

# Cabotegravir

Updated: September 30, 2025

Reviewed: September 30, 2025

Cabotegravir (CAB, Vocabria)

Cabotegravir for Intramuscular Injection (CAB, Apretude)

Cabotegravir and Rilpivirine for Intramuscular Injections (Long-Acting Injectable CAB and RPV, Cabenuva)

Formulations	
<p><b>Tablet</b></p> <ul style="list-style-type: none"> <li>[Vocabria] Cabotegravir: 30 mg</li> </ul> <p><b>Single-Dose Vial for Intramuscular Injection</b></p> <ul style="list-style-type: none"> <li>[Apretude] Cabotegravir 600-mg/3-mL (200-mg/mL) suspension for intramuscular injection for use as HIV pre-exposure prophylaxis only</li> </ul> <p><b>Co-packaged Formulations</b></p> <ul style="list-style-type: none"> <li>[Cabenuva Kit] Cabotegravir 400-mg/2-mL (200-mg/mL) and rilpivirine 600-mg/2-mL (300-mg/mL) suspension for intramuscular injection (each drug packaged in a separate syringe)</li> <li>[Cabenuva Kit] Cabotegravir 600-mg/3-mL (200-mg/mL) and rilpivirine 900-mg/3-mL (300-mg/mL) suspension for intramuscular injection (each drug packaged in a separate syringe)</li> </ul> <p>When using the co-packaged formulation, refer to the <a href="#">Rilpivirine</a> section for additional information.</p> <p>For additional information, see <a href="#">Drugs@FDA</a> or <a href="#">DailyMed</a>.</p>	
Dosing Recommendations	Selected Adverse Events
<p><b>[Apretude] Cabotegravir (CAB) for Intramuscular Injection</b></p> <ul style="list-style-type: none"> <li>CAB 600 mg/3 mL for intramuscular (IM) injection is approved by the U.S. Food and Drug Administration (FDA) for use as HIV pre-exposure prophylaxis (PrEP) in adults and adolescents weighing <math>\geq 35</math> kg; an oral dosing lead-in period of approximately 1 month is optional. See package insert for additional information about dosing and administration of CAB as PrEP; this indication is not addressed in the Pediatric Antiretroviral Guidelines.</li> </ul> <p><b>[Cabenuva] CAB and Rilpivirine (RPV) for IM Injection (Long-Acting Injectable CAB and RPV)</b></p> <p><i>Pediatric Dose</i></p> <ul style="list-style-type: none"> <li>CAB tablets and co-packaged long-acting injectable CAB and RPV (LA CAB/RPV) are not FDA approved for the treatment of HIV in children aged &lt;12 years.</li> </ul>	<ul style="list-style-type: none"> <li>Depression</li> <li>Insomnia</li> <li>Headache</li> <li>Rash (can be severe and include drug reaction with eosinophilia and systemic symptoms) or hypersensitivity</li> <li>Hepatotoxicity</li> <li>Altered adrenocorticotrophic hormone stimulation test of uncertain clinical significance</li> <li>Injection site reactions</li> <li>Creatine phosphokinase elevation following IM injection</li> <li>Weight gain</li> </ul>

<p><b>Child and Adolescent (Aged ≥12 Years and Weighing ≥35 kg) and Adult Dose</b></p> <ul style="list-style-type: none"> <li>• CAB and RPV is a two-drug co-packaged product for IM injection that is FDA approved as a complete regimen for the treatment of HIV-1 in people with HIV RNA levels &lt;50 copies/mL on a stable antiretroviral (ARV) regimen with no history of treatment failure and no known or suspected resistance to CAB or RPV.</li> <li>• Oral lead-in dosing with CAB and RPV for at least 28 days can be used to assess tolerability prior to initiating LA CAB/RPV injections, or people can proceed directly to LA CAB/RPV on the last day of their current ARV regimen.</li> <li>• Refer to the package insert for instructions about changing the frequency of IM injections, i.e., from monthly to every-2-month dosing or from every-2-month to monthly dosing.</li> </ul> <p><b>Oral Lead-in Dosing</b></p> <ul style="list-style-type: none"> <li>○ CAB 30 mg orally and RPV 25 mg orally once daily with a meal for at least 28 days.</li> </ul> <p><b>Dosing for Monthly Administration of LA CAB/RPV</b></p> <ul style="list-style-type: none"> <li>○ On the last day of oral lead-in therapy or the current oral ARV regimen, a loading dose of CAB 600 mg (3 mL) and RPV 900 mg (3 mL) should be given as two separate IM injections in separate ventrogluteal sites.</li> <li>○ Continuation therapy of CAB 400 mg (2 mL) and RPV 600 mg (2 mL) IM is given 1 month after the loading dose and once a month thereafter, with allowance for a ±7-day administration window.</li> </ul> <p><b>Dosing for Every-2-Month Administration of LA CAB/RPV</b></p> <ul style="list-style-type: none"> <li>○ To initiate every-2-month dosing, CAB 600 mg (3 mL) and RPV 900 mg (3 mL) should be given as two separate IM injections in separate ventrogluteal sites on the last day of oral lead-in or the current oral ARV regimen and 1 month after the initial injections.</li> <li>○ After these two initiation injections 1 month apart for 2 months, continuation therapy with IM CAB 600 mg (3 mL) and RPV 900 mg (3 mL) is administered every 2 months, with allowance for a ±7-day administration window.</li> </ul> <p>Children should be monitored for approximately 10 minutes for post-injection reactions. A 23-gauge, 1.5-inch IM needle is recommended for the injection and is provided in the packaging. Longer, 2-inch needles (not included with packaging) should be used in children with a body mass index &gt;30 kg/m<sup>2</sup>. The Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV recommends that providers review instructions available with the package insert prior to beginning IM administration of LA CAB/RPV. <a href="#">Additional clinical resources</a>, including injection education, are available from the manufacturer, ViiV.</p>	<p style="text-align: center;"><b>Special Instructions</b></p> <ul style="list-style-type: none"> <li>• Coadministering oral RPV with drugs that increase gastric pH may decrease plasma concentrations of RPV. Refer to the RPV package insert for specific instructions regarding use of these products during the oral lead-in dosing.</li> <li>• If monthly injections are missed or delayed by more than 7 days and oral therapy has not been taken, clinically reassess the child to determine if resumption of injection dosing remains appropriate. Refer to the package insert for information about managing planned and unplanned missed doses.</li> <li>• LA CAB/RPV is a complete regimen. Coadministration with other ARV drugs is not recommended.</li> <li>• When LA CAB/RPV injections are stopped, residual concentrations may remain measurable for up to 12 months or longer. It is essential to initiate an alternative, fully suppressive ARV regimen no later than 1 month after the final injections of LA CAB/RPV.</li> <li>• Use CAB and RPV with caution when coadministering with a drug that has a known risk of prolonging the QT corrected for heart rate interval or causing Torsades de Pointes (for more information, see <a href="#">CredibleMeds</a>).</li> </ul> <p style="text-align: center;"><b>Metabolism/Elimination</b></p> <ul style="list-style-type: none"> <li>• CAB is metabolized by uridine diphosphate-glucuronosyl transferase 1A1.</li> <li>• RPV is a cytochrome P450 3A substrate.</li> </ul> <p><b>Dosing in Children with Hepatic Impairment</b></p> <ul style="list-style-type: none"> <li>• No dose adjustment of CAB or LA CAB/RPV is necessary in children with mild or moderate hepatic impairment.</li> </ul> <p><b>Dosing in Children with Renal Impairment</b></p> <ul style="list-style-type: none"> <li>• RPV decreases tubular secretion of creatinine and slightly increases measured serum creatinine, but it does not affect glomerular filtration.</li> <li>• No dose adjustment of CAB or LA CAB/RPV is necessary in children with mild or moderate renal impairment. However, LA CAB/RPV should be used with caution in children with severe renal impairment or end-stage renal disease. These children should be monitored more frequently for adverse events.</li> </ul>
--	---

## Drug Interactions

Additional information about drug interactions is available in the [Adult and Adolescent Antiretroviral Guidelines](#) and the [HIV Drug Interaction Checker](#).

- *Metabolism:* Cabotegravir (CAB) is metabolized primarily by uridine diphosphate glucuronosyltransferase 1A1 (UGT1A1). CAB **is contraindicated** in children receiving strong inducers of UGT1A1 because such inducers decrease CAB plasma concentrations which may result in a loss of virologic response.
- Rilpivirine (RPV) is a cytochrome P450 (CYP) 3A substrate, and RPV concentrations may be affected when administered with CYP3A-modulating medications.
- A child's medication profile should be carefully reviewed for potential drug interactions before CAB plus RPV is administered.
- CAB and RPV are both highly protein bound and unlikely to be removed by hemodialysis.
- Coadministering oral RPV with drugs that increase gastric pH may decrease plasma concentrations of RPV.
  - Antacids should not be taken 2 hours before or 4 hours after oral RPV.
  - H2 receptor antagonists should not be administered 12 hours before or 4 hours after oral RPV.
  - Oral RPV **is contraindicated** with proton pump inhibitors.
- Rifamycin drugs significantly reduce CAB and RPV plasma concentrations. For children who are concomitantly receiving rifabutin and oral RPV, the dose of RPV should be doubled to 50 mg once daily and taken with a meal. Coadministration of the following drugs **is contraindicated**:
  - Rifampin and oral RPV
  - Rifampin or rifapentine and CAB
  - Rifabutin and long-acting injectable CAB and RPV (LA CAB/RPV)

## Major Toxicities

- *More common:* Injection site reactions, insomnia, headache, rash, elevated creatine phosphokinase serum concentrations
- *More common:* In studies of adults, 7.3% of participants who were treated with RPV showed a change in adrenal function characterized by an abnormal 250-microgram adrenocorticotrophic hormone stimulation test (peak cortisol level <18.1 micrograms/dL). In a study of adolescents, 6 of 30 participants (20%) developed this abnormality.<sup>1</sup> The clinical significance of these results is unknown.
- *Less common (more severe):* Depression or mood changes, suicidal ideation
- *Rare:* Hepatotoxicity and post-injection reactions, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure
- *Rare:* RPV drug-induced liver injury has been reported.<sup>2</sup>

## Resistance

The International Antiviral Society–USA maintains a list of updated [HIV Drug Resistance Mutations](#), and the [Stanford University HIV Drug Resistance Database](#) offers a discussion of each mutation.

## Pediatric Use

### *Approval*

CAB oral tablets (Vocabria) and co-packaged LA CAB/RPV (Cabenuva) are approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV in children or adolescents aged  $\geq 12$  years and weighing  $\geq 35$  kg (2022) and adults (2021). They are not approved for use in children aged  $< 12$  years. CAB tablets were approved by the FDA in 2021 for use in adults as part of the oral lead-in prior to beginning LA CAB/RPV or as an oral interim treatment when people miss planned injections.<sup>3,4</sup> CAB and RPV co-packaged extended-release injectable suspensions for IM use are approved for use in people (monthly or every 2 months) who are virologically suppressed on a stable antiretroviral (ARV) regimen with no history of virologic failure or known resistance affecting either of the component drugs.<sup>3</sup>

In December 2021, the FDA approved CAB IM (Apretude) for HIV pre-exposure prophylaxis (PrEP) in adults and adolescents weighing at least 35 kg; an oral lead-in period of approximately 1 month may be used to assess safety and tolerability but is optional. Refer to the package insert for additional information about dosing and administration,<sup>5</sup> and see the Centers for Disease Control and Prevention [Guidelines for Pre-Exposure Prophylaxis for the Prevention of HIV in the United States](#) for further information about the use of CAB for PrEP.

### *Efficacy and Pharmacokinetics in Clinical Trials*

#### **Clinical Trials in Children and Adolescents 12 Years to $< 18$ Years**

The safety and efficacy of CAB, an HIV-1 integrase inhibitor, given in combination with RPV, a non-nucleoside reverse transcriptase inhibitor (NNRTI), has been characterized in a series of clinical trials conducted in adults, which form the basis for approval.

The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) [Network Study 2017, More Options for Children and Adolescents \(MOCHA\)](#), is currently in progress to evaluate the safety, tolerability, acceptability, and pharmacokinetics of this injectable regimen in adolescents ([MOCHA Trial](#)) and has reported results leading to FDA approval in this age group.

MOCHA evaluated the safety and pharmacokinetics of intramuscular (IM) long-acting CAB and long-acting RPV in virologically suppressed adolescents aged 12 to 17 years weighing  $\geq 35$  kg). In cohort 1, after 4 to 6 weeks of oral CAB (n=30) or RPV (n=25), participants received IM long-acting CAB or long-acting RPV every 4 weeks or 8 weeks per the adult dosing regimens while continuing pre-study ART. Injection site reactions were observed but did not lead to any treatment discontinuations. Two adolescents experienced Grade 3 drug-related adverse events, one due to insomnia (CAB arm) and one due to hypersensitivity reaction to oral RPV, which led to discontinuation.<sup>6,7</sup> In a concurrent assessment of adolescent and parental experiences with IM treatment in MOCHA, overall perceptions of the injectable treatment were favorable. Of the 21

adolescents who received all three study injections, >90% “definitely” or “probably” wanted to continue IM treatment.<sup>8,9</sup> For participants receiving IM CAB or IM RPV, exposures were similar to those observed in adults. In cohort 2, 144 virologically suppressed adolescents with HIV-1 received 4 weeks of oral CAB plus RPV followed by IM CAB 600 mg and IM RPV 900 mg every 2 months. The 1st and 2nd injections were 4 weeks apart, with subsequent injections every 8 weeks. Adverse reactions were reported in 35% of adolescents receiving CAB plus RPV with the majority classified as Grade 1 or Grade 2 injection site reactions. Two participants had Grade 3 injection site reactions: injection site abscess (n = 2) and injection site pain (symptoms resolved in both participants). Non-injection-site associated adverse reactions reported by more than one participant (regardless of severity) were headache (n = 3), nausea (n = 2), rash (n = 2) and pruritic rash (n = 2).<sup>10</sup> No virologic failure was observed through Week 24. Predose concentrations of CAB and RPV were similar to those in adults. One participant had a low CAB pre-dose concentration at Week 24 (0.03 µg/mL). Overall, 97% participants at week 8 and 99% of participants at week 24 preferred injectable medications over daily oral dosing which was driven primarily by convenience and burden reduction (i.e., adherence-related stress and increased privacy).<sup>11</sup>

Intermittent viremias have been reported in young adults transitioned to LA CAB/RPV with oral lead-in.<sup>12</sup> The Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV notes that significant questions remain regarding the use of LA CAB/RPV in children and adolescents, including whether an oral lead-in is beneficial in the adolescent population, whether there are additional adverse effects specific to the pediatric population, whether the use of a two-drug nucleoside-sparing regimen for children with significant ARV treatment history is appropriate, and what potential implementation challenges might exist (e.g., cost, procurement and access, retention in care).<sup>13</sup>

## Clinical Trials in Adults

The Phase 3 Antiretroviral Therapy as Long-Acting Suppression (ATLAS) study randomized stable, virologically suppressed adults to receive either CAB and RPV (n = 308) or continue their oral antiretroviral therapy (ART) (n = 308). Participants assigned to CAB and RPV initiated therapy with an oral regimen for 4 weeks prior to beginning monthly IM injections. The initial assessment at 48 weeks demonstrated that switching to monthly LA CAB/RPV was noninferior to continuing a three-drug oral therapy. After 48 weeks, participants were allowed to transition to injections every 2 months in a follow-up study (ATLAS-2M, see below); 52 participants remaining on the original ATLAS study were included in the 96-week analysis. Adverse events were more common among participants receiving injectable ART; injection site reactions were common, but only 1% withdrew from the study because of these events.<sup>14</sup> The ATLAS-2M trial randomized participants to monthly IM CAB 400 mg and RPV 600 mg (n = 523) or every-2-month injections of CAB 600 mg and RPV 900 mg (n = 522); it enrolled both new participants and those continuing from the ATLAS trial. After 96 weeks, the every-2-month injections were noninferior to monthly injections, with 11 (2%) confirmed virologic failures in the every-2-month injection group and 6 (1%) in the monthly injection group. No new safety signals were identified, and the rate of injection site reactions—the most common adverse event—was similar across treatment arms. Of those failing the every-2-month injection regimen, a majority had NNRTI resistance-associated mutations.<sup>15</sup>

The First Long-Acting Injectable Regimen (FLAIR) study enrolled 631 treatment-naïve adults and initiated treatment with a standard oral ARV regimen consisting of dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) for 20 weeks. Those participants with documented HIV-1 RNA <50 copies/mL after 16 weeks were randomized to either continue oral DTG/ABC/3TC (n = 283) or switch to oral

CAB and RPV for 4 weeks, followed by monthly injections of CAB and RPV (n = 283). After 96 weeks of randomized therapy, nine participants (3.2%) in each arm had HIV RNA >50 copies/mL. Adverse events were common in both treatment groups, but adverse events leading to withdrawal from the study were observed in only 14 (5%) participants in the LA CAB/RPV group and 4 (1%) in the oral standard care group. Injection site reactions were the most common adverse events, reported by 245 (88%) participants in the LA CAB/RPV, and lasted a median of 3 days.<sup>16</sup> The FLAIR study was extended to include an assessment of switching those participants remaining in the oral ARV arm after 120 weeks to LA CAB/RPV either with or without the initial oral lead-in phase. There were no differences between the lead-in group and the direct-to-injection group in terms of safety, tolerability, or efficacy through an additional 24 weeks on the study.<sup>17</sup>

These studies demonstrated noninferiority of switching to monthly LA CAB/RPV compared to continuing oral ART. In all studies, adults expressed a high degree of treatment satisfaction and preference for the LA CAB/RPV regimen. Although documented virologic failure with the LA CAB/RPV regimen has been rare to date, investigators have attempted to assess the baseline factors associated with treatment failure. In a multivariate analysis of the adult LA CAB/RPV Phase 3 trials, presence of at least two baseline factors of RPV resistance–associated mutations, HIV-1 subtype A6/A1, and body mass index >30 kg/m<sup>2</sup> was associated with increased risk of virologic failure at 48 weeks.<sup>18</sup>

### ***Pharmacokinetics***

The pharmacokinetics (PK) of IM CAB are driven by slow absorption from the injection site. IM CAB reaches its maximum plasma concentration in adults in about 7 days and has a mean half-life of 5.6 to 11.5 weeks. Measurable levels of CAB can be detected in plasma for up to a year or longer. Due to this prolonged drug exposure, it is essential to initiate an alternative, fully suppressive ARV regimen no later than 1 month after the final injections of CAB and RPV to minimize the potential risk of developing viral resistance.<sup>3</sup> The PK profiles observed in adolescents enrolled in MOCHA were comparable to those observed in adults receiving monthly long-acting injectable CAB and RPV in the ATLAS and FLAIR studies described above.<sup>6</sup>

## References

1. Vocabria (cabotegravir) tablets, for oral use [package insert]. Food and Drug Administration. 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/212887s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/212887s011lbl.pdf).
2. Lee MJ, Berry P, D'Errico F, et al. A case of rilpivirine drug-induced liver injury. *Sex Transm Infect*. 2020;96(8):618-619. Available at: <https://pubmed.ncbi.nlm.nih.gov/31974214>.
3. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension), co-packaged for intramuscular use [package insert]. Food and Drug Administration. 2023. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/212888s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212888s011lbl.pdf).
4. Vocabria (cabotegravir) tablets, for oral use [package insert]. Food and Drug Administration. 2023. Available at: [https://gskpro.com/content/dam/global/hcpportal/en\\_US/Prescribing\\_Information/Vocabria/pdf/VOCABRIA-PI-PIL.PDF](https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Vocabria/pdf/VOCABRIA-PI-PIL.PDF).
5. Apretude (cabotegravir extended-release injectable suspension), for intramuscular use [package insert]. Food and Drug Administration. 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/215499s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215499s009lbl.pdf).
6. Moore CB, Capparelli E, Calabrese K, et al. Safety and PK of long-acting cabotegravir and rilpivirine in adolescents. Presented at: Conference on Retroviruses and Opportunistic Infections 2022. Virtual. Available at: <https://www.croiconference.org/abstract/safety-and-pk-of-long-acting-cabotegravir-and-rilpivirine-in-adolescents/>.
7. Gaur AH, Capparelli EV, Calabrese K, et al. Safety and pharmacokinetics of oral and long-acting injectable cabotegravir or long-acting injectable rilpivirine in virologically suppressed adolescents with HIV (IMPAACT 2017/MOCHA): a phase 1/2, multicentre, open-label, non-comparative, dose-finding study. *Lancet HIV*. 2024;11(4):e211-e221. Available at: <https://pubmed.ncbi.nlm.nih.gov/38538160>.
8. Lowenthal E, Chapman J, Calabrese K, et al. Adolescent and parent experiences with long-acting injectables in the MOCHA study. Presented at: Conference on Retroviruses and Opportunistic Infections; 2022. Virtual. Available at: <https://www.croiconference.org/abstract/adolescent-and-parent-experiences-with-long-acting-injectables-in-the-mocha-study>.
9. Lowenthal ED, Chapman J, Ohrensall R, et al. Acceptability and tolerability of long-acting injectable cabotegravir or rilpivirine in the first cohort of virologically suppressed adolescents living with HIV (IMPAACT 2017/MOCHA): a secondary analysis of a phase 1/2, multicentre, open-label, non-comparative dose-finding study. *Lancet HIV*. 2024;11(4):e222-e232. Available at: <https://pubmed.ncbi.nlm.nih.gov/38538161>.

10. Gaur A, Capparelli E, Baltrusaitis K, et al. Long-acting cabotegravir plus rilpivirine in adolescents with HIV: week 24 IMPAACT 2017(MOCHA) study Presented at: Conferences on Retroviruses and Opportunistic Infections 2024. Denver, CO. Available at: <https://www.croiconference.org/abstract/long-acting-cabotegravir-plus-rilpivirine-in-adolescents-with-hiv-week-24-impaact-2017mocha-study>.
11. Lowenthal ED, Chapman J, Vaca MZ, et al. IMPACCT 2017 Adolescent/Parent experiences with LA Cabotegravir plus Rilpivirine for HIV treatment. Presented at: Conference on Retroviruses and Opportunistic Infections; 2024. Denver, Colorado. . Available at: [https://www.natap.org/2024/CROI/croi\\_49.htm](https://www.natap.org/2024/CROI/croi_49.htm).
12. Rakhmanina N, Richards K, Adeline Koay WL. Transient viremia in young adults with HIV after the switch to long-acting cabotegravir and rilpivirine: considerations for dosing schedule and monitoring. *J Acquir Immune Defic Syndr*. 2023;92(3):e14-e17. Available at: <https://pubmed.ncbi.nlm.nih.gov/36480701>.
13. Rakhmanina N. Are we ready for long-acting HIV treatment for adolescents? *Lancet HIV*. 2024;11(4):e200-e201. Available at: <https://pubmed.ncbi.nlm.nih.gov/38538156>.
14. Swindells S, Lutz T, Van Zyl L, et al. Week 96 extension results of a Phase 3 study evaluating long-acting cabotegravir with rilpivirine for HIV-1 treatment. *AIDS*. 2022;36(2):185-194. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/34261093>.
15. Jaeger H, Overton ET, Richmond G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 96-week results: a randomised, multicentre, open-label, Phase 3b, non-inferiority study. *Lancet HIV*. 2021;8(11):e679-e689. Available at: <https://pubmed.ncbi.nlm.nih.gov/34648734>.
16. Orkin C, Oka S, Philibert P, 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. *Lancet HIV*. 2021;8(4):e185-e196. Available at: <https://pubmed.ncbi.nlm.nih.gov/33794181>.
17. Orkin C, Bernal Morell E, Tan DHS, et al. Initiation of long-acting cabotegravir plus rilpivirine as direct-to-injection or with an oral lead-in in adults with HIV-1 infection: week 124 results of the open-label Phase 3 FLAIR study. *Lancet HIV*. 2021;8(11):e668-e678. Available at: <https://pubmed.ncbi.nlm.nih.gov/34656207>.
18. Cutrell AG, Schapiro JM, Perno CF, et al. Exploring predictors of HIV-1 virologic failure to long-acting cabotegravir and rilpivirine: a multivariable analysis. *AIDS*. 2021;35(9):1333-1342. Available at: <https://pubmed.ncbi.nlm.nih.gov/33730748>.