Age and Gender Effects on the Pharmacokinetics of HCV NS5A Inhibitor MK-8742

Subject Demographics

- Of the 24 subjects enrolled, 26 were White and 8 were Asian (Table 1).

Safety and Tolerability

- A single dose of 100 mg MK-8742 was well tolerated in the healthy elderly male and female subjects in this study.
- There were no deaths, serious AEs, or laboratory AEs reported during the study. There were also no significant changes in the safety laboratory profiles, vital signs, or ECG assessments during the study.

MK-8742 Pharmacokinetics

- The observed gender effect may partially be explained by the differences in body weight and BMI.

Study Design:

A single-dose 100 mg administration of MK-8742 results in peak plasma concentrations that are approximately 33% greater in healthy elderly female subjects when compared with elderly male subjects (Table 2).

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Table 2. Statistical Comparison Summary of Plasma Pharmacokinetics of MK-8742 Following the Administration of a Single Dose of 100 mg MK-8742 to Healthy Elderly Male and to Healthy Elderly Female Subjects

Conclusions

- The mean plasma AUC parameters, following a single 100 mg dose of MK-8742 in healthy elderly female subjects is approximately 70% greater than that observed in healthy elderly male subjects. The mean plasma AUC parameters, following a single 100 mg dose of MK-8742, was generally similar between healthy elderly male and female subjects from MK-8742 PN001-Part I.

Table 3. Statistical Comparison Summary of Plasma Pharmacokinetics of MK-8742 Following the Administration of a Dose of 100 mg MK-8742 to Healthy Elderly Male and to Healthy Young Male Subjects (Panel C and Historical Control Data)

Exploratory Analyses of BMI and Total Body Weight

• The weight effect was not apparent in elderly female subjects who were lower than 70 kg.
• No effect of increased weight on decreased MK-8742 exposures was apparent in male subjects.
• Similar results were observed for C₂₀₀₀ and C₀₂₀₀₀.
• Overall, the results suggested that the observed gender effect may partially be explained by the difference in body weight between sexes.

Disclosures

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