REAL-WORLD DATA ON SAFETY AND EFFECTIVENESS OF GLECAPREVIR/PIBRENTASVIR FOR THE TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C VIRUS INFECTION ON OPIOID SUBSTITUTION THERAPY: LATEST RESULTS FROM THE GERMAN HEPATITIS C-REGISTRY

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Background:
The coformulated direct-acting antivirals glecaprevir/pibrentasvir (G/P) are approved to treat chronic hepatitis C virus (HCV) genotype 1–6 infection. In clinical trials, G/P demonstrated high efficacy, but real-world data in patients on opioid substitution therapy (OST), a population for which antiviral treatment is critical for HCV elimination, are limited. Here we report the first real-world data on the effectiveness and safety of G/P for OST patients within the German Hepatitis C-Registry (DHC-R).

Methods:
The DHC-R is an ongoing, non-interventional, multicenter, prospective, monitored registry study. Data were collected between July 28, 2017 and February 9, 2018 from 104 sites in Germany. The analysis included adult HCV-infected patients who were treated with G/P according to the European Medicines Agency label. The primary endpoint was sustained virologic response at post-treatment week 12 (SVR12). Safety and tolerability were assessed in patients that completed treatment.

Results:
As of February 9, 2018, 638 patients had initiated on-label treatment with G/P and are included in the baseline analysis. Patients on OST comprised 26% (168/638) of the baseline population, of which most patients were treatment-naive, without cirrhosis and had HCV genotype 1a or 3. Among patients with available SVR12 data, 96% (27/28) of OST patients and 97% (66/68) of non-OST patients achieved SVR12. There were no virologic failures: of three early discontinuations, one OST patient was lost to follow-up and two non-OST patients discontinued treatment due to adverse events (AE). In the modified intention-to-treat population which excluded non-virologic failures, SVR12 was 100% for both OST and non-OST patients. The safety population included 321 patients in total. Among OST patients, 2% (2/84) experienced serious AEs (SAE) without any treatment discontinuations due to AE/SAE.

Conclusion:
In this real-world analysis, G/P treatment yielded favorable effectiveness and safety results in patients on OST. Updated data and SVR12 results will be presented.

Disclosure of Interest Statement:
Data were derived from the German Hepatitis C-Registry (Deutsches Hepatitis C-Register), a project of the German Liver Foundation (Deutsche Leberstiftung), managed by Leberstiftungs-GmbH Deutschland in cooperation with the Association of German gastroenterologists in private practice (bng). Financial support of analysis and publication was provided by AbbVie. The German Hepatitis C Registry is financially supported by AbbVie Deutschland GmbH & Co. KG, Bristol-Myers Squibb GmbH & Co. KGaA, Gilead Sciences GmbH, Janssen-Cilag GmbH, MSD Sharp & Dohme GmbH as well as Roche Pharma AG (financial support until 2017-07-14).

J Reimer: Speaker / advisory board / unrestricted educational grant: AbbVie, Bristol-Myers Squibb, Gilead, Janssen-Cilag, MSD.
A Stoehr: Speaker: AbbVie, Gilead, Janssen, and MSD; Advisor: AbbVie and ViiV.
U Naumann: Speaker/advisory board for AbbVie, Bristol-Myers Squibb, Gilead Sciences, Janssen, Mundipharma, MSD, Roche, ViiV.
G Teuber: Speaker/Teaching: AbbVie, BMS; Advisory Board: Janssen, Gilead, MSD.
C Zamani: Advisory board: AbbVie
S Mauss: Speaker: AbbVie, Gilead, Falk, Janssen and MSD; Advisor: AbbVie and MSD.
N Qurishi: Speaker/Teaching: AbbVie, Gilead, Janssen, MSD, ViiV, Mundipharma, Hexal
K Lohmann, H Kleine and A Pangerl: employees of AbbVie and may hold stock or options
S Christensen: Honoraria for consulting or speaking at educational events from AbbVie, Gilead, Indivior, Janssen-Cilag, MSD, ViiV.
Acknowledgements: Medical writing support was provided by Eleanor Broadberry, MSc, and Scott Battle, PhD, of Medical Expressions and funded by AbbVie.