P2068

FURI Study: Outcomes in Subjects with Intraabdominal Candidiasis Treated with Oral Ibrexafungerp

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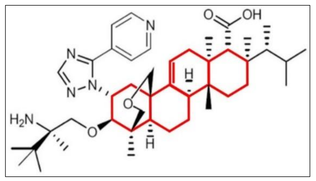
BACKGROUND

Intraabdominal Candidiasis (IAC) is the second most common form of invasive candidiasis after candidemia. *Candida albicans* is still the most common organism causing IAC, but the number of non-*albicans Candida* species causing IAC is growing. Tissue penetration has been identified as a limitation of echinocandin treatment. Ibrexafungerp (IBX) is a glucan synthase inhibitor with excellent tissue penetration. We review outcomes of 17 subjects with IAC from the FURI study (NCT03059992).

Novel Class Broad-spectrum Triterpenoid Antifungal



Ibrexafungerp
Chemical Structure

Activity against

- *Candida* spp., including commonly resistant strains *C. auris, C. glabrata, C. krusei)*
- *Aspergillus* spp.
- Mucorales
- Dimorphic fungi
- *Pneumocystis* spp.

METHODS

FURI is an ongoing Phase 3 open-label single-arm study of oral IBX for the treatment of adult patients with refractory or resistant fungal diseases, and/or intolerance to Standard of Care (SoC) antifungal therapies. IAC subjects were eligible for enrolment if they had proven or probable invasive candidiasis with or without candidemia. Patients received a loading dose of oral IBX 750 mg BID for 2 days followed by 750 mg QD with a duration of therapy for ≥14 days and ≤180 days. Global response at End of Treatment (EOT) was adjudicated by an independent data review committee (DRC).

CONCLUSION

Preliminary analysis of these 17 patients indicates that oral IBX is a promising orally available option for the treatment of patients with IAC who have limited therapeutic options.

RESULTS

17 patients had a diagnosis of IAC. The mean age was 52 years (26-80 years). Patients had the following forms of invasive candidiasis: 12 had intraabdominal abscess, 2 had hepatosplenic candidiasis, 1 patient each had liver, pancreas, and visceral candidiasis. 82% (14/17) of patients were enrolled based on disease refractory to current treatment, and 71% (10/14) of these had previously failed an echinocandin therapy. There were 21 *Candida* isolates identified in the 17 patients. The predominant organisms were non-albicans Candida species (C. glabrata, C. krusei, C. tropicalis) in 57% (12/21) with C. glabrata being the most commonly reported in 38% (8/21). Outcomes for these subjects were as follows: Complete or Partial Response in 47% (8/17), Stable Disease in 41% (7/17) and Progressive Disease in 12% (2/17). One patient died during the study and death was attributed to other causes than fungal disease.

FURI Study Demographics

Patient Demographics	
Age, years (mean, range)	52 (26-80)
Gender	10 (59%)male 7 (41%) female
Prior echinocandin exposure	12 (71%)
Days on IBX (mean, range)	59 (4-341)
US / Europe	11/6

Patient Outcome by Fungal Pathogen

	N	Complete or Partial Response	Stable Disease	Progressive Disease
Total	**17**	**8 (47%)**	**7 (41%)**	**2 (12%)**
C. glabrata	5	3	1*	1
C. albicans	3	1	1	1
C. krusei	2	1	1	-
C. glabrata & C. albicans	2	1	1	-
C. tropicalis & C. albicans	1	1	-	-
C. tropicalis & C. glabrata	1	1	-	-
Unidentified	3	-	3	-

*Patient was deemed stable by DRC but died of other causes and not fungal disease after 5 days of IBX

For additional information, contact info@scynexis.com