

RESULTS IN PATIENTS WITH ESOPHAGEAL (EC), OROPHARYNGEAL (OPC), OR INVASIVE (IC) CANDIDIASIS FROM THE CASPOFUNGIN (CAS) COMPASSIONATE USE (CU) STUDY

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Objectives: Immunocompromised patients with documented EC, OPC or IC often fail therapy with amphotericin B (AmB), lipid amphotericin formulations (L-AmB), and/or azoles. CAS, an echinocandin antifungal, is fungicidal against *Candida* species. *Candida* cross-resistance of CAS with the polyenes and azoles has not been seen. Although efficacy has been shown for CAS as a first-line agent for EC and OPC, its role in patients failing AmB, L-AmB, and azoles is not known.

Methods: Patients with documented EC, OPC, and IC who were refractory (R) to or intolerant (I) of amB or a L-amB were enrolled in a CU study. CAS was administered at 50 mg/day (a 70 mg loading dose was added in IC patients). Efficacy was assessed based on the patient's symptomatic (and, in IC, microbiological) response to CAS therapy.

Results: The first 20 patients enrolled predominantly included patients with a primary diagnosis of late-stage HIV infection (40%), hematological malignancy (30%), or diabetes mellitus (10%). There were 8 (40%) with EC, 1 (5%) with OPC, and 11 (55%) with IC. The 11 IC infections included 1 blood infection, 2 abscess (kidney; peritoneal), 2 complicated urinary tract infections, 3 chronic disseminated (hepatosplenic) infections, and 3 patients with multiple sites of infection. 17 of the patients were R to amB or L-amB; 3 were I of amB or L-amB. Of the 17 R patients, 13 had failed multiple prior antifungals (including azoles and 5-FC). One patient was not evaluated for efficacy by the investigator. A favorable response was seen in 14 (74%) of the 19 evaluable patients.

				All Patients (n=19)
				14 (74%)
Complete Response	4	1	4	9
Partial Response	1	-	4	5
Unfavorable Response	3 (37%)	NA	2 (20%)	5 (26%)
Stable Disease	1	-	-	3
Failure	2	-	-	2

CAS was dosed for 7 to 57 days. Based on the limited safety data, CAS was generally well tolerated. No serious drug-related adverse experiences (AEs) were noted. Only 2 non-serious drug-related AEs were noted: phlebitis and increased serum AST in 1 patient each. There were no discontinuations because of a drug-related AE. Four EC/OPC patients received multiple CAS courses. No drug-related AEs were noted during retreatment.

Conclusion: In this study, CAS was effective in patients with EC, OPC, or IC who were refractory to or intolerant of amphotericin formulations.