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INTRODUCTION

Bocceprevir (BOC) is approved in Germany in combination with peginterferon alfa-2a or alfa-2b plus ribavirin in chronic hepatitis C (CHC) patients infected with HCV genotype 1. The efficacy and safety of BOC is well characterized in randomized clinical trials but real world experience is currently limited.

Since 2003 the Association of German Gastroenterologists in Private Practice (BNG, Berufsverband Niedergelassener Gastroenterologen Deutschlands e.V.) in cooperation with Roche, Germany, has been conducting an real world nation wide observational studies to determine the quality of treatment for CHC in routine clinical practice.

Since 2011 the Bng has been conducting a new German-wide, non-interventional study (PAN) in cooperation with Roche. Within this observational study HCV triple therapy including BOC or telaprevir (TVP), peginterferon alfa-2a and ribavirin (RBV) is being investigated.

OBJECTIVE

In this interim analysis after 12 weeks of treatment with BOC, PegIFN alfa-2a 180 µg and RBV HCV genotype 1 patients were evaluated for efficacy and safety parameters.

METHODS

This evaluation is part of a large ongoing German multicentre, open-label observational study including adults with detectable HCV RNA. The study allowed the choice of either of the less currently approved protease inhibitors with the dose and duration of HCV treatments including PegIFN alfa-2a (40KD) and RBV at the discretion of the physician. Patients were eligible if they were prescribed TVR or BOC plus PegIFN alfa-2a/RBV.

The screening data include patient age, sex, weight, height, duration of and risk factors for infection, prior antiviral treatment, clinical symptoms, histology, genotype, viral load, concomitant diseases and social status.

Here we report the analysis to treatment naive patients receiving BOC plus PegIFN alfa-2a/RBV who had or had the potential to, complete 12 weeks of treatment including a 4 week lead-in phase with PegIFN alfa-2a/RBV. Patients who initiated BOC ≥21 days or >30 days after starting PegIFN alfa-2a/RBV were excluded from the analysis.

The data collection was performed online via the internet.

The data collected should reflect the routine clinical practice of the participating physicians and only descriptive statistics were reported.

Due to the ongoing nature of the study, the status of data was frozen on August 15th, 2012.

RESULTS

Patients

Between October 2011 and August 2012 129 treatment-naive patients with BOC containing triple therapy and data up to week 12 were included (see Figure 1).

In 68 of these patients, BOC was started between day 21 and 30 after the initiation of PegIFN alfa-2a/RBV. 9 patients were excluded because they started BOC ≥21 days after starting PegIFN alfa-2a/RBV and 52 were excluded because they started BOC >30 days after starting PegIFN alfa-2a/RBV.

Baseline Data

52.9% of the patients were male.

The mean age of the patients was 47.8 ± 10.1 years.

The mean BMI was 27.0 ± 5.2 kg/m².

The mean HCV RNA was 6.0 ± 0.9 log10 IU/mL.

51.5% of patients with a positive test result for aminotransferases had undetectable HCV RNA at week 4.

CONCLUSIONS

Real world experience with BOC plus PegIFN alfa-2a/RBV in Germany show similar virological outcomes and side effects to the phase 3 trials.

Week 8 HCV RNA values essential to determine suitability for reduced treatment duration were not collected in a significant proportion of patients.