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

Activity vs. Azole-Resistant Aspergillus

MIC: minimal inhibitory concentration
VRCZ: Voriconazole

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