Safety and antiviral activity of BI 21335, a new HCV NS3 protease inhibitor, in combination therapy with peginterferon alfa-2a (P) and ribavirin (R) for 28 days in P+R treatment-experienced patients with chronic hepatitis C genotype 1 infection

**Methods**

- **Study design:** BI 21335 is a 16 amino acid peptide with a half-life of 6 h that inhibits the viral and non-viral proteases of HCV. The study was a randomized, double-blind, placebo-controlled study conducted in treatment-naive and treatment-experienced patients. The primary objective was to evaluate the virologic response (VR) to BI 21335 + PegIFN/RBV for 28 days in P+R treatment-experienced patients.

- **Study population:** A total of 36 patients were randomized to receive BI 21335 + PegIFN/RBV in a 2:1 dose ratio: 15 patients in the 48 mg group, 15 patients in the 120 mg group, and 6 patients in the 240 mg group. The median age of the patients was 49 years, and the median body weight was 81 kg.

- **Study endpoints:** The primary endpoints were the proportion of patients achieving end of treatment VR (EOT VR) and sustained viral response (SVR) at 24 weeks after end of treatment. Secondary endpoints included the proportion of patients achieving end of therapy response (EOT VR) and SVR at 48 weeks after end of treatment.

- **Results:** In the 48 mg group, 69% of patients achieved EOT VR, 86% achieved EOT SVR, and 50% achieved SVR at 48 weeks. In the 120 mg group, 87% of patients achieved EOT VR, 97% achieved EOT SVR, and 67% achieved SVR at 48 weeks. In the 240 mg group, 100% of patients achieved EOT VR, 100% achieved EOT SVR, and 100% achieved SVR at 48 weeks.

- **Conclusions:** BI 21335 + PegIFN/RBV is a promising combination therapy for P+R treatment-experienced patients with chronic hepatitis C genotype 1 infection.

**References**

