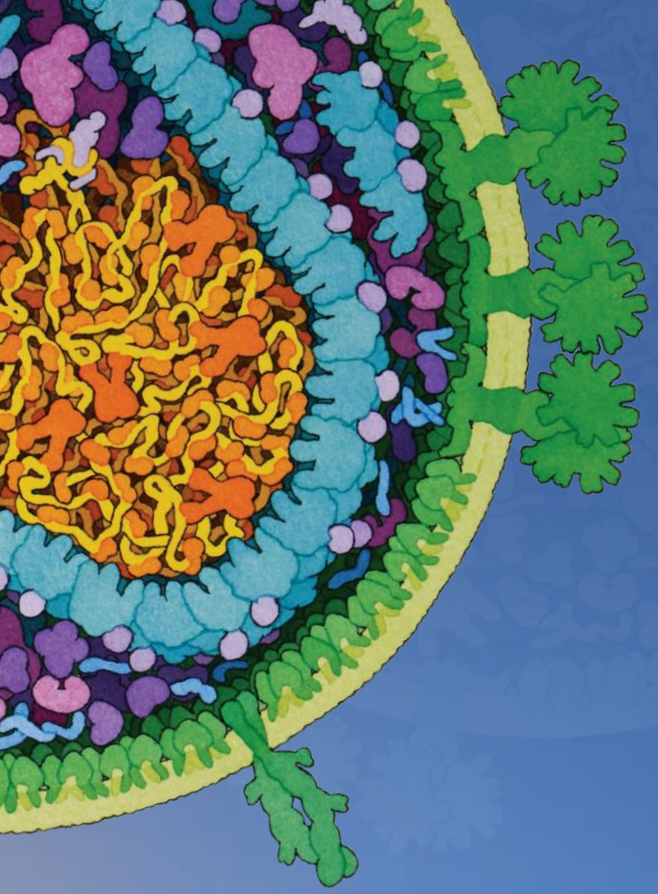

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LONG-ACTING CABOTEGRAVIR + RILPIVIRINE IN OLDER ADULTS: POOLED PHASE 3 WEEK 48 RESULTS

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Disclosure: *Employee of ViiV Healthcare and stockholder of GlaxoSmithKline

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CAB + RPV LA in Adults ≥50 Years of Age: Background

- Owing to the benefits of contemporary ART, there is an increasing proportion of PLWH aged ≥50 years[1]
- Cabotegravir (CAB), an INSTI, and rilpivirine (RPV), an NNRTI, have been approved in the US, Canada, and Europe as the first complete long-acting (LA) injectable regimen indicated for the maintenance of virologic suppression in PLWH[2–4]
- The Week 48 efficacy, safety and tolerability, adherence, and treatment satisfaction data pooled from ATLAS, FLAIR, and ATLAS-2M are presented, stratified by age, in order to compare outcomes for older participants (≥50 y [years]) vs. younger participants (<50 y)

ART, antiretroviral therapy; INSTI, integrase strand transfer inhibitor; PLWH, people living with HIV-1; NNRTI, non-nucleoside reverse transcriptase inhibitor.

1. Wing EJ. Int J Infect Dis. 2016;53:61–68.
2. ViiV Healthcare. Cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension (Cabenuva) Prescribing Information. US, January 2021.
3. ViiV Healthcare. Vocabria Summary of Product Characteristics. EU, January 2020.
4. ViiV Healthcare. Vocabria (cabotegravir tablets) and Cabenuva (cabotegravir and rilpivirine extended release injectable suspensions) Product Monograph. Canada, March 2020.

CAB + RPV LA in Adults ≥50 Years of Age: Methods

- Pooled data from ATLAS, FLAIR, and ATLAS-2M were stratified by age (≥50 y and <50 y)
- Data from ATLAS-2M participants who transitioned to ATLAS-2M from CAB + RPV in ATLAS were excluded. This ensured all participants included in the analysis had only 48 weeks of CAB + RPV follow-up
- Week 48 efficacy endpoints (FDA Snapshot, intention-to-treat exposed) were:
  - Proportion of participants with plasma HIV-1 RNA ≥50 copies/mL (virologic non-response)
  - Proportion of participants with plasma HIV-1 RNA <50 copies/mL (virologic suppression)
- Other secondary endpoints at Week 48 included:
  - Incidence of CVF (two consecutive measurements of ≥200 copies/mL)
  - Safety
  - Adherence
  - Treatment satisfaction (as measured by HIVTSQs)

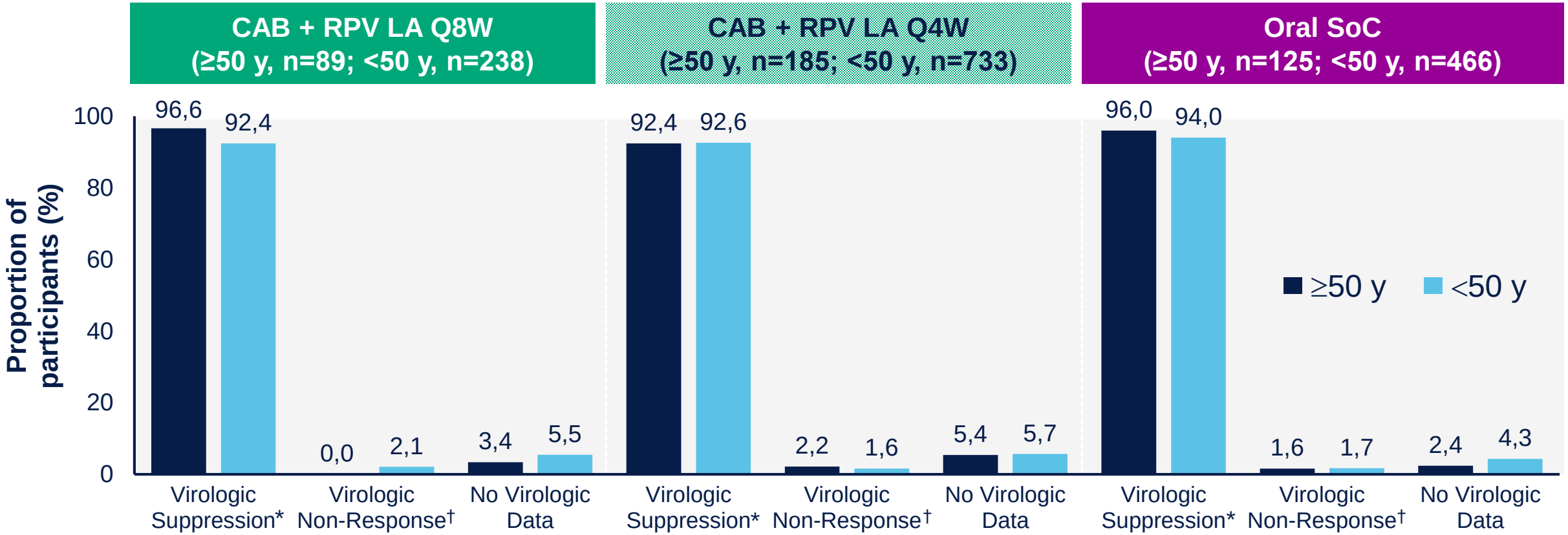
CAB, cabotegravir; CVF, confirmed virologic failure; FDA, U.S. Food and Drug Administration; HIVTSQs, HIV Treatment Satisfaction Questionnaire (status version); LA, long-acting; RPV, rilpivirine; y, years.

CAB + RPV LA in Adults ≥50 Years of Age: Baseline Characteristics

	CAB + RPV LA Q8W, n (%)		CAB + RPV LA Q4W, n (%)		Oral SoC, n (%)	
Parameter	**≥50 y, n=89**	**<50 y, n=238**	**≥50 y, n=185**	**<50 y, n=733**	**≥50 y, n=125**	**<50 y, n=466**
Female (sex at birth)	24 (27)	49 (21)	64 (35)	173 (24)	48 (38)	120 (26)
Age, median (range, years)	56 (50–83)	37 (20–49)	55 (50–74)	36 (19–49)	55 (50–82)	35 (18–49)
Body mass index ≥30 kg/m^2	16 (18)	43 (18)	37 (20)	115 (16)	30 (24)	73 (16)
Race						
White	69 (78)	169 (71)	140 (76)	546 (74)	89 (71)	319 (68)
Comorbidities* at baseline						
0	12 (13)	70 (29)	28 (15)	221 (30)	21 (17)	183 (39)
1–2	33 (37)	81 (34)	54 (29)	290 (40)	37 (30)	159 (34)
≥3	44 (49)	87 (37)	103 (56)	222 (30)	67 (54)	124 (27)
Cardiovascular risk factor†	41 (46)	46 (19)	68 (37)	106 (14)	51 (41)	55 (12)
Metabolism and nutrition disorder	27 (30)	39 (16)	55 (30)	99 (14)	35 (28)	46 (10)
Musculoskeletal and connective tissue disorder	23 (26)	33 (14)	49 (26)	88 (12)	38 (30)	39 (8)
Psychiatric disorder	19 (21)	55 (23)	51 (28)	156 (21)	36 (29)	81 (17)
Gastrointestinal disorder	16 (18)	28 (12)	51 (28)	114 (16)	27 (22)	58 (12)
Skin and subcutaneous tissue disorder	17 (19)	42 (18)	28 (15)	107 (15)	21 (17)	63 (14)
Comedications at baseline						
0	22 (25)	96 (40)	26 (14)	225 (31)	9 (7)	136 (29)
1–2	30 (34)	82 (34)	64 (35)	290 (40)	35 (28)	186 (40)
≥3	37 (42)	60 (25)	95 (51)	218 (30)	81 (65)	144 (31)

*The six most common comorbidities are listed. †Includes angina pectoris, diabetes, hyperlipidemia, hypertension, myocardial infarction, and stroke.
CAB, cabotegravir; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; SoC, standard of care; RPV, rilpivirine; y, years.

CAB + RPV LA in Adults ≥50 Years of Age: Virologic Outcomes Were Similar Across Arms and Age Groups



- Rates of virologic suppression were high (~92–97%) and rates of virologic non-response were low (~2%)
- The incidence of CVF was low across treatment arms and comparable by age group
  - Q8W: ≥50 y, 0%; <50 y, 2.1%; Q4W: ≥50 y, 1.1%; <50 y, 1.0%; SoC: ≥50 y, 0.8%; <50 y, 1.3%

*HIV-1 RNA <50 copies/mL. †HIV-1 RNA ≥50 copies/mL.
CAB, cabotegravir; CVF, confirmed virologic failure; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; SoC, standard of care; RPV, rilpivirine; y, years.

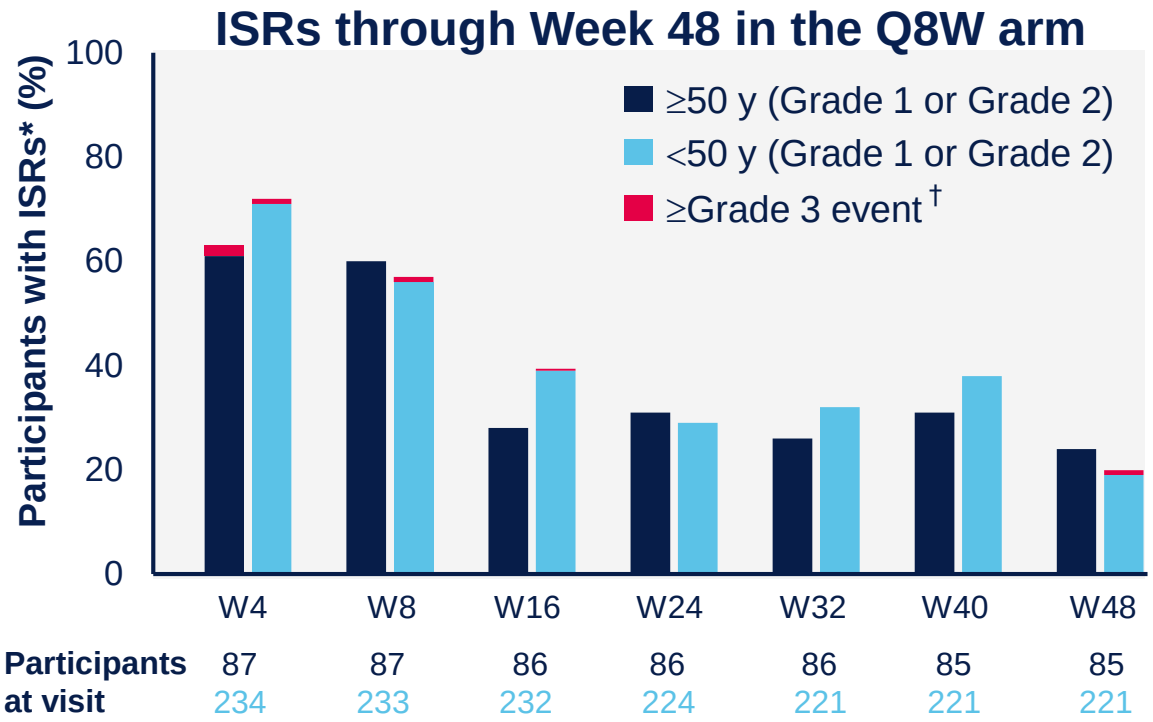
CAB + RPV LA in Adults ≥50 Years of Age: Safety Profiles Were Similar Across Arms and Age Groups at Week 48

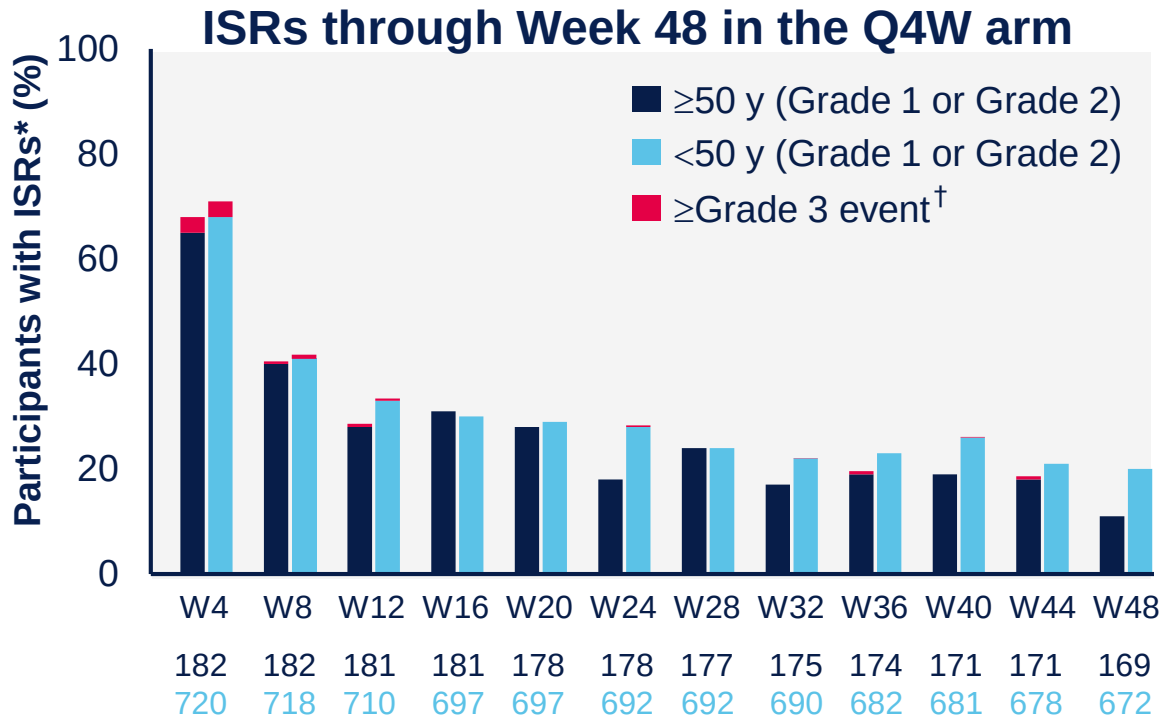
Parameter	CAB + RPV LA Q8W, n (%)		CAB + RPV LA Q4W, n (%)		Oral SoC, n (%)	
	≥50 y n=89	<50 y n=238	≥50 y n=185	<50 y n=733	≥50 y n=125	<50 y n=466
Any AE	81 (91)	222 (93)	176 (95)	692 (94)	99 (79)	367 (79)
Drug-related	69 (78)	203 (85)	155 (84)	606 (83)	11 (9)	85 (18)
AEs leading to withdrawal	4 (4)	5 (2)	7 (4)	25 (3)	3 (2)	6 (1)
Drug-related	3 (3)	3 (1)	6 (3)	14 (2)	0	4 (<1)
Any serious AE	6 (7)	9 (4)	7 (4)	30 (4)	4 (3)	25 (5)
Drug-related*	0	1 (<1)	1 (<1)	1 (<1)	0	1 (<1)

- Safety profiles of participants ≥50 y and <50 y were similar for both LA regimens, and similar to that of SoC (excluding ISRs)
- Few AEs led to withdrawal

*Includes right knee monoarthritis (n=1), suicidal ideation (n=1), injection site abscess (n=1), and hypersensitivity and suspected (partial) intravenous administration of RPV (n=1).
AE, adverse event; CAB, cabotegravir; ISR, injection site reaction; LA, long-acting; Q4W, every 4 weeks, Q8W, every 8 weeks; SoC, standard of care; RPV, rilpivirine; y, years.

CAB + RPV LA in Adults ≥50 Years of Age: ISRs Decreased in Incidence Across Both LA Arms and Age Groups

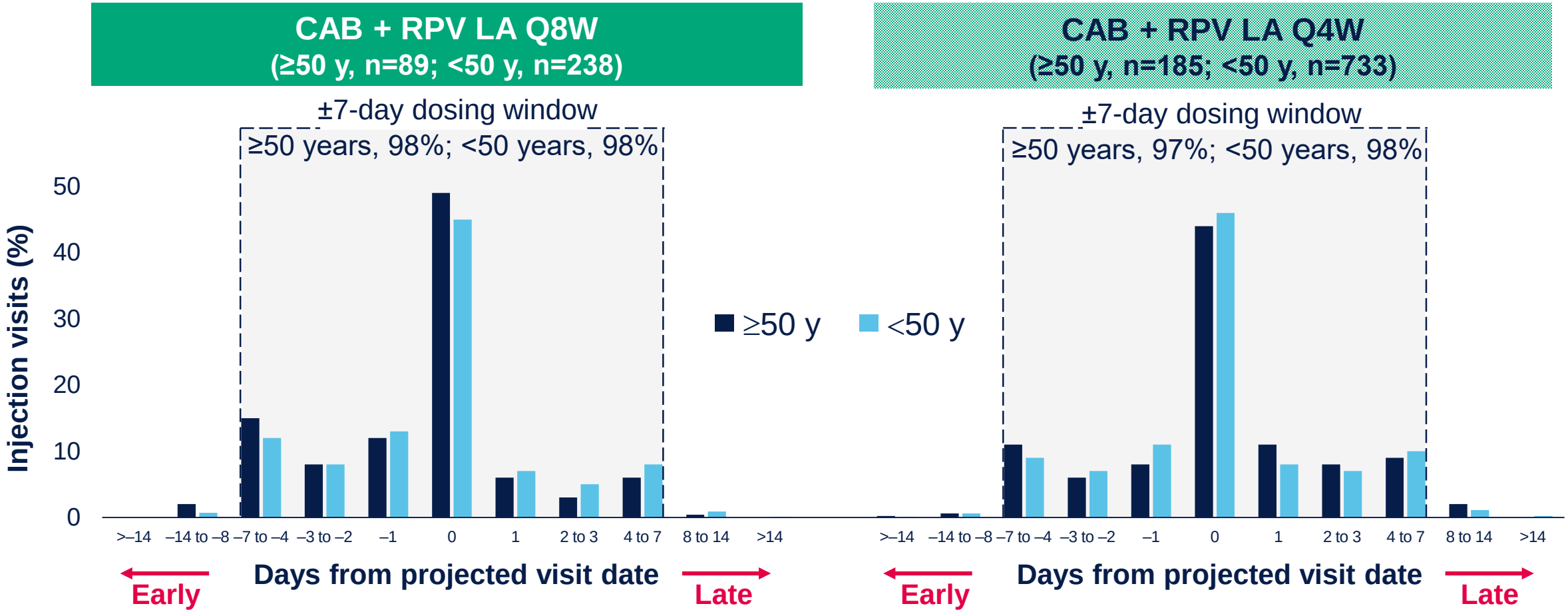




- Participants aged ≥50 y and <50 y experienced similar types of ISRs, with injection site pain the most commonly observed (21% of all injections)
- Overall, most ISRs were classified as Grade 1 (80%) or 2 (18%), the majority had a duration ≤7 days (median duration of 3 days), and few led to withdrawal

An error was found in the analysis of the ISR data included in the abstract. This has been corrected for this presentation but remains uncorrected in the abstract.
*AE grade is the maximum grade reported by the participant at each visit. †There were no Grade 4 or Grade 5 ISRs.
AE, adverse event; CAB, cabotegravir; ISR, injection site reaction; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; W, week; y, years.

CAB + RPV LA in Adults ≥50 Years of Age: High Rates of Adherence Between Age Groups and Dosing Regimens

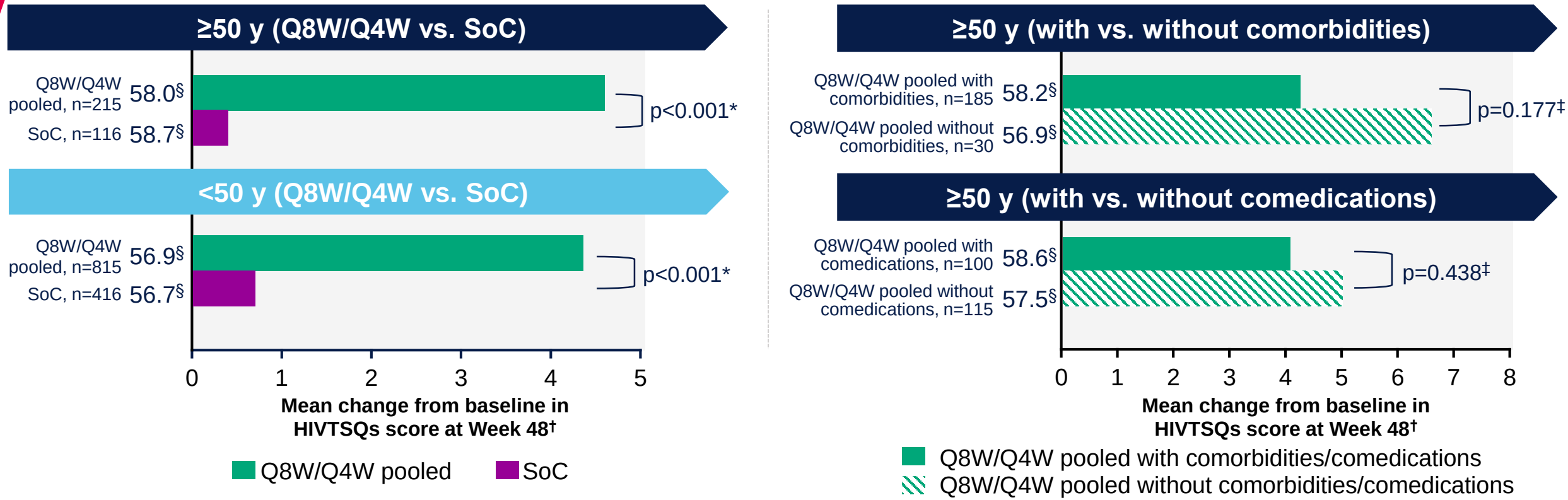


- Adherence to the LA regimen was comparable between age groups and dosing regimens, with ~98% of the total injection visits occurring within the ±7-day dosing window

CAB, cabotegravir; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; y, years.

CAB + RPV LA in Adults ≥50 Years of Age:

High Treatment Satisfaction Irrespective of Age Group or Comorbidities/Comedication



- Irrespective of age group, mean change from baseline in HIVTSQs score was significantly greater in participants receiving LA therapy in comparison to participants receiving SoC
- When stratified for the presence of comorbidities and comedications, no significant differences were observed in mean change from baseline in HIVTSQs score for participants aged ≥50 y receiving LA therapy

*P-value for difference of means ([Q4W+Q8W]–CAR). †As HIVTSQs score was not collected at Week 48 in the ATLAS and FLAIR study, Week 44 values from ATLAS and FLAIR were pooled with Week 48 scores from ATLAS-2M.
‡P-value for difference of means (individuals with comorbidities/comedications vs. individuals without). §Mean baseline HIVTSQs score.
CAB, cabotegravir; CAR, current antiretroviral regimen; HIVTSQs, HIV Treatment Satisfaction Questionnaire (status version); LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; SoC, standard of care; RPV, rilpivirine; y, years.

CAB + RPV LA in Adults ≥50 Years of Age: Conclusions

- CAB + RPV LA demonstrated similar efficacy, safety, and tolerability between participants aged ≥50 y and <50 y
- CVF was infrequent and occurred at a similar rate between participants aged ≥50 y and <50 y
- Adherence to CAB + RPV LA was comparable between participants aged ≥50 y and <50 y
- Treatment satisfaction improved with CAB + RPV LA and was comparable by age, with no significant difference observed between participants with and without comorbidities and comedications who were aged ≥50 y
- These data support the therapeutic potential of CAB + RPV LA in PLWH aged ≥50 y

CAB, cabotegravir; CVF, confirmed virologic failure; LA, long-acting; PLWH, people living with HIV-1; RPV, rilpivirine; y, years.

Acknowledgments

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