Real-World Use of Long-Acting Cabotegravir Plus Rilpivirine in Virologically Suppressed People Living With HIV

Summary

- Overall, the real-world evidence (RWE) presented to date shows that the rate of maintaining virologic suppression with long-acting cabotegravir plus rilpivirine (CAB + RPV LA) is similar to what has been reported in phase 3 clinical trials.
- Below please find a summary of the data available to date from OPERA, BEYOND, the Trio Cohort Study, CARLOS, and COMBINE-2.
    - Other RWE citations can be found in the reference list below.
- Important Safety Information can be found in the Prescribing Information and can also be accessed from the Our HIV Medicines section of viivhealthcare.com/us.

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OPERA[1]

OPERA is a prospectively captured cohort that includes more than 155,000 people living with HIV from 96 sites in the US.

Through February 2023, 1578 people were included who received CAB + RPV LA and were virologically suppressed at the start of the regimen. Of these, 469 (30%) had a body mass index (BMI) ≥30 kg/m^2.

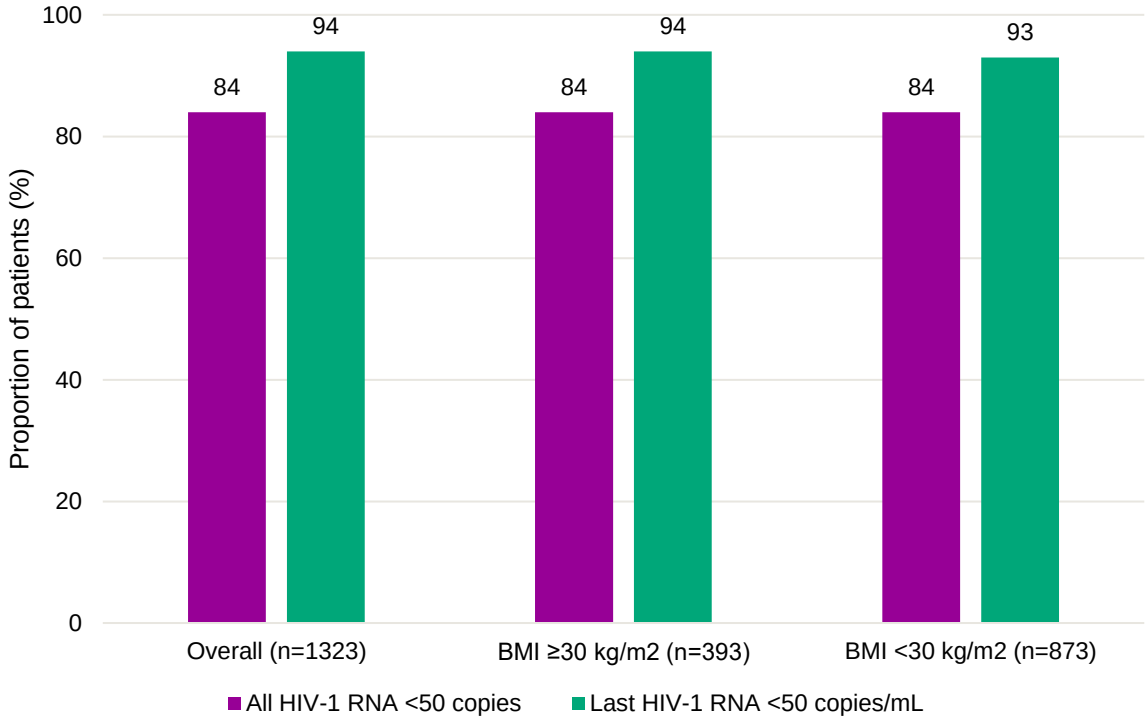
Overall, the median (interquartile range [IQR]) age was 40 (32, 53) years. Patients included were mostly male (83%) and White (48%) or Black (41%). Most patients (71%) received CAB + RPV LA every 2 months. The median (IQR) time of follow up was 7.4 (3.9, 10.9) months.

Virologic outcomes (at least 1 HIV-1 RNA after the first injections) are available for 1323 (86%) of patients. See Figure 1 below.

Confirmed virologic failure, defined as 2 consecutive HIV-1 RNA ≥200 copies/mL or 1 HIV-1 RNA ≥200 copies/mL followed by discontinuation, was reported in 1% of patients overall as well as in patients with a BMI ≥30 kg/m^2.

No safety data or whether resistance occurred at virologic failure is available from OPERA currently.

Figure 1. Virologic Outcomes from OPERA



BEYOND[2]

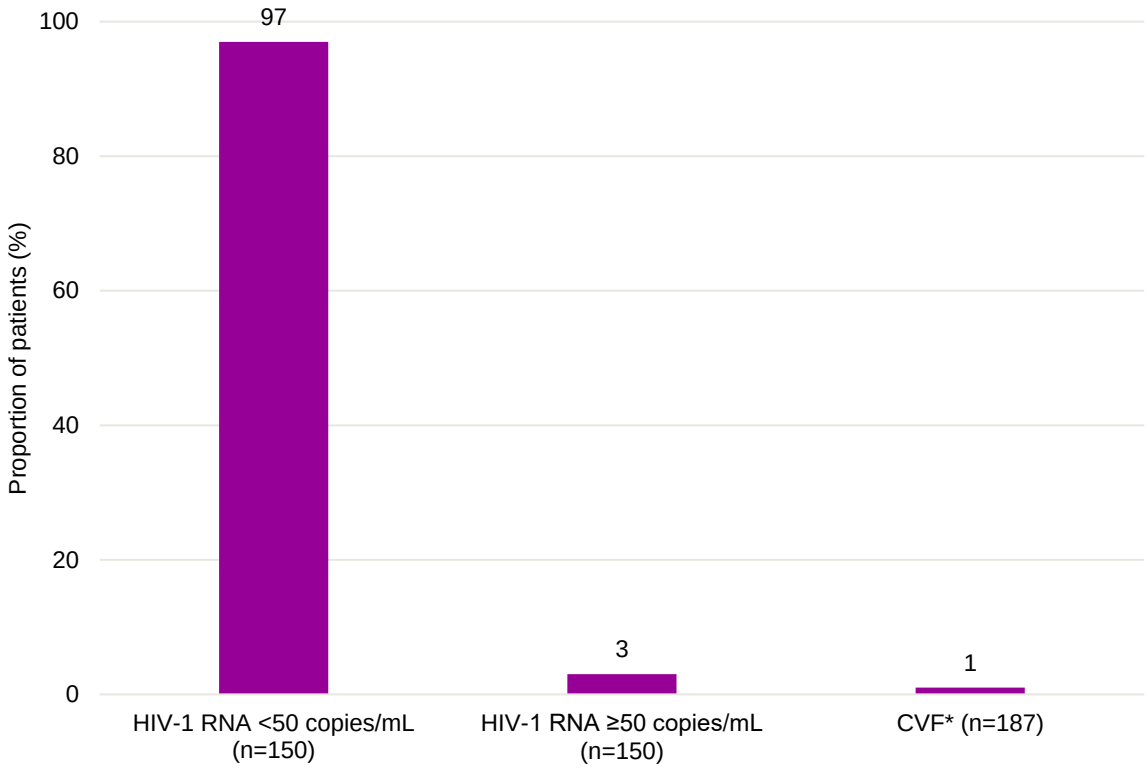
BEYOND is an ongoing 2-year prospective, observational real-world study of the use of CAB + RPV LA across 27 sites in the US. Only interim data from patients who were virologically suppressed at baseline through the Month 6 cutoff are included here.

The mean (standard deviation [SD]) age was 46 (13) years. Patients included were mostly male (88%) and White (49%) or Black (39%). Half of patients included were initiated on every-2-month CAB + RPV LA. The most common prior regimen was bictegravir/tenofovir alafenamide/emtricitabine (37%).

The median (range) number of CAB + RPV LA injections administered was 4 (0-7). Eighty-two percent of patients were reported by the HCP to have received CAB + RPV LA +/-7 days from their target treatment date. The most common reason given was the patient forgot or canceled their appointment (n=6 injection appointments) or other (n=9 injection appointments).

Virologic data was available at both baseline and Month 6 for 150 patients. See Figure 2 below.

Figure 2. Virologic Outcomes from BEYOND at Month 6 Cutoff (interim results)



*includes patients with at least 1 HIV-1 RNA available (n=187).

CVF = confirmed virologic failure (defined as 2 consecutive HIV-1 RNA ≥200 copies/mL or 1 HIV-1 RNA ≥200 copies/mL followed by discontinuation with 3 months of the test result)

Of the 248 patients who reached the Month 6 time point (those who were virologically suppressed at the start of CAB + RPV LA and those who were not), 64 adverse events were reported in 52 patients. The most common adverse events were injection site reactions (11%). Twenty-five patients (10%) discontinued CAB + RPV LA as of the data cut off including 16 who virologically suppressed at the time of CAB + RPV LA initiation. The most common reasons for discontinuation were ISRs (n=4) and medication cost/access issues (n=4).

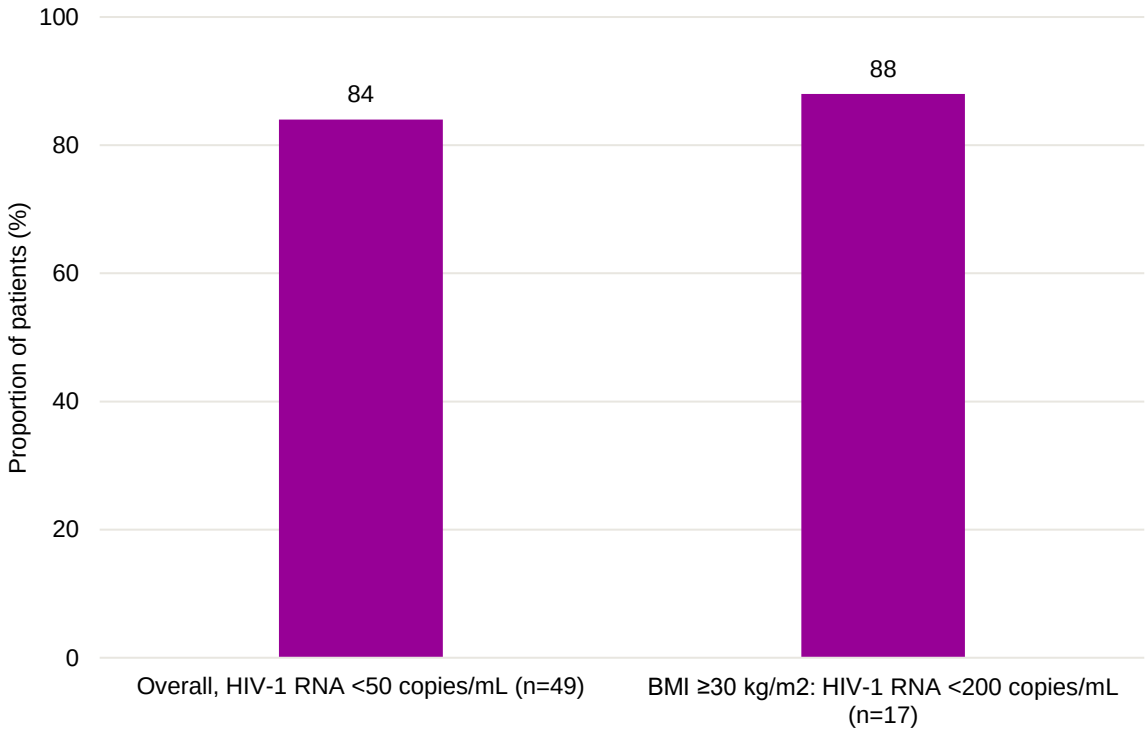
TRIO COHORT STUDY[3]

The Trio observational cohort study utilizes electronic medical records to prospectively collect longitudinal data. Data are available through September 2022 for 170 patients who were virologically suppressed at the time of switching to CAB + RPV LA.

The median (IQR) age was 46 (36, 55) years. Patients included were mostly male (68%) and White (45%) or Black (36%). BMI was ≥30 kg/m^2 in 36% (n=60) of patients. The median (IQR) time of follow up was 5.1 (2.9, 8.1) months; 95% of virologically suppressed patients at initiation remained on CAB + RPV LA at the time of the analysis.

Of the 170 virologically suppressed patients included, 49 had a follow up HIV-1 RNA available after initiation of CAB + RPV LA. Of the 60 patients with a BMI ≥30 kg/m^2, 17 had a follow up HIV-1 RNA after initiation of CAB + RPV LA. See Figure 3 below.

Figure 3. Virologic Outcomes from the Trio Cohort Study



No safety data or whether resistance occurred at virologic failure is available from the Trio Cohort Study.

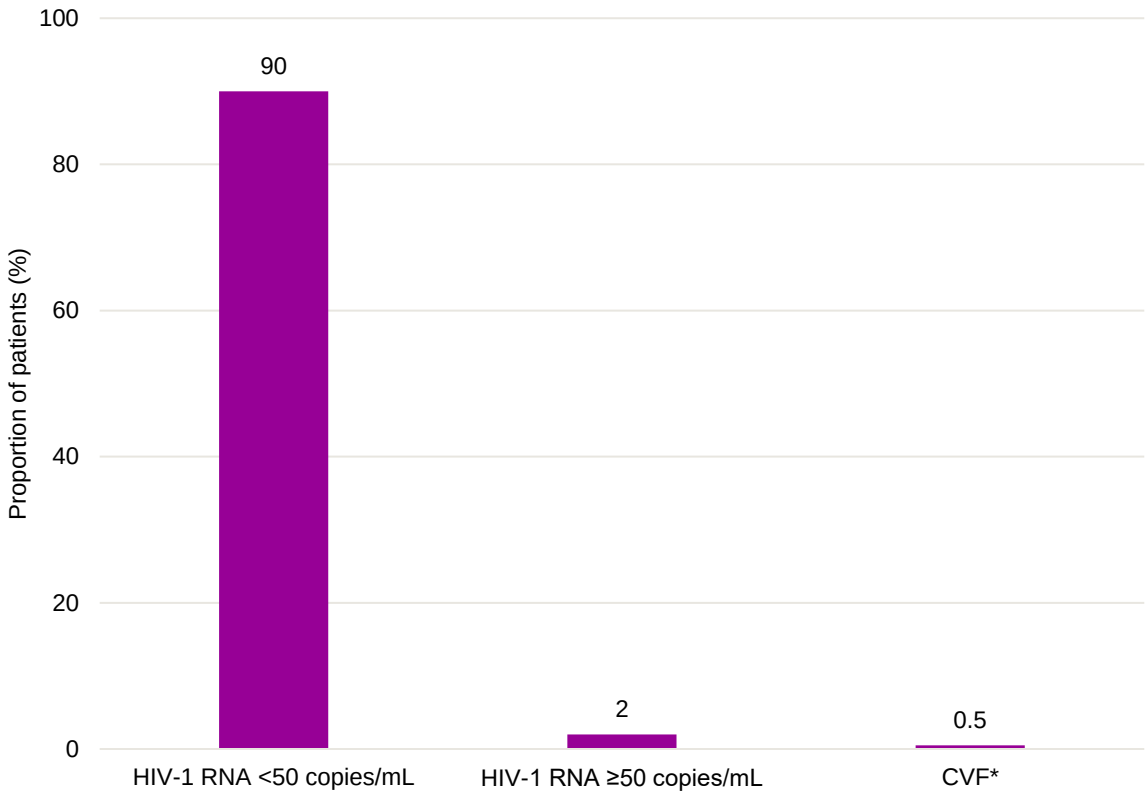
CARLOS[4]

CARLOS is a non-interventional, 3-year, multicenter, prospective German cohort study of virologically suppressed people living with HIV (PLHIV) who switched to CAB + RPV LA administered every 2 months. An interim analysis after the fourth injection (Month 6) was conducted. Data are available for 236 patients.

The median (IQR) age was 43 (36, 50) years and 75% were <50 years of age. Patients included were predominantly male (95%). BMI was ≥30 kg/m² in 12% of patients. The median (IQR) time of follow up was 5.1 (2.9, 8.1) months; 95% of virologically suppressed patients at initiation remained on CAB + RPV LA at the time of the analysis.

Of the 236 patients included, 230 received at least 1 round of CAB + RPV LA injections, and 200 had virologic outcome data available. See Figure 4 below.

Figure 4. Virologic Outcomes from CARLOS at Month 6 (interim results; n=200)



CVF = confirmed virologic failure (confirmed HIV-1 RNA ≥200 copies/mL or a single HIV-1 RNA ≥200 copies/mL followed by treatment discontinuation

The single CVF occurred in the setting of on-time injections and was associated with integrase strand-transfer inhibitor ([INSTI] L74I, T97A, E138K, Q148R, and N155H) and non-nucleoside reverse transcriptase inhibitor ([NNRTI] Y181C) resistance associated mutations (RAMs).

The most common (>2 events) drug-related adverse events (AEs) excluding injection site reactions (ISRs) were pyrexia (n=10), pain (n=6), headache (n=6), pain in extremity (n=3), nausea (n=3), fatigue (n=3), and sleep disorder (n=3). Six patients (6/200, 2.5%) discontinued the study due to drug-related AEs and an additional 6 patients (6/230, 2.6%) discontinued due to ISRs.

Overall, 97.2% (615/633 injection visits) of injections occurred within the dosing window or earlier (± 7 days from the target treatment date). Of the 18 late injections, 6 were covered with oral therapy.

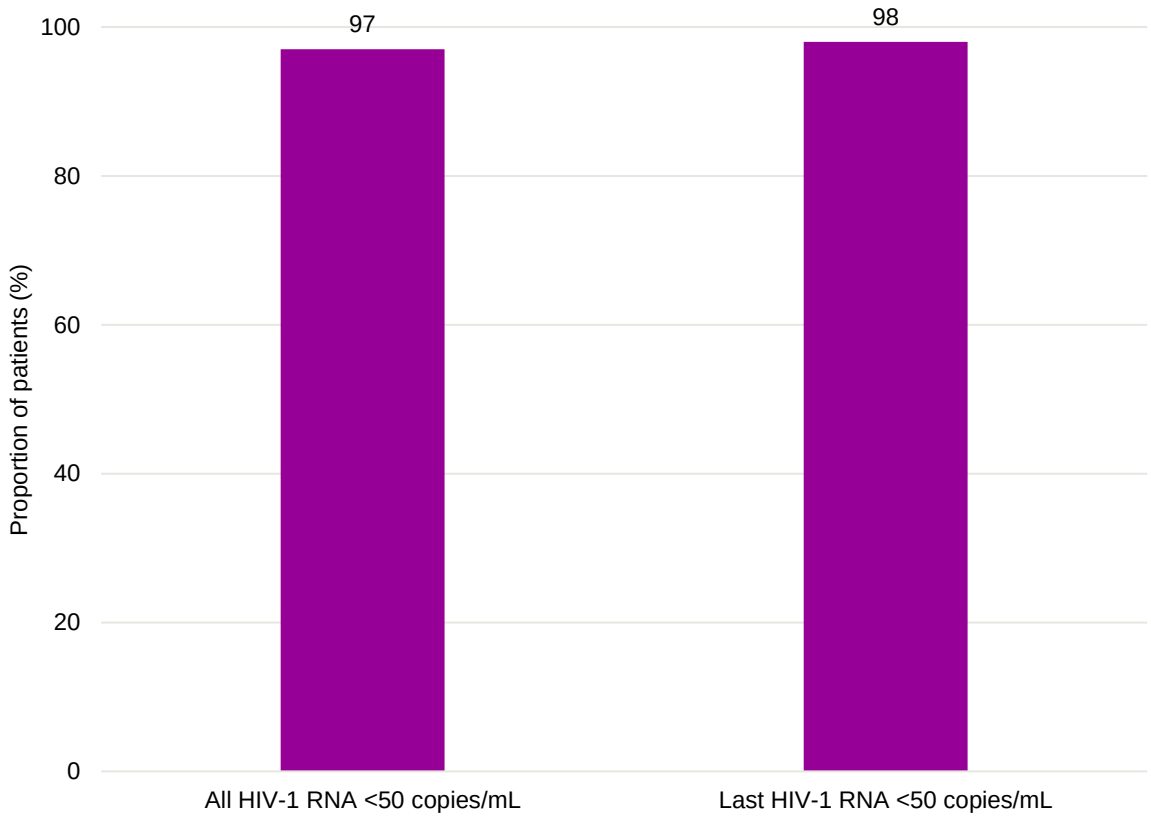
COMBINE-2[5]

COMBINE-2 includes virologically suppressed patients enrolled at NEAT ID Network sites from 5 European countries. Patients received CAB + RPV LA every 2 months from June 2021 through April 2023.

The median (IQR) age was 47 (39, 54) years and 36% were >50 years of age. Patients included were predominantly male (83%) and White (78%). BMI was ≥30 kg/m² in 8% of patients. The median (IQR) time of follow up was 5.2 (1.0, 10.8) months. Nine patients had a prior history virologic failure; 4 had a history of INSTI or NNRTI RAMs.

Among the 120 patients included, 89 had an HIV-1 RNA available after the first injections. See Figure 5 below.

Figure 5. Virologic Outcomes from COMBINE-2 (n=89)



There was 1 CVF reported 35 days after the initiation of CAB + RPV LA. The NNRTI RAM E138A was detected at failure. No INSTI RAMs were detected. This patient was switched to darunavir/cobicistat/emtricitabine/tenofovir alafenamide; no outcome information is available.

No safety data is available from COMBINE-2.

OTHER STUDIES REPORTING REAL WORLD EVIDENCE

Please see the reference list below for other RWE presentations or publications.[6-27]

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This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

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