Dolutegravir-Lamivudine as Initial Therapy in HIV-infected, ARV Naive Patients: First Results of the PADDLE Trial

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Abstract LBPS4/1

PADDLE STUDY: Design

DTG + 3TC for ART Naïve Patients
Phase IV, Pilot, Open-Label, Single Arm Exploratory Trial

ARV- Naïve Patients,
≥18 Years
HIV-1 RNA
>5,000 Copies/mL and <100,000 Copies/mL
CD4 Count ≥200 Cells/mL
HB(s)Ag Negative
(n= 20)

1st Cohort (n= 10)	2nd Cohort (n= 10)
DTG 50 mg QD LMV 300 mg QD	DTG 50 mg QD LMV 300 mg QD

Second Cohort to Be Enrolled After Confirming Success of First Cohort at Week 8

Viral Load was Measured at Baseline,
Days 2,4,7,10,14, and Weeks 4,8,12 and 24

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PADDLE STUDY: Baseline Characteristics

Baseline Characteristics	DTG/3TC n=20
Gender (Male:Female)	19/1
Age, Years, Median (IQR)	34 (31-43)
Mode of Transmission (n) MSM Heterosexual	 15 5
HIV RNA (Copies/mL), Median (IQR)	24,128 (11,686-36,794)
CD4 Count, Cells/mm^3, Median (IQR)	507 (296-517)
CDC Stage (%) A/B/C	 90/10/0

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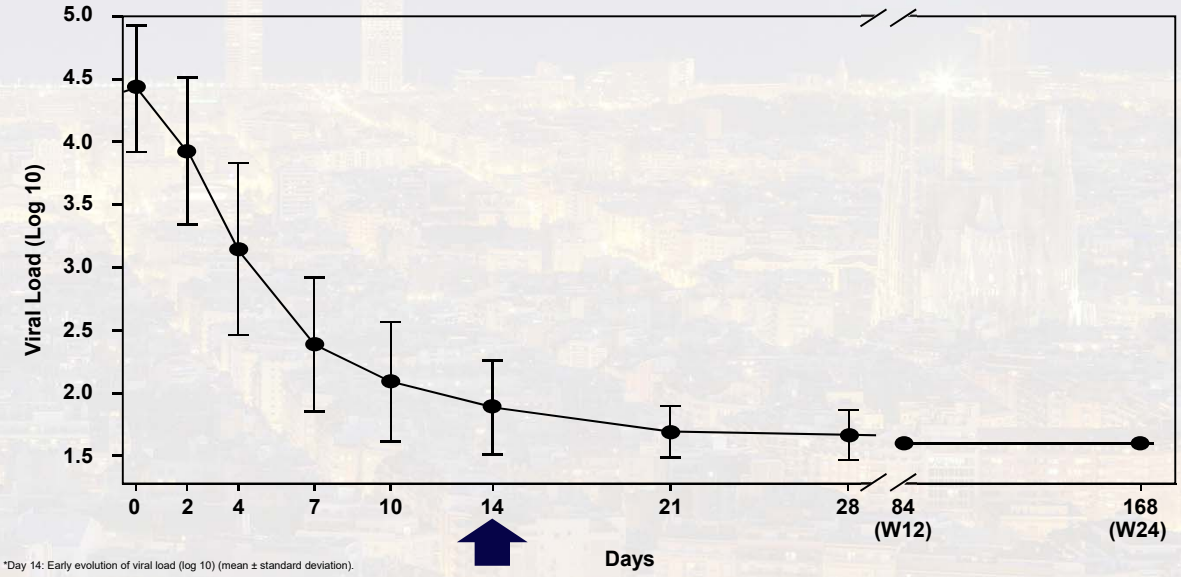
PADDLE STUDY: Viral Load Decay



*Day 14: Early evolution of viral load (log 10) (mean ± standard deviation).

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PADDLE STUDY: Viral Suppression and CD4 Change at Week 24

#	SCR	BSL	DAY 2	DAY 4	DAY 7	DAY 10	W.2	W.3	W.4	W.6	W.8	W.12	W.24
1	5.584	10.909	3.701	383	101	71	< 50	< 50	< 50	< 50	< 50	< 50	< 50
2	8.887	10.233	5.671	318	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
3	67.335	151.569	37.604	1.565	1.178	266	97	53	< 50	< 50	< 50	< 50	< 50
4	99.291	148.370	11.797	3.303	432	179	178	55	< 50	< 50	< 50	< 50	< 50
5	34.362	20.544	4.680	1.292	570	168	107	< 50	< 50	< 50	< 50	< 50	< 50
6	16.024	14.499	3.754	1.634	162	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
7	37.604	18.597	2.948	819	61	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
8	25.071	24.368	6.264	1.377	Not done	268	105	< 50	< 50	< 50	< 50	< 50	< 50
9	14.707	10.832	Not done	516	202	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
10	10.679	7.978	5.671	318	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
11	50.089	273.676	160.974	68.129	3.880	2.247	784	290	288	147	< 50	< 50	< 50
12	13.508	64.103	3.496	3.296	135	351	351	84	67	< 50	< 50	< 50	< 50
13	28.093	33.829	37.350	26.343	539	268	61	< 50	< 50	< 50	< 50	< 50	< 50
14	15.348	15.151	3.994	791	198	98	< 50	61	64	< 50	< 50	< 50	< 50
15	23.185	23.500	15.830	4.217	192	69	< 50	< 50	< 50	Not done	< 50	< 50	< 50
16	11.377	3.910	370	97	143	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50
17	39.100	25.828	11.879	1.970	460	147	52	< 50	< 50	< 50	< 50	< 50	< 50
18	60.771	73.069	31.170	2.174	692	358	156	< 50	< 50	< 50	< 50	< 50	< 50
19	82.803	106.320	35.517	2.902	897	352	168	76	< 50	< 50	< 50	< 50	< 50
20	5.190	7.368	3.433	147	56	< 50	< 50	< 50	< 50	< 50	< 50	< 50	< 50

CD4 Change at W24: 204.35
No Grade 3-4 Laboratory Toxicities Were Reported Through 24 Weeks
No SAEs Reported

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PADDLE STUDY: Adverse Events

	Adverse Events possibly related to DTG	
AE	GRADE I	GRADE II
Somnolence	1	
Epigastric pain	1	
Headache	2	1
Diarrhea	1	
Nausea	2	

No Grade 3-4 Laboratory Toxicities Were Reported Through 24 Weeks
No SAEs Reported

All AEs were reported at the first week of treatment

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