

#### IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M



# IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Design

- Background: Phase 3, randomized, open-label trial assessing IM CAB plus IM RPV maintenance ART administered every 8 weeks versus every 4 weeks
- Inclusion Criteria
  - Age ≥18 years
  - Taking an uninterrupted first or second oral standard of care ART regimen for ≥6 months
  - HIV RNA <50 copies/mL ≥6 months at screening and >2x in prior year
  - No history of virologic failure
  - No INSTI or NNRTI resistance, except that K103N mutation allowed

	Lead-In	Maintenance		
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	Oral 7 CAB + RPV	CAB 600 mg (3 mL) + RPV 900 mg (3 mL) 3 mL IM injections Every 8 weeks^ (n = 522)		
	Oral CAB + RPV	CAB 400 mg (2 mL) + RPV 600 mg (2 mL) 2 mL IM Injections Every 4 weeks <sup>#</sup> (n = 523)		

\*Some individuals enrolled from ATLAS trial; those already receiving IM CAB + RPV through ATLAS did not require oral lead-in for ATLAS-2M ^Participants first received loading doses of CAB 600 mg (3 mL) + RPV 900 mg (3 mL) 3 mL IM injections given at study weeks 4 and 8 #Participants first received loading dose of CAB 600 mg (3 mL) + RPV 900 mg (3 mL) 3 mL IM injections given at study week 4



## IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Baseline Characteristics

AILAS-2M:	Baseline	Charac	teristics

Characteristic	IM CAB + RPV Every 8 Weeks (n = 522)	IM CAB + RPV Every 4 Weeks (n = 523)
Age, years, median	42	42
Female sex at birth, n, %	137 (26)	143 (27)
White, n, %	370 (71)	393 (75)
Black, n, %	101 (19)	90 (17)
Median body-mass index	25.7	25.9
Median CD4 T-cell count	642	688
Previous exposure to long-acting CAB+RPV, n, %		
None	327 (63)	327 (63)
1-24 weeks	69 (13)	68 (13)
>24 weeks	126 (24)	128 (24)

Source: Overton ET, et al. Lancet. 2020:396:1994-2005.



## IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Results

Weeks 48: Virologic Response by FDA Snapshot Analysis



HIV RNA ≥50 copies/mL at 48 weeks: 9/522 (2%) in q8-week arm, 5/523 (1%) in q4-week arm



## IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Results

#### Participants with Viral Rebound Meeting Protocol-Defined Criteria for Genotype Resistance Testing

	Total Number of Participants	Archived (Baseline) RPV RAMs*	Archived (Baseline) INSTI RAMs*	RPV RAMs Detected at Time of VF	INSTI RAMs Detected at Time of VF
Q8 Weeks	8	5/8	1/8	6/8	5/8
Q4 Weeks	2	0/2	0/2	1/2**	2/2

\*Detected by archive (DNA) genotype

\*\*One participant had RPV RAMs; the other an NNRTI polymorphism that reduced RPV activity >100-fold

Abbreviations: RAMs = resistance associated mutations; VF = virologic failure



## IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Results

Injection Site Reactions (ISRs)*				
Types of Reactions	IM CAB + RPV Every 8 Weeks, n (%)	IM CAB + RPV Every 4 Weeks, n, %		
Participants who received injections, n	516	517		
Any reaction, n (%)	392 (76)	390 (75)		
Serious reaction, n (%)	1 (<10)	0 (0)		
Reaction leading to discontinuation, n (%)	6 (1)	11 (2)		
Pain, n (%)	371 (72)	363 (70)		
Nodule, n (%)	54 (10)	89 (17)		
Induration, n (%)	41 (8)	39 (8)		
Swelling, n (%)	32 (6)	27 (5)		

\*The majority of ISRs (98%) were grade 1-2.

Source: Overton ET, et al. Lancet. 2020:396:1994-2005.



#### IM Cabotegravir and IM Rilpivirine Every 2 Months for HIV Maintenance ATLAS-2M Study: Conclusions

**Conclusions**: "The efficacy and safety profiles of dosing every 8 weeks and dosing every 4 weeks were similar. These results support the use of cabotegravir plus rilpivirine long-acting administered every 2 months as a therapeutic option for people living with HIV-1."



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