Long-Acting Cabotegravir+Rilpivirine in Adolescents: IMPAACT 2017 Week 96 & End of Study Results

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Abstract 155
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Background

- IMPAACT 2017 study participants are the first group of adolescents living with HIV-1 to receive long-acting (LA) cabotegravir (CAB LA) plus rilpivirine (RPV LA) and stop their oral antiretrovirals.
- IMPAACT 2017 data informed FDA and other regulatory approvals for CAB LA + RPV LA in virologically suppressed adolescents (≥12 years and weighing ≥35 kg)
- We report:
  - Through Week 96 data analysis
  - Through end of study data analysis that includes data from the subset of study participants who were provided, as part of a study extension, up to 48 weeks of study drug access beyond Week 96 until they could get alternate sourcing of CAB LA + RPV LA.

Safety, antiviral activity, and pharmacokinetics of long-acting ….. Lancet HIV. 2026 Jan 14:S2352-3018(25)00242-5. doi: 10.1016/S2352-3018(25)00242-5.
Acceptability and tolerability of long-acting injectable…... Lancet HIV. 2026 Jan 14:S2352-3018(25)00241-3. doi: 10.1016/S2352-3018(25)00241-3.
Safety of combined long-acting injectable….. Lancet HIV. 2025 Mar;12(3):e191-e200. doi: 10.1016/S2352-3018(24)00344-8.
Safety and pharmacokinetics….. of Lancet HIV. 2024 Apr;11(4):e211-e221. doi: 10.1016/S2352-3018(23)00300-4.
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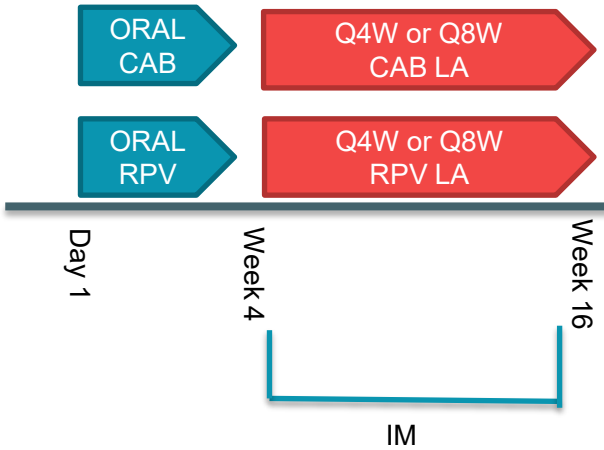
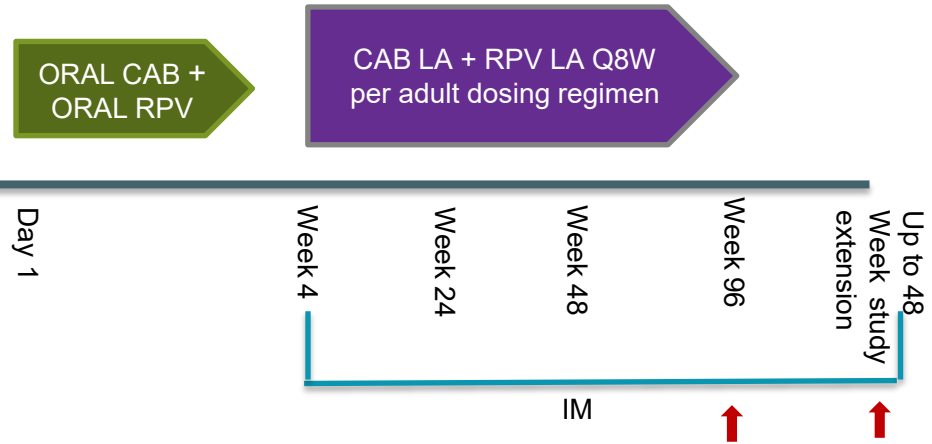
Study Design

Cohort 1
(retain background cART)
Total n = 55:
30 (CAB) + 25 (RPV)



Cohort 2
(switch from background cART)
Total n = 144: 44 (Rollover) + 100 (Cohort 1-naïve)

Primary Objective: To assess the safety of CAB LA + RPV LA through Week 24 in virologically suppressed adolescents living with HIV.



18 IMPAACT 2017 sites from 5 countries enrolled in Cohort 2

2 Botswana
4 South Africa
3 Thailand
2 Uganda
7 US

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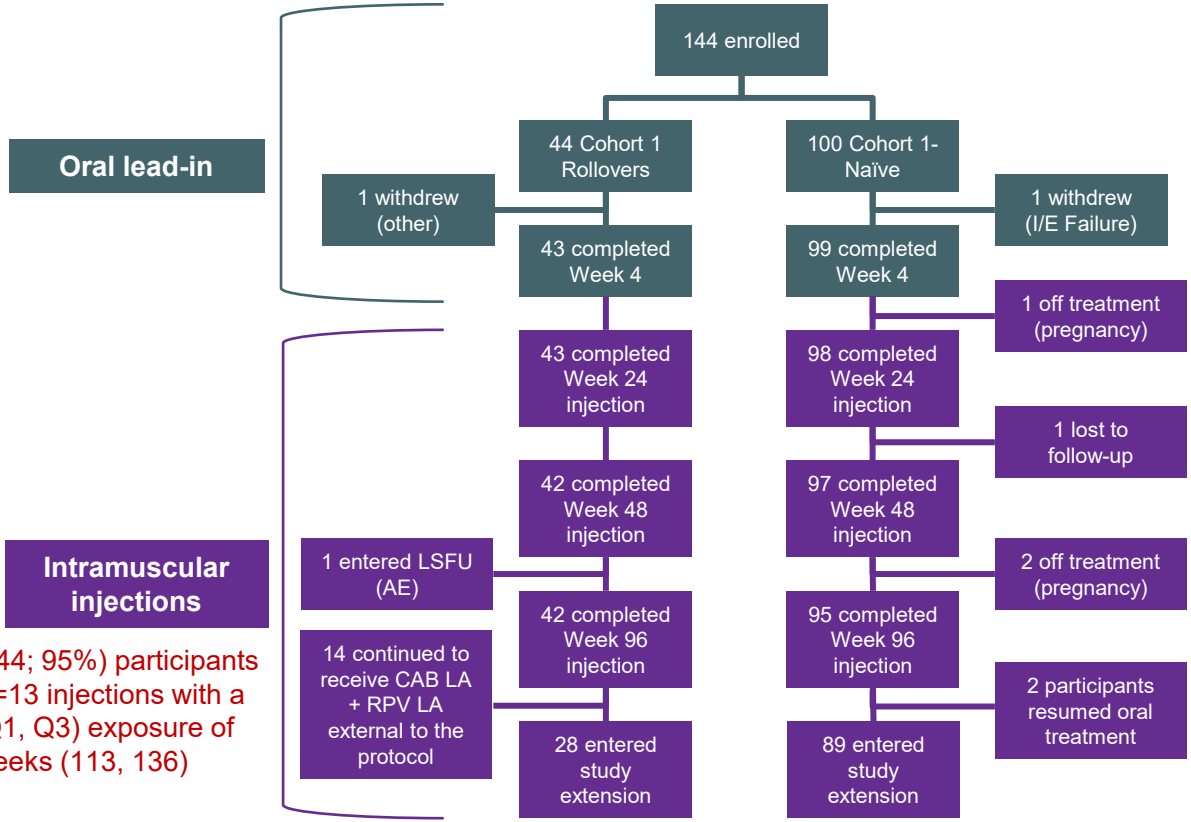
IMPAACT 2017 Cohort 2: Study Flow



Most (137/144; 95%) participants received >=13 injections with a median (Q1, Q3) exposure of 128 weeks (113, 136)

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Study participants at baseline (N = 144)

Variable	Value
Age (median [min, max])	15 years (12, 17)
Female	51%
Black or African American	74%
Acquired HIV Vertically	92%
Body Mass Index (median [min, max])	19.5 kg/m^2 (16, 34)
Weight (median [min, max])	48 kgs (35, 101)

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Cohort 2 Safety, Acceptability, Tolerability, Antiviral Activity and Pharmacokinetics (PK)

All treated analysis shown

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Safety assessments*

- 44 of 144 (31%) participants had a ≥ Grade 3 adverse event (AE), the most common of which was increase in blood creatine phosphokinase (n=18/144 [12.5%]).
- 60 of 144 (42%) participants experienced a drug-related AE.
- 3 of 144 (2%) experienced a drug-related ≥ Grade 3 AE:
  - 2 Grade 3 AEs (abscess [n=1] and concurrent pain and abscess [n=1]).
  - 1 Grade 4 AE (anaphylaxis per site; post-injection reaction per protocol team; resolved but led to study drug discontinuation).
- There were no deaths.

**End of study results unless noted specifically as Week 96 result.*

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Injection Site Reactions (ISRs) versus Post-injection reactions (PIRs): What's the difference?

- ISRs: Pain out of proportion to what would be expected when a person receives an intramuscular injection or other local findings, such as tenderness, erythema, redness, induration, swelling, or pruritus.

- PIRs: In prior clinical trials, serious PIRs were reported within minutes after the injection of rilpivirine, including symptoms such as dyspnea, agitation, bronchospasm, abdominal cramping, rash, urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure and pain (e.g., back and chest pain).[1]

  These events were reported in less than 1% of participants and began to resolve within a few minutes after the injection.

[1]https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212888s005s006lbl.pdf

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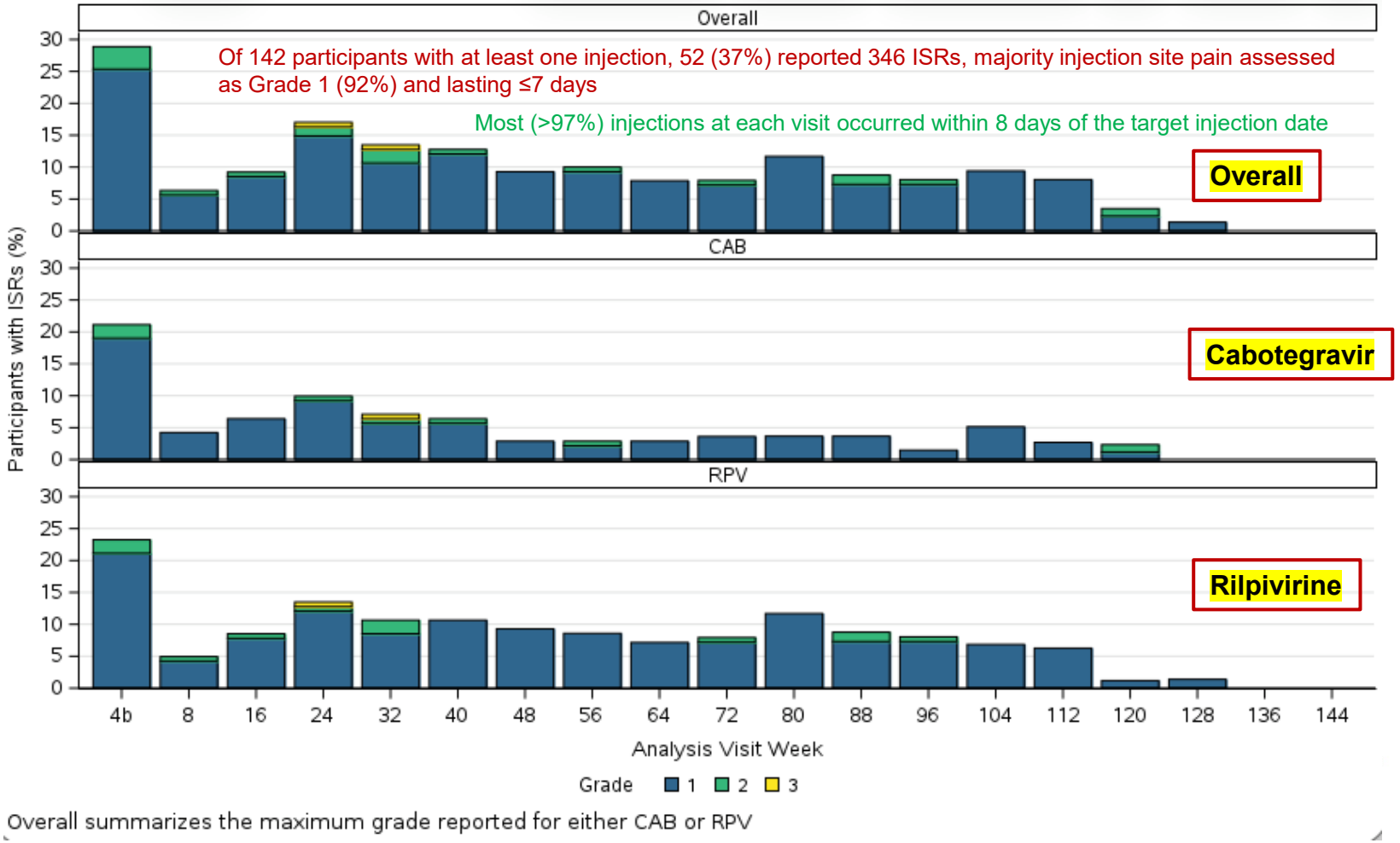
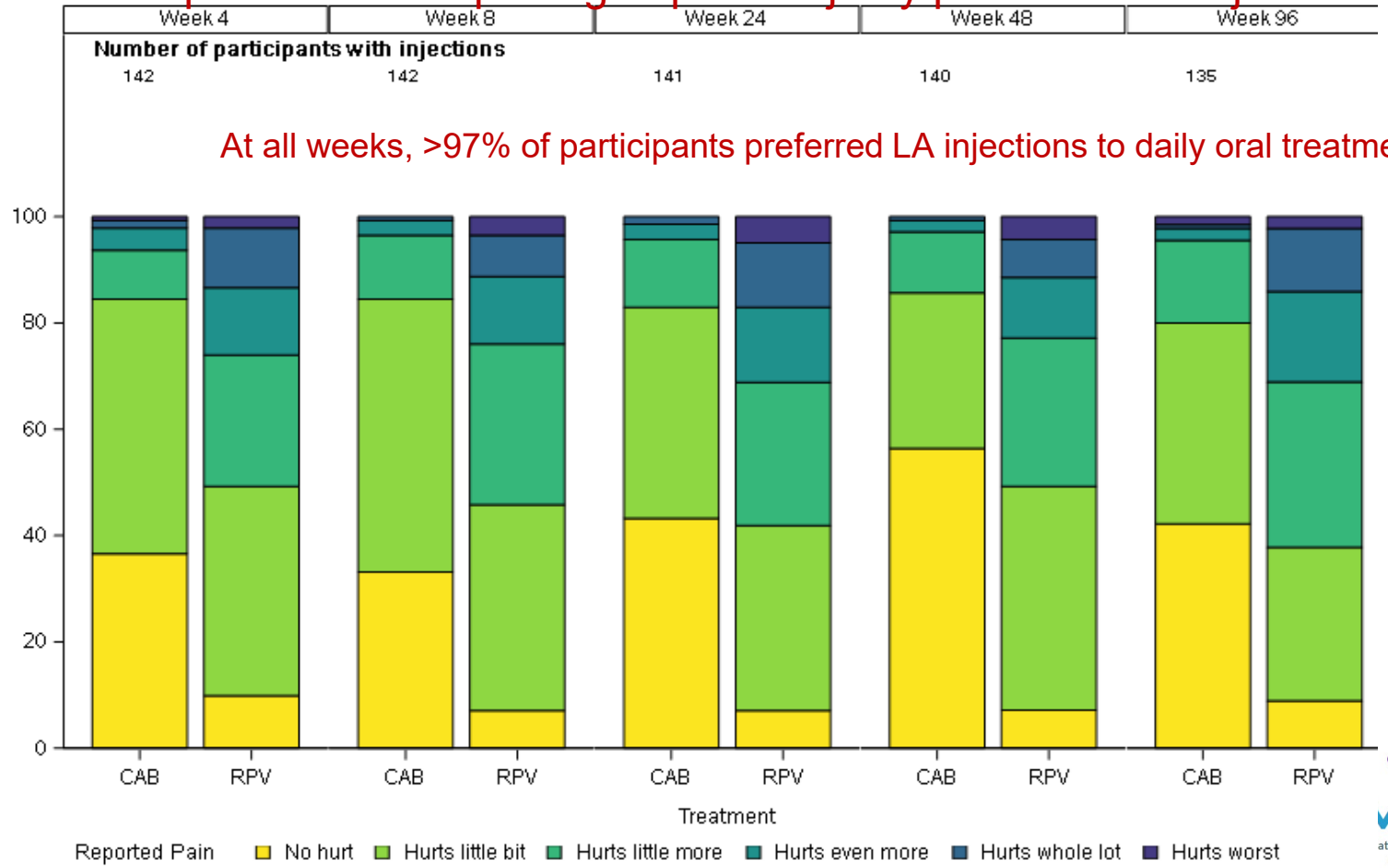
Injection Site Reactions (ISR): Common, mild and self-resolving



Post-injection reactions (PIRs) were uncommon – when recognized by site investigators none led to drug discontinuation

- In protocol amendment 4.0 (May 2022) a description of PIRs and a process for sites to assess and report suspected PIRs was added.
- Eight 'possible' PIRs based on a constellation of signs and symptoms were reported by the study site investigators to the Clinical Monitoring Committee (CMC); all appeared within minutes of study injections and none led to study drug discontinuation.
- Additionally, one Grade 4 AE was reported as anaphylaxis by the site and study drug was discontinued, but the CMC assessed this AE as being most consistent with a PIR

Acceptability and Tolerability:
Despite variable reporting of pain majority preferred the injectable treatment



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Antiviral activity:
Majority of participants showed sustained viral load suppression

- Majority (94.4%) of participants maintained virologic suppression (HIV-1 RNA < 50 copies/mL, per the FDA Snapshot algorithm) at Week 96.
- Viral blips during injection phase: There were eleven Cohort 2 participants with at least one viral load >50 copies/mL, two of whom were >200 copies/mL.
- There were no confirmed virologic failure (2 consecutive HIV VL ≧ 200 copies/mL) through Week 96.

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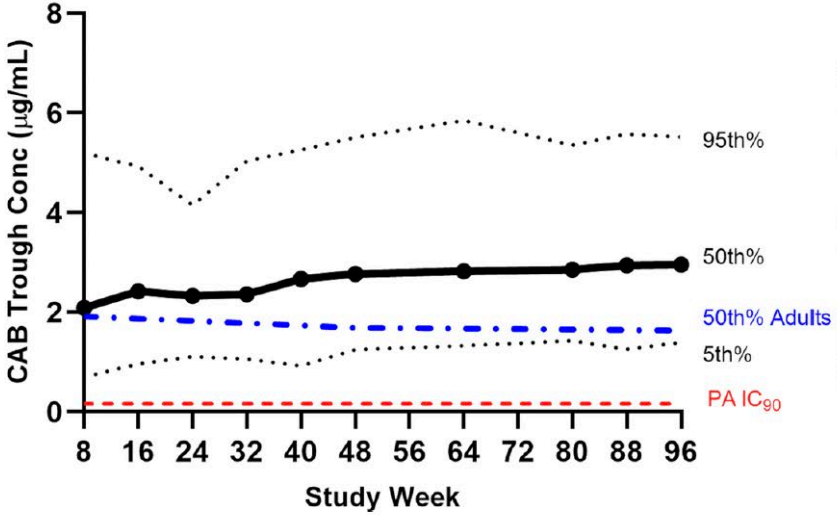
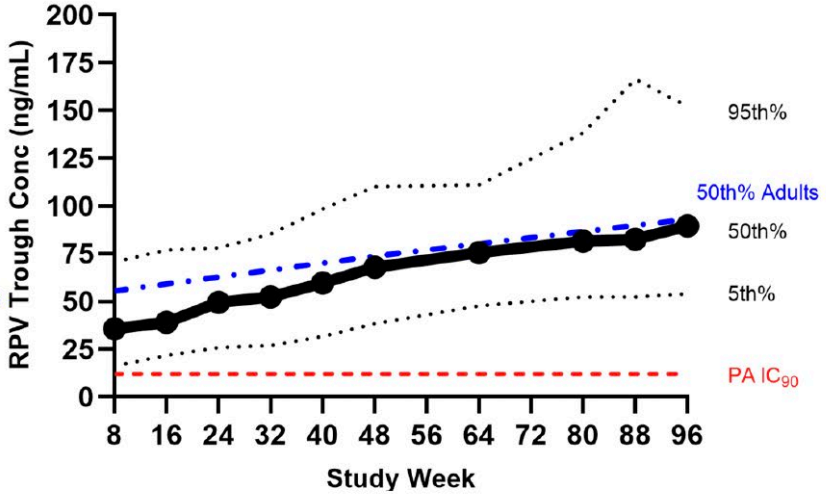
Pharmacokinetics: acceptable and comparable to adults





CAB at steady state but RPV still accumulating at 96 weeks

Cabotegravir (**CAB**) and rilpivirine (**RPV**) trough concentrations in IMPAACT 2017 (MOCHA) participants over 96 weeks. Median troughs (solid black lines) and the 5th% and 95th% (dotted black lines) were compared with the median troughs of adults from the ATLAS-2M Phase 3b randomized study (blue dashed lines) and protein-adjusted IC_{90}s (red dashed lines).

Conclusions from IMPAACT 2017 Cohort 2

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In summary

- IMPAACT 2017 Week 96 and end-of-study data from the first study in adolescents ≥12 years and weighing ≥35 kg with well controlled HIV who switched from daily oral treatment to intramuscular long-acting cabotegravir + rilpivirine every 8 weeks shows:
  - An acceptable safety/PK profile,
  - Sustained viral suppression,
  - Strong participant preference and
  - Informs the global use of this all-injectable treatment regimen.
- The described experience also provides a practical reminder to clinicians to differentiate post injection reactions from anaphylaxis or allergic reactions.

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