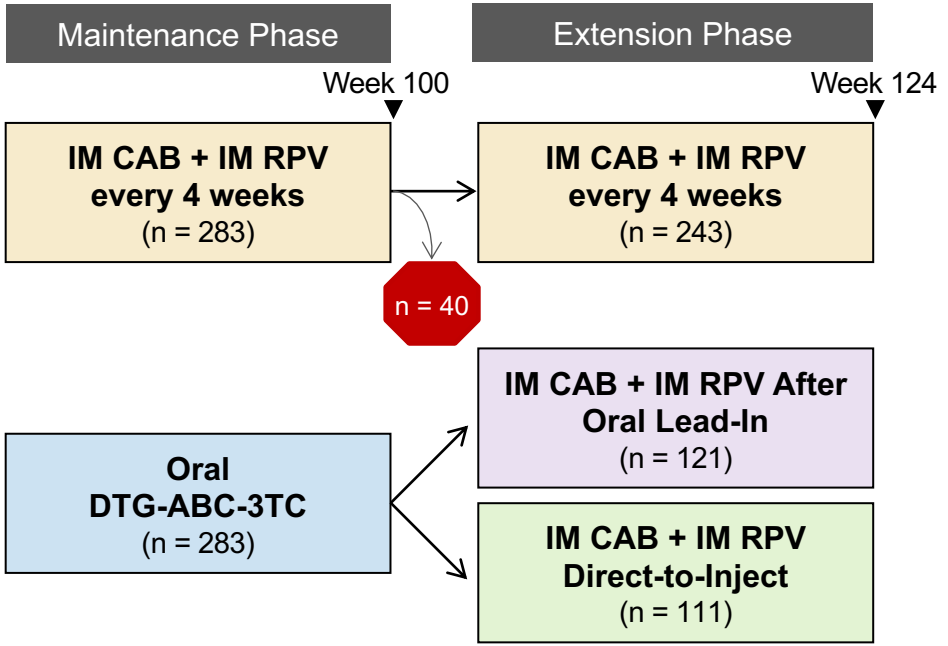
Long-Acting Cabotegravir and Rilpivirine with Oral Lead In versus Direct-to-Inject

# FLAIR Study: Week 124 Extension Phase

# Long-Acting IM CAB and IM RPV With or Without Oral Lead In FLAIR Study (124-Week Extension): Design

- **Background**: Extension of phase 3, randomized, open-label trial assessing IM CAB + IM RPV compared to DTG-ABC-3TC for treatment-naïve adults
- **Inclusion Criteria**: After 100-week maintenance phase, participants receiving IM CAB + IM RPV every 4 weeks could choose to continue (*Continuation Group*) or withdraw; those assigned to oral ART could choose to transition (*Switch Group*) to IM CAB + IM RPV after oral lead in or without oral lead in ("direct to inject")

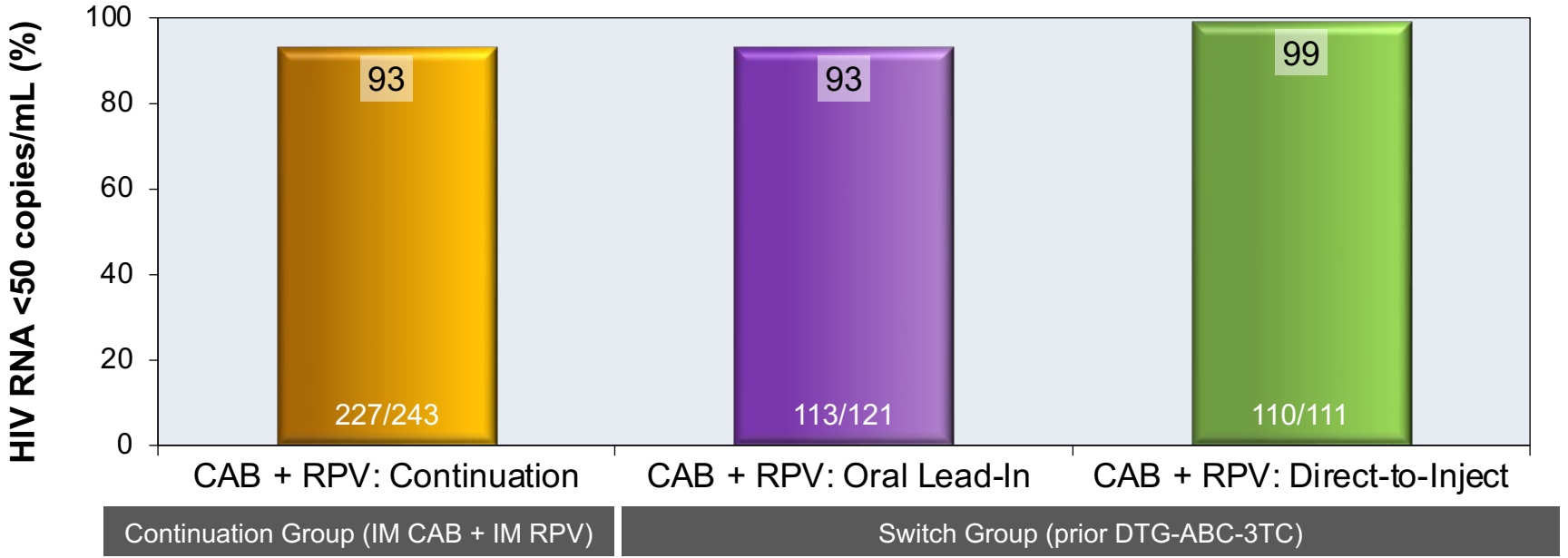



Oral lead in dosing: cabotegravir 30 mg daily and rilpivirine 25 mg daily x 4 weeks
Loading injections: cabotegravir 600 mg IM and 900 mg rilpivirine IM x 1
Maintenance injections: cabotegravir 400 mg IM and 600 mg rilpivirine IM monthly

Source: Orkin C, et al. Lancet HIV. 2021;8:e185-e196.

# Long-Acting IM CAB and RPV With or Without Oral Lead In FLAIR Study (124-Week Extension): Results in Extension Phase

## Virologic Responses During 24-Week Extension Phase




Continuation group: randomized to IM CAB + IM RPV at baseline and at week 100 opted to continue IM CAB + IM RPV until week 124.
Switch group: randomized to DTG-ABC-3TC and at week 100 switched to IM CAB + IM RPV with either oral lead in or direct-to-inject strategy

Source: Orkin C, et al. Lancet HIV. 2021;8:e185-e196.

# Long-Acting IM CAB and RPV With or Without Oral Lead In FLAIR Study (124-Week Extension): Conclusion

**Interpretation**: “After 24 weeks of follow-up, switching to long-acting treatment with or without an oral lead-in phase had similar safety, tolerability, and efficacy, supporting future evaluation of the simpler direct-to-injection approach. The week 124 results for participants randomly assigned originally to the long-acting therapy show long-acting cabotegravir plus rilpivirine remains a durable maintenance therapy with a favourable safety profile.”

Source: Orkin C, et al. Lancet HIV. 2021;8:e185-e196.

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