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# Rezafungin Overall Phase 3 Development Plan

## Phase 3 Treatment Trial

**POTENTIAL INDICATION**  
Treatment of candidemia & invasive candidiasis

**PHASE 3 SIZE**  
187 patients¹ (20% NI margin)

**OVERALL OBJECTIVE**  
FDA: Day 30 All-Cause Mortality vs SOC

## Phase 3 Prophylaxis Trial

**POTENTIAL INDICATION**  
Prophylaxis against *Aspergillus, Candida* & *Pneumocystis* in allogeneic blood and marrow transplant patients

**PHASE 3 SIZE**  
462 patients (12.5% NI margin)

**OVERALL OBJECTIVE**  
Day 90 Fungal free survival vs standard of care

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¹ mITT population.
ReSTORE PHASE 3 TRIAL DESIGN

- A Phase 3, prospective, double-blind, randomized, international, multicenter trial
- Evaluate the efficacy and safety of once-weekly IV rezafungin vs once-daily caspofungin followed by optional oral fluconazole step-down in the treatment of documented candidemia and/or IC
- mITT population: All subjects in safety population who had documented Candida infection

Global Cure is defined as Clinical Cure (as assessed by the Primary Investigator), Mycological Eradication and Radiological Cure (for qualifying invasive candidiasis patients only).
ReSTORE PHASE 3 TRIAL RESULTS SUMMARY

Primary Efficacy Endpoints

- Both the FDA All-Cause Mortality at Day 30 as well as the EMA Global Cure at Day 14 endpoints were achieved

Secondary Efficacy Endpoints

- Early efficacy outcomes (Day 5 Global Cure, Day 5 Mycological Eradication) were either similar or trended higher in the rezafungin arm

Exploratory Efficacy Endpoints

- Blood cultures were cleared more quickly in the rezafungin arm though the difference was not significant
- Duration of ICU stay was lower in the rezafungin group compared to caspofungin

Safety

- Rates of Adverse Events and Serious Adverse Events were similar between the two study arms
# Key Baseline Demographics Similar Across Arms

<table>
<thead>
<tr>
<th>Demographic or Characteristic</th>
<th>Rezafungin n (%)</th>
<th>Caspofungin n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age: ≥65 years</td>
<td>38 (40.9)</td>
<td>38 (40.4)</td>
</tr>
<tr>
<td>Sex: Female</td>
<td>31 (33.3)</td>
<td>38 (40.4)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>23 (24.7)</td>
<td>31 (33.0)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>5 (5.4)</td>
<td>4 (4.3)</td>
</tr>
<tr>
<td>White</td>
<td>59 (63.4)</td>
<td>55 (58.5)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.1)</td>
<td>2 (2.1)</td>
</tr>
<tr>
<td>Not reported</td>
<td>4 (4.3)</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Final Diagnosis: Candidemia</td>
<td>64 (68.8)</td>
<td>67 (71.3)</td>
</tr>
<tr>
<td>Final Diagnosis: Invasive Candidiasis</td>
<td>29 (31.2)</td>
<td>27 (28.7)</td>
</tr>
<tr>
<td>Modified APACHE II score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥20</td>
<td>12 (12.9)</td>
<td>17 (18.1)</td>
</tr>
<tr>
<td>10–19</td>
<td>42 (45.2)</td>
<td>40 (42.6)</td>
</tr>
<tr>
<td>&lt;10</td>
<td>38 (40.9)</td>
<td>37 (39.4)</td>
</tr>
<tr>
<td>Absolute neutrophil count &lt;500/μL</td>
<td>7 (7.5)</td>
<td>5 (5.3)</td>
</tr>
</tbody>
</table>
The upper limit of the 95% confidence interval for ACM is 14.4%, which is within the noninferiority margin of 20% established with the FDA.

DAY 30 ALL-CAUSE MORTALITY (Primary Endpoint for FDA was Achieved)

- Rezafungin 400 mg/200 mg weekly (N=93): 23.7% (95% CI: -9.7 to 14.4)
- Caspofungin 70 mg/50 mg daily (N=94): 21.3%
The lower limit of the 95% confidence interval for Day 14 Global Cure is −14.9%, which is within the noninferiority margin of −20% established with the EMA.
Day 30 All-Cause Mortality and Day 14 Global Cure were similar for rezafungin and caspofungin across these predefined subgroups.
GLOBAL CURE AT DAY 5, DAY 14, AND DAY 30

Day 5 and Day 30 are Secondary Endpoints

Global Cures were similar between study arms across multiple timepoints.
Day 5, Day 14, and Day 30 are Secondary Endpoints, in Candidemia Only

Mycological Eradication was numerically higher for rezafungin at Day 5 and similar across arms at later timepoints.
PHASE 3 EARLY EFFICACY AND MEDIAN ICU STAY
SECONDARY AND EXPLORATORY ANALYSES

% Neg. Blood Culture\textsuperscript{1,2}

<table>
<thead>
<tr>
<th>Day</th>
<th>1 DAY</th>
<th>7 DAYS</th>
<th>14 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rz</td>
<td>53.7</td>
<td>74.2</td>
<td>78.1</td>
</tr>
<tr>
<td>Cf\textsuperscript{2}</td>
<td>46.2</td>
<td>64.1</td>
<td>68.7</td>
</tr>
<tr>
<td>n/N</td>
<td>36/67</td>
<td>49/66</td>
<td>50/64</td>
</tr>
<tr>
<td>n/N</td>
<td>30/65</td>
<td>41/64</td>
<td>46/67</td>
</tr>
</tbody>
</table>

1. Patients with candidemia only
2. Not powered for statistical comparison
3. All patients in the ICU on day 1 included except for those who died prior to ICU discharge
### Phase 3 Early Efficacy and Median ICU Stay

**Secondary and Exploratory Analyses**

**% Neg. Blood Culture**
- **Rezafungin**: 53.7% (n/N 36/67)
- **Caspofungin**: 46.2% (n/N 30/65)

**Median Days in ICU**
- **Rezafungin**: 5.0 ICU days
- **Caspofungin**: 14.5 ICU days

**Difference in ICU Stay**
Not powered for statistical comparison

**% Mycological Eradication**
- **Rezafungin**: 74.2% (n/N 49/66)
- **Caspofungin**: 64.1% (n/N 41/64)

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<table>
<thead>
<tr>
<th></th>
<th>All-Cause Mortality Day 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHASE 2</strong></td>
<td></td>
</tr>
<tr>
<td>All-Cause Mortality Day 30</td>
<td>2/46 4.4%</td>
</tr>
<tr>
<td></td>
<td>12/76 15.8%</td>
</tr>
<tr>
<td></td>
<td>8/61 13.1%</td>
</tr>
<tr>
<td><strong>PHASE 3</strong></td>
<td></td>
</tr>
<tr>
<td>All-Cause Mortality Day 30</td>
<td>22/93 23.7%</td>
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<td></td>
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**Differences in Trials**
- Overall mortality higher in Ph3
- Ph3 enrolled during COVID (75% of Ph3 subjects were enrolled after March 2020)
- Ph2 run in NA and Europe
- Ph3 added Australia, South America, East Asia including China

*Impact of the above on study outcomes is unknown*
**REZAFUNGIN PHASE 2 AND PHASE 3 DAY 14 CURE RESULTS**

### PHASE 2 \(^1\)
**Overall Cure Day 14**
- Rezafungin 400 mg/400 mg weekly: 46/76 (60.5%)
- Rezafungin 400 mg/200 mg weekly: 41/61 (67.2%)

### PHASE 3 \(^2\)
**Global Cure Day 14**
- Rezafungin 400 mg/400 mg weekly: 55/93 (59.1%)
- Caspofungin 70 mg/50 mg daily: 57/94 (60.6%)

**Global Cure Day 14**
- Overall: 46/76 (60.5%)
- Ph 3 enrolled during COVID
- Expanded regions of enrollment
- Increased rates of IC

**Impact of the above on study outcomes is unknown**

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1. Overall Cure (Phase 2): resolution of systemic signs attributable to candidemia or invasive candidiasis AND mycological eradication as demonstrated by a single tissue/fluid culture or 2 negative blood cultures at least 12 hours apart
2. Global Cure (Phase 3): investigator assessment of clinical cure AND mycological eradication as demonstrated by a single negative blood or tissue/fluid culture AND (if pertinent) improvement or resolution of evidence of invasive candidiasis on radiographic imaging
Rezafungin was generally well tolerated and had a similar safety profile to caspofungin.
SAFETY: RELATED SERIOUS ADVERSE EVENTS AS DETERMINED BY THE PI's

Both SAEs in the rezafungin arm were associated with placebo administration

- Rezafungin arm
  - Infusion-related reaction (Day 3)
    - Hypersensitivity reaction during the Day 3 infusion of saline placebo
  - Urticaria (Day 15)
    - Urticarial rash following oral placebo administration

- Caspofungin arm
  - Hypertransaminasaemia (Day 14)
    - High liver function tests
  - Liver injury (Day 8)
    - High liver function tests
  - Anaphylactic shock (Day 3)
    - Anaphylactic reaction to Day 3 study drug infusion
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ReSTORE PROVIDES EXCELLENT FOUNDATION FOR COMMERCIALIZATION

REZAFUNGIN

• No new treatments for IC in 15 years
• NDA and EMA Filing expected mid-2022
• Go-to-market strategy optionality while preparing
• Highly efficient market
• Supply chain in place and launch supplies on hand
• Fast Track, QIDP, Orphan designation for C/IC
• Validated by Mundipharma partnership
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**ADVANTAGES**

- Only drug in development successfully compared head-to-head in Ph3 with standard of care echinocandin in 1st line *Candida* treatment
- 1st and only once-weekly antifungal candidate
- High front-loaded dosing for rapid *Candida* clearance
- Substantial tissue and organ penetration
- No DDIs across two studies with relevant drugs
- May enable early discharge (ICU and Hospital)
- Active against tough to treat *Candida* strains including *C. auris* and azole-resistant *Candida*
1. 30% of patients with Candida receive therapy for documented disease whereas 70% receive empiric therapy only (Internal estimate).

2. 30% of patients who start on an echinocandin are still on an echinocandin on the last day of hospitalization because they could not be stepped down. Sofjan, Garey et al. Journal of Antimicrobial Resistance. Vol 14, Sept 2018

INPATIENT REZAFUNGIN TARGETS
1. Documented *Candida* (not empiric)
2. Higher front-loaded dosing may be of benefit in critically ill (ICU, etc.)
3. Cannot step down (azole issues)
4. Potential for early discharge (ICU and Hospital), increasing importance with COVID pandemic

OUTPATIENT REZAFUNGIN TARGETS
1. Remain on echinocandin due to azole resistance
2. Remain on echinocandin due to azole tox/DDI
3. Unknown *Candida* pathogen
4. Once-weekly facilitates administration and adherence
Rezafungin is the only antifungal in clinical stage development for both 1st-line treatment and prophylaxis...

...Fluconazole and voriconazole, which sold $1B and $800M at peak\(^1,2\) respectively, had a similar approach
THANK YOU