formulary inclusion.