



U.S. Food and Drug Administration

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**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**  
*Endocrinologic and Metabolic Drugs Advisory Committee*  
The Inn and Conference Center, University of Maryland University College  
September 16, 2010  
LORQESS (lorcaserin hydrochloride) Tablets

**QUESTIONS TO THE ADVISORY COMMITTEE**

Taking into account the material provided in the background documents and presented at the advisory committee meeting, please respond appropriately below:

1. Has adequate evidence been provided to establish lorcaserin's efficacy as a weight-loss drug? Are there additional studies that you would recommend pre- or post approval to further evaluate lorcaserin's efficacy?
2. Has adequate evidence been provided to assess the potential risk for lorcaserin-induced valvular heart disease?
  - A. Are there additional animal or clinical studies that you would recommend pre- or post-approval to further assess this potential risk?
  - B. If approved, please discuss the need for monitoring and possible monitoring strategies.
3. Has adequate evidence been provided to assess the potential risk to human subjects of lorcaserin-related neoplasms in rats? These neoplasms involve breast, brain, peripheral nerve, skin and subcutis.
  - A. Are there additional animal or clinical studies that you would recommend pre- or post-approval to further assess this potential risk?
  - B. If approved, please discuss the need for monitoring and possible monitoring strategies.
4. Has adequate evidence been provided to assess and characterize the potential risk for psychiatric adverse events, such as dissociative disorders and depression/suicidality?
  - A. Are there additional animal or clinical studies that you would recommend pre- or post-approval to further assess this potential risk?
  - B. If approved, please discuss the need for monitoring, possible monitoring strategies, and contraindications for use.
5. Has adequate evidence been provided to assess and characterize the potential risk for adverse events related to disorders of attention, memory, and other cognitive disorders?
  - A. Are there additional animal or clinical studies that you would recommend pre- or post-approval to further assess this potential risk?
  - B. If approved, please discuss the need for monitoring and possible monitoring strategies.

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*-continued-*

6. Please vote whether the available data demonstrate that the potential benefits of lorcaserin outweigh the potential risks when used long-term in a population of overweight and obese individuals to allow marketing approval.

**Vote:            Yes/No/Abstain**

If voting 'Yes', please provide your rationale and comment on the need for and approach to post-approval risk management.

If voting 'No', please provide your rationale and comment on what additional preclinical or clinical information should be required to potentially support approval.