Oral Ibrexafungerp Outcomes in Patients with Oropharyngeal Candidiasis and Esophageal Candidiasis from an Interim Analysis of a Phase 3 Open-label Study (FURI)

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BACKGROUND

- *Candida albicans* is the predominant organism causing esophageal candidiasis (EC) and oropharyngeal candidiasis (OPC).
- These infections may arise from subjects colonized with *Candida* who are predisposed due to illness or a local reduction in host resistance to an overgrowth of this fungi.
- Patients with mucocutaneous *Candida* infections can generally be treated in the outpatient setting, yet there is only one antifungal class that can be administered orally (azoles) and no options are available for patients who are unresponsive to or who are intolerant to them.
- Oral ibrexafungerp is an investigational broad-spectrum glucan synthase inhibitor antifungal with activity against Candida 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 who are intolerant of or with fungal disease refractory to standard antifungal therapy.

METHODS

- An independent Data Review Committee (DRC) provided an assessment of treatment response for patients who completed therapy by October 2020.
- Patients enrolled in the FURI study were from 22 centers in the US, UK and EU who were treated with ibrexafungerp for severe mucocutaneous or invasive fungal infections from 2016- 2020.

FURI subjects were eligible for enrolment if they had:

- Proven or probable severe mucocutaneous candidiasis,
- Invasive candidiasis, aspergillosis, or other fungal disease
- 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.

Screening (Day -1) → Baseline: Treatment Day 1 → Treatment: (Days 3-5, 7-10, and every 14 days through end of treatment (EoT) → EoT: (up to 90 days of treatment with ibrexafungerp) → Week 6 after EoT Visit → Survival: Day 42 after Treatment Day 1 → Survival: Day 84 after Treatment Day 1

RESULTS

Site	Pt Age	Pt Sex	Case Type	Isolated organism
EC	43	Female	Refractory	*Candida glabrata*
EC	63	Male	Refractory	Biopsy confirmed but not isolated
EC	66	Female	Refractory	*Candida albicans* and *glabrata*
EC	57	Female	IV step-down	*Candida albicans* and *glabrata*
EC	45	Female	Refractory	*Candida glabrata*
EC	56	Female	Refractory	*Candida krusei*
EC	31	Female	Refractory	*Candida glabrata*
EC	43	Male	Intolerant	*Candida albicans*
EC	39	Female	Refractory	*Candida albicans* and *tropicalis*
EC	75	Female	Refractory	*Candida albicans*
OPC	59	Male	Refractory	*Candida albicans* and *glabrata*
OPC	34	Male	Intolerant	*Candida albicans*
OPC	60	Male	Refractory	*Candida glabrata* and *dubliniensis*
OPC	63	Female	Refractory	*Candida kruseii*
OPC	48	Female	Refractory	*Candida albicans*
OPC	67	Male	Toxicity	*Candida albicans*
OPC	34	Male	Refractory	*Candida glabrata*
OPC	46	Male	Refractory	*Candida glabrata* and *dubliniensis*
OPC	48	Female	Refractory	*Candida kruseii*
OPC	44	Female	Refractory	*Candida albicans*
OPC	49	Male	Refractory	*Candida albicans*
OPC	27	Male	Refractory	*Candida albicans*
OPC	55	Female	Refractory	*Candida albicans*
OPC	32	Female	Refractory	*Candida albicans*

- A total of 24 FURI subjects were diagnosed with OPC or EC.
- Twenty of the OPC/EC patients were refractory.
- The causative organisms are listed at the right.
- Six patients cultured more than one isolate.
- Mean patient age of the EC/OPC population at enrollment was 54.6 years and median patient age at enrollment was 56 years.
- A total of 10 male patients and 14 female patients had EC/OPC.
- Outcomes are presented in the Table below.

Type (n)	Complete or Partial Response	Stable Disease	Progression of Disease
Esophageal/EC (n=10)	6 (60%)	4 (40%)	0
Oropharyngeal/OPC (n=14)	9 (64%)	3 (21%)	2 (14%)

SAFETY

- 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

CONCLUSIONS

- Analysis of 24 EC and OPC pts who were intolerant or refractory to standard of care treatment had good outcomes with ibrexafungerp.
- Oral ibrexafungerp provides a favorable therapeutic response in patients with limited antifungal treatment options.

For additional information contact SCYNEXIS at info@scynexis.com