Safety, Efficacy and Durability of Long-acting Cabotegravir (CAB) and Rilpivirine (RPV) as Two-Drug IM Maintenance Therapy for HIV-1 Infection: LATTE-2 Week 160 Results

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Introduction
- Long-acting (LA) injectable suspensions of cabotegravir (CAB) and rilpivirine (RPV) are in phase III development
- LATTE-2 Week 48/96 data supported the decision to evaluate the Q4W and Q8W CAB LA + RPV LA IM arms in ongoing phase III studies1
- The Week 160 analysis evaluated the long-term efficacy, safety, and tolerability of both IM dosing regimens

Methods
- Phase III, multicenter, parallel-group, open-label study in ART-naive HIV-infected adults
- Figure 1. LATTE-2 Study Design

Results
- 309 patients were enrolled (ITT-exposed) 91% male, 20% non-white, and 19% ≥100,000 c/mL HIV-1 RNA. 286 patients were randomized into the MP; 258 completed MP with 252 entering EP
- Table 1. Snapshot Outcomes at Week 160

Table 2. Adverse Events Through Week 160

Adverse Events
- Through Week 160, the most commonly reported non-injection-site reaction (ISR) adverse events (AEs) for the randomized Q8W-Q4W IM arms included nasopharyngitis (38%; 87/230), diarrhea (22%; 50/230), and headache (22%; 50/230)
- The most commonly reported non-ISR AEs for the randomized Q8W-Q4W IM arms included nasopharyngitis (14%; 6/44), back pain (11%; 5/44), and influenza (11%; 5/44)
- The most commonly reported non-ISR, drug related (per investigator) AEs for the optimized Q8W-Q4W IM arms were asthenia, fatigue and palpitations, each at 2% (1/44)

Conclusions
- CAB LA + RPV LA, dosed every 8 or 4 weeks, successfully maintained HIV-1 viral load <50 c/mL. The Week 160 data demonstrate long-term durability and tolerability of both dosing options
- 2 patients on LA dosing met PVDV criteria, no subjects after Week 48 across arms
- Good injection tolerability was demonstrated over time
- Majority of ISRs were grade 1/2 pain with a median duration of 3 days
- 4–7% of patients had an ISR that led to discontinuation through 3 years of dosing
- Q8W and Q4W dosing are both under evaluation in ongoing phase III studies

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