mycovia Pharmaceuticals

Cocci Drug Development FDA Workshop

Small Biotech Experience and Perspective

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About Us

- Mycovia Pharmaceuticals is passionate about developing novel drugs in areas of unmet medical need, with two clinical candidates—VT-1161 and VT-1598—in development for fungal infections
- We were founded in 2018 following the acquisition of Viamet Pharmaceuticals by NovaQuest Capital Management
- Our antifungal pipeline is derived from a rational drug design that maximizes potency *and* selectivity of fungal CYP51 inhibitors that, in turns, maximizes therapeutic index

VT-1161	
Recurrent Vulvovaginal Candidiasis (RVVC)	• Global Phase 3 program underway • Qualified Infectious Disease Product (QIDP) designation • Fast Track status • Expected to be 1st FDA-approved therapy

VT-1598†	
Cryptococcal Meningitis	• Eligible for FDA's Priority Review Voucher program
Coccidioidomycosis (Valley Fever)	• QIDP designation • Fast Track status • Orphan designation
Drug-resistant *Candida auris* outbreak	• Demonstrated compelling in vitro and in vivo activity
Invasive Aspergillosis	• Demonstrated compelling in vitro and in vivo activity
Talaromyces marneffei	• Demonstrated compelling in vitro activity

†VT-1598 is owned by NQP 1598, Ltd. and supported by Mycovia

Mycovia's Small Biotech Experience in Developing VT-1598

- Significant VT-1598 preclinical development was funded externally
  - R21/R33 grant from NIH NIAID supported primary pharmacology and preliminary PK and safety
  - DMRDP grant from DOD supported majority of GLP safety studies some primary pharmacology
  - Several contract services through NIH NIAID DMID to support primary pharmacology, as well as drug product manufacturing
  - Separate from VT-1598 development, a NIH TRND program to develop VT-1129 for treatment of cryptococcal meningitis helped pave the way for similar development of VT-1598
- Likewise, the majority of VT-1598 clinical development is dependent on external funding
  - NIH NIAID DMID is currently conducting the VT-1598 Phase 1 SAD study
  - Several funding avenues for Phase 1 MAD and Phase 2/3 are being explored, for cryptococcal meningitis (primary) and possibly for coccidiomycosis (secondary)
- Obtained various FDA incentives (QIDP, Fast Track, Orphan) and led effort to add cryptococcal meningitis to list of neglected tropical diseases
- Significant reliance on KOLs in shaping clinical design (both Mycosis Study Group and Cocci Study Group)

Mycovia's Small Biotech Perspective on Cocci Drug Development

- Significant medical need but low commercial value, therefore, dependent on external funding for both nonclinical and clinical development
  - > External funding clinical path = each study is separate and sequential, with additional timeline for funding decisions; therefore, overall path extremely slow
- Phase 2 POC could be defined by previous MSG studies, but Phase 3 is poorly defined
  - > Ph3 questions: endpoints, disease definition and numbers of patients, length of study
- Mycovia's current development path for VT-1598
  - > Phase 2 and pivotal Phase 3 studies on treatment of cryptococcal meningitis, with reliance on external funding (ACTG, Wellcome Trust, NIH grants, etc.)
    - Very large medical need and PRV incentive
  - > In parallel to Phase 3 CM studies, explore a U01 grant for a Phase 2 POC study in refractory coccidiomycosis, using MGS design as guide
- Unfiltered thoughts
  - > Expansion of infection to include all endemic fungi (e.g., addition of histo and blast) could help enrollment, but would complication of different diseases outweigh that advantage?
  - > Would FDA consider decreasing patient numbers, if Cocci approval was secondary to a more typical indication with a robust safety database (e.g., cryptococcal meningitis)?