

FDA Advisory Committee

January 10, 2001

CANCIDAS[®] (caspofungin acetate)

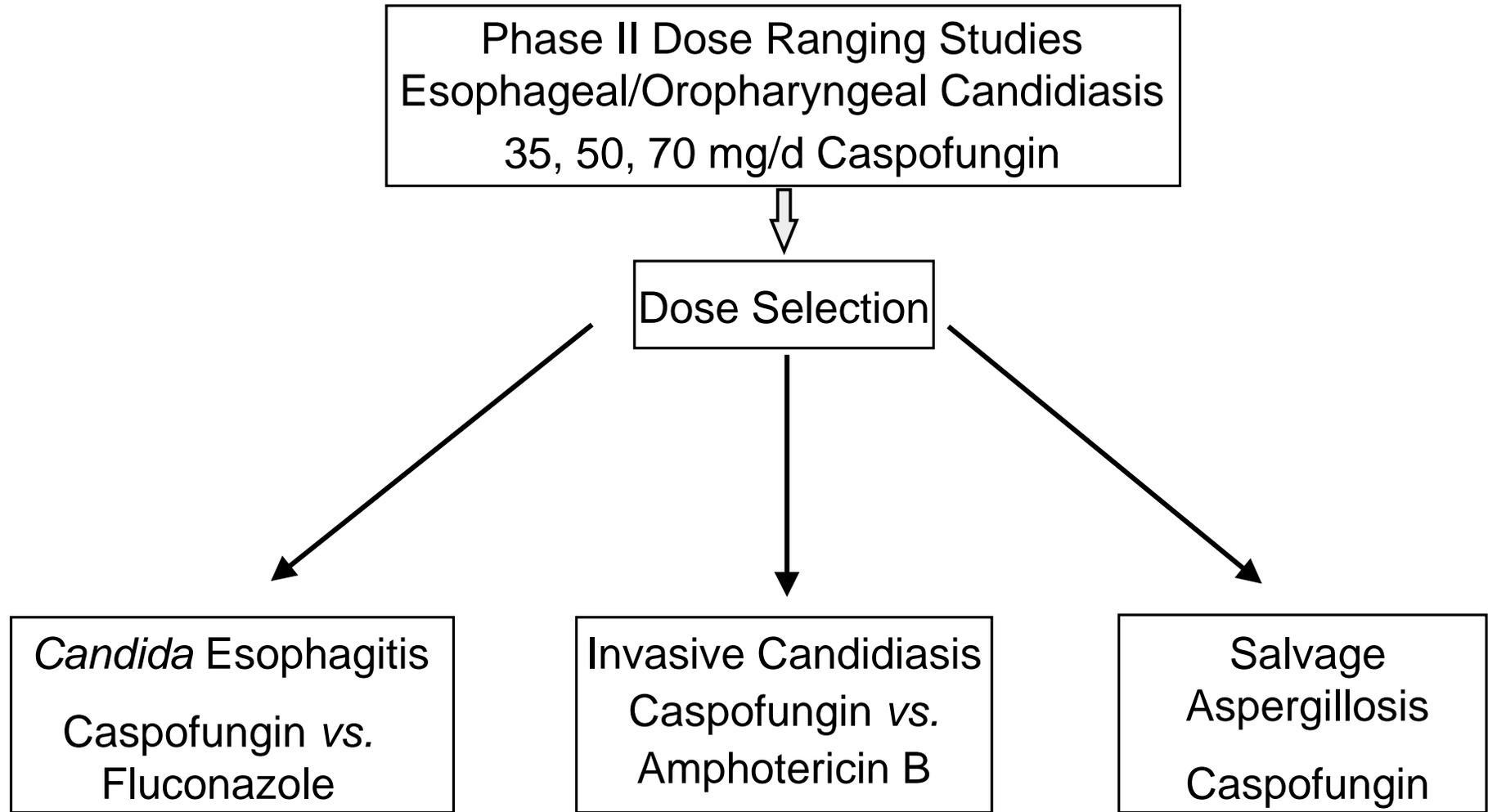
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Proposed Indication

CANCIDAS[®] Is Indicated for:

- The treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies

Caspofungin Clinical Development Program



CANCIDAS[®] Pharmacology

- CANCIDAS is fungicidal for *Candida* spp.
- CANCIDAS demonstrates clear in vitro activity but does not fit classic definition of fungicidal or fungistatic for *Aspergillus* spp.
- CANCIDAS exhibits uncommon pharmacokinetic, metabolism, and elimination properties

CANCIDAS® Development Program: Unique Aspects

- Dose selection performed in patients with *Candida* infections
- CANCIDAS activity in Aspergillosis evaluated in a noncomparative trial with strict definitions of disease and outcomes
- Activity against *Aspergillus* evaluated in small but well characterized patient population
- Historical control study conducted for comparison of efficacy of CANCIDAS with standard therapy

CANCIDAS[®] Development Program

CANCIDAS[®]

- Is effective in the treatment of invasive aspergillosis in patients with poor prognostic factors who are refractory to or intolerant of standard therapies
- Exhibits a favorable safety profile and is generally safe and well tolerated

Consultants

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Clinical Presentation

- Presentation by Dr. Carole Sable
 - Background
 - Preclinical Microbiology
 - Clinical Pharmacology
 - Clinical Efficacy
 - Clinical Safety
- Presentation by Dr. Jeff Chodakewitz
 - Summary and concluding remarks

