# VL-2397: A Novel Approach to Treat Life-Threatening Invasive Fungal Infections

BIO 2016 Global Workshop for Novel Anti-Infectives

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# VL-2397: Addressing a High Unmet Need

**UNMET NEED**

**Invasive aspergillosis in immunocompromised patients**

- Annual incidence ~150,000 (U.S. and EU combined)
- ~50% mortality in high risk groups
- Increasing resistance

***No new antifungal classes in 15 years***

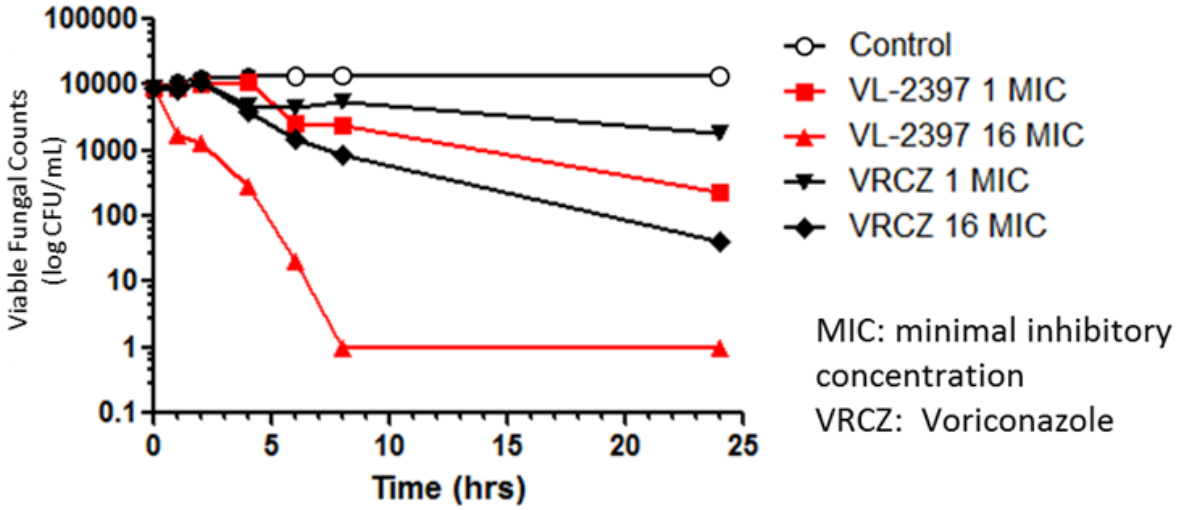
**PRODUCT CANDIDATE**

**Differentiated antifungal with novel mechanism of action**

- Cyclic peptide in new antifungal class
- Isolated from Malaysian national park leaf litter fungus
- Rapid activity against a broad spectrum of *Aspergillus*, including azole-resistant isolates
- Activity against other difficult-to-treat fungal pathogens

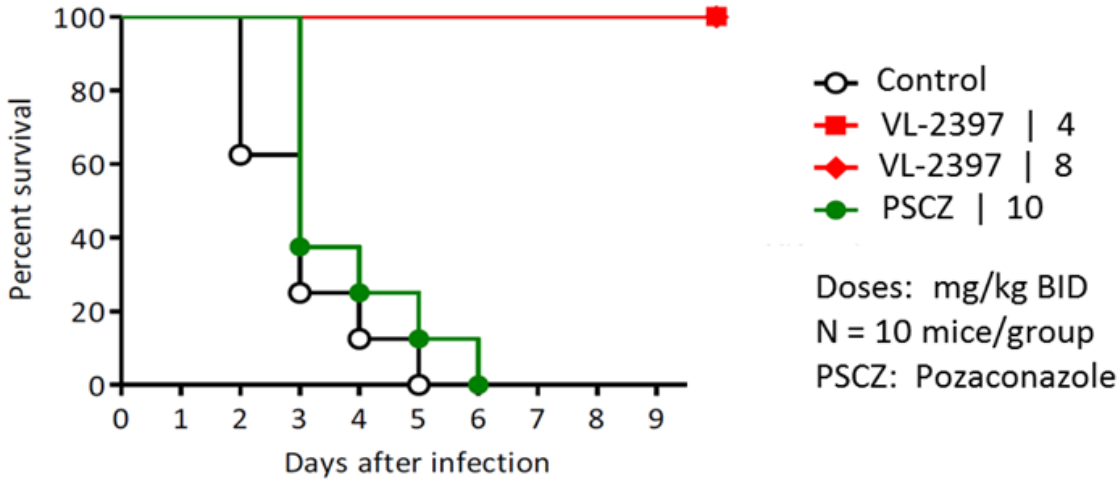
# VL-2397: Rapid Activity Against Aspergillus Including Drug-Resistant Isolates

## Rapid Onset of Antifungal Activity




MIC: minimal inhibitory concentration
VRCZ: Voriconazole

## Activity vs. Azole-Resistant *Aspergillus*




Doses: mg/kg BID
N = 10 mice/group
PSCZ: Pozaconazole

Vical

# VL-2397: Status and Development Plans for Treatment of Invasive Aspergillosis

- **Phase 1 trial of VL-2397 underway in healthy volunteers**
  - Evaluating safety & PK of single & multiple ascending doses
- **Streamlined development path to commercialization**
  - QIDP, orphan drug and Fast Track designations
  - Leading experts guiding development
- **Potential for substantial impact on survival in immunocompromised patients**