1.0 Premise

TMC435 is a once-daily oral NS3/4A protease inhibitor currently in Phase IIb clinical development for the treatment of hepatitis C virus (HCV) infection.

2.0 Methods

2.1 Study design

A total of 37 patients were enrolled across Germany, Belgium, and Thailand (GT 2 [n=6]; GT 3 [n=8]; GT 4 [n=8]; GT 5 [n=7]; GT 6 [n=8]).

2.2 Study population

Eligible patients were male or female aged 18–70 years with documented chronic HCV infection, with or without cirrhosis (up to Child Pugh A liver disease), and an HCV RNA level of 25 IU/mL undetectable at Day 8, and the proportion of patients experiencing 1 log10 IU/mL increase in HCV RNA level from nadir, not detectable at Day 8.

2.3 Patient demographics and baseline disease characteristics

A summary of patient demographics and baseline characteristics is shown in Table 1, and a summary of disease parameters is shown in Table 2.

2.4 Assessments

10h 20 3 4 5 6 7 8 9 10 11 FUP1 FUP2

Figure 1. Individual changes in plasma HCV RNA (log10 IU/mL) for each GT cohort.

3.0 Results

3.1 Safety and tolerability

4.0 Conclusions

Table 4. Mean (± SE) baseline and Day 7 hepatic parameters for each GT cohort.

Table 3. Adverse events occurring in at least 5% of patients during the TMC435 treatment period is shown in Table 3.

Table 2. Mean (±SE) change from baseline in plasma HCV RNA (log10 IU/mL) for each GT cohort.

Figure 2. Mean (±SE) change from baseline in plasma HCV RNA (log10 IU/mL) for each GT cohort.

Figure 3. Mean (±SE) change from baseline in plasma HCV RNA (log10 IU/mL) for each GT cohort.

Figure 4. Change from baseline in HCV RNA (log10 IU/mL) for each GT cohort.

Poster 859

A Phase IIa, open-label study to assess the antiviral activity of TMC435 monotherapy in patients infected with HCV genotypes 2–6


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