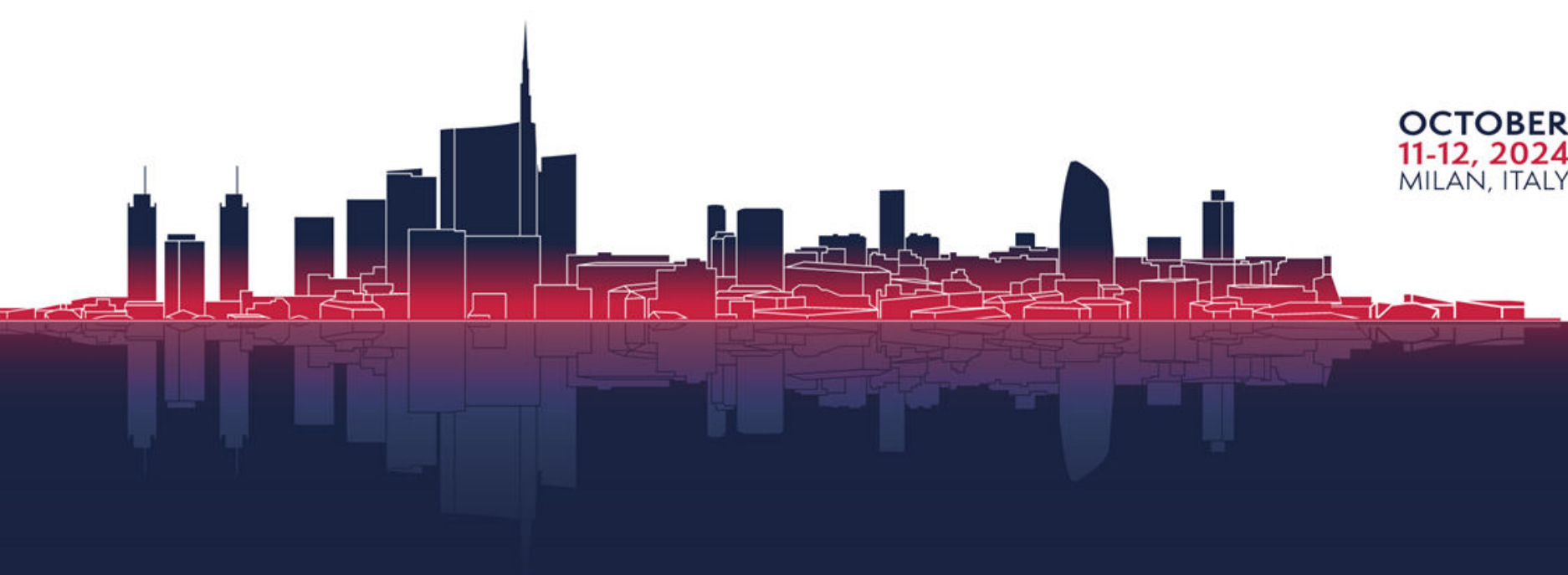

OCTOBER 11-12, 2024 MILAN, ITALY

DeltaCure 3rd International Meeting

Bulevirtide in EU: SAVE-D Study Update

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Elisabetta Degasperi - COIs

- Research Grant: Gilead Sciences
- Travel Support: Advanz Pharma, Gilead Sciences
- Advisory Board: Roche
- Speaker Bureau: Abbvie, Gilead Sciences

SAVE-D Study: Materials and Methods

Study Design	Retrospective, multicenter, investigator-driven, real-world
Enrolling Centers	46 European Centers (Italy, France, Austria, Germany, Greece, Portugal, Sweden, Switzerland, United Kingdom)
Enrollment Period	September 2019 – February 2023
Inclusion Criteria	Consecutive HDV patients with cirrhosis starting BLV
Treatment	BLV 2 mg/day monotherapy self-administered (s.c. injections)
Monitoring	Baseline and every 24 weeks or according to investigator discretion
Primary Endpoint	Virological response (HDV RNA ≥2 Log IU/mL decline or undetectable) HDV RNA levels tested locally°
Secondary Endpoints	HDV RNA undetectable Biochemical response (ALT normalization§) Combined response (virological and biochemical response) Adverse events (AEs) Liver-related events and mortality

§ALT<40 U/l (EASL criteria); °Robogene 2.0 (LOD 6 IU/mL), Eurobioplex (LOD 100 IU/mL), Bosphore V1 (LOD 45 cp/mL), in-house PCR (LOD 100 cp/mL) most used assays
HDV: hepatitis Delta Virus; BLV: Bulevirtide; ALT: alanine aminotransferase; AE: adverse event

Patients' Features at Baseline (BLV start)

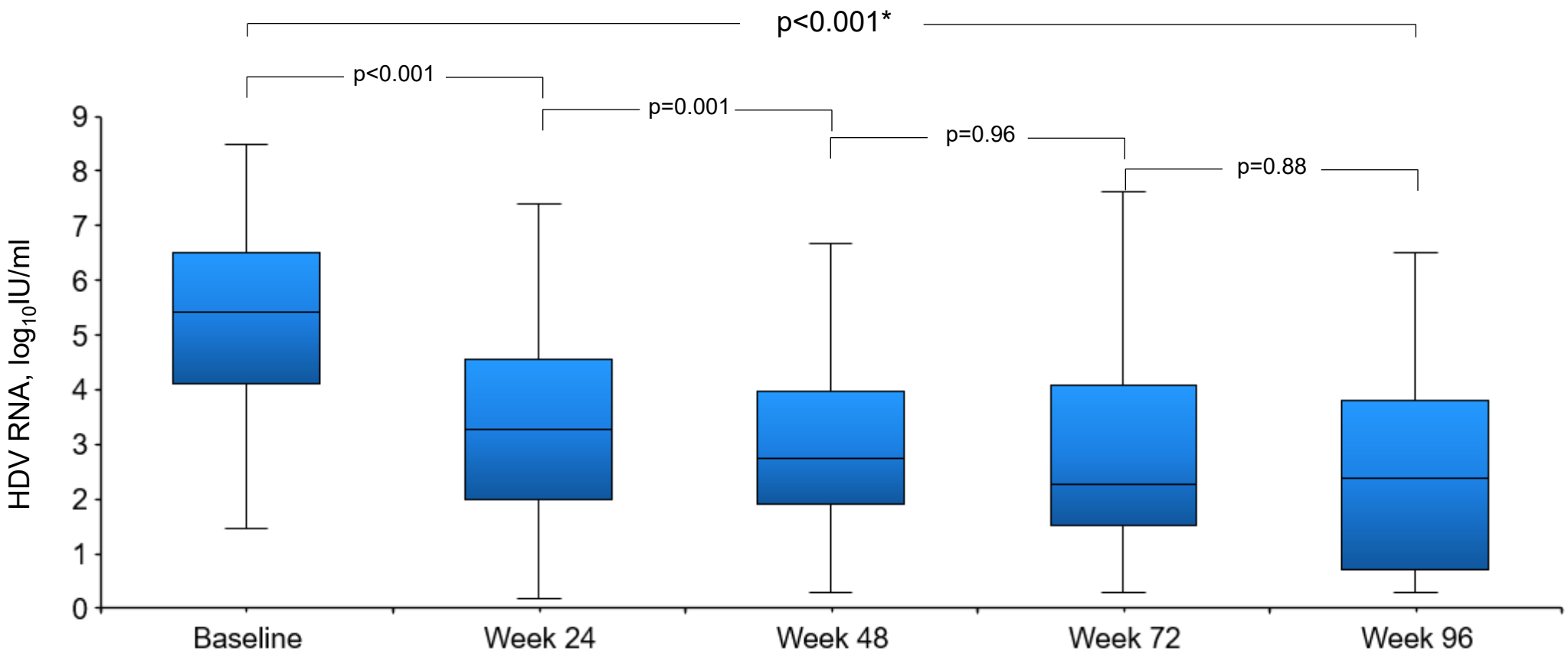
Baseline Variables	Overall (n=244)
Age, years	49 (40-58)
Males	148 (61%)
Caucasians	201 (82%)
HDV genotype 1*	77 (94%)
HIV coinfection°	24 (10%)
BMI, Kg/m^2	25 (23-28)
CPT score A§	233 (95%)
Spleen diameter, cm	15 (12-17)
Esophageal varices@	91 (54%)
Previous decompensation+	37 (15%)
History of HCC#	18 (7%)
Previous IFN treatment	142 (58%)
NUC treatment	224 (92%)

Baseline Variables	Overall (n=244)
LSM, kPa	18.3 (13.0-26.0)
Bilirubin, mg/dL	0.9 (0.6-1.4)
AST, U/L	75 (54-113)
ALT, U/L	80 (55-130)
GGT, U/L	68 (39-114)
Albumin, g/dL	3.9 (3.5-4.3)
Creatinine, mg/dL	0.8 (0.7-0.9)
PLT, 10^3/mm^3	94 (67-145)
Bile acids, µmol/L	15 (9-32)
qHBsAg, Log IU/mL	3.8 (3.4-4.1)
HBeAg negative	227 (93%)
HBV DNA detectable°°	55 (21%)
HDV RNA, Log IU/mL	5.4 (4.1-6.5)

*available in 82 patients; °all patients HIV RNA undetectable; §CPT A6 in 59 (24%), CPT B7 in 11 (5%); @available in 169 (69%) patients; 62 (37%) on prophylaxis; +ascites in 30 (12%), bleeding in 7 (3%); #active HCC in 14 (6%); °°according to local laboratory, median 1.4 (1.0-1.5) logIU/mL

Values are expressed as number (percentage) or median (IQR)

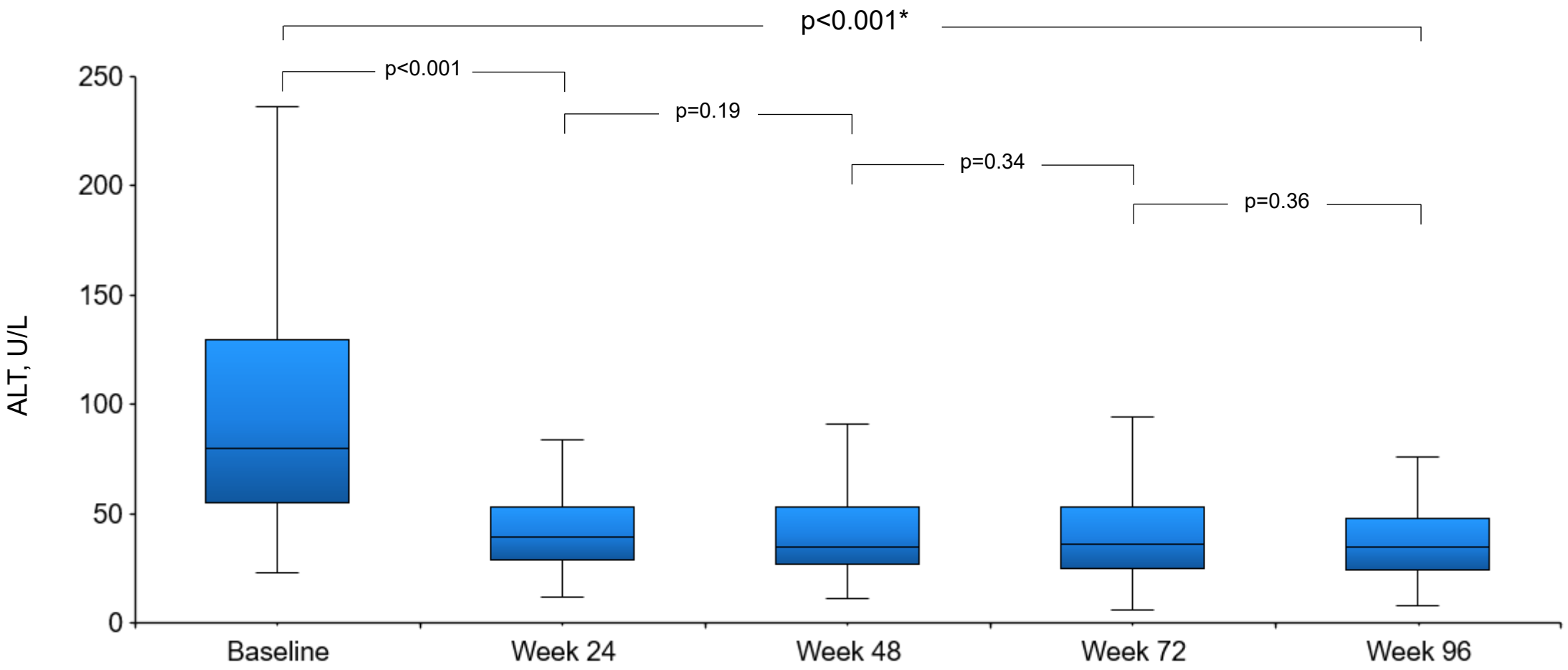
HDV RNA Levels During BLV Monotherapy



	Baseline	Week 24	Week 48	Week 72	Week 96
Pts n°	244	242	209	164	87
Median IQR	5.4 (4.1-6.5)	3.3 (2.0-4.6)	2.7 (1.9-4.0)	2.3 (1.5-4.1)	2.4 (0.7-3.8)
HDV RNA Decline (Log)		**1.8 (1.0-2.7)**	**2.5 (1.3-3.7)**	**2.5 (1.3-3.9)**	**2.7 (1.6-4.1)**

* All timepoints *vs.* baseline

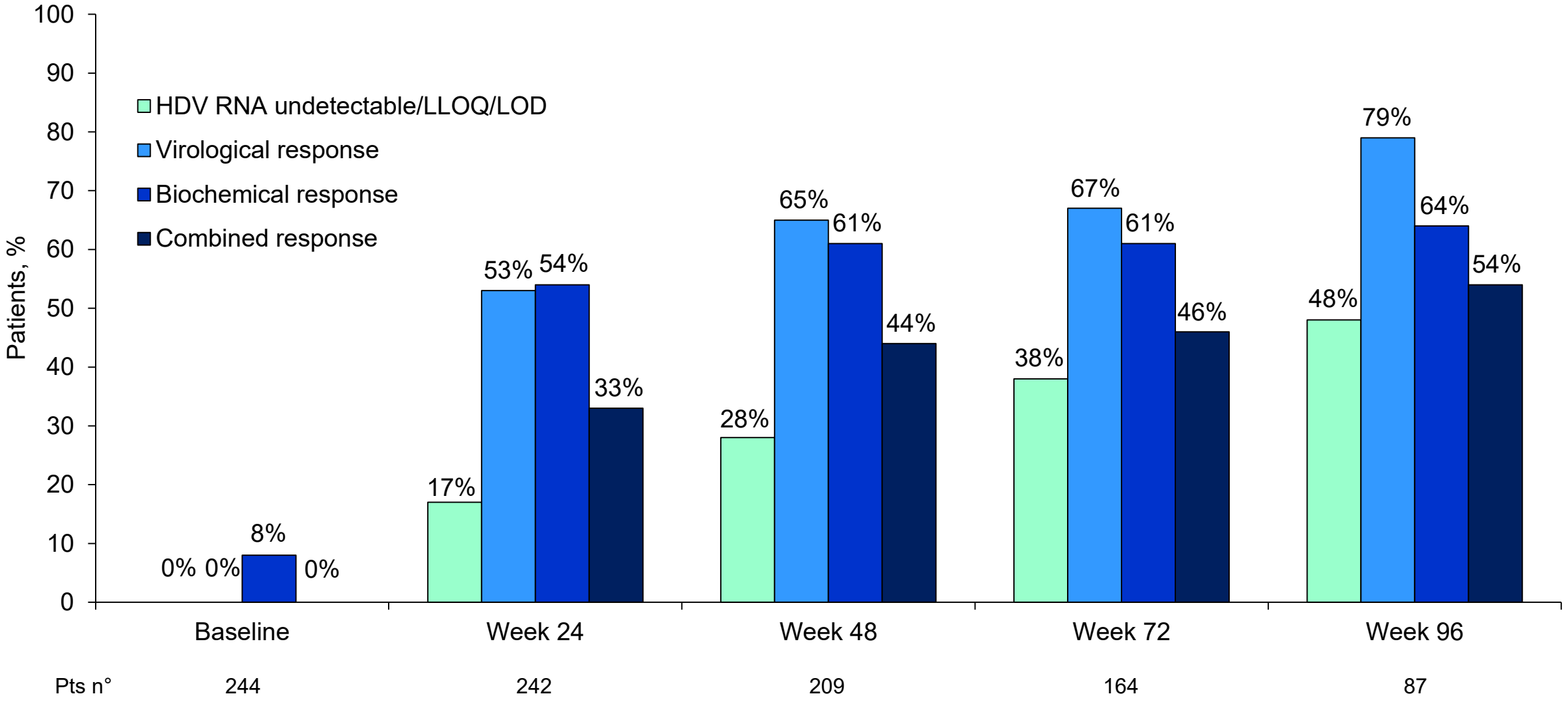
ALT Levels During BLV Monotherapy



	Baseline	Week 24	Week 48	Week 72	Week 96
Pts n°	244	242	209	164	87
Median IQR	80 (55-130)	39 (29-53)	35 (27-53)	36 (25-53)	35 (24-48)

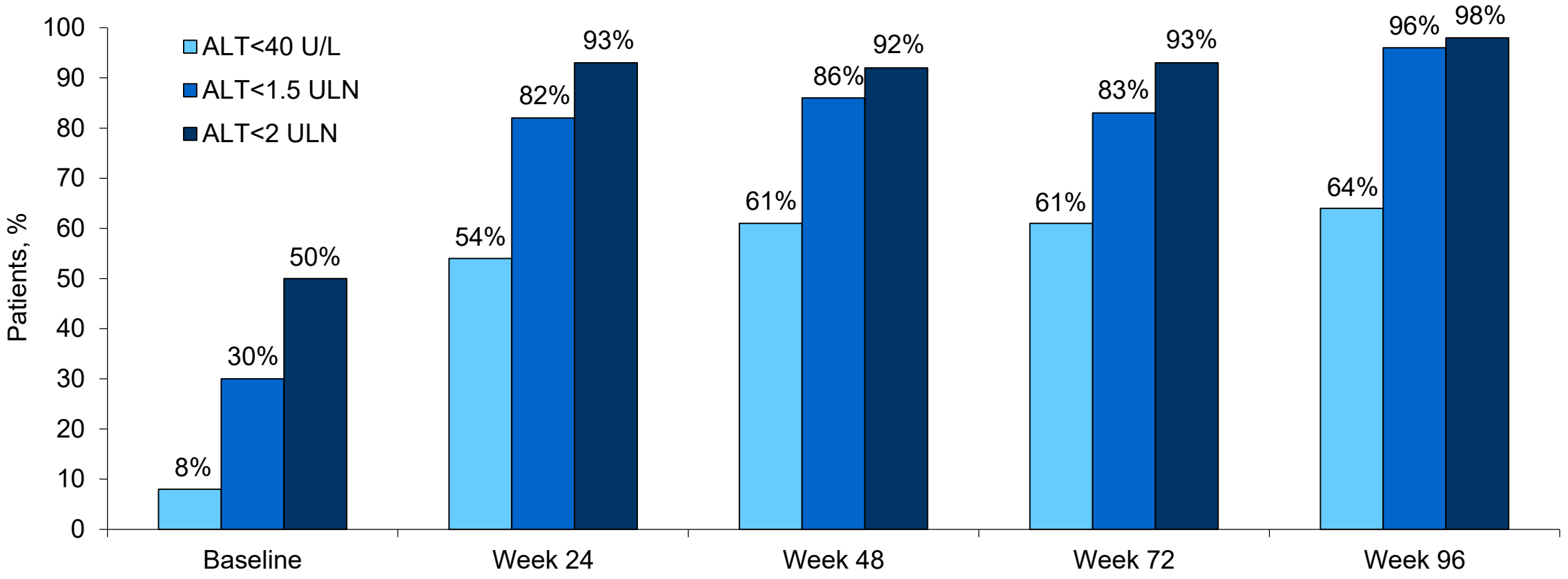
* All timepoints *vs.* baseline

Effectiveness of BLV Treatment Up to 96 Weeks



Virological response: Undetectable HDV RNA or ≥2 log decline from baseline; Biochemical response: ALT <40 U/L; Combined response: virological and biochemical
Undetectable: Target Not Detected (TND), Below the Limit of Quantification (<LLOQ) or Below the Limit of Detection (<LOD)

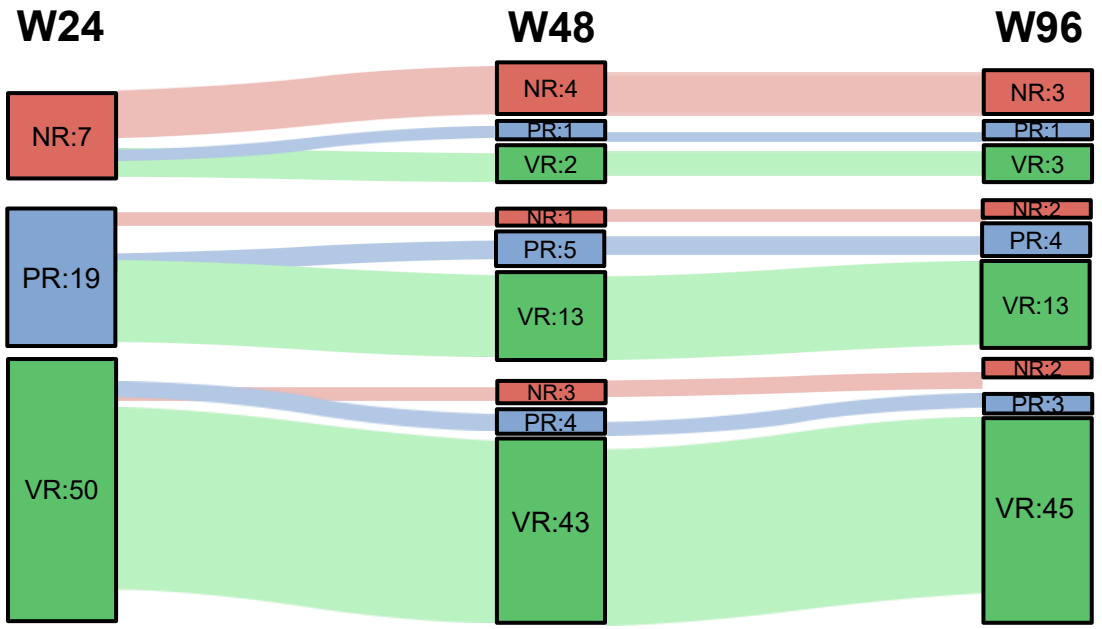
Biochemical Response During BLV Monotherapy

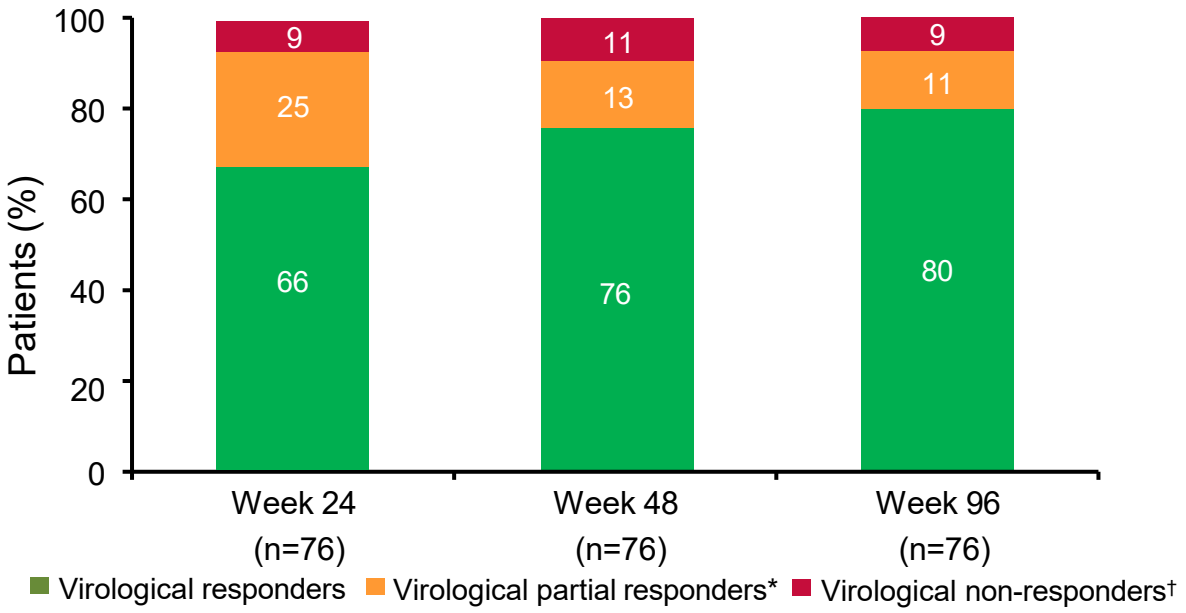


*EASL Criteria; ALT: Alanine aminotransferase; ULN: Upper limit of normal

Course of Suboptimal Responders During BLV Treatment

Subnalysis in n=76 patients with paired W24 – W48 – W96 assessments





OVERALL ANALYSIS (n=244)

- Virological NR: 22% (W24) - 19% (W48) - 10% (W96)
- Biochemical Response in NR: 33% (W24) - 36% (W48) - 25% (W96)
- ≥50% ALT decrease in NR patients: 31% (W24) - 30% (W48) - 50% (W96)
- Virological NR and no ALT decrease compared to baseline: 8% (W96)

68% 13/19 virological partial responders at Week 24 became virological responders at Week 96

43% 3/7 virological non-responders at Week 24 became virological responders at Week 96

57% 4/7 patients who remained virological non-responders achieved ALT declines of >50% from BL at Week 96

* Virological partial responders: patients achieving HDV RNA decline of ≥1 but <2 $\log_{10}$ IU/mL from baseline

† Virological non-responders: patients with an HDV RNA decline of <1 $\log_{10}$ IU/mL from baseline

Baseline Predictors of Responses at Week 48: Univariate Logistic Regression Analysis

Week 48 (n=209)									
		Virological Response		HDV RNA Undetectable		Biochemical Response		Combined Response	
Baseline variables	Category	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value
Age, years	Continuous	1.00 (0.98-1.03)	0.91	0.99 (0.96-1.01)	0.33	1.05 (1.02-1.08)	0.003	1.02 (0.99-1.05)	0.05
Male sex	yes vs. no	0.99 (1.53-1.89)	0.99	1.11 (0.56-2.21)	0.76	0.66 (0.35-1.22)	0.19	0.60 (0.33-1.11)	0.11
Caucasian	yes vs. no	0.79 (0.35-1.81)	0.59	0.48 (0.21-1.06)	0.07	0.68 (0.31-1.50)	0.34	0.65 (0.30-1.40)	0.27
LSM, kPa	Continuous	1.03 (0.99-1.06)	0.07	1.00 (0.98-1.03)	0.80	0.99 (0.97-1.01)	0.66	1.00 (0.98-1.03)	0.52
Esophageal varices	yes vs. no	1.16 (0.55-2.41)	0.70	1.44 (1.02-5.86)	0.05	0.96 (0.46-1.99)	0.91	0.71 (0.34-1.46)	0.35
ALT, U/L	Continuous	0.99 (0.98-1.01)	0.20	0.99 (0.98-1.01)	0.29	0.99 (0.98-1.00)	0.12	0.99 (0.98-1.01)	0.13
GGT, U/L	Continuous	0.99 (0.99-1.01)	0.64	0.99 (0.99-1.01)	0.32	0.98 (0.97-0.99)	**0.01**	0.98 (0.97-0.99)	**0.04**
Albumin, g/dL	Continuous	0.67 (0.39-1.27)	0.24	1.29 (0.69-2.42)	0.42	0.63 (0.36-1.12)	0.12	0.68 (0.38-1.19)	0.17
PLT, x10^3/mm^3	Continuous	1.00 (0.99-1.01)	0.20	1.00 (0.99-1.01)	0.71	0.99 (0.98-1.00)	0.85	1.00 (0.99-1.01)	0.16
Bile acids, µmol/L	Continuous	0.99 (0.98-1.01)	0.46	0.99 (0.98-1.00)	0.39	1.00 (0.99-1.02)	0.19	0.99 (0.99-1.01)	0.78
HBsAg, $\log_{10}$ IU/mL	Continuous	3.15 (1.57-6.31)	**0.001**	0.76 (0.41-1.42)	0.41	1.22 (0.69-2.14)	0.48	2.58 (1.28-5.21)	**0.01**
HDV RNA, $\log_{10}$ IU/mL	Continuous	1.31 (1.07-1.60)	**0.01**	0.74 (0.60-0.92)	**0.01**	0.84 (0.69-1.02)	0.08	1.06 (0.88-1.27)	0.54

Univariate logistic regression analysis; LSM: liver stiffness measurement; ALT: Alanine Aminotransferase; GGT: Gamma glutamyl transferase; PLT: platelets; HDV: Hepatitis Delta Virus

Virological response: HDV RNA undetectable or ≥2 $\log_{10}$ IU/mL decline vs. baseline; Biochemical response: ALT normalization; Combined response: HDV RNA undetectable or ≥2 $\log_{10}$ IU/mL decline vs. baseline and ALT normalization

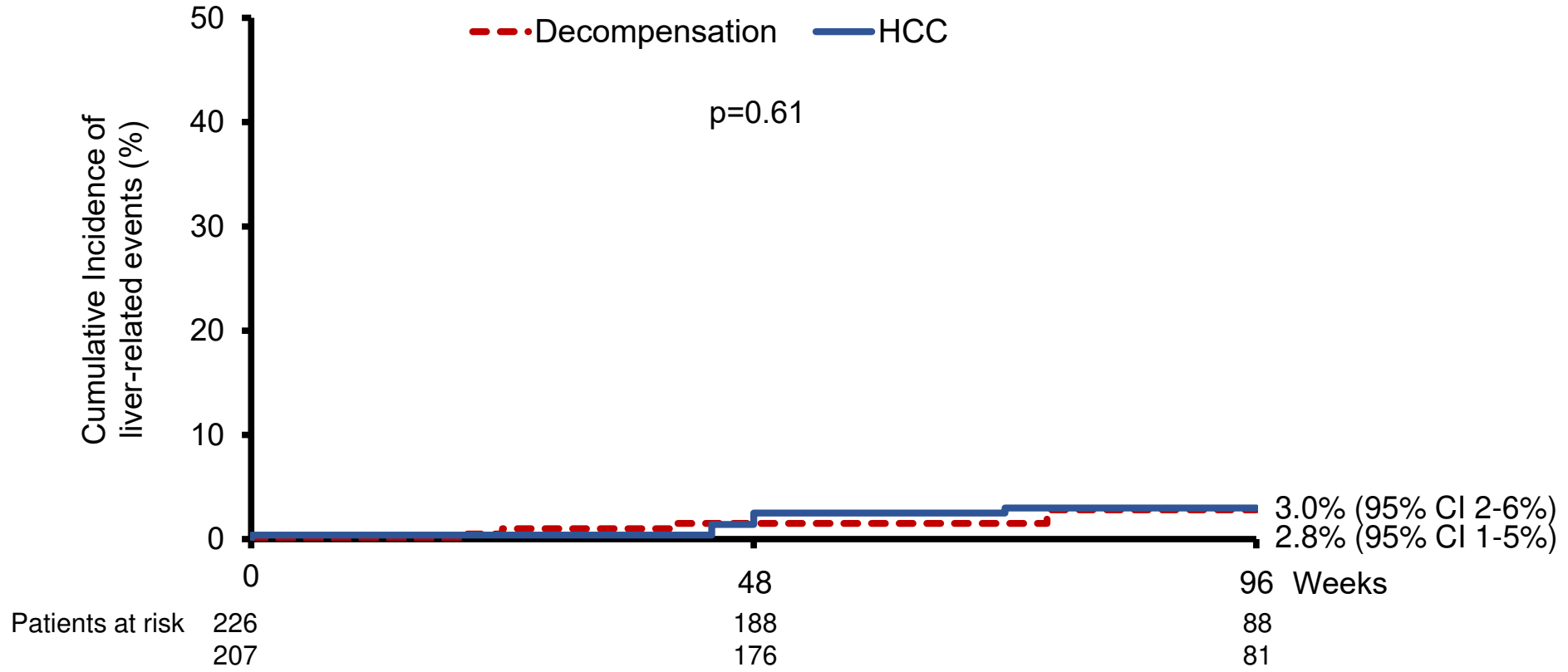
Time Course of Biochemical, Virological Features and Non-Invasive Tests During BLV Monotherapy

Variables	Baseline	Week 24	Week 48	Week 72	Week 96	p value[A]	p value[B]
Bilirubin, mg/dl	0.9 (0.6-1.4)	0.8 (0.5-1.3)	0.9 (0.6-1.3)	0.8 (0.5-1.2)	0.8 (0.6-1.2)	0.42	0.07
AST, U/L	75 (54-113)	42 (33-56)	40 (30-55)	35 (30-55)	36 (29-50)	<0.001	<0.001
ALT, U/L	80 (55-130)	39 (29-53)	35 (27-53)	36 (25-53)	35 (24-48)	<0.001	<0.001
GGT, U/L	68 (39-114)	42 (28-72)	38 (22-62)	38 (21-62)	31 (19-53)	<0.001	<0.001
Albumin, g/dL	3.9 (3.5-4.3)	4.1 (3.6-4.4)	4.1 (3.8-4.5)	4.2 (3.8-4.6)	4.1 (3.8-4.5)	<0.001	0.04
PLT, $10^3/mm^3$	94 (67-145)	102 (66-145)	103 (67-151)	92 (60-137)	91 (62-125)	<0.001	0.04
AFP, µg/L	6 (3-12)	5 (3-8)	4 (3-6)	3 (2-4)	3 (2-4)	0.02	<0.001
IgG, mg/dL	2,020 (1,700-2,458)	1,716 (1,456-2,028)	1,697 (1,396-1,899)	1,600 (1,379-1,850)	1,616 (1,479-1,938)	<0.001	<0.001
HBsAg, $\log_{10}$ IU/mL	3.8 (3.4-4.1)	3.7 (3.4-4.1)	3.6 (3.3-4.1)	3.6 (3.3-4.0)	3.5 (3.4-3.9)	0.001	<0.001
LSM	18.3 (13.0-26.3)	14.6 (10.9-25.0)	14.4 (9.6-23.2)	15.4 (11.6-21.7)	14.0 (11.0-19.8)	<0.001	<0.001
APRI	2.2 (1.4-4.3)	1.3 (0.7-2.3)	1.1 (0.7-2.0)	1.3 (0.8-2-2)	1.2 (0.7-2.9)	<0.001	<0.001
FIB-4	4.6 (2.3-7.4)	3.4 (2.0-5.7)	3.1 (1.9-5.6)	3.5 (2.2-6.2)	3.7 (2.2-5.7)	<0.001	<0.001

Values are expressed as median (IQR); Repeated measures analysis of variance (ANOVA) in patients with paired W48 (A) or W96 (B) data *vs.* baseline (Bonferroni corrected)
AST: aspartate aminotransferase; ALT: alanine aminotransferase; GGT: Gamma glutamyl transferase; PLT: platelets; AFP: Alpha-fetoprotein; HBsAg: Hepatitis B surface Antigen; LSM: Liver stiffness measurement; APRI: AST-to-Platelet ratio; FIB-4: Fibrosis-4 index

De-Novo Liver-Related Events During BLV Monotherapy

- Median follow-up: 92 (72- 96 weeks)
- 11 (5%) Liver-related events
  - 6 (2.5%) HCC
  - 5 (2.0%) Decompensating events (3 ascites; 2 variceal bleedings)



HCC: hepatocellular carcinoma; ESLD: end-stage liver disease

De-Novo Liver-Related Events: Details

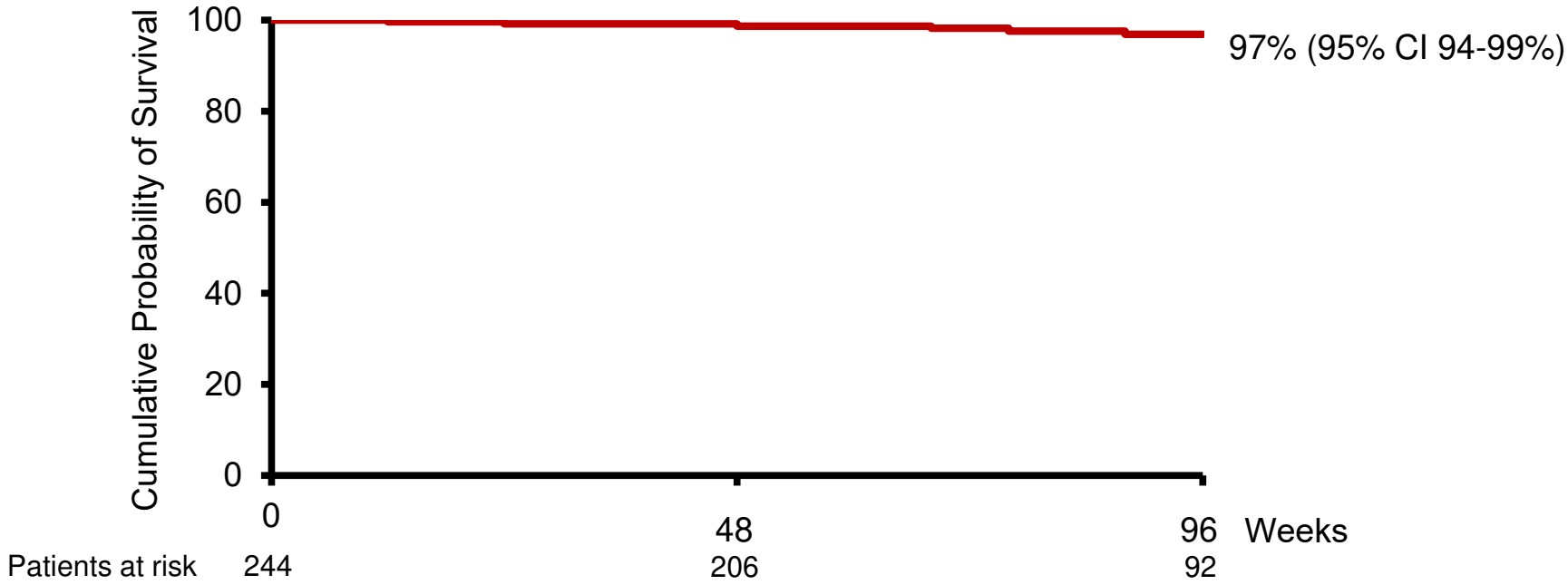
Patient	CPT Baseline	CSPH	Event	Features	Time to Event	VR at Event
#13	A5	Yes	HCC	BCLC A	6	PR
#57	A5	No	HCC	BCLC A	6	VR
#63	A5	Yes	HCC	BCLC A	11	NR
#134	A6	Yes	HCC	BCLC A	11	VR
#178	A6	Yes	HCC	BCLC C	18	VR
#200	A5	Yes	HCC	BCLC A	12	PR
#83	A6	Yes	Ascites	Acute Cholecystitis	10	NR
#177	A6	Yes	Ascites	No trigger events	6	VR
#190	A6	Yes	Ascites	No trigger events	18	VR
#204	A5	Yes*	Bleeding	No trigger events	18	VR
#226	A5	Yes°	Bleeding	No trigger events	6	NR

*Esophageal varices on primary prophylaxis with non-selective beta-blockers; °Refused baseline upper endoscopy

CPT: Child Pugh Turcotte; CSPH: Clinically Significant Portal Hypertension; HCC: hepatocellular carcinoma; BCLC: Barcelona Clinic Liver Cancer; VR: Virological Response; PR: Partial Response; NR: Non-Response

Survival, Lost to Follow-up & BLV Discontinuations

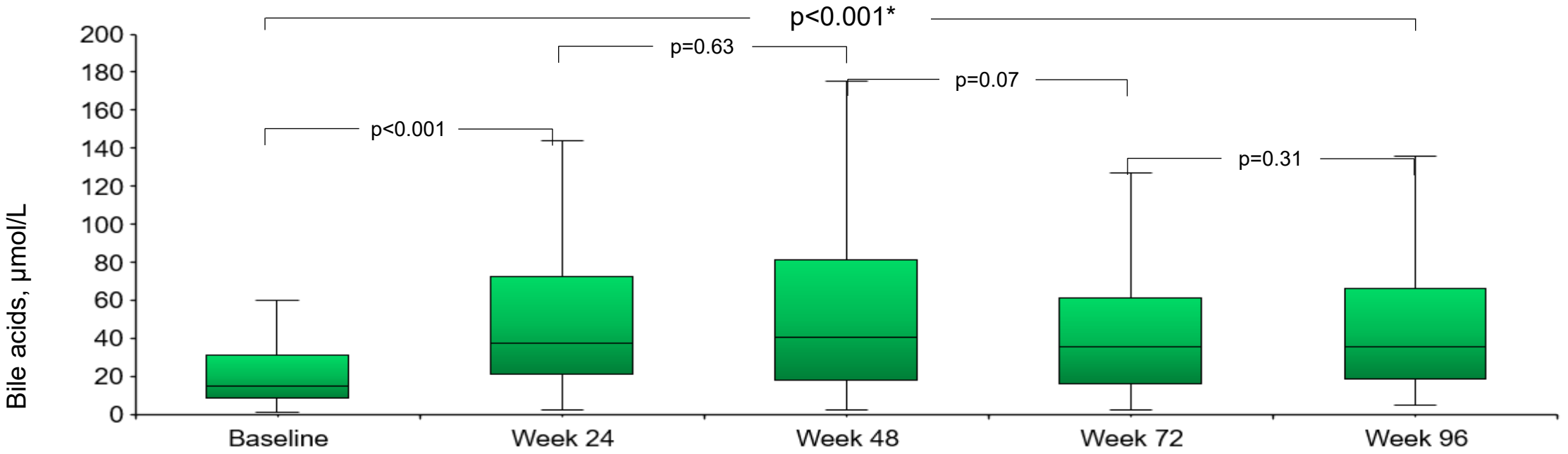
- 19 (8%) deaths/LT (median time 68 [39-73] weeks)
  - 13 LT (n=11 for HCC, n=2 for ESLD)
  - 6 deaths (pneumonia; intestinal infarction; non-hepatic neoplasm; HCC progression; ACLF)



- 12 (5%) BLV discontinuations* (median time 48 [26-79] weeks)
- 7 (3%) PegIFN added to BLV
- 7 (3%) patients lost to follow-up (median time 30 [25-44] weeks)

*Non-compliance n=2; virological non-response n=4, BLV-related adverse event n=1; liver decompensation n=2; long-term HDV RNA undetectability n=3
LT: Liver Transplant; HCC: hepatocellular carcinoma; ESLD: end-stage liver disease; ACLF: Acute-on-chronic liver failure; BLV: Bulevirtide; PegIFN: PegInterferon

Bile Acids Levels and Adverse Events During BLV



Median (IQR)	15 (9-32)	37 (21-73)	41 (18-82)	39 (17-66)	36 (19-66)

- Mild, transient pruritus in 10%, mostly within the first 24 weeks of treatment
- Injection site reactions in 3%
- N=1 grade 3 maculopapular rash with mild eosinophilia (BLV discontinued)

* All timepoints *vs.* baseline

SAVE-D: Submitted Abstracts & Full Text Manuscript

EASL ILC – 2024:

- *Long-term virological and clinical outcomes of patients with HDV-related cirrhosis treated with Bulevirtide monotherapy for up to 120 weeks: a retrospective multicenter European study (SAVE-D) –* ***Poster#WED-391***

- *Bulevirtide Monotherapy Prevents Liver Decompensation and Reduces Mortality in Patients with HDV-related Cirrhosis: A Case-Control Study With Propensity Score Weighted Analysis –* ***Oral Communication #OS-120***

AASLD TLM – 2024:

- *Bulevirtide monotherapy may reduce liver decompensation in patients with HDV-related compensated cirrhosis: a case control study with propensity score weighted analysis –* ***Poster Presentation***
- *Long-term Bulevirtide monotherapy in patients with HDV-related compensated cirrhosis: effectiveness, safety and clinical outcomes from the retrospective multicenter European study (SAVE-D) –* ***Oral Communication***

FULL TEXT MANUSCRIPT:

- *Virological and clinical outcomes of patients with HDV cirrhosis treated with Bulevirtide monotherapy for up to 96 weeks: a multicenter European study (SAVE-D) –* ***J Hepatol Submitted 20th July 2024, Accepted 10th October***

Bulevirtide Monotherapy Prevents Liver Decompensation (but not HCC) in Patients with HDV-related Cirrhosis: A Case-Control Study With Propensity Score Weighted Analysis

- Case-control study in patients with HDV-related compensated cirrhosis
- 140 BLV-Untreated patients from a single-center retrospective natural history study (*Romeo et al. Gastroenterology 2009*) *vs.* 176 BLV-Treated patients from the multicenter European SAVE-D study; follow-up censored 24 months

- Liver-related Events: Untreated n=21 (ascites n=10, bleeding n=2, HCC n=9); BLV-treated n=12 (ascites n=5, bleeding n=1)
- **2-year cumulative incidences of de-novo HCC: 6.6% *vs.* 3.7% (p=0.34); decompensation 9.1% *vs.* 3.6% (p=0.06)**

- **No liver decompensation among baseline CPT-A5 patients in the BLV-Treated cohort vs. 9.2% in the Untreated cohort (p=0.003)**

Outcomes	Category	Unadjusted Univariate Analysis		IPTW-Adjusted Cox Regression Analysis		IPTW-Adjusted Competing Risks Regression Model	
		HR (95% CI)	p value	HR (95% CI)	p value	SHR (95% CI)	p value
OVERALL POPULATION							
Liver-related Event	Treated *vs.* Untreated	0.52 (0.25-1.05)	0.07	0.38 (0.23-0.62)	**<0.0001**	0.38 (0.23-0.61)	**<0.0001**
Liver decompensation	Treated *vs.* Untreated	0.48 (0.18-1.28)	0.14	0.32 (0.16-0.63)	**0.001**	0.32 (0.17-0.61)	**0.001**
De-novo HCC	Treated *vs.* Untreated	0.57 (0.20-1.62)	0.29	0.50 (0.24-1.06)	0.07	0.50 (0.24-1.04)	0.06

A 24-month course of BLV monotherapy may prevent decompensation but not HCC in patients with compensated HDV-related cirrhosis

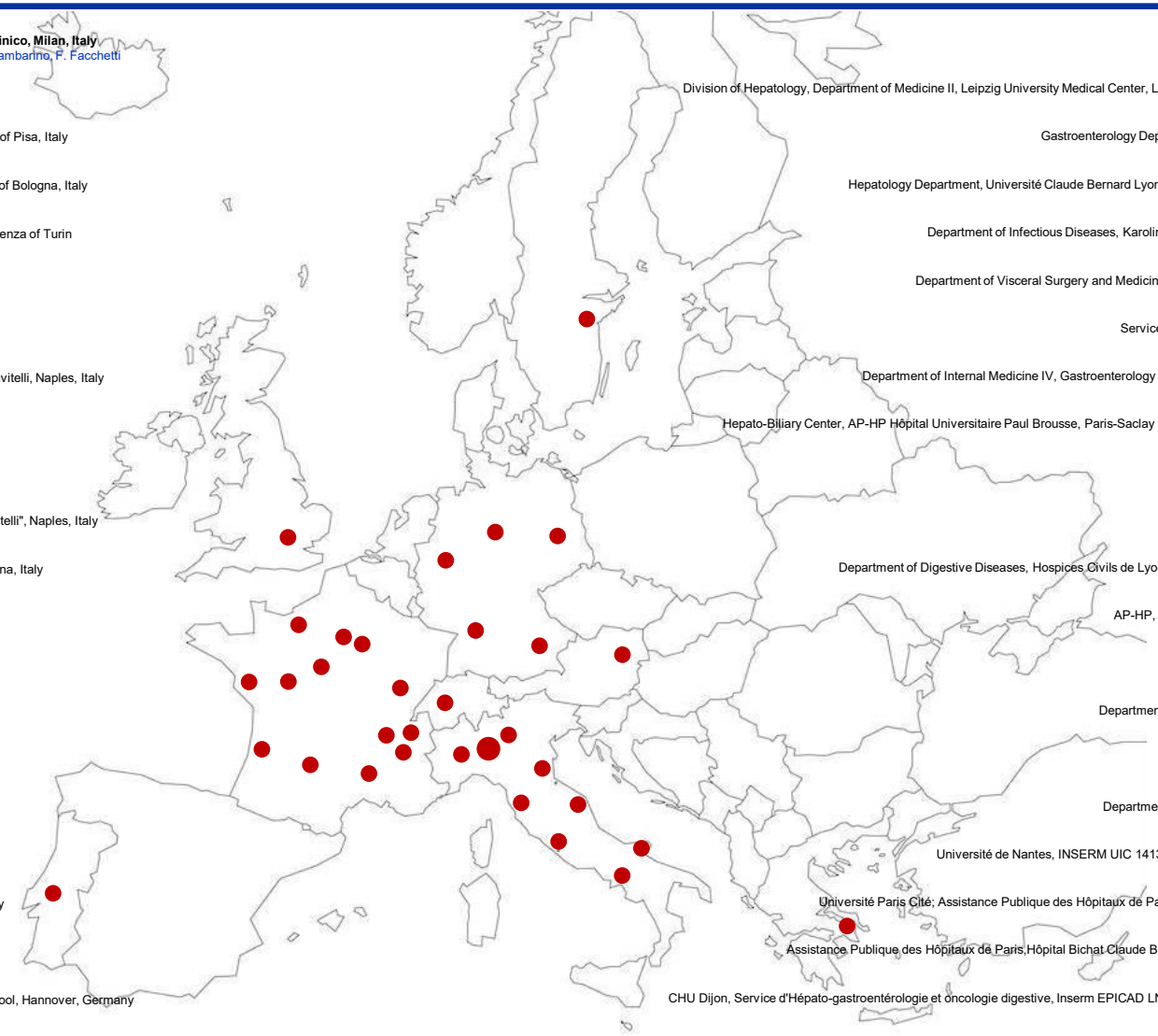
Degasperi E. et al, EASL 2024, OS-120

Research Pipeline – SAVE-D Study

- Update Week 144: Effectiveness & Events
- On-treatment Predictors of response
- Suboptimal responders: outcomes
- Liver stiffness/Non-invasive Tests on-treatment & Clinical outcomes
- Clinical outcomes of BLV-treated patients *vs.* untreated historical cohorts

FEEL FREE TO CONTRIBUTE! – OTHER SUGGESTIONS WELCOME

Acknowledgements: SAVE-D Participating Centers



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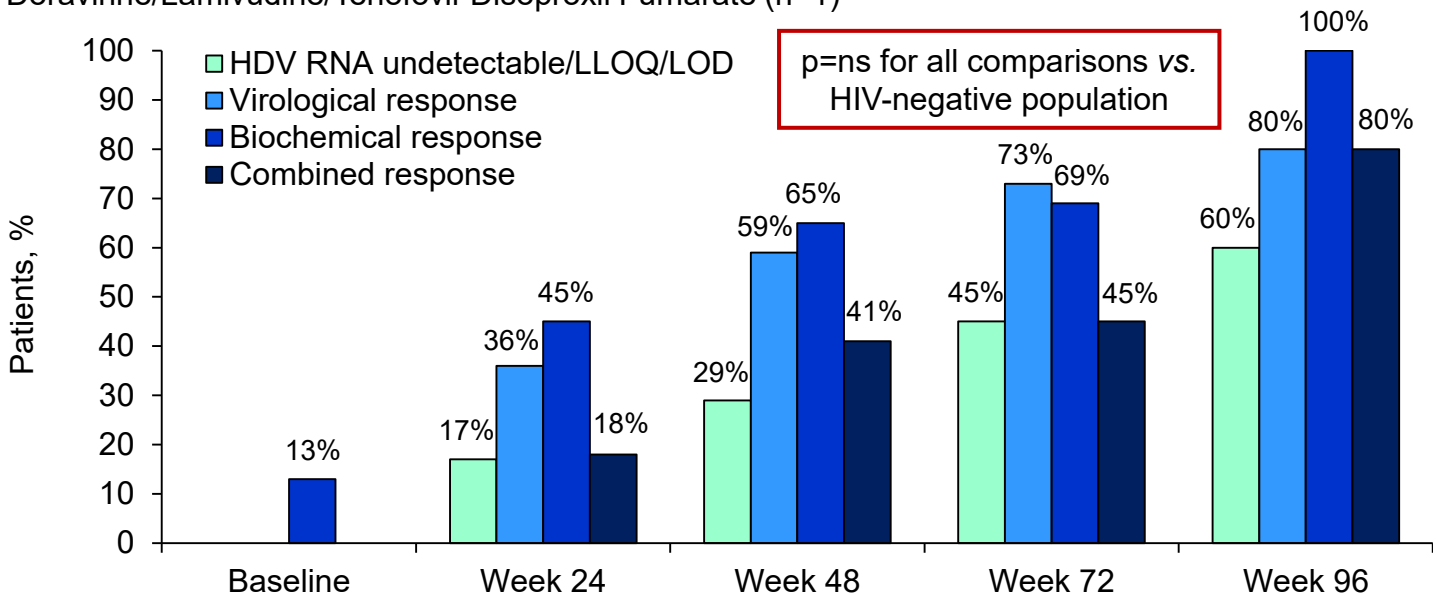
Special Populations: HIV-Coinfected Patients

Baseline Variables	Overall (n=24)
Age, years	**56 (48-59)**
Males	17 (71%)
Caucasians	23 (96%)
BMI, Kg/m^2	25 (24-29)
CPT score A	24 (100%)
Esophageal varices@	10 (42%)
History of HCC	3 (13%)
Previous IFN treatment	13 (54%)
NUC treatment for HBV	24 (100%)
LSM, kPa	20.9 (13.3-26.3)
AST, U/L	67 (48-124)
ALT, U/L	73 (51-141)
Albumin, g/dL	4.1 (3.8-4.4)
PLT, 10^3/mm^3	100 (84-127)
qHBsAg, Log IU/ml	3.3 (2.4-3.9)
HBeAg negative	20 (83%)
HDV RNA, Log IU/ml	5.3 (3.8-5.9)
HIV RNA detectable	0%
CD4 T cells, mm^3	338 (257-444)
CD4 T cells, %	27 (22-35)

HIV treatments during BLV course:

- Bictegravir/Emtricitabine/Tenofovir Alafenamide (n=11)
- Raltegravir/Emtricitabine/Tenofovir Alafenamide (n=5)
- Emtricitabine/Ripivirine/Tenofovir Alafenamide (n=4)
- Darunavir/Raltegravir/Emtricitabine/Tenofovir Disoproxil Fumarate (n=1)
- Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (n=1)
- Dolutegravir/Lamivudine (n=1)
- Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate (n=1)



HIV RNA detectable	0%	0%	0%	0%	0%
CD4 count (%)	338 (27%)	457 (31%)	474 (30%)	189 (24%)	186 (24%)

Values are expressed as number (percentage), median (IQR); @ Upper GI endoscopy available in 16

HDV: hepatitis D virus; HIV: human immunodeficiency virus; BMI: body mass index; CPT: Child Pugh score; IFN: Interferon; NUC: nucleos(t)ige analogue HCC: hepatocellular carcinoma; LSM: Liver stiffness measurement; AST: aspartate aminotransferase; ALT: alanine aminotransferase; PLT: platelets; qHBsAg: Quantitative Hepatitis B surface Antigen; HBeAg: Hepatitis B e Antigen; HBV: Hepatitis B virus; CD: Cluster of differentiation

Thank You for Your Attention!

FONDAZIONE IRCCS CA' GRANDA
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