SCY-078 is a novel intravenous and oral triterpenoid antifungal in clinical development for the treatment of invasive and mucocutaneous fungal infections. It has broad-spectrum activity against both Candida and Aspergillus.

SCY-078, a glucan synthase inhibitor with fungicidal activity against Candida spp., exhibits an extensive tissue distribution, making it a suitable candidate for the treatment of vulvovaginal candidiasis (VVC). The purpose of this study was to evaluate the safety and efficacy of oral SCY-078 in subjects with moderate to severe VVC. Here we present the result of the in vitro activity of SCY-078 against clinical isolates obtained from subjects enrolled in this proof-of-concept study.

Subjects were randomized in a 1:1:1 ratio to one of three treatment arms:
- Oral SCY-078 loading dose (1250mg), followed by 750mg QD for 2 days
- Oral SCY-078 loading dose (1250mg), followed by 750mg QD for 4 days
- Oral Fluconazole (FLU) 150mg for 1 day

Subjects were evaluated on Day 24 (test of cure visit) Day 60, Day 90 and Day 120 days (end of study). The analysis included:
- Clinical cure, mycological eradication, and therapeutic cure (defined as 100% clinical and mycological response)
- Comparison of the SCY-078 MIC to FLU to determine if there was resistance development

Vaginal samples were collected at baseline (pre-treatment) and on Day 24, Day 60, Day 90 and Day 120 day for species identification and susceptibility testing.

Determination of Candida sp. was done via API 20C Aux or growth pattern on CHROMagar®.

The majority of subjects presented with C. albicans (N=60 [86%]). All of the baseline isolates were susceptible to SCY-078 and fluconazole.

MICs for SCY-078 and fluconazole, from subjects enrolled in this proof-of-concept study.

The rate of mycological response after treatment with SCY-078 was maintained during the 4-month follow up period.

No significant differences in MICs were observed between baseline and post-treatment isolates among subjects presenting with non-albicans Candida infections.

CONCLUSION

The results of this study indicate that SCY-078 possesses potent activity against Candida spp, resulting in high mycological and clinical cure rates in VVC. The rate of mycological response after treatment with SCY-078 was maintained during the 4-month follow up and there was no development of resistance following treatment.