# The ReSTORE Study: CD101 Compared to Caspofungin Followed by Oral Step-Down Treatment in Subjects With Candidemia and/or Invasive Candidiasis

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## Study Objective
To demonstrate that Rezafungin for Injection is non-inferior to caspofungin for all-cause mortality (ACM) at Day 30 in the modified intent-to-treat (mITT) population.

To demonstrate that Rezafungin for Injection is non-inferior to caspofungin for global cure as assessed by the Investigator plus mycological eradication, as confirmed by the Data Review Committee at Day 14.

Compare safety and tolerability and evaluate the pharmacokinetics of Rezafungin

## Inclusion Criteria
- Mycological diagnosis of candidemia (at least 1 blood culture positive for Candida) from a sample taken ≤ 96 hour before randomization
- Presence of one or more systemic signs or symptoms attributable to candidemia
- Willing to initiate or continue medical treatment to cure infections, including receipt of antibiotics and surgical procedures, if required
- Males or Females, 18 years or older, willing and able to provide written informed consent; legally authorized representative may not consent on behalf of the subject

## Exclusion Criteria
- Septic arthritis in a prosthetic joint (septic arthritis in a native joint is allowed), Osteomyelitis, Endocarditis, Myocarditis, Meningitis, Endophthalmitis, Chorioretinitis or any CNS infection
• Received systemic treatment with an antifungal agent at approved doses for treatment of candidemia for >48 hours within 96 hours before randomization
• Alanine aminotransferase or aspartate aminotransferase levels >10-fold the upper limit of normal.
• Severe hepatic impairment in subjects with a history of chronic cirrhosis
• Presence of an indwelling vascular catheter or device that cannot be removed or an abscess that cannot be drained and is likely to be the source of candidemia or invasive candidiasis
• History of severe ataxia, tremor, or neuropathy or a diagnosis of multiple sclerosis or a movement disorder (including Parkinson’s Disease or Huntington’s Disease)
• Planned or ongoing therapy at screening with a known neurotoxic medication
• Severe renal impairment during Screening (Creatinine Clearance < 30 mL/min by Cockcroft-Gault)

Affiliations & Sponsors
Cidara Therapeutics

Status
Open to enrollment

Keywords
Mycoses, Candidemia, Fungemia, Sepsis, Infection, Candidiasis, Invasive Candidiasis, Systemic Inflammatory Response Syndrome, SIRS, Inflammation, Pathologic Processes, Fluconazole, Caspofungin, Echinocandins, Antifungal Agents, Anti-Infective Agents, 14-alpha Demethylase Inhibitors, Cytochrome P-450 Enzyme Inhibitors, Enzyme Inhibitors Molecular Mechanisms of Pharmacological Action, Steroid Synthesis Inhibitors, Hormone Antagonist Hormones, Hormone Substitutes, and Hormone Antagonists, Physiological Effects of Drugs, Cytochrome P-450 CYP2C9 Inhibitors, Cytochrome P-450 CYP2C19 Inhibitors