Treatment Outcomes of Oral Ibrexafungerp in Patients with Severe Fungal Infections, Refractory to or Intolerant of Standard of Care Antifungals: Results from the Phase 3 FURI Study Second Interim Analysis

N. Azie, D. Angulo, on behalf of the FURI Investigators

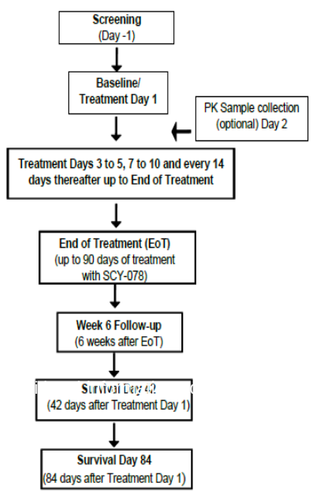
SCYNEXIS, Inc., Jersey City, NJ

INTRODUCTION

There are limited oral treatment options for patients with serious fungal infections. Antifungal triazoles currently provide the only oral option to treat patients who require therapy in an outpatient setting. Ibrexafungerp is a novel IV/oral broad-spectrum glucan synthase inhibitor (triterpenoid class) antifungal with demonstrated *in vivo* activity against *Candida*, *Aspergillus* and *Pneumocystis*. A Phase 3 open-label, single-arm study of ibrexafungerp (FURI) (Clinicaltrials.gov NCT03253094) is ongoing for the treatment of patients with severe fungal diseases who are intolerant of or refractory to standard antifungal therapies.

METHODS

Patients were eligible for enrollment if they had proven or probable, invasive or severe mucocutaneous candidiasis and documented evidence of failure of, intolerance to, or toxicity related to a currently approved standard-of-care antifungal treatment or could not receive approved oral antifungal options (e.g., susceptibility of the organism) and a continued IV antifungal therapy was undesirable or unfeasible due to clinical or logistical circumstances. An independent Data Review Committee assessed treatment responses for 21 patients who completed therapy from October 2018 to October 2019. Patients were enrolled in 11 centers in five countries.



RESULTS

Of the 21 patients analyzed, 14 (66%) were enrolled with invasive candidiasis/candidemia and 7 (33%) with mucocutaneous candidiasis infections with primary underlying diseases listed.

Table 1: FURI Study Patient Demographics

Demographics	Ibrexafungerp
# of patients	21
Mean Days of Therapy	37.1
Primary Underlying Disease:	
• Candidemia	6
• Oropharyngeal Candidiasis	6
• Intra-abdominal Candidiasis	4
• Other *Candida* infections	5

Oral ibrexafungerp was well-tolerated with the most common treatment-related adverse events being gastrointestinal. No safety signals warranting changes in the study were observed.

CONCLUSIONS

Consistent with the first interim analysis, this second interim analysis indicated that oral ibrexafungerp provided a favorable therapeutic response in the majority of patients non-responsive or intolerant to standard of care treatment for *Candida* infections. Continued enrollment in the FURI study is warranted.

Of the 21 patients analyzed, oral ibrexafungerp showed clinical benefit in 17 patients (81%), with 12 patients (57%) achieving a complete or partial response and 5 patients (24%) maintaining stable disease. Four patients (19%) did not respond to the ibrexafungerp treatment (one patient died while on therapy due to the primary underlying disease; the death was deemed not drug-related).

Table 2: FURI Study Outcomes

	Complete/ Partial Response	Stable Disease	Progression of Disease
All Patients (21)	12 (57%)	5 (24%)	4(19%)

Candida glabrata was the most common pathogen isolated, representing 52% of the *Candida* species from these refractory patients. Additionally, there were two pathogens isolated in 5 (24%) patients.

Table 3: FURI Study Outcomes by Pathogen

Pathogen (n)	Complete/Partial Response	Stable Disease	Progression of Disease
***C. glabrata* (8)**	4	2	2
***C. albicans* (4)**	3	1	
***C. krusei* (2)**	1	1	
***C. parapsilosis* (2)**	2		
Two Pathogens			
***C. glabrata/C. albicans* (2)**	1		1
***C. krusei/C. albicans* (1)**	1		
***C. tropicalis/C. albicans* (1)**		1	
***C. glabrata/C. dubliniensis* (1)**			1