EFFECTIVENESS, SAFETY AND QUALITY OF LIFE IN PATIENTS TREATED WITH OMBITASVIR/PARITAPREVIR/R ± DASABUVIR ± RIBAVIRIN UNDER REAL-LIFE CONDITIONS – DATA FROM THE GERMAN OBSERVATIONAL STUDY LIFE-C

P. Buggisch[1], U. Naumann[2], R. Link[3], C. Antoni[4], G. Teuber[5], J. Hülsenbeck[6], K. Lohmann[6], M. R. Kraus[7]

[1]ifi Institut, Hamburg, Germany; [2]Praxiszentrum Kaiserdamm, Berlin, Germany; [3]MVZ Offenburg, Offenburg, Germany; [4]Universitätsmedizin Mannheim, Mannheim, Germany; [5]Private Practice, Frankfurt/Main, Germany; [6]AbbVie GmbH & Co. KG, Wiesbaden, Germany; [7]Kreiskliniken Altötting-Burghausen, Burghausen. Germany

Presented at the 2017 International Liver Congress, April 19 – 23, 2017, Amsterdam, The Netherlands

BACKGROUND

In clinical trials and first real-life data, the interferon-free combination regimen of ombitasvir/paritaprevir/r ± dasabuvir (3D REGIMEN) ± ribavirin (RBV) for the treatment of chronic hepatitis C (CHC) has shown high rates of sustained virologic response (SVR) and good tolerability.
Nevertheless, real-life data regarding the health-related quality of life (QoL) are limited, especially for the German population. Therefore, we conducted a non-interventional observational study (LIFE-C) to assess effectiveness, safety, and health-related QoL in patients treated with 3D REGIMEN ± RBV in Germany.

METHODS

All adult patients treated with 3D REGIMEN ± RBV according to the local label were eligible for the study. Before enrollment, all patients voluntarily signed and dated informed consent. Patients' visits were scheduled at the physician's discretion and according to clinical practice. Study documentation was possible at baseline, during and at the end of the treatment, and at post-treatment week 4, 12, and 24. Additionally, at these study time points, patients filled in several questionnaires regarding patient-related QoL outcomes.

Figure 1. Patient Flow through the Study

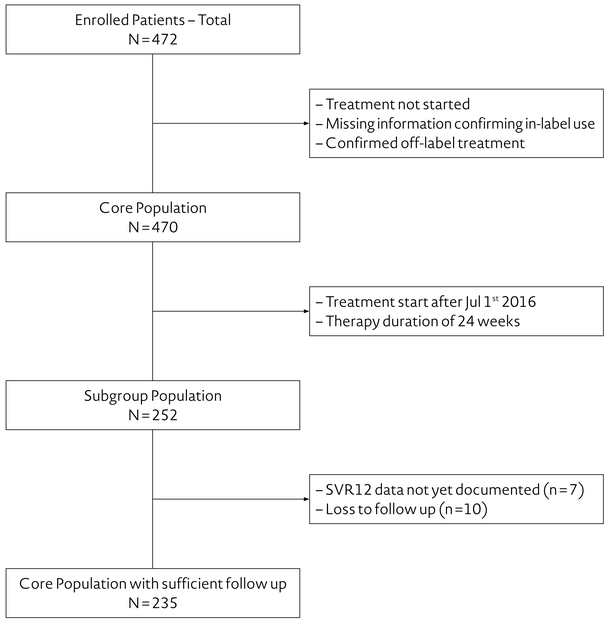

Figure 1 shows the patient flow through the study LIFE-C. Displayed patient numbers / sample sizes are based on the data snapshot from March 31st, 2017. Patient enrollment was closed on Dec 31, 2016.

METHODS CONT'D

Assessments

1. Effectiveness:
Effectiveness is analyzed in the Core Population with sufficient follow up. This population includes all patients with known end of study treatment and one of the following conditions:

- evaluable HCV RNA data ≥ 70 days after the last actual dose, or
- a HCV RNA value ≥ 50 IU/mL at the last measurement or
- HCV RNA value is missing due to safety or efficacy reasons (i.e. patients without a value due to adverse events or breakthrough are included, however, patients lost to follow up are excluded)

2. Safety (evaluation of occurrence of adverse events): includes all patients of the subgroup population

3. Adherence: assessed in all patients of the subgroup population with the respective documentation available

4. Quality of Life Assessments: assessed in all patients of the subgroup population with the respective documentation available

a) Pictorial Representation of Illness and Self-Measure (**PRISM**)[1]: A brief quantitative method to assess the perceived burden of suffering due to illness.
b) Functional Assessment of Chronic Illness Therapy-Fatigue (**FACIT-Fatigue**)[2]
c) Assessment of work productivity and activity impairment (**WPAI** Hep C V2.0)[3]
d) Patient Activation Measure (**PAM-13**)[4]

RESULTS

Table 1. Patient characteristics at baseline (Core population vs. Subgroup population)

Characteristics	Core Population (N = 470)	Subgroup Population (N = 252)
Mean Age (years; mean ± SD) [IQR]	52 ± 13.3 [43 – 62]	53 ± 13.6 [45 – 63]
Male Sex (%, n)	63.4 % (n = 298)	61.5 % (n = 155)
HCV Genotype (%, n)		
GT1a	30.9 % (n = 145)	27.8 % (n = 70)
GT1b	59.1 % (n = 278)	61.9 % (n = 156)
GT4	10.0 % (n = 47)	10.3 % (n = 26)
Cirrhosis (%, n)	10.2 % (n = 48)	7.5 % (n = 19)
Transition to Cirrhosis (%, n)	6.8 % (n = 32)	5.6 % (n = 14)
No Cirrhosis (%, n)	83.0 % (n = 390)	86.9 % (n = 219)
Treatment-experienced (%, n)	33.6 % (n = 158)	33.3 % (n = 84)
HCV RNA (log10 IU/mL; mean ± SD) [IQR]	5.86 ± 0.93 [5.47 – 6.49]	5.92 ± 0.80 [5.49 – 6.49]
HIV (%, n)	6.6 % (n = 31)	7.9 % (n = 20)
HBV (%, n)	2.6 % (n = 12)	2.0 % (n = 5)
At least 1 comorbidity (%, n)	68.9 % (n = 324)	71.0 % (n = 179)

IQR = interquartile range

RESULTS CONT'D

Figure 2. Effectiveness – SVR Rates

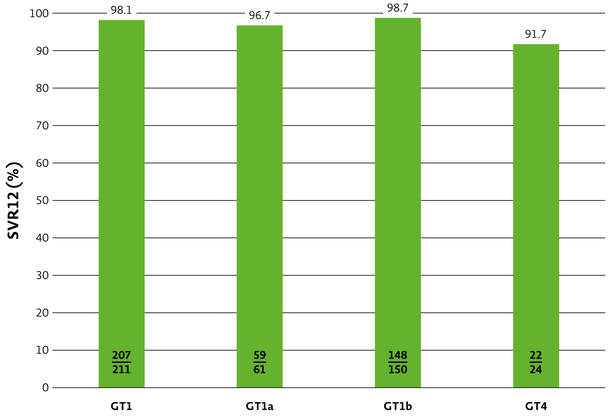

Table 2. Quality of Life – Patient Reported Outcomes

Questionnaire	Baseline (Mean)	On Treatment (Mean Delta)	End of Treatment (Mean Delta)	SVR 12 (Mean Delta)
PRISM	11.8 (n = 251)	–	–	+6.35 (n = 206)
FACIT	36.0 (n = 241)	+0.99 (n = 198)	+1.96 (n = 189)	+4.74 (n = 166)
WPAI (Work Prod. Imp.)	17.3 (n = 96)	–	+4.4 (n = 78)	–5.4 (n = 67)
WPAI (Total Activ. Imp.)	26.8 (n = 236)	–	–1.5 (n = 176)	–11.7 (n = 158)
PAM-13	65.6 (n = 205)	–	+0.18 (n = 139)	–

Changes over time are presented as delta from BL scores for the subgroup of patients that completed the respective evaluation time point (OT, EoT, SVR12).

Altogether, 45 study sites participated in the study, including 32 private practices / private hospitals, 9 academic / university hospitals, and 4 other institution types. Most of the sites (n = 30) see 25 – 100 CHC-patients per month, followed by 8 sites with more than 100 CHC-patients, and 7 sites seeing less than 25 CHC-patients.
The study started in 2015, December. Enrollment was terminated on December 31st, 2016. Altogether, 472 patients were enrolled. Sufficient data for baseline, safety and effectiveness were available for 470, 252, and 235 patients, respectively (**Figure 1**). Overall SVR12 was 97.4 % (n = 229/235) (**Figure 2**) with fatigue, pruritus and rash as the most common adverse events (**Table 3**). Within the subgroup population it could be demonstrated that high rates of adherence (95 – 105 %) were achieved by 95.6 % of antivirally treated patients (n = 215/225). The course of assessed QoL data is displayed in **Table 2**.

RESULTS CONT'D

Table 3. Safety – Adverse Events

TEAE	Subgroup Population (N = 252)
Adverse Events	
Patients with at least 1 AE	66 (26.2 %)
Total number of AEs	113
Type of Adverse Event	
Fatigue	19 (7.5 %)
Pruritus	10 (4.0 %)
Rash	8 (3.2 %)
Serious Adverse Events	
Patients with at least 1 SAE	5 (2.0 %)
Total number of SAEs	5

CONCLUSIONS

- Under real-world conditions, ombitasvir / paritaprevir/r ± dasabuvir ± RBV is highly effective and well tolerated. Overall SVR12 was 97.4 % with the highest effectiveness in **GT1b** (98.7 %).
- Perceived burden of disease (**PRISM**) and work productivity / activity (**WPAI scores**) showed the most distinct improvements regarding health-related QoL.

REFERENCES

1. Büchi et al. Psychother Psychosom 2002; 71:333 – 41.
2. Webster K et al. Qual Life Res 1999;8:604.
3. Reilly MC et al. Pharmacoeconomics 1993;4:353 – 65.
4. Hibbard JH et al. Health Serv Res 2004; 39:1005 – 26.

ACKNOWLEDGEMENTS

We thank all the participating patients and physicians of the LIFE-C study. The study was sponsored by AbbVie Deutschland GmbH & Co. KG. The authors wish to thank Ina Burghaus, Prometris GmbH, for providing statistical support and Arne Schaefer for medical writing support in the development of this poster. The financial support for these services was provided by AbbVie.

DISCLOSURES

AbbVie sponsored this study and contributed to the design, study conduct, and analysis. AbbVie participated in the interpretation of data, review, and approval of the poster. All authors had access to all relevant data. P.B. has received research funding and/or has acted as a speaker or consulter for AbbVie, BMS, Falk, Gilead, Janssen, Merz, MSD, and Roche. U.N. has received research funding and/or has acted as a speaker or consulter for Gilead, BMS, Janssen, MSD, Roche, AbbVie, and ViiV. R.L. – nothing to disclose. C.A. has acted as a speaker or consultant for Gilead, MSD, AbbVie, Janssen, Roche, Falk, BMS, Bayer. G.T. has received research funding and/or has acted as a speaker or consulter for AbbVie, BMS, Gilead, MSD, Janssen, Roche. M.R.K. has received research funding and/or has acted as a speaker or consulter for AbbVie, BMS, Gilead, Janssen, Falk, MSD, Intercept and Roche. K.L. and J.H. are AbbVie employees and may hold stock or options.