

Outcomes of *Candida* Bone and Joint Infections in Eight Patients from a Phase 3 Open-label Study (FURI)



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BACKGROUND

- *Candida* osteoarticular infections are often preceded by candidemia with the intervertebral discs and knee joints the most common area for candidemic seeding.
- *Candida* osteomyelitis has significant morbidity and diagnosis is often delayed & difficult to treat. Treatment courses are usually long and there are limited oral options available for patients who have an azole-resistant infection.
- Oral ibrexafungerp is an investigational broad-spectrum glucan synthase inhibitor antifungal with activity against *Candida* and *Aspergillus* species, including azole- and echinocandin-resistant strains.
- A Phase 3 open-label, single-arm study of ibrexafungerp (FURI; NCT03059992) is ongoing for the treatment of patients with fungal disease refractory or who are intolerant of to standard of care antifungal therapy.
- Patients enrolled in the FURI study were from 22 centers in US, UK and EU who were treated with ibrexafungerp for severe mucocutaneous or invasive fungal infections from 2016- 2020.

METHODS

- FURI subjects were eligible for enrollment if they had:**
- Proven or probable severe mucocutaneous candidiasis,
 - Invasive candidiasis or aspergillosis, other fungal diseases,
 - Evidence of treatment failure, intolerance, or toxicity related to a currently approved standard-of-care antifungal treatment, or
 - Unable to receive an approved oral antifungal option (e.g., susceptibility of the organism) and a continued IV antifungal therapy was clinically undesirable or unfeasible.
- An independent Data Review Committee (DRC) provided an assessment of treatment response for patients who completed therapy by October 2020.

SAFETY RESULTS

- Ibrexafungerp was well-tolerated with the most common treatment-related adverse events being of gastrointestinal origin.
- No deaths due to progressive fungal disease were reported

EFFICACY RESULTS

Site	AGE	SEX	Case type	Isolated organism
Bone-spondylodiscitis	50	Male	Intolerant	<i>Candida albicans</i>
Bone-spondylodiscitis	75	Female	Refractory	<i>Candida tropicalis</i>
Bone-spondylodiscitis	58	Male	Refractory	<i>Candida albicans</i>
Bone-spondylodiscitis	86	Male	IV step-down	<i>Candida glabrata</i>
Bone-tibia	50	Male	IV step-down	<i>Candida albicans</i> and <i>glabrata</i>
Bone-zygomatic arch	50	Male	Refractory	<i>Candida glabrata</i>
Articular knee (prosthetic joint infection)	75	Female	IV step-down	<i>Candida glabrata</i>
Bone-spondylodiscitis	86	Male	Intolerant	<i>Candida albicans</i>

- There were 8 subjects (6 male, 2 female) who were diagnosed with various bone and joint infections, 5 with spinal infections, 1 with a knee/prosthetic joint infection and 2 subjects with osteomyelitis, one in the tibia and one in the zygomatic arch.
- All patients with bone or joint infections were white.
- The mean age for this subpopulation at time of enrollment was 55.6 years; the median age at enrollment was 58 years of age.
- The median days of therapy for this group was 210.5 days.

Anatomic Location (n)	Complete/Partial Response	Stable Disease	Progression of Disease	Indeterminate
Bone/spondylodiscitis (5)	2 (40%)	1 (20%)	1 (20%)	1 (20%)
Knee /prosthetic joint (1)	1 (100%)	0	0	0
Tibia (1)	1 (100%)	0	0	0
Zygomatic arch (1)	1 (100%)	0	0	0
Totals (N=8)	5 (63%)	1 (13%)	1 (13%)	1 (13%)



FURI PATIENT FLOW



CONCLUSIONS

- Five of the 8 patients who were refractory or intolerant to standard of care showed a good therapeutic response.
- These data indicate that oral ibrexafungerp provides a promising therapeutic response option for patients with fungal infections of the bones or joints.