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Real world use of lenacapavir in France: a national, observational study

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PURPOSE

French guidelines recommend lenacapavir (LEN) for persons with HIV (PWH) with multidrug-resistant virus who cannot achieve viral suppression with oral antiretroviral therapy (ART).

Since June 2023, the early access program for LEN has ended, and the drug is now commercially available. However, due to its high cost and limited indications, prescriptions must be validated locally in hospitals by a multidisciplinary committee.

The LENAddOn national study aims to:

1. **Characterize PWH initiating LEN post-early access programme in France,**
2. **Assess LEN continuation rates at M6 and M12,**
3. **Describe reasons for LEN discontinuation.**

METHODS

We conducted an observational, retrospective study across 19 centres, including people with HIV-1 who initiated LEN between 20/06/2023 and 30/06/2024.

Socio- demographic, clinical, and laboratory data were extracted from medical records.

The primary outcome was the proportion of individuals receiving a second LEN injection 6 months after initiation (M12 data pending). We collected reasons for switching to LEN. Safety and virological efficacy of LEN-based regimens were also evaluated.

Study was approved by the Sud-Est II Ethics Committee (ref. number: 24.05319.000402).

CONCLUSIONS

PWH receiving LEN-based ART in France since its commercialization (after the end of the early access program) had distinct profiles compared to participants in the pivotal CAPELLA trial(ref.). Some of these PWH were experiencing virological failure, with multidrug-resistant viruses, but more than two-thirds had a pVL <200 cp/mL when LEN was initiated. LEN simplified antiretroviral combinations in PWH with multiple vulnerability factors and difficulties with oral ART.

The LEN continuation rate was high (94.8%) at M6, with good treatment tolerance reported (no interruption of injections due to ISRs). When the recommended schedule was not respected, injections were most often administered in advance.

This data will soon be supplemented by M12 data.

RESULTS

77 PWH were included, with frequent histories consistent with adherence issues and vulnerability factors (**Table 1**).

Table 1. Patient characteristics.

Age, years, median (IQR)	57 (44-63)
Gender, n (%)	
- Cis-men	52 (67.5)
- Cis-women	24 (31.2)
- Trans-woman	1 (1.3)
Birth country, n (%)	
- France	49 (63.6)
- Other	28 (36.4)
Transmission route, n (%)	
- MSM	28 (36.4)
- Heterosexual	32 (41.5)
- Other	17 (22.1)
Time from HIV diagnosis, years, median (IQR)	30 (21-34)
CD4 nadir, cells/µL, median (IQR)	58 (10-142)
AIDS-defining event, n (%)	47 (61.0)
HBV coinfection, n (%)	5 (6.5)
Time from ART initiation, years, median (IQR)	25 (17-29)
Vulnerability factors, n (%)	
- No stable employment	33 (42.9)
- Insufficient financial resources to cover basic needs	16 (20.8)
- Irregular administrative status	7 (9.1)
- Homeless	6 (7.8)
- Poor level of French	3 (3.9)
Psychiatric issues, n (%)	17 (22.1)
Problems with HIV / ART, n (%)	
- Previous unplanned ART discontinuations	30 (39.0)
- Difficulties in adhering to oral ART	35 (45.5)
- Non-acceptance of HIV	17 (22.1)
- Poor understanding of HIV and/or ART	14 (18.2)
- Stigmatisation from friends and relatives	6 (7.8)
Addictive behaviours, n (%)	
- Smoking	20 (26.0)
- Chronic alcoholism	4 (5.2)
- Drug use	1 (1.3)
Plasma viral load (pVL) at LEN initiation, n (%)	
- <50 cp/mL	43 (55.8)
- 50-199 cp/mL	12 (15.6)
- ≥200 cp/mL	22 (28.6)
CD4 count at LEN initiation, cells/µL, median (IQR)	418 (174-700)

Participants had a median of 6 prior RNA/DNA genotypes per patient (IQR 3-10, range 1-26) (**Table 2**). Cumulatively, 42 participants (54.6%) had viral resistance to ≥2 drugs in ≥3 classes.

At LEN initiation, 22 participants (28.6%) had a pVL ≥200 copies/mL and 43 (55.8%) a pVL <50 copies/mL (**Table 1**).

Main reasons for LEN initiation were multidrug resistance (63.6%), adherence challenges (35.1%), person-requested treatment simplification (27.3%), poor tolerability of oral ART (19.5%) and avoidance of drug-drug interactions (19.5%) (**Figure 1**).

Table 2. History of ART resistance.

NRTIs	
Zidovudine, n (%)	44 (57.1)
3TC / FTC, n (%)	56 (72.7)
Abacavir, n (%)	60 (77.9)
Tenofovir, n (%)	45 (58.4)

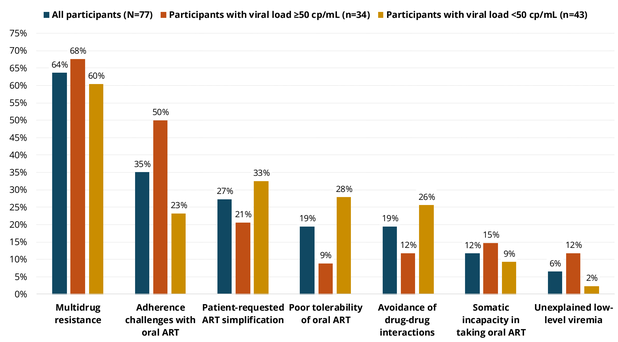
PIs	
Lopinavir, n (%)	42 (54.5)
Atazanavir, n (%)	48 (62.3)
Darunavir QD, n (%)	27 (35.1)
Darunavir BID, n (%)	15 (19.5)

NNRTIs	
Nevirapine, n (%)	62 (80.5)
Efavirenz, n (%)	61 (79.4)
Rilpivirine, n (%)	63 (81.8)
Etravirine, n (%)	55 (71.4)
Doravirine, n (%)	50 (64.9)

INSTIs	
Raltegravir, n (%)	31 (40.3)
Elvitegravir, n (%)	32 (41.6)
Dolutegravir QD / bictegravir / cabotegravir, n (%)	26 (33.8)
Dolutegravir BID, n (%)	16 (20.8)

In this table, resistance was considered in case of partial of full resistance, according to the last version of the French ANRS-MIE algorithm.

Figure 1. Clinician-reported reasons for LEN use, according to pVL at LEN initiation.



21 participants (27.3%) received a fully injectable ART: 16 with LEN plus cabotegravir, and 5 with LEN + cabotégravir + rilpivirine.

59.7% of participants had a genotypic sensitivity score (GSS) ≥2 before LEN initiation, which increased to 91.9% after LEN initiation (p<0.001). The proportion of participants with 3 or more molecules included in the oral ART before and after LEN initiation decreased from 37.7% to 22.1% (p<0.001).

For the oral loading dose of LEN, 30 participants (39.0%) received 600 mg on D1, 600 mg on D2, and 300 mg on D8 with a LEN 927 mg SC injection on D15, while 47 (61.0%) received 600 mg on D1 and 600 mg on D2 with a LEN 927 mg SC injection on D1.

LEN continuation rate was 94.8% (95%CI 87.2-98.6) at M6, with 4 treatment discontinuations due to persistence of viral replication (n=2, participants with multiresistant viruses), lost to follow-up (n=1) and death (n=1, metastatic squamous cell carcinoma of the cervix) (**Table 3**).

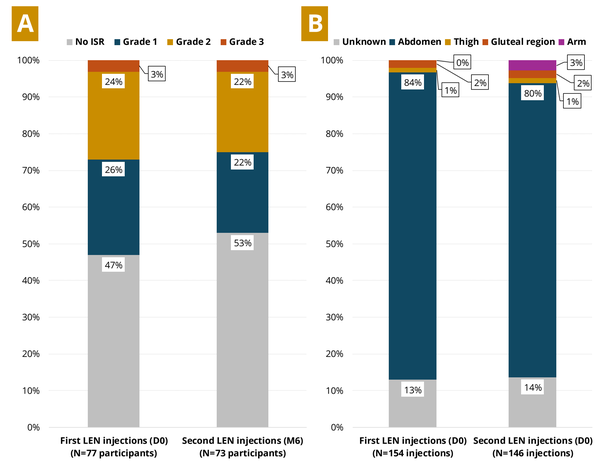
Table 3. LEN discontinuations at M6.

Cause of LEN discontinuation	n/N (%)
Lost to follow-up	1/77 (1.3%)
Death	1/77 (1.3%)
Persistence of viral replication	2/77 (2.6%)

Injection site reactions (ISRs) were reported in 41/77 participants (53.2%) at time of first injections (D0), and 34/73 (46.6%) at time of second injections (M6) (**Figure 2A**). It included 2 grade 3 ISRs at time of first injections (pain + nodule +/- erythema) that did not lead to LEN discontinuation, and 2 grade 3 ISRs at time of second injections (pain + nodule +/- erythema as well).

No other grade ≥3 clinical or biological adverse events (AEs) were reported between first and second LEN injections.

Figure 2. Injection sites (A) and injection site reactions (B) at D0 and M6.



Among participants for whom data was available, 96.3% (129/134) of D0 injections and 92.9% (117/126) of M6 injections were administered in the abdomen (**Figure 2B**).

At M6, injections were 'on time' for 59/73 PWH (80.8%), early for 11/73 (15.1%, with a median duration between injections of 22.4 weeks, IQR 21.0-23.4), and late for 3 (4.1%, with a median duration between injections of 28.4 weeks, IQR 28.1-30.0).

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Reference:

Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. Segal-Maurer S, et al. 2022. NEJM.