# Oral Ibrexafungerp Outcomes in Patients with Invasive Candidiasis and Candidemia from the FURI and CARES Studies

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## BACKGROUND

- There are limited oral treatment options available for patients with *Candida* infections who fail currently available antifungals or need oral outpatient therapy.
- Ibrexafungerp is an investigational broad-spectrum glucan synthase inhibitor antifungal with activity against *Candida* and *Aspergillus* species, including azole- and echinocandin-resistant strains.
- Two ongoing open-label, single-arm Phase 3 trials (22 global sites) for the treatment of patients (≥18 years) intolerant of or with fungal disease refractory to standard antifungal therapy (FURI; NCT03059992), and CARES (NCT03363841) for the treatment of adult patients with *Candida auris* infections.

## METHODS

- FURI subjects were eligible for enrollment if they had proven or probable:
  - mucocutaneous candidiasis, and
  - invasive candidiasis.
- CARES subjects were eligible for enrollment if they had documented *Candida auris* infections including candidemia.
- Clinical outcomes were assigned based on review by a Data Review Committee (DRC) each year: complete/partial response, stable response, and progression of disease.

## RESULTS

- This interim analysis reviews outcomes for 49 patients with invasive candidiasis and candidemia from the CARES (n=10) and FURI (n=39) studies from the years 2018-2020. Patient counts and ibrexafungerp treatment responses are listed by baseline infection in **Table 1.** Mean time on therapy with ibrexafungerp was 38 days.

### Table 1. Patient Counts and Clinical Response, by Baseline Infection

| Category | Baseline Fungal Disease | Patients, n | Complete or Partial Response | Stable Response | Progression of Disease | Indeterminate | Deaths* |
|---|---|---|---|---|---|---|---|
| **Candidemia** | Candidemia | **18** (7 CARES) | 13 | 1 | 1 | 2 | 1 |
| **Invasive Candidiasis** | Intra-abdominal | **12** (1 CARES) | 7 | 2 | 2 | - | 1 |
| | Bone and/or joint | **8** | 5 | 2 | - | 1 | - |
| | Lower urinary tract/bladder | **3** (2 CARES) | 2 | 1 | - | - | - |
| | Subcutaneous wound | **2** | 2 | - | - | - | - |
| | Chronic disseminated candidiasis | **2** | - | 1 | - | 1 | - |
| | Endocarditis | **1** | 1 | - | - | - | - |
| | Liver | **1** | 1 | - | - | - | - |
| | Mediastinum | **1** | 1 | - | - | - | - |
| | Empyema | **1** | 1 | - | - | - | - |
| **Total Patients with IC or Candidemia** | | **49** | **33 (68%)** | **7 (14%)** | **3 (6%)** | **4 (8%)** | **2 (4%)** |

*Both deaths were due to progression of underlying disease.

### Table 2. Organisms Isolated

| | N | *C. albicans* | *C. glabrata* | *C. parapsilosis* | *C. auris* | *C. tropicalis* | *C. krusei* | *C. glabrata* + *C. albicans* | *C. glabrata* + *C. tropicalis* |
|---|---|---|---|---|---|---|---|---|---|
| **Candidemia** | **18** | 3 | 6 | 2 | 7 | - | - | - | - |
| **Intra-abdominal** | **12** | 2 | 5 | - | 1 | - | 2 | 1 | 1 |
| **Bone and/or joint** | **8** | 3 | 2 | - | - | 2 | - | 1 | - |
| **Lower urinary tract/bladder** | **3** | - | 1 | - | 2 | - | - | - | - |
| **Subcutaneous wound** | **2** | - | 1 | 1 | - | - | - | - | - |
| **Chronic disseminated candidiasis** | **2** | 1 | - | - | - | - | 1 | - | - |
| **Endocarditis** | **1** | - | 1 | - | - | - | - | - | - |
| **Liver** | **1** | 1 | - | - | - | - | - | - | - |
| **Mediastinum** | **1** | - | 1 | - | - | - | - | - | - |
| **Empyema** | **1** | - | 1 | - | - | - | - | - | - |

## SUMMARY

- Several species of *Candida* were isolated from patients with infections as outlined in **Table 2**. The most common were *C. glabrata* and *C. albicans*.
- The majority of outcomes as assessed by the DRC in this patient population was favourable, i.e. complete or partial response (68%).
- Mean duration of ibrexafungerp treatment for the entire population was 38 days.

## CONCLUSIONS

- This is an interim analysis of 2 continuing studies.
- In patients with limited treatment options, ibrexafungerp treatment led to favorable responses in 68% of this population.
- Mortality rate was 4% and appears low for a population with invasive candidiasis and candidemia.
- Ibrexafungerp is a promising antifungal for *Candida* infections.