Safety and Pharmacokinetics of Multiple Doses of CD101 IV: Results From a Phase 1, Dose-Escalation Study
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ABSTRACT
CD101 IV is a novel echinocandin being developed as a high-exposure, once-weekly agent for the treatment and prevention of invasive fungal infections. It is orally bioavailable, which enables bioavailability from mixed regimens. CD101 IV is a single-dose, continuous infusion, placebo-controlled, single-center, dose-escalation study of CD101 IV in healthy adults (ages 18-50 years) to establish the safety, tolerability, and pharmacokinetics (PK) of multiple intravenous doses of CD101 IV. Extensive plasma and urine sampling over 21 days was performed for PK analysis. Safety and tolerability was assessed by adverse events (AEs), vital signs, physical exams, electrocardiograms (ECGs), and hematology and clinical chemistry laboratories up to 21 days after dosing.

RESULTS

Safety

Adverse Events
• Overall incidences of AEs similar between CD101 IV and placebo
• Treatment-emergent AEs (TEAEs) were generally mild, with relatively higher incidence in the group receiving 400 mg 3 doses
• Most common TEAE was truncal distention (bloating, feeling full, nausea, chest tightness), occurring in 36% of subjects with the third dose of 400 mg and 13% of subjects with the second dose of 100 mg
• All these reactions resolved within minutes of infusion without sequelae or interruption/interruption of infusion
• The most frequent TEAE occurring in ≥2 subjects was constipation, in 26% of the 400 mg group
• No SAEs, severe AEs, study withdrawals due to an AE, or deaths

Pharmacokinetics
• Plasma CD101 concentrations were detectable in all subjects through 144 hr after the first dose and through 480 hr after the last dose
• C₀ and AUC increased dose-proportionally with peak plasma concentrations observed at the end of the 480 hr
• PK of CD101 IV supported continued development as a once-weekly therapy for invasive fungal infections.

RESULTS (cont’d)

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REFERENCES

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METHODOLOGY
Study Design and Treatments
• Double-blind, placebo-controlled, single-center, dose-escalation study of CD101 IV in healthy adults (ages 18-50 years)

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