Cabotegravir

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

Formulations
Tablet • [Vocabria] Cabotegravir: 30 mg **Single-Dose Vial for Intramuscular (IM) Injection** • [Apretude] Cabotegravir 600-mg/3-mL (200-mg/mL) suspension for IM injection for use as HIV pre-exposure prophylaxis (PrEP) only **Co-packaged Formulations** • [Cabenuva Kit] Cabotegravir 400-mg/2-mL (200-mg/mL) and rilpivirine 600-mg/2-mL (300-mg/mL) suspension for IM injection (each drug packaged in a separate syringe) • [Cabenuva Kit] Cabotegravir 600-mg/3-mL (200-mg/mL) and rilpivirine 900-mg/3-mL (300-mg/mL) suspension for IM injection (each drug packaged in a separate syringe) When using the co-packaged formulation, refer to the Rilpivirine section for additional information. For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations	Selected Adverse Events
[Apretude] Cabotegravir (CAB) for IM Injection • CAB 600 mg/3 mL for IM injection is approved by the U.S. Food and Drug Administration (FDA) for use as HIV PrEP in adults and adolescents weighing ≥35 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 (ARV) Guidelines. **[Cabenuva] CAB and Rilpivirine (RPV) for IM Injection (Long-Acting Injectable CAB and RPV)** *Pediatric Dose* • 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 <12 years.	• Depression • Insomnia • Headache • Rash (can be severe) or hypersensitivity • Hepatotoxicity • Altered adrenocorticotropic hormone stimulation test of uncertain clinical significance • Injection site reactions (pain, tenderness, induration, nodules, erythema; common and typically mild to moderate) • Postinjection reactions • Creatine phosphokinase elevation following IM injection • Weight gain

Child and Adolescent (Aged ≥12 Years and Weighing ≥35 kg) and Adult Dose

- 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 <50 copies/mL on a stable ARV regimen with no history of treatment failure and no known or suspected resistance to CAB or RPV.
- 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; however, many providers initiate therapy without an oral lead-in when there are no concerns regarding tolerability, drug interactions, or resistance.
- 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).

Oral Lead-in Dosing

- o CAB 30 mg orally and RPV 25 mg orally once daily with a meal for at least 28 days.

Dosing for Monthly Administration of LA CAB/RPV

- o 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.
- o 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.

Dosing for Every-2-Month Administration of LA CAB/RPV

- o 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.
- o 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.

Special Instructions

- Refer to the Rilpivirine section for considerations related to oral lead-in dosing, including administration requirements and potential drug interactions.
- Serious hypersensitivity reactions have been reported with CAB- and RPV-containing regimens. Severe cutaneous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported with CAB. Discontinue therapy immediately if hypersensitivity is suspected. See the Rilpivirine section for additional information.
- 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 whether resumption of injection dosing remains appropriate. Refer to the package insert for information about managing planned and unplanned missed doses.
- LA CAB/RPV is a complete regimen. Coadministration with other ARV drugs is not recommended.
- 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.
- 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 CredibleMeds).

Metabolism/Elimination

- CAB is metabolized by uridine diphosphate-glucuronosyltransferase 1A1.
- RPV is a cytochrome P450 3A substrate.

Dosing in Children With Hepatic Impairment

- No dose adjustment of CAB or LA CAB/RPV is necessary in children with mild or moderate hepatic impairment.

Dosing in Children With Renal Impairment

- RPV decreases tubular secretion of creatinine and slightly increases measured serum creatinine, but it does not affect glomerular filtration.
- 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.

Children should be monitored for approximately 10 minutes for postinjection reactions. A 23-gauge, 1.5-inch IM needle is recommended and is provided in the packaging. Longer 2-inch needles (not included with packaging) should be used in children with a body mass index >30 kg/m^2. 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. Additional clinical resources, including injection education, are available from the manufacturer, ViiV.	

Drug Interactions

Additional information about drug interactions is available in the Liverpool 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 (mild to moderate pain, tenderness, induration, nodules, erythema), 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 adrenocorticotropic hormone stimulation test (peak cortisol level <18.1 micrograms/dL). In a study of adolescents, 6 of 30 participants (20%) developed this abnormality.[1] The clinical significance of these results is unknown.
- *Less common (more severe):* Depression or mood changes and suicidal ideation
- *Rare:* Serious hypersensitivity reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis
- *Rare:* Serious postinjection reactions have been reported with LA CAB/RPV and are primarily associated with the RPV component. These reactions should be distinguished from hypersensitivity reactions. Symptoms may include dyspnea, bronchospasm, agitation, abdominal cramping, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest pain). These events are uncommon, generally occur within minutes after injection, and typically resolve with supportive care. See the Rilpivirine section for additional information.
- *Rare:* RPV drug-induced liver injury has been reported.[2]

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 ≥12 years and weighing ≥35 kg (2022) and in 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.[1,3] 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.[3]

In December 2021, the FDA approved CAB IM (Apretude) for HIV pre-exposure prophylaxis (PrEP) in adults and adolescents weighing ≥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,[4] 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.

Safety, 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), evaluated the safety, tolerability, acceptability, and pharmacokinetics (PK) 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 PK of intramuscular (IM) LA CAB/RPV in virologically suppressed adolescents aged 12–17 years weighing ≥35 kg). In cohort 1, after 4 to 6 weeks of oral CAB (n = 30) or RPV (n = 25), participants received IM LA CAB or long-acting (LA) RPV every 4 weeks or 8 weeks per the adult dosing regimens while continuing pre-study antiretroviral therapy (ART). Injection site reactions were observed but did not lead to any treatment discontinuations. Two adolescents experienced Grade 3 drug-related adverse events (AEs), one due to insomnia (CAB arm) and one due to hypersensitivity reaction to oral RPV, which led to discontinuation.[5,6] 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.[7,8] 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 first and second injections were 4 weeks apart, with subsequent injections every 8 weeks. The primary outcome in Cohort 2 was safety, including all AEs, at Week 24. Overall, 10.8% of participants in the evaluable analysis population had at least one AE of Grade 3 or above by Week 24.[9] Among participants who received at least one injection, 30% experienced at least one injection site reaction. All injection site reactions were either Grade 1 or Grade 2, and 91.5% resolved within 7 days. Nonserious injection site reactions were common but did not lead to treatment discontinuation in the majority of participants. The most common injection site reaction was pain disproportionate to what would be expected when a person receives an IM injection. No participant experienced a drug-related serious AE or prematurely discontinued treatment due to a drug-related AE. 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).[10] No virologic failure was observed through Week 24. Pre-dose 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).[11] In a separate real-world, single-center, cross-sectional survey among adolescents and young adults with HIV, most participants (n = 17; 94.4%) receiving the LA injectable regimen found it to be acceptable. Facilitators to acceptance included reduced pill burden and medication fatigue and thinking less about HIV diagnosis. Barriers to acceptance included concerns about side effects and the need for more frequent clinic visits.[12,13]

Intermittent viremias have been reported in young adults transitioned to LA CAB/RPV with oral lead-in.[14] The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV notes that questions remain regarding the use of LA CAB/RPV in children and adolescents, including whether there are additional adverse effects specific to the pediatric population and what potential implementation challenges might exist (e.g., cost, procurement and access, retention in care).[15]

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 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 non-inferior 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. AEs were more common among participants receiving injectable ART; injection site reactions were common, but only 1% withdrew from the study because of these events.[16] 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 non-inferior 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 AE—was similar across treatment arms. Of those failing the every-2-month injection regimen, a majority had NNRTI resistance–associated mutations.[17]

The First Long-Acting Injectable Regimen (FLAIR) study enrolled 631 adults who were treatment-naive 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. AEs were common in both treatment groups, but AEs leading to withdrawal from the study were observed in only 14 (5%) participants in the LA CAB/RPV group and 4 (1%) participants in the oral standard care group. Injection site reactions were the most common AEs, reported by 245 (88%) participants in the LA CAB/RPV, and lasted a median of 3 days.[18] 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.[19]

These studies demonstrated noninferiority of switching to monthly LA CAB/RPV compared with 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^2 was associated with increased risk of virologic failure at 48 weeks.[20]

Oral Lead-In

An oral lead-in with CAB/RPV may be used prior to initiation of LA CAB/RPV to assess short-term tolerability. The original rationale for the oral lead-in was to identify hypersensitivity reactions or other clinically significant adverse effects before administration of the LA IM injection. Because both CAB and RPV have prolonged elimination phases after IM administration, drug concentrations persist for months, and the drugs cannot be removed rapidly after being injected. The oral lead-in was therefore intended to minimize the risk of prolonged exposure in individuals who might not tolerate one or both agents.

However, accumulating clinical trial data in adults—including studies directly comparing oral lead-in with direct-to-injection initiation—have demonstrated similar safety, tolerability, and efficacy outcomes between approaches, with no meaningful differences in hypersensitivity or serious AEs.[21] PK analyses have also shown that LA CAB exposure is similar with or without an oral lead-in.[22] Based on these data, routine use of an oral lead-in is not required. The decision to use an oral lead-in may be individualized based on clinical judgment, including prior history of medication intolerance, concerns about potential drug–drug interactions, patient or caregiver preference, or other clinical factors. CAB/RPV experience is more limited in adolescents than in adults; however, available data

suggest a safety profile comparable to that observed in adult studies, and many providers initiate therapy without an oral lead-in.

Pharmacokinetics

The 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.[3] The PK profiles observed in adolescents enrolled in MOCHA were comparable to those observed in adults receiving monthly LA injectable CAB and RPV in the ATLAS and FLAIR studies described above.[5]

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.

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. 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/212888Orig1s017lbl.pdf.

4. 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.

5. 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.

6. 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.

7. 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.

8. Lowenthal ED, Chapman J, Ohrenschall 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.

9. Moore CB, Baltrusaitis K, Best BM, et al. Safety of combined long-acting injectable cabotegravir and 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*. 2025;12(3):e191-e200. Available at: https://pubmed.ncbi.nlm.nih.gov/40049924.

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, CO. Available at: https://www.natap.org/2024/CROI/croi_49.htm.

12. Williams T, Unternaher J, Koay WLA, et al. Efficacy, safety and retention in care among adolescents and youth with HIV on long-acting injectable cabotegravir/rilpivirine treatment: real-world observational cohort outcomes. *Pediatr Infect Dis J*. 2025;44(7):650-656. Available at: https://pubmed.ncbi.nlm.nih.gov/39853281.

13. Unternaher J, Craddock C, Koay WLA, et al. Acceptability, facilitators, and barriers of long-acting injectable cabotegravir/rilpivirine among youth with HIV in the United States. *J Adolesc Health*. 2025;77(6):1135-1143. Available at: https://pubmed.ncbi.nlm.nih.gov/40965392.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. Llibre JM, Sax PE. Reassessing oral lead-in for injectable long-acting HIV therapy. *Lancet HIV*. 2021;8(11):e660-e661. Available at: https://pubmed.ncbi.nlm.nih.gov/34656209.

22. Han K, Patel P, McCallister S, et al. Long-acting cabotegravir pharmacokinetics with and without oral lead-in for HIV PrEP. *Antimicrob Agents Chemother*. 2024;68(6):e0147523. Available at: https://www.ncbi.nlm.nih.gov/pubmed/38709006.