MEM0404

Outcomes of Oral Ibrexafungerp in Subjects with Urinary Tract Infections from Two Phase 3 Open-Label Studies: Difficult-to-Treat Invasive Fungal Infections (FURI) and Infections with *Candida auris* (CARES)

33rd ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

R.S. Siebert [1], D. Juneja [2], M.H. Nguyen [3], J. Vazquez [4], N.E. Azie [5], D.A. Angulo [5]

[1]Life Groenkloof Hospital , [2]Max Super Specialty Hospital, [3]University of Pittsburgh, [4]University of Augusta, [5]SCYNEXIS, Inc

BACKGROUND

Fungal urinary tract infections (UTI) are increasing in frequency and are often difficult to treat with current therapy. *Candida* spp. is commonly implicated in fungal UTI, but UTI with *Candida auris* is on the rise. Ibrexafungerp (IBX) is a novel class triterpenoid antifungal with a broad spectrum of activity against *Candida* spp., *Aspergillus* spp., *Pneumocystis* and *Mucorales*. Though urinary excretion of IBX is only 1-2%, IBX has high tissue penetration into the kidney and bladder that offers additional depot for drug to elute into the urine and protection for the urinary tract tissues. We report outcomes from 7 subjects with UTI treated with ibrexafungerp that were treated in the FURI (NCT03059992) and CARES (NCT03363841) studies.

METHODS

FURI subjects (≥18 years) were eligible for enrollment if they had proven or probable, severe mucocutaneous candidiasis, invasive candidiasis or invasive aspergillosis and documented evidence of failure to, 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 clinically undesirable or unfeasible. CARES is recruiting where *Candida auris* infections have been observed (South Asia, South Africa). Eligible subjects have a documented *Candida auris* infection. The treatment dose for FURI and CARES is a loading dose of oral IBX 750 mg BID the first 2 days, then subsequent oral IBX 750 mg QD.

RESULTS

There were 2 UTI subjects from the FURI Study (one with *Candida glabrata* resistant to oral fluconazole and caspofungin, and one with a refractory infection with *Candida* spp.), and 5 subjects from CARES with *Candida auris* UTI. Of the 7 UTI cases, 2 subjects from the CARES study with *C auris* UTI had no previous therapies, 3 subjects had previous echinocandin treatment and 5 subjects had previous fluconazole treatment. All UTI cases showed a response to IBX , 6/7 (86%) showed a complete response and 1/7 (14%) showed a partial response to IBX.

Table 1: Subject Demographics

UTI Patient Demographics	
Mean Age (range)	64 (44-97)
Gender	Male- 2 (29%) Female- 5 (71%)
Previous History of Echinocandin	3 (43%)
Mean Days of IBX therapy (range)	31 days (4-76)

Table 2: Outcomes for all subjects and by fungal pathogen

UTI Patients	N	Complete Response	Partial Response
All subjects	**7**	**6 (86%)**	**1 (14%)**
C. auris	4	3	1
C. glabrata	1	1	
C. lusitaniae	1	1	
C. parapsilosis/C. auris	1	1	

CONCLUSION

Preliminary analysis of these cases indicate that oral IBX provides a favorable therapeutic response for subjects with UTI associated with difficult-to-treat *Candida auris* or other *Candida* spp.