CUSTOMIZE: Implementation of Long-Acting Cabotegravir Plus Rilpivirine in Clinical Practice – Patient Perspectives

Summary

- In CUSTOMIZE, nearly 50% of patients reported having no problems taking daily HIV medicines. However, patient-reported concerns included having to hide their medications, problems remembering to take daily medicines, and concerns about running out of daily HIV medications.
- At baseline through Month 12, >90% of study participants across the HIV care settings found long-acting cabotegravir and rilpivirine (CAB + RPV LA) to be acceptable and appropriate.
- Nearly three-quarters of patients reported no logistical challenges with monthly CAB + RPV LA injection visits, supported by high patient adherence (94%) to injection visits.
- Important safety information is found in the attached Prescribing Information.

CUSTOMIZE is a novel, hybrid III, implementation-effectiveness study assessing healthcare staff and patient perspectives over a 12-month period to determine barriers, and facilitators for successful implementation of the CAB LA + RPV LA injectable regimen in real-world settings. Virologically suppressed patients were enrolled across 8 clinics in the US to receive CAB + RPV LA. Baseline and interim month 4 results are available. Two survey components and additional 7- and 10-item questionnaires were reported:

- Acceptability of intervention measure (AIM): 4-item survey at baseline and Month 4 that utilized a 5-point scale (1 = completely disagree to 5 = completely agree)
- Intervention appropriateness measure (IAM): 4-item survey at baseline and Month 4 that utilized a 5-point scale (1 = completely disagree to 5 = completely agree),
- 7- and 10-item questionnaires assessed attitudes and expectations of patients regarding the CAB + RPV LA regimen

Results

One hundred nine and 102 patients completed the baseline and Month 12 surveys, respectively. Approximately one-third of patients were from federally qualified health centers, 25% were from private practices, 14% were from AIDS Healthcare Foundation clinics, 14% were from health maintenance organizations, and 11% were from university health centers. Patients were predominantly male (86%) and white (59%) with a mean age of 39 years.

The most common patient-reported concerns with taking daily oral antiretroviral therapy (ART) were hiding oral ART from others, remembering to take daily oral ART, and running out of ART. Approximately 47% of patients reported no problems taking daily HIV medications. See Figure 1 below for details.

Men were significantly more likely than women to report having no concerns with prior daily HIV medications (50.5% vs 21.4%; P<0.05). Women were significantly more likely than men to report concerns about remembering to take their daily HIV medications (42.9% vs 18.9%; P<0.05). Participants aged 40 to 49 years were the most likely to report hiding their daily HIV medications from others (P<0.05).
Interest in a more convenient treatment option was a top reason (83%) for choosing CAB + RPV LA treatment.3

**Figure 1. Proportion of Patients with Reported Concerns with Daily Oral ART at Baseline3**

![Proportion of Patients with Reported Concerns with Daily Oral ART at Baseline](chart)

At baseline through Month 12, >90% of study participants across the HIV care settings found long-acting cabotegravir and rilpivirine (CAB + RPV LA) to be acceptable and appropriate.

**AIM and IAM**

The proportion of patient participants who agreed or completely agreed with the AIM and IAM survey questions can be found in Figures 2 and 3 below, respectively.3,5 At baseline through Month 12, >90% of study participants across the HIV care settings found long-acting cabotegravir and rilpivirine (CAB + RPV LA) to be acceptable and appropriate.
Figure 2. Proportion of Study Participants Who Agreed or Completely Agreed with Survey Questions About Acceptability of Intervention (AIM) at Baseline through Month 12

<table>
<thead>
<tr>
<th>Question</th>
<th>Baseline</th>
<th>Month 4</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean proportion of respondents who agreed or completely agreed that CAB + RPV LA was acceptable</td>
<td>94%</td>
<td>94%</td>
<td>98%</td>
</tr>
<tr>
<td>Q1. CAB + RPV LA meets my needs to treat HIV</td>
<td>97%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Q2. CAB + RPV LA injection is appealing to me</td>
<td>94%</td>
<td>95%</td>
<td>97%</td>
</tr>
<tr>
<td>Q3. I like the idea of CAB + RPV LA injection to treat HIV</td>
<td>92%</td>
<td>92%</td>
<td>96%</td>
</tr>
<tr>
<td>Q4. I welcome the CAB + RPV LA injection to treat HIV</td>
<td>95%</td>
<td>95%</td>
<td>97%</td>
</tr>
</tbody>
</table>

Figure 3. Proportion of Staff Study Participants Who Agreed or Completely Agreed with Survey Questions About Intervention Appropriateness Measure (IAM) at Baseline and Month 4

<table>
<thead>
<tr>
<th>Question</th>
<th>Baseline</th>
<th>Month 4</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean proportion of respondents who agreed or completely agreed that CAB + RPV LA was appropriate</td>
<td>95%</td>
<td>95%</td>
<td>96%</td>
</tr>
<tr>
<td>Q1. CAB + RPV LA injection seems fitting for my life</td>
<td>95%</td>
<td>95%</td>
<td>95%</td>
</tr>
<tr>
<td>Q2. CAB + RPV LA injection seems suitable for my life</td>
<td>97%</td>
<td>96%</td>
<td></td>
</tr>
<tr>
<td>Q3. CAB + RPV LA injection seems applicable to my life</td>
<td>95%</td>
<td>94%</td>
<td>98%</td>
</tr>
<tr>
<td>Q4. CAB + RPV LA injection seems like a good match for my life</td>
<td>96%</td>
<td>94%</td>
<td>96%</td>
</tr>
</tbody>
</table>
Expectations and Attitudes

Nearly all participants (98%) reported feeling very or extremely positive about receiving the CAB + RPV LA injection treatment at Month 12. At baseline, injection pain or soreness was the most common concern (57.8%) regarding CAB + RPV LA treatment. At Month 4, 28% of participants reported injection pain or soreness as a concern but by Month 12 this number decreased to 15%. At Month 12, 74% of patients reported that nothing is interfering with their ability to receive CAB + RPV LA injections. See Figure 4 below for more details.

At Month 12, the top 5 rated CUSTOMIZE resources provided were:

- Verbal information (98%)
- Reminder calls (89%)
- Information and resources (88%)
- Reminder text messages (80%)
- Written materials (73%)
Patient-reported results on the acceptability of the time spent in the clinic or practice and coming to the clinic or practice for each injection visit were assessed. At Month 12, 93% of participants reported that the amount of time spent in the clinic/practice for each injection visit was very or extremely acceptable, and 87% reported that monthly clinic visits were very or extremely acceptable. See Figures 5 and 6 below for more detail.

**Figure 4. Patient-Reported Factors Interfering with Ability to Receive CAB + RPV LA at Months 4 and 12**

**Figure 5. Acceptability of Time Spent in the Clinic or Practice at Month 12**
Adherence to Treatment

Through Month 12, 94% of injection visits occurred within a ±7-day dosing window around the target treatment date and <1% of injection visits occurred >7 days late. Eight injection visits were missed due to COVID-19 but were covered with oral cabotegravir and rilpivirine.

ONGOING STUDIES

A Study Evaluating Implementation Strategies for Cabotegravir (CAB)+ Rilpivirine (RPV) Long-acting (LA) Injectables for Human Immunodeficiency Virus (HIV)-1 Treatment in European Countries.

Some information contained in this response may not be included in the approved Prescribing information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. Please note that reports of adverse events in the published literature often lack causality assessments and may contain incomplete information; therefore, conclusions about causality generally cannot be drawn.

In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877–844–8872. Please consult the attached Prescribing Information.

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

REFERENCES

1. ClinicalTrials.gov identifier NCT04001803. Available at: https://ClinicalTrials.gov/show/NCT04001803.


