Dry powder inhaled ribavirin in healthy volunteers: safety, tolerability, lung and systemic pharmacokinetics

Introduction

This study aimed to investigate the safety, tolerability, and lung and systemic pharmacokinetics of inhaled ribavirin (Ribavirin [ELF]) in healthy subjects. The study was funded by GlaxoSmithKline, Collegeville, Pennsylvania, United States; Hammarmedic Sciences Research, London, United Kingdom; GlaxoSmithKline, Stockley Park, Middlesex, United Kingdom.

Study Design

A double-blind, placebo-controlled, randomized, 3-dose escalating, phase 1b study was conducted at 2 sites in the United States. A single dose of ribavirin was administered to healthy adult male and female subjects aged 18-65 years. The study design is outlined in Table 1.

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Primary

- To investigate the safety and tolerability of inhaled dry powder ribavirin following single escalating doses in healthy volunteers.
- To investigate systemic PK of inhaled dry powder ribavirin following single escalating doses in healthy subjects.
- To assess the concentration of ribavirin following single escalating doses of inhaled dry powder ribavirin in healthy subjects.
- To investigate the safety and tolerability of inhaled dry powder ribavirin following single escalating doses in healthy volunteers.

Secondary

- To assess dose proportionality of inhaled dry powder ribavirin compared with systemic PK parameters.

Results

Subjects

A total of 96 healthy subjects were enrolled; 48 of whom received ribavirin subject characteristics are presented in Table 2.

Safety and Tolerability

- There were no deaths or serious adverse events (SAEs) reported in the study.
- No reported SAEs or deaths were reported in the laboratory, electrocardiogram (ECG), intensity, spirituality, or other assessments.
- No serious adverse events were observed in the study.
- No significant trend was observed in the laboratorio, electrocardiogram (ECG), intensity, spirituality, or other assessments.

Conclusion

- These data show that the safety and tolerability of inhaled ribavirin are consistent with published data.

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- The authors declare no conflicts of interest.
- This study was supported by GlaxoSmithKline, Collegeville, Pennsylvania, United States.

References