International Coalition of
Hepatology Education Providers

Best of HCV from EASL 2014

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Best of HCV from EASL 2014

- **Candidacy for Treatment of HCV Patients: The Clinical Experience from Kaiser Permanente**
- The New Treatment Regimens for HCV
- Assessment of Patient-related Outcomes During HCV treatment

Comorbid Conditions Associated With Decision-Making Regarding Treating or Not Treating Chronic Hepatitis C in a Large U.S. Health Maintenance Organization

L.M. Nyberg[1], K.M. Chiang[2], Z. Li[2], A.H. Nyberg[1], Z.M. Younossi[3], T.C. Cheetham[2]

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Methods

- Study Design
  - A retrospective study using the database of Kaiser Permanente, Southern California, a large Health Maintenance Organization including 3.5 – 4 million members
- Inclusion Criteria
  - ≥ 18 years old with a diagnosis code or a positive lab test result for HCV RNA from January 1, 2002 through December 31, 2012
  - ≥ 6 months continuous membership plus drug benefit prior to HCV treatment
  - Index date was defined as the date of the first treatment course or first chronic HCV diagnosis

Nyberg, L. et al. EASL 2014, Abstract #O67

ethods

dentification of comorbid illnesses representing elative or absolute contraindications to HCV eatment with interferon-based therapy were etermined by diagnosis codes and/or lab tests for

- Comorbid illness identified in the study: cancer, anemia, autoimmune disorder, renal dysfunction, thrombocytopenia, diabetes, HIV, CVD, psychosis/bipolar disorder, depression, severe lung disease, substance abuse, Hepatitis B, MELD ≥ 12

Multivariate logistic regression was used to etermine predictors of treatment vs non-treatment

esults

Entire Population (Patients with a diagnosis code or positive lab test for HCV)	Study Population (After applying inclusion/exclusion criteria)
▪ N=51,984 patients	▪ N= 32,283 patients
▪ 7,945 patients (15%) of this population received treatment	▪ 5,533 patients (17%) in the study population received treatment

esults

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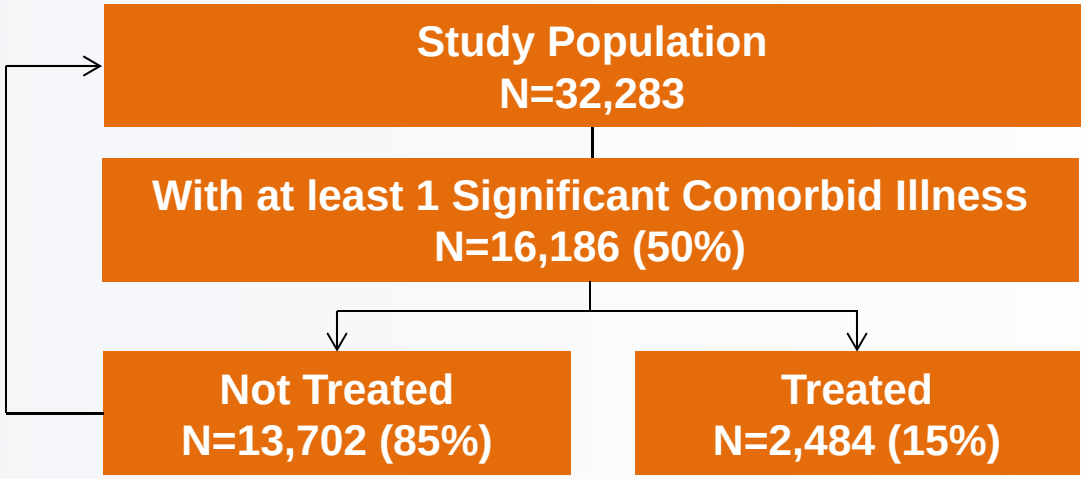
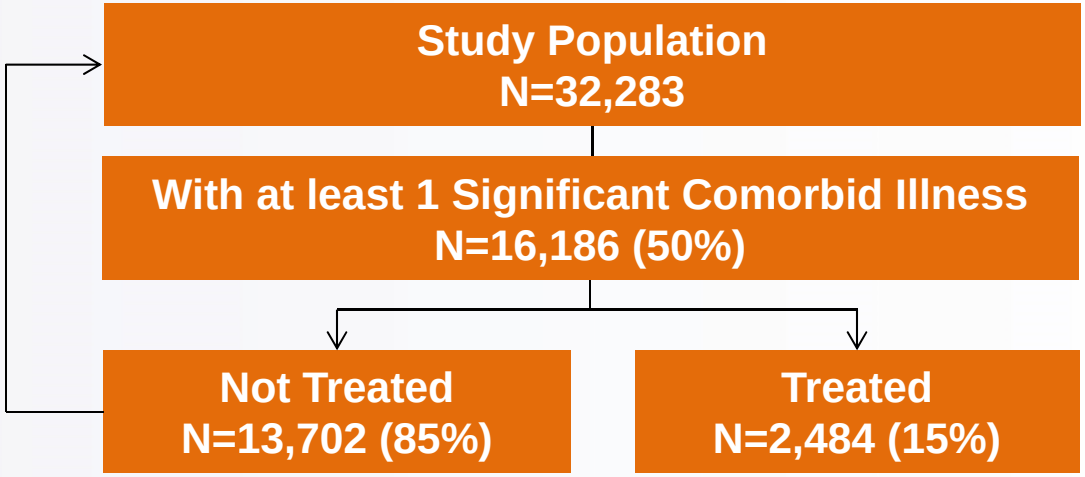
esults

the patients with at least 1 significant comorbid illness



esults

the patients with at least 1 significant comorbid illness



0% (16,186/32,283) of the study population had a
gnificant comorbid illness

- 15% (2,484/16,186) were treated
- 85% (13,702/16,186) were not treated

esults

ctors Associated with Receiving Treatment

n multivariate logistic regression analysis, factors ssociated with receiving treatment included ounger age (age<65), male gender, presence of irrhosis, HIV co-infection, and a history of liver ansplantation (P = 0.0012 to <0.0001)

esults

ctors Associated with NOT Receiving Treatment

n multivariate logistic regression analysis, factors ssociated with not receiving treatment for HCV ncluded presence of anemia, autoimmune isorders, renal dysfunction, CVD, psychosis/bipolar, ubstance abuse, severe lung disease and MELD>12 (P = 0.0195 to <0.0001)

mmary

- n this large database representing a real world opulation, only 15-17% of those identified with HCV ere treated with interferon-based regimens
- 2% of the total study population were likely nterferon ineligible or intolerant
- 0% had no apparent contraindications to interferon-ased therapy
- 0% had comorbid conditions representing relative or bsolute contraindications to interferon-based herapy
- ew, interferon-free regimens may offer new eatment options for this group

est of HCV from EASL 2014

Candidacy for Treatment of HCV Patients: The Clinical Experience from Kaiser Permanente

he New Treatment Regimens for HCV

ssessment of Patient-related Outcomes During CV treatment

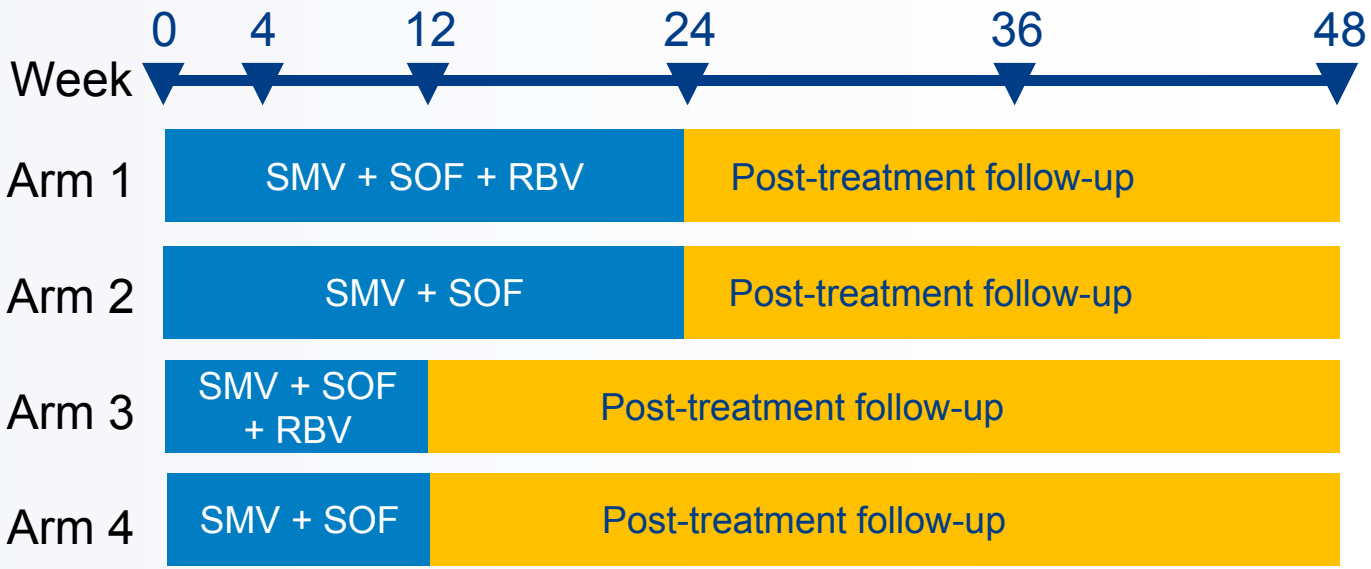
ct #O165

Simeprevir Plus Sofosbuvir With/Without Ribavirin in HCV Genotype-1 Prior Null-responder / atment-naïve Patients (COSMOS Study): Primary Endpoint SVR12) Results in Patients With METAVIR F3-4 (Cohort 2)

. Lawitz[1], R. Ghalib[2], M. Rodriguez-Torres[3], Z.M. Younossi[4], A. Corregidor[5], M.S. Sulkowski[6], E. DeJesus[7], B. Pearlman[8], M. Rabinovitz[9], N. Gitlin[10], J.K. Lim[11], P.J. Pockros[12], B. Fevery[13], T. Lambrecht[14], S. Ouwerkerk-Mahadevan[13], K. Callewaert[13], W.T. Symonds[15], G. Picchio[16], K. Lindsay[16], M. Beumont-Mauviel[13], I.M. Jacobson[17]

kas Liver Institute, San Antonio, [2]Medicine and Gastroenterology and Hepatology, The Liver Institute, as, TX, [3]Fundaci_n de Investigaci_n, San Juan, PR, [4]Department of Medicine, Inova Fairfax Hospital, s Church, VA, [5]Borland-Groover Clinic, 4800 Belfort Rd, Jacksonville, FL, [6]Johns Hopkins University ool of Medicine, Baltimore, MD, [7]Orlando Immunology Center, Orlando, FL, [8]Atlanta Medical Center, Atlanta, GA, [9]University of Pittsburgh Medical Center, Pittsburgh, PA, [10]Atlanta Gastroenterology ciation, Atlanta, GA, [11]Yale School of Medicine, New Haven, CT, [12]Scripps Clinic, La Jolla, CA, United ates, [13]Janssen Research & Development, Beerse, [14]Novellas Healthcare, Zellik, Belgium, [15]Gilead iences Inc, Foster City, CA, [16]Janssen Research & Development LLC, Titusville, NJ, [17]Weill Cornell Medical College, New York, NY, United States

OSMOS Study Design: Randomised, ulticentre, Open-label Trial



SMV 150 mg QD + SOF 400 mg QD±RBV 1000/1200 mg/day (BID)

ndomised
2:1:2:1

hort 1: METAVIR F0-F2, prior null responders

hort 2: METAVIR F3-F4, prior null responders or treatment-naïve

Stratified by treatment history, HCV GT 1a/1b

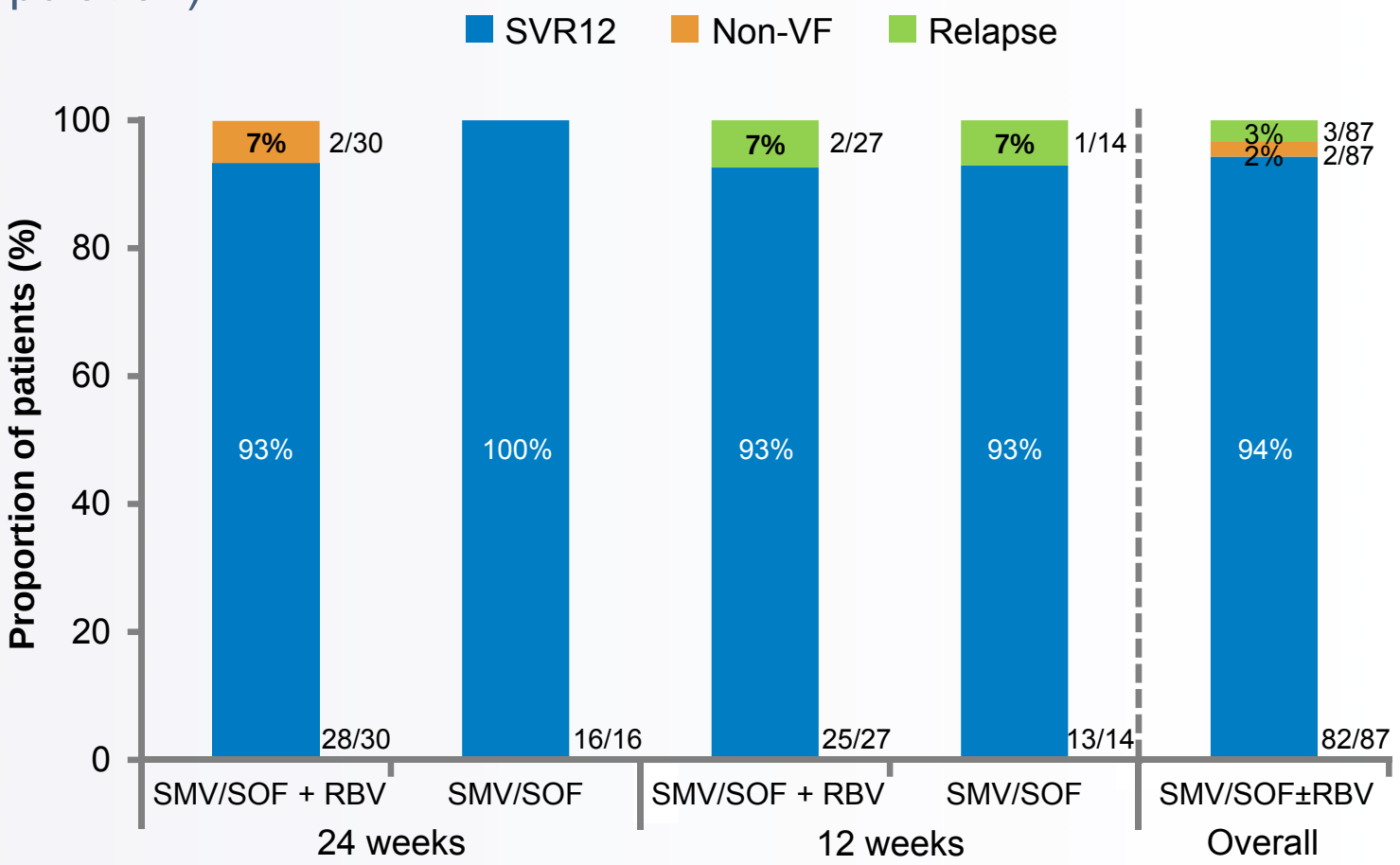
imary endpoint: SVR12

condary endpoints: RVR, on-treatment failure, relapse rate, safety and tolerability

vice daily; GT, genotype; QD, once daily; RBV, ribavirin; RVR, rapid virologic response;
imeprevir; SOF, sofosbuvir; SVR12, sustained virologic response 12 weeks after end of treatment

OSMOS Cohort 2: SVR12 – Primary Endpoint

population)



F, patients who did not achieve SVR12 for reasons other than virologic failure

ent-to-treat; Non-VF, Non-virologic failure; RBV, ribavirin; SMV, simeprevir; SOF, sofosbuvir; SVR12, ed virologic response 12 weeks after planned treatment end

vice daily; GT, genotype; QD, once daily; RBV, ribavirin; RVR, rapid virologic response; SMV, simeprevir; ofosbuvir; SVR12, sustained virologic response 12 weeks after end of treatment

OSMOS Cohort 2: Conclusions

MV/SOF QD led to SVR12 rates of 93-100% (ITT) HCV GT 1 infected treatment-naïve and prior ull-responder patients with METAVIR F3-4

VR12 rates were high, regardless of baseline haracteristics:

- HCV GT 1 subtype, Q80K polymorphism, METAVIR score, *IL28B* GT, prior treatment history

MV/SOF QD +/- RBV was safe and well tolerated

wo Phase 3 trials investigating SMV/SOF without BV are ongoing (OPTIMIST-1 and -2)

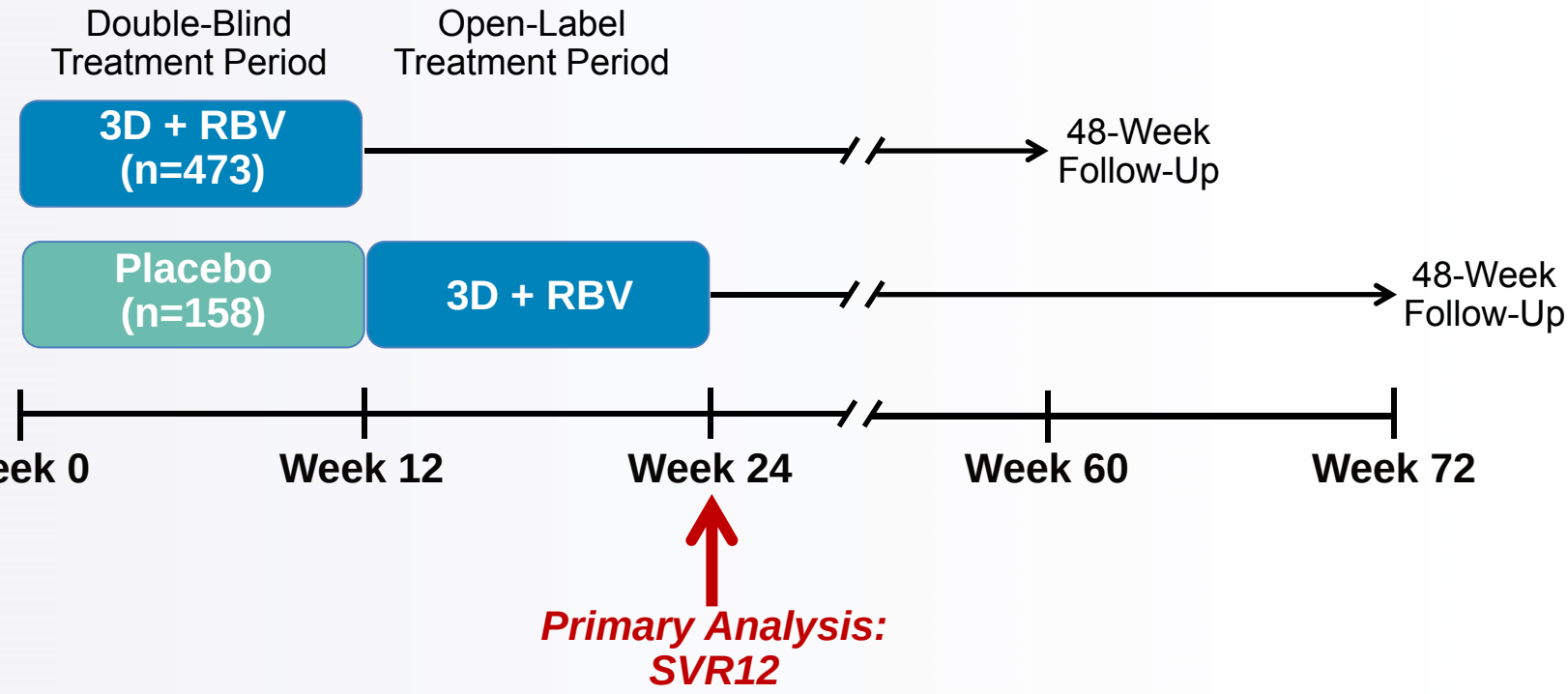
notype; ITT, Intent-to-treat; QD, once daily; RBV, ribavirin; SMV, simeprevir; SOF, sofosbuvir; SVR12, ed virologic response 12 weeks after end of treatment

SAPPHIRE I: Phase 3 Placebo-Controlled Study Of Interferon-Free, 12-Week Regimen Of ABT-450/r/ABT-267, ABT-333, And Ribavirin In 631 Treatment-Naïve Adults With Hepatitis C Virus Genotype 1

Feld[1], K.V. Kowdley[2], E. Coakley[3], S. Sigal[4], D. Nelson[5], D. Crawford[6,7], O. Weiland[8], H. Aguilar[9], J. Xiong[3], B. DaSilva-Tillmann[3], L. Larsen[3], T. Podsadecki[3]

onto Western Hospital Liver Centre, Toronto, ON, Canada, [2]Digestive Disease Institute, Virginia Mason dical Center, Seattle, WA, [3]AbbVie Inc., North Chicago, IL, [4]NYU Langone Medical Center, New York, [5]University of Florida College of Medicine, Gainesville, FL, United States, [6]Gallipoli Medical Research oundation, [7]The University of Queensland, Brisbane, QLD, Australia, [8]Karolinska University Hospital ddinge, Karolinska Institutet, Stockholm, Sweden, [9]Louisiana Research Center, LLC, Shreveport, LA, United States

APPHIRE-I: Placebo-Controlled Design (=631)



D: co-formulated ABT-450/r/ombitasvir, 150 mg/100 mg/25 mg QD; dasabuvir, 0 mg BID

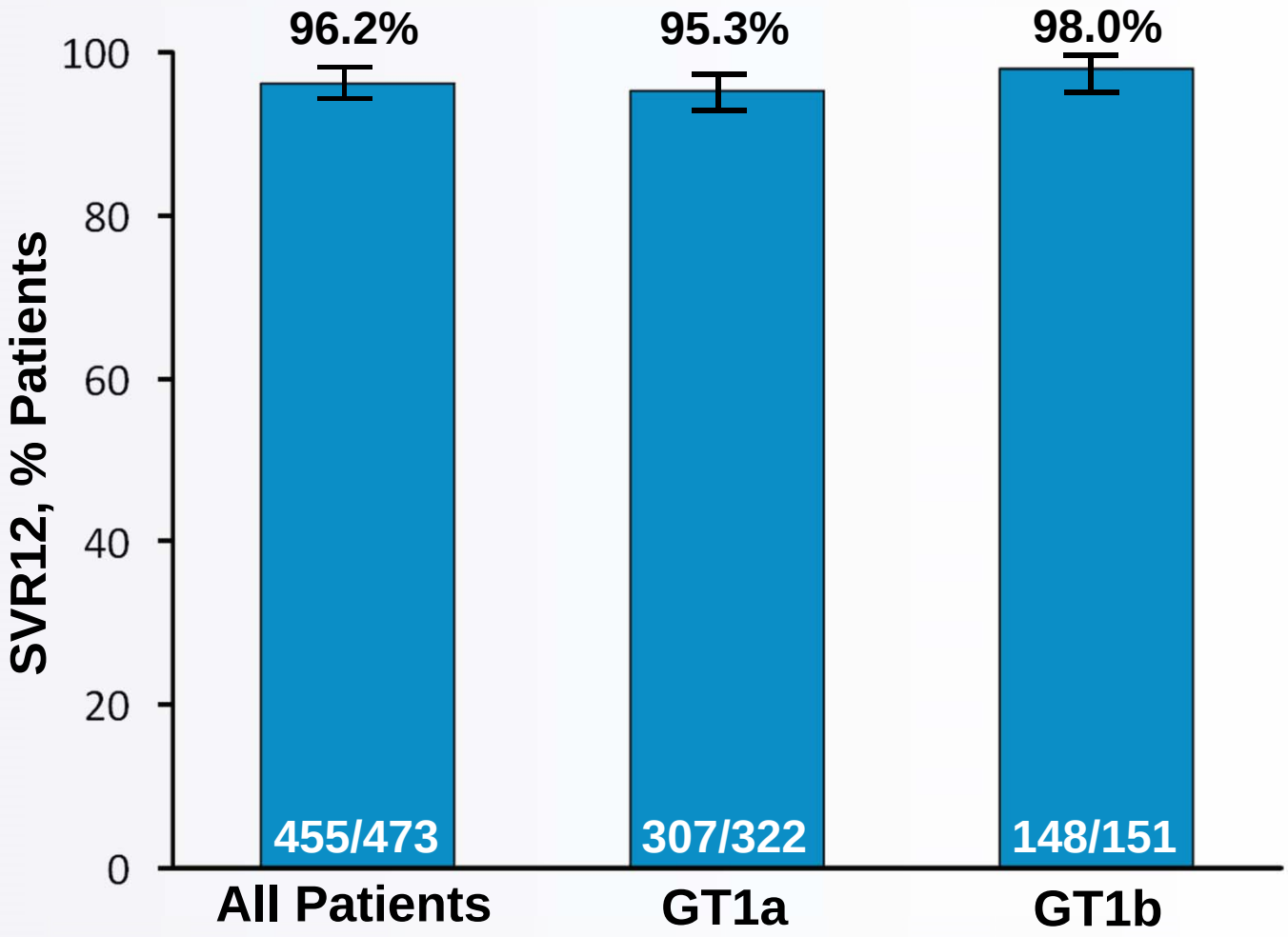
BV: 1000-1200 mg daily according to body weight (<75 kg and >75kg, respectively)

APPHIRE-I: Baseline Patient Characteristics

	3D + RBV (N=473)	Placebo (N=158)
e, n (%)	271 (57.3)	73 (46.2)
e, n (%)		
hite	428 (90.5)	144 (91.1)
ack	26 (5.5)	8 (5.1)
panic/Latino ethnicity, n (%)	27 (5.7)	5 (3.2)
lian age, years (range)	52.0 (18.0-70.0)	52.0 (21.0-70.0)
lian BMI, kg/m^2 (range)	25.2 (18.0-38.4)	25.5 (18.5-39.4)
osis stage, n (%)		
0-F1	363 (76.7)	116 (73.4)
2	70 (14.8)	27 (17.1)
3	40 (8.5)	15 (9.5)
3B non-CC genotype, n (%)	329 (69.6)	108 (68.4)
V subtype, n (%)		
a	322 (68.1)	105 (66.5)
b	151 (31.9)	53 (33.5)
lian HCV RNA, $\log_{10}$ IU/mL (range)	6.51 (3.58-7.60)	6.64 (3.71-7.51)

enotype and subtype were assessed using the Versant HCV Genotype Inno-LiPA Assay, v2.0.

APPHIRE-I Results: ITT SVR12 Rates (Superiority to Calculated Placebo Rate)



APPHIRE-I: Conclusions

- The ITT SVR12 rate was 96.2% (455/473) for treatment-naïve GT1-infected patients receiving 12 weeks of co-formulated ABT-450/r/ombitasvir + asabuvir + RBV
- SVR12 rates (ITT) were high regardless of HCV subtype
- The rate of virologic failure was low:
  - 0.2% breakthrough rate
  - 1.5% relapse rate
- The regimen was generally well-tolerated, with a low rate of study drug discontinuation due to AE(s) (0.6%)

ct #O166

All-Oral Dual Therapy With Daclatasvir And Asunaprevir In Patients With HCV Genotype 1b Infection: Phase 3 Study Results

anns[1], S. Pol[2], I. Jacobson[3], P. Marcellin[4], S. Gordon[5], C.-Y. Peng[6], T.-T. Chang[7], G. Everson[8], J. G. Gerken[10], B. Yoffe[11], W.J. Towner[12], M. Bourliere[13], S. Metivier[14], C.-J. Chu[15], W. Sievert[16], J.-P. Bronowicki[17], D. Thabut[18], Y.-J. Lee[19], J.-H. Kao[20], F. McPhee[21], J. Kopit[21], P. Mendez[22], M. Linaberry[22], E. Hughes[22], S. Noviello[22], HALLMARK DUAL Study Team

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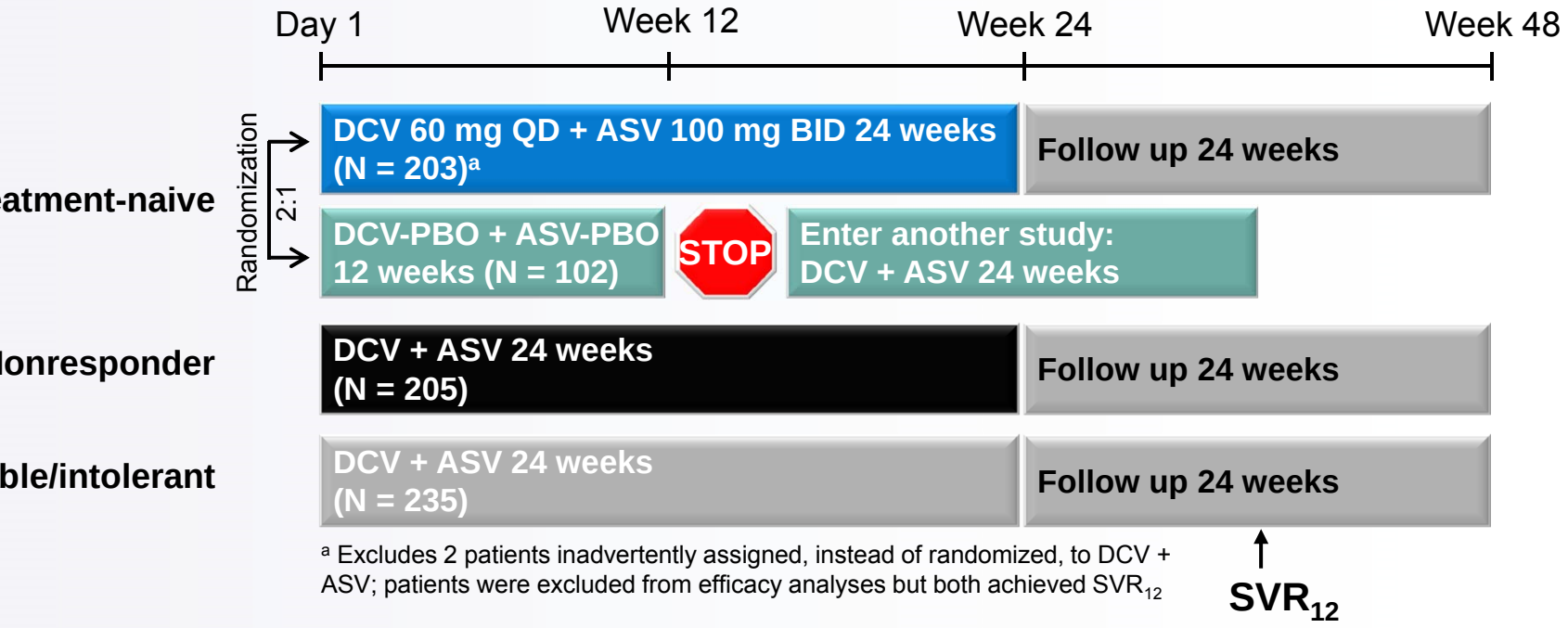
obal Phase 3 Study: HALLMARK-DUAL (M447-028)



[a] Excludes 2 patients inadvertently assigned, instead of randomized, to DCV + ASV; patients were excluded from efficacy analyses but both achieved SVR_{12}

imary endpoint: proportion of DCV + ASV-treated patients with SVR_{12}

tients infected with HCV genotype 1b

Treatment-naive

Nonresponders: prior null or partial response to pegIFN/RBV

Interferon-ineligible/intolerant (treatment-naive or -experienced) due to

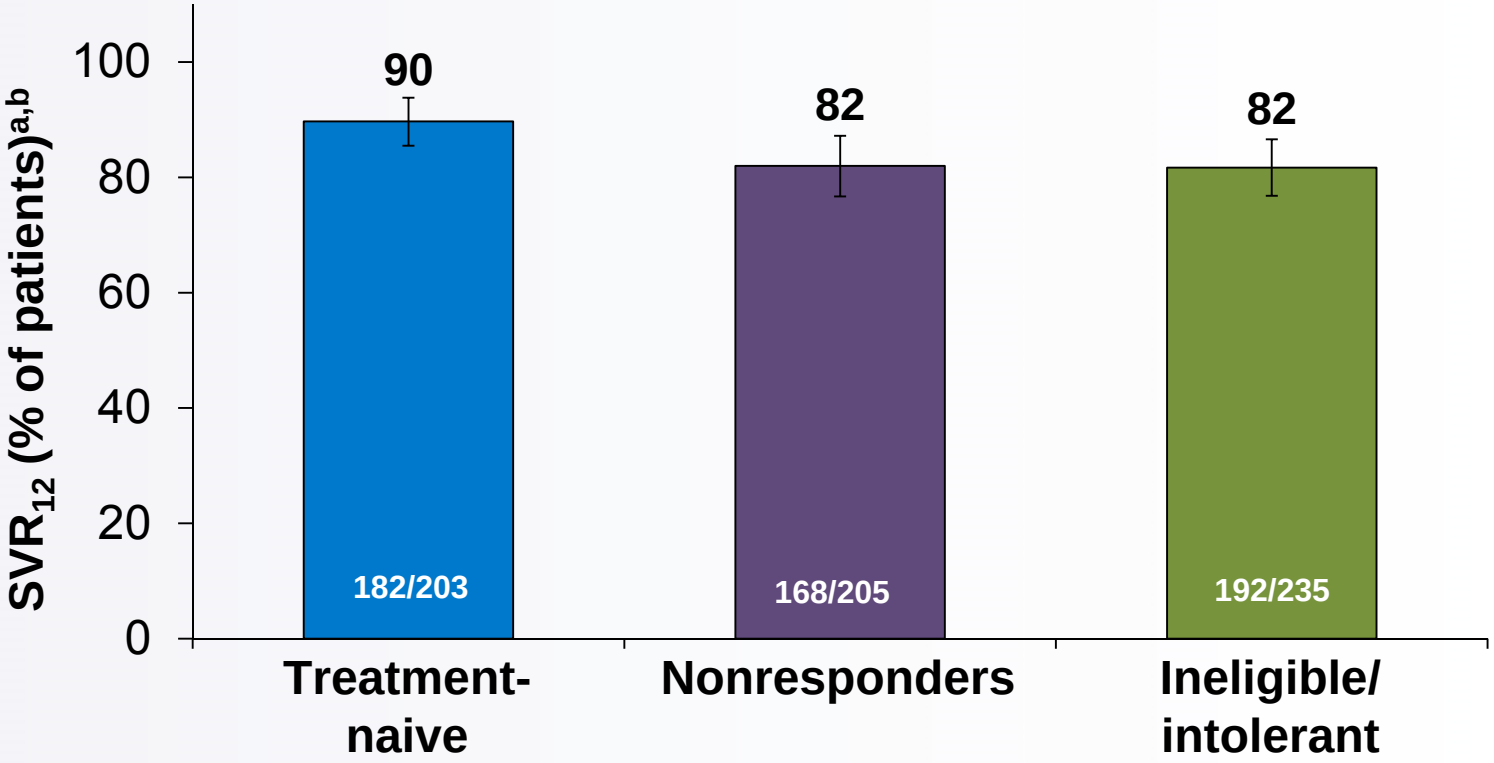
- Depression
- Anemia/neutropenia
- Compensated advanced fibrosis/cirrhosis (F3/F4) with thrombocytopenia

tient Baseline Characteristics

eter	Treatment-naive DCV + ASV (N = 205)	Treatment-naive Placebo (N = 102)	Nonresponder[a] (N = 205)	Ineligible/ intolerant[b] (N = 235)
edian years	55	54	58	60
(%)	101 (49)	54 (53)	111 (54)	98 (42)
n (%)				
	135 (66)	59 (58)	148 (72)	169 (72)
	14 (7)	8 (8)	10 (5)	10 (4)
	52 (25)	33 (32)	45 (22)	56 (24)
NA, n (%)				
,000 $\log_{10}$ IU/mL	53 (26)	26 (25)	27 (13)	48 (20)
000 $\log_{10}$ IU/mL	152 (74)	76 (75)	178 (87)	187 (80)
is, n (%)	33 (16)	16 (16)	63 (31)	111 (47)
genotype, n (%)				
	76 (37)	N/A	29 (14)	82 (35)
CC	129 (63)	N/A	173 (84)	143 (61)

s 119 (58%) null responders, 84 (41%) partial responders, and 2 (1%) relapsers.
s 71 (30%) patients with depression, 87 (37%) with anemia/neutropenia, and 77 (33%) with compensated advanced rrhosis with thrombocytopenia (6 with advanced fibrosis [F3], 70 with cirrhosis [F4], and 1 not reported).

rologic Response: SVR_{12}



- SVR_{12} rates documented on or after posttreatment Week 12
  - Treatment-naive: 91%
  - Nonresponders: 82%
  - Ineligible/intolerant: 83%

RNA < lower limit of assay quantitation (25 IU/mL)
nts with missing SVR_{12} data counted as treatment failures

mmary

ll-oral DCV + ASV therapy achieved SVR_{12} rates up to 1% in treatment-naive, 82% in nonresponder, and 3% in ineligible/intolerant patients with genotype 1b

- SVR_{12} rates were similar in non-cirrhotic (85%) and cirrhotic (84%) patients
- No differences by age, gender, race, *IL28B* genotype, or prior IFN/RBV treatment experience

CV + ASV was generally safe and well tolerated

- Only 2% of patients discontinued treatment due to adverse events

CV is being further evaluated in all-oral combinations multiple patient populations of high unmet need

Safety and Efficacy of the All-oral Regimen of MK-5172/MK-8742 + Ribavirin in Treatment-naïve, Non-cirrhotic Patients With Hepatitis C Virus Genotype 1 Infection: The C-WORTHy Study

ezode[1], L. Serfaty[2], J.M. Vierling[3], M. Kugelmas[4], B. Pearlman[5], W. Sievert[6], W. Ghesquiere[7], E. uckerman[8], F. Sund[9], M. Shaughnessy[10], P. Hwang[10], J. Wahl[10], M.N. Robertson[10], B. Haber[10]

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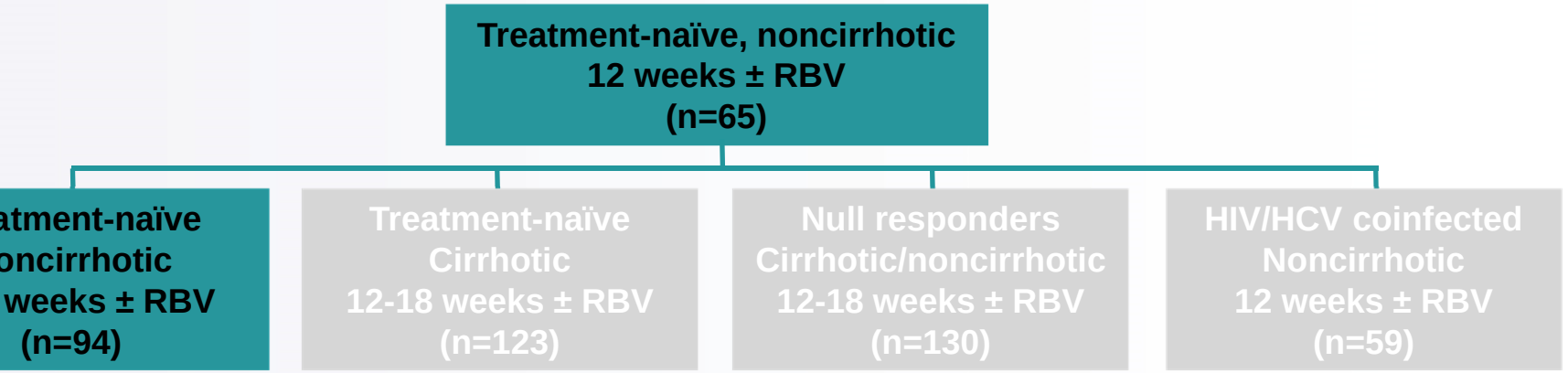
m: C-WORTHy TN

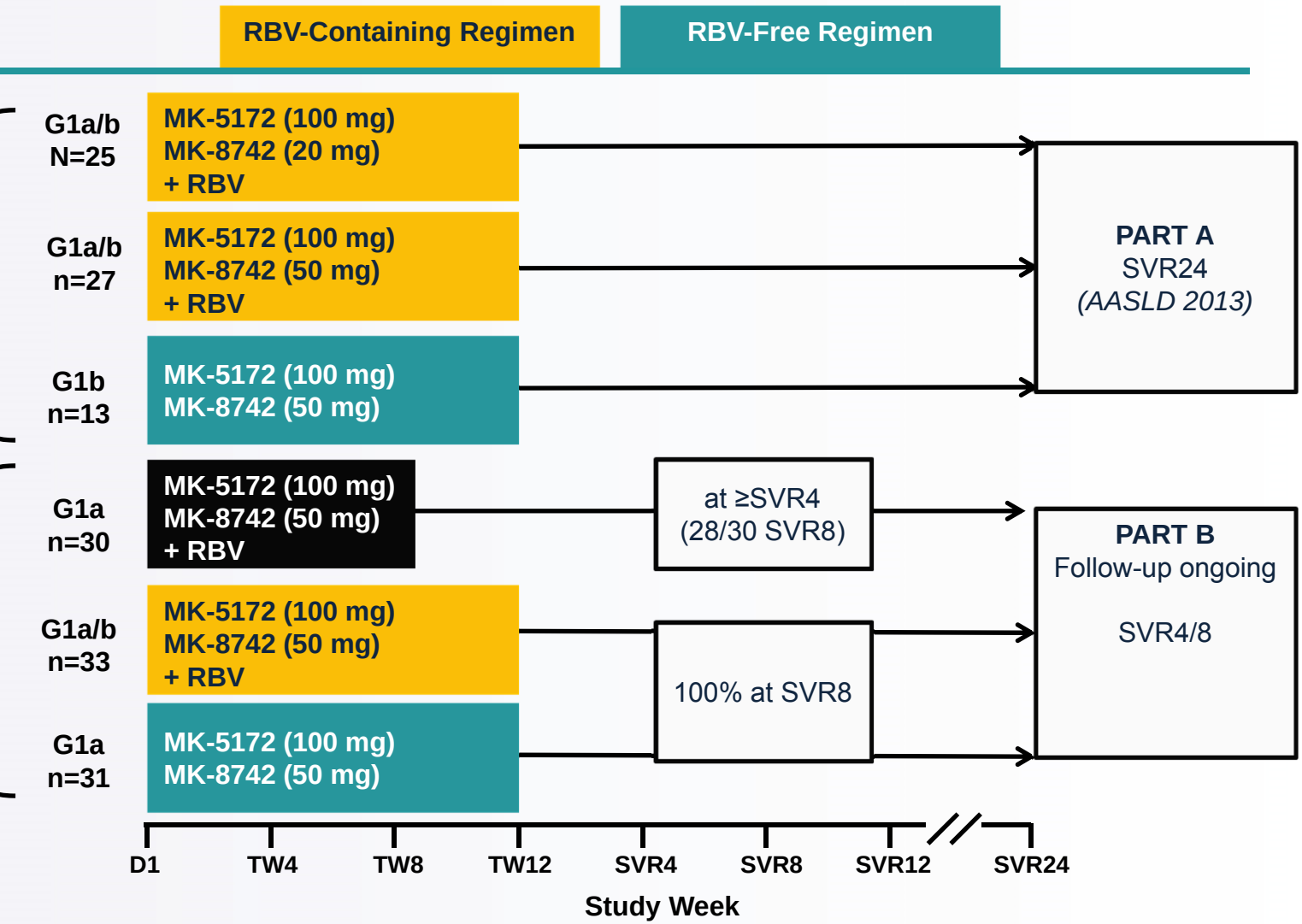
o assess the efficacy/safety of an 8- to 12-week regimen of MK-5172 + K-8742 ± weight-based ribavirin in treatment-naïve, noncirrhotic atients with HCV G1 infection



ey inclusion/exclusion criteria:

- Treatment-naïve patients ≥ 18 years old with chronic HCV G1a or G1b infection
- Liver biopsy or noninvasive test (METAVIR F0-F3)
- Minimum baseline hemoglobin: 12 g/dL (females) or 13 g/dL (males)
- HIV and hepatitis B virus negative
- Alanine aminotransferase (ALT) as aspartate aminotransferase (AST) <350 IU/L

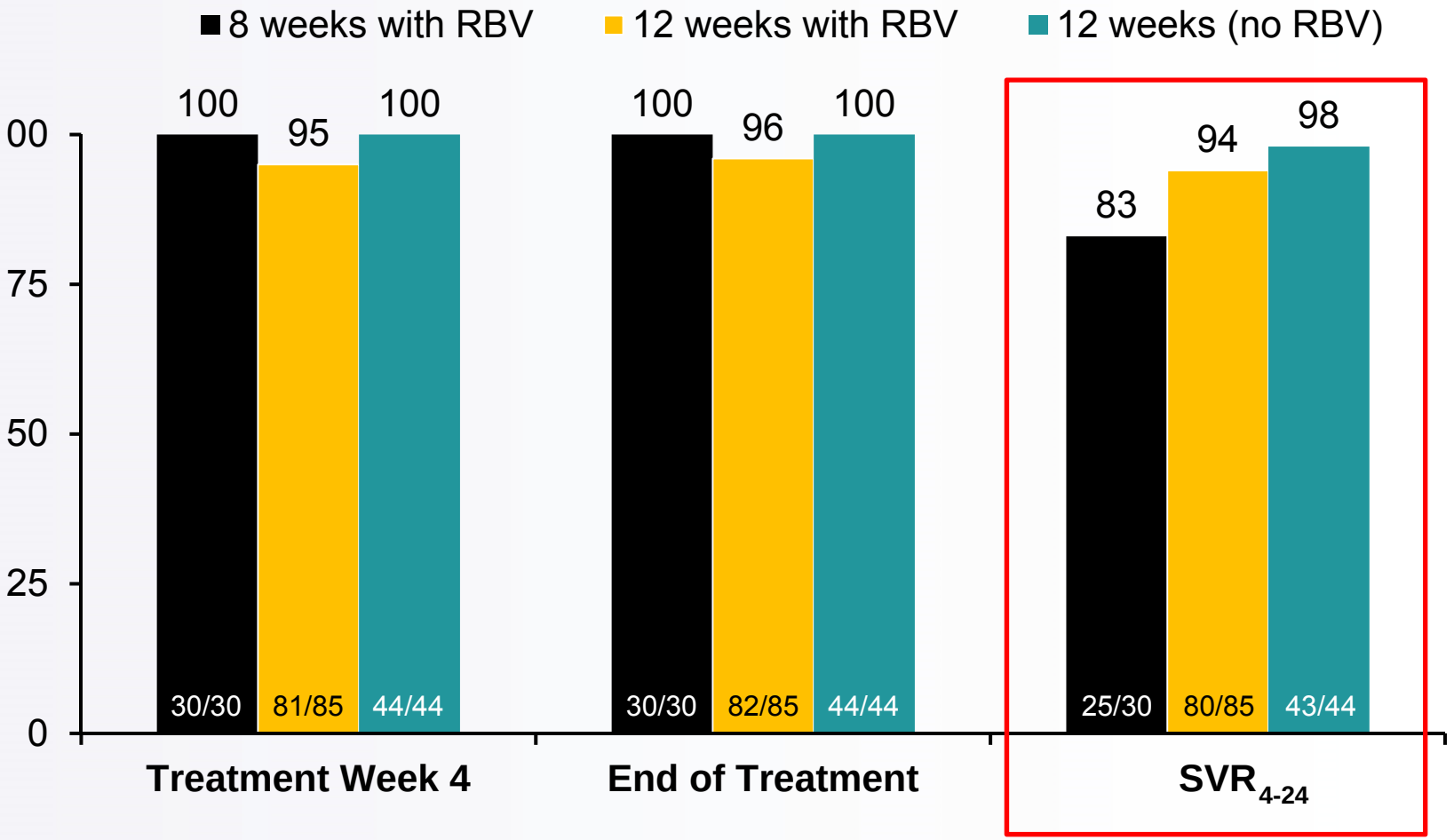
udy Design



ustained virologic response; TW = treatment week.

WORTHy (A+B) – Overall Efficacy (SVR_{4-24})*

ntion-to-Treat (Nonvirologic Discontinuation = Failure)



: 100% of patients have completed SVR24; Part B: 8-week arm, 93% of patients have completed SVR8;
ek arms, 100% of patients have completed SVR8; 2 patients (Part A), 2 patients (Part B) discontinued early
re counted as failures).

mmary

fficacy

- MK-5172/MK8742 once daily with or without RBV for 12 weeks is highly efficacious with a SVR of 94%-98%
- MK-5172/MK-8742 + RBV for 8 weeks in patients with HCV G1a infection had an $SVR4_{4/8}$ of 83%
- Most common type of virologic failure was relapse after a treatment duration of 8 weeks

afety

- All treatment regimens were generally safe and well-tolerated
- There were no early discontinuations due to drug-related Aes
- No grade 3 or 4 laboratory abnormalities

dipasvir/Sofosbuvir With and Without Ribavirin for 8 Weeks Compared to Ledipasvir/Sofosbuvir for 12 Weeks in Treatment-Naïve Noncirrhotic Genotype-1 HCV-Infected Patients: The Phase 3 ION-3 Study

V. Kowdley[1], Stuart C. Gordon [2], K. Rajender Reddy[3], Lorenzo Rossaro[4], David E. Bernstein[5], Di An[6], Evguenia S. Svarovskaia[6], Robert H. Hyland[6], Phillip S. Pang[6], William T. Symonds[6], John G. McHutchison[6], Andrew J. Muir[7], Paul J. Pockros[8], David C. Pound[9], Michael W. Fried[10]

Virginia Mason Medical Center, Seattle, WA, USA; [2]Henry Ford Health System, Detroit, MI, USA; astroenterology and Hepatology, University of Pennsylvania, Philadelphia, PA, USA; [4]University of ornia Davis Medical Center, Sacramento, CA, USA; [5]North Shore University Hospital, Manhasset, NY, A; [6]Gilead Sciences, Inc., Foster City, CA; [7]Division of Gastroenterology and Duke Clinical Research te, Duke University School of Medicine, Durham, NC, USA; [8]Scripps Clinic, La Jolla, CA; [9]Indianapolis penterology Research Foundation, Indianapolis, IN, USA; [10]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

ackground and Aims

1 Treatment-Naïve (ION-3)

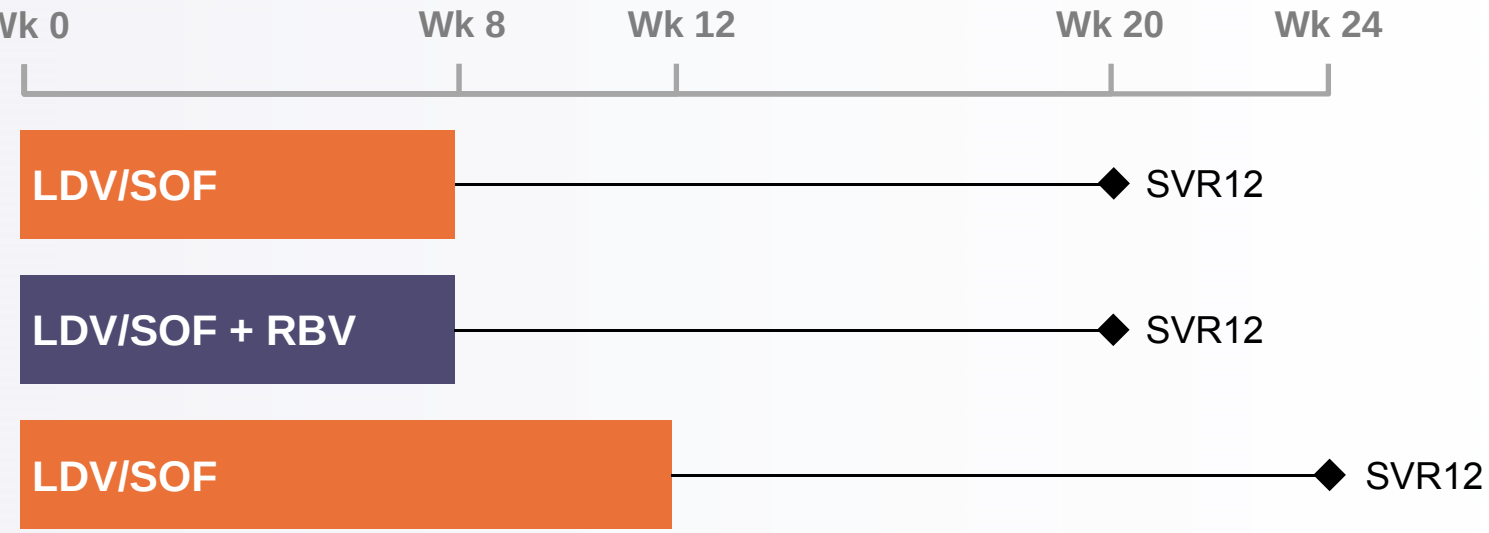
DV/SOF ± RBV for 8 weeks and LDV/SOF for 12 eeks demonstrated high SVR rates in the Phase LONESTAR study in treatment-naïve HCV atients without cirrhosis[1]

o evaluate whether LDV/SOF for 8 weeks is ffective for HCV treatment-naïve, non-cirrhotic, GT patients or if RBV or a longer treatment duration f 12 weeks is required to achieve high SVR rate

tz E, et al. *Lancet*. 2014;383:515-23

udy Design

1 Treatment-Naïve (ION-3)



T 1 treatment-naïve patients without cirrhosis

road inclusion criteria

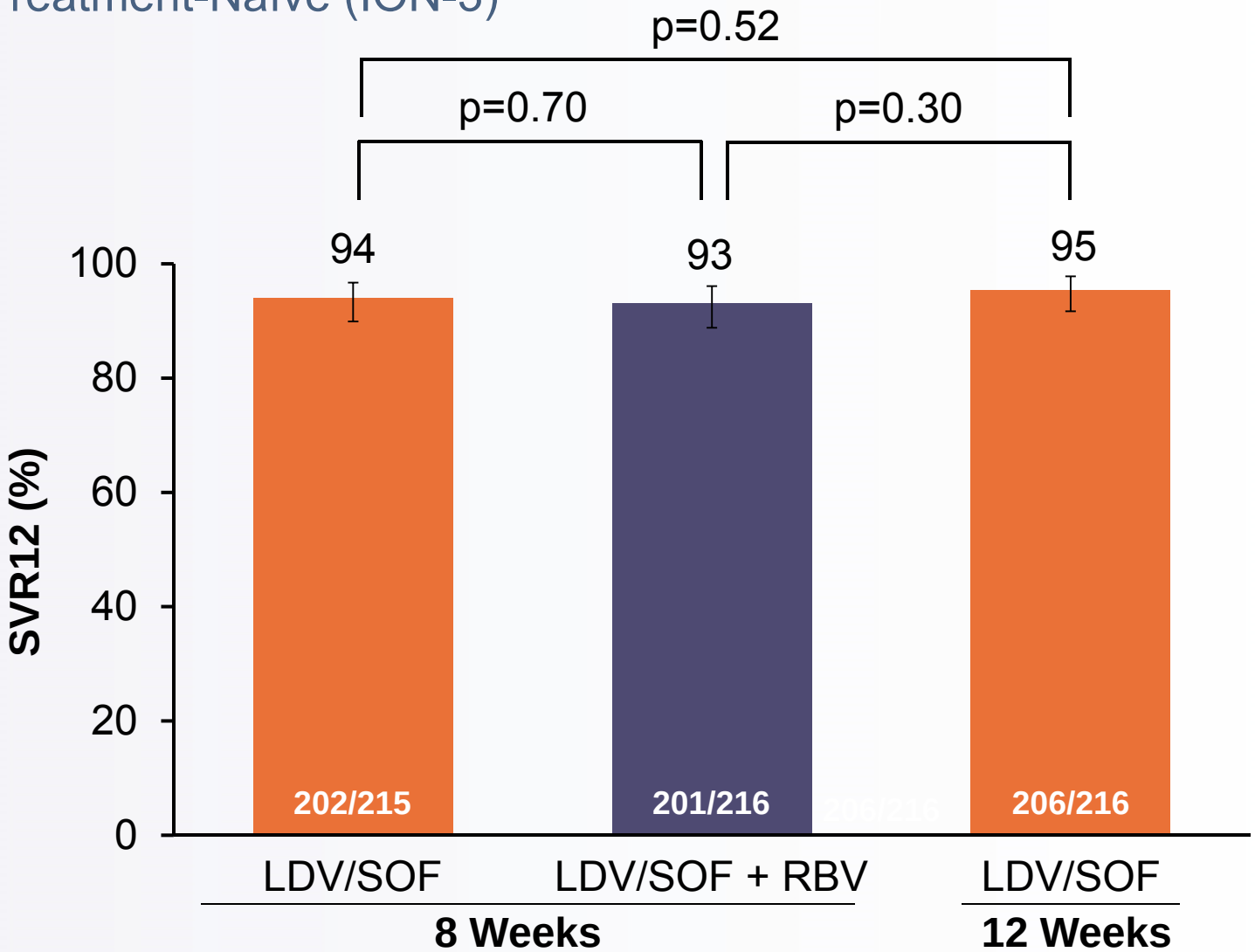
- No upper age or BMI limit
- Opiate substitution therapy allowed

47 patients randomized 1:1:1 across three arms

tratified by HCV subtype (1a or 1b)

esults: Non-Inferiority Comparison

1 Treatment-Naïve (ION-3)



ars represent 95% confidence intervals.

onclusions

1 Treatment-Naïve (ION-3)

- DV/SOF ± RBV for 8 or 12 weeks results in high VR12 rates
- o difference in efficacy among the groups was observed
- ost and viral factors traditionally associated with lower VR rates did not affect SVR12 rates
- DV/SOF ± RBV was safe and well tolerated
  - RBV contributed to a higher incidence of AEs and laboratory abnormalities
- n 8 week LDV/SOF treatment regimen is a safe and ffective treatment for treatment-naïve non-cirrhotic patients ith HCV GT 1 infection

ev K, et al. *NEJM In Press*

ct #P1324

lipasvir (LDV) and Sofosbuvir (SOF) Combination Improves Patient-Reported Outcomes (PRO) During Treatment of ronic Hepatitis C (CH-C) Patients: Results From the ION-1 Clinical Trial

Z. Younossi[1], M. Stepanova[1], P. Marcellin[2], N. Afdhal[3], F. Nader[1], S. Hunt[4]

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ackground

nterferon-based treatment for chronic hepatitis C
CH-C) causes substantial side effects that
egatively impact patient-reported outcomes (PROs).

he use of ribavirin (RBV) is associated with
dditional burden on PROs

merging interferon- and ribavirin-free regimens are
xpected to result in less if any adverse events and,
herefore, better PROs in patients undergoing anti-
CV treatment

m

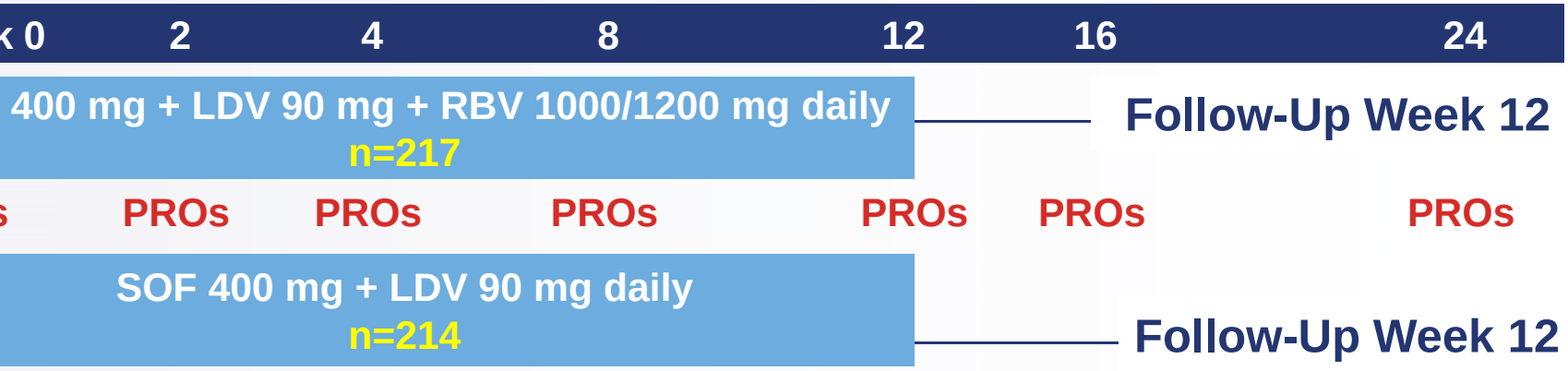
o assess patient reported outcome of CH-C
atients treated with sofosbuvir and ledipasvir
LDV+SOF) with or without ribavirin in the 12
eeks arms of ION-1 clinical trial

N-1 Multicenter Phase 3 Clinical Trial

31 HCV genotype 1 treatment-naïve patients in 12 weeks arm of the study

inical data: 52±11 years old, 59% male, 16% cirrhotic, 56% from USA

atient-reported outcome (PRO) questionnaires were completed at aseline, during and post-treatment: SF-36, FACIT-F, CLDQ-HCV, WPAI:SHP

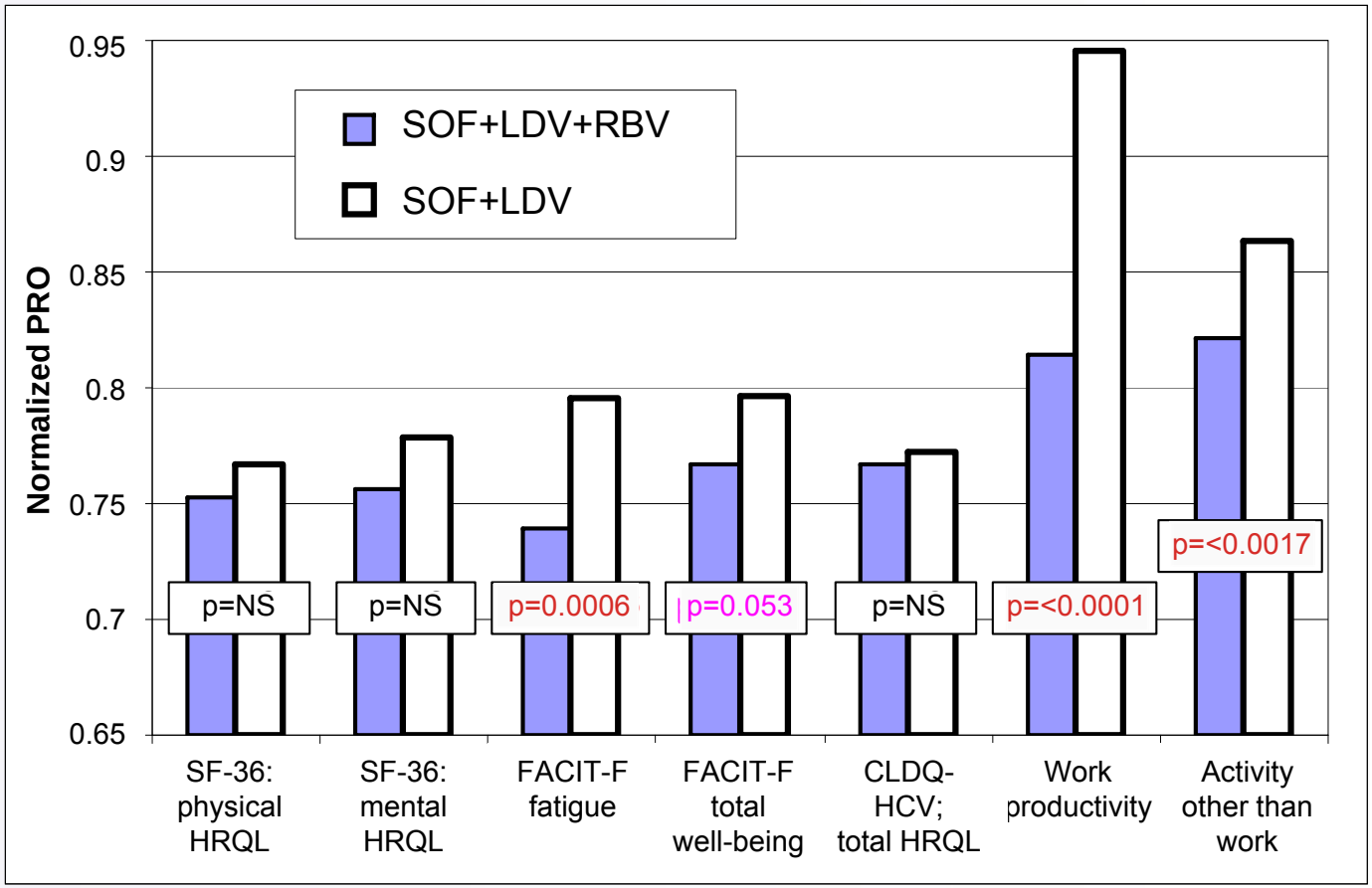


eatment-related anemia: 74.2% in LDV+SOF+RBV, 7.0% in LDV+SOF <0.01)

VR rate: 97.2% in LDV+SOF+RBV, 98.6% in LDV+SOF (p=NS)

-treatment and post-treatment HCV RNA viral load results were blinded to patients and investigators

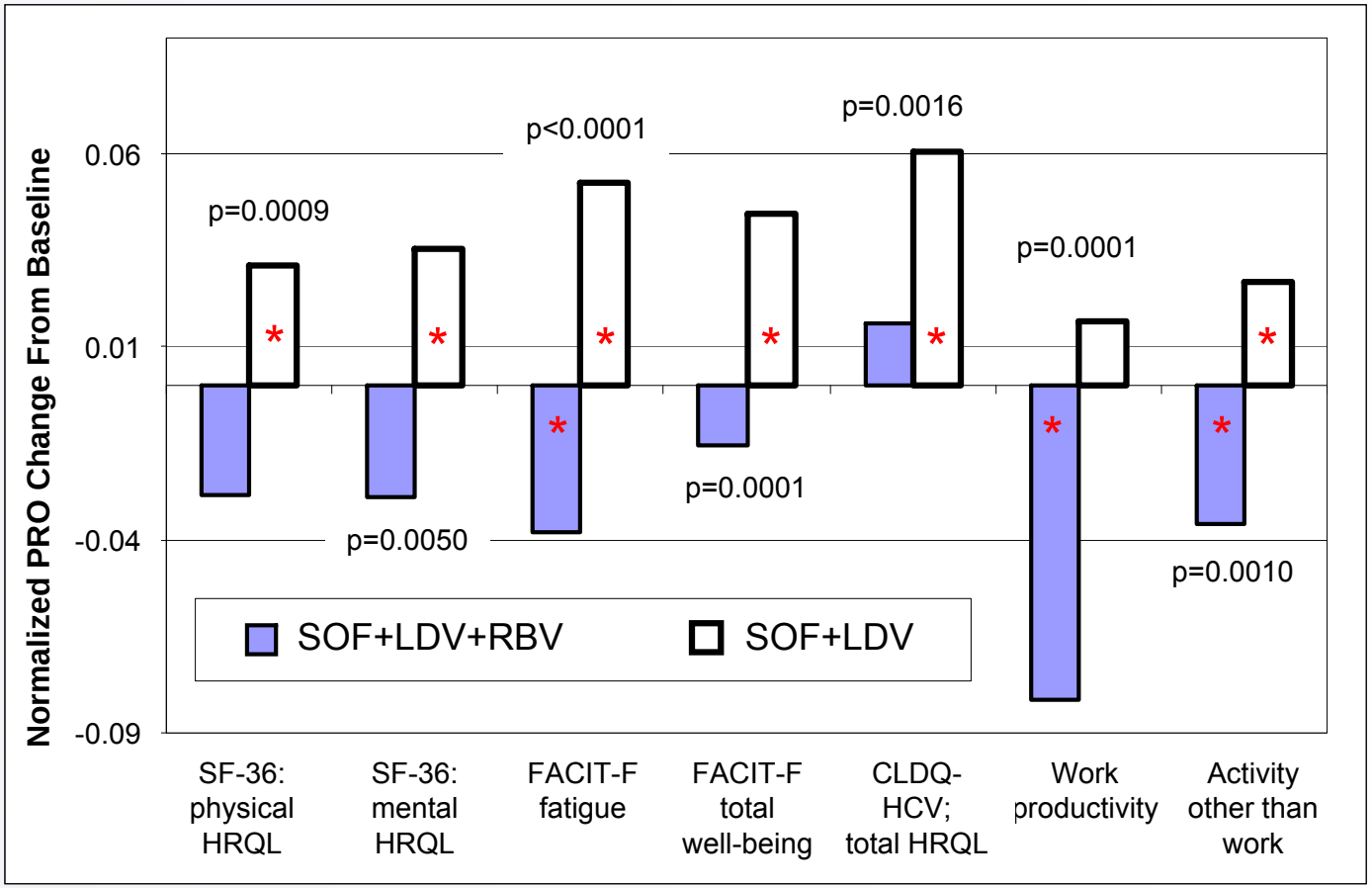
RO Scores in Patients Treated With Ledipasvir d Sofosbuvir With or Without Ribavirin: eatment Week 12



ues represent differences between treatment regimens

not significant (p>0.05)

hanges in PRO Scores From Baseline to eatment Week 12



ues represent differences between treatment regimens

0.05 for the difference from baseline

onclusions

reatment-naïve genotype 1 CH-C patients eceiving sofosbuvir+ledipasvir have similar SVR nd superior PROs compared to patients receiving he same regimen with added ribavirin

he RBV-free regimen is associated with improved RO scores during treatment and after achieving VR-12

est of HCV from EASL 2014

During this year's EASL meeting (ILC-2014, ondon, England), exciting data regarding a umber of new regimens to treat HCV were resented

he data presented showed that these regimens ave high efficacy, improved safety, and shorter uration of treatment

urthermore, some of these regimens can clearly mprove patient reported outcomes such as fatigue nd HRQL