

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Pulmonary-Allergy Drugs Advisory Committee (PADAC)
Hilton Washington DC/Silver Spring, The Ballrooms
Silver Spring, MD
June 23, 2011

Questions to Committee

1. Discuss the efficacy and safety data for icatibant (**Discussion Question**)
 2. Do the data provide substantial and convincing evidence of a clinically meaningful benefit for icatibant in the treatment of acute attacks of hereditary angioedema? (**Voting Question**)
 - a. *If not, what further data should be obtained?*
 3. Has the safety of icatibant been adequately assessed for the treatment of acute attacks of hereditary angioedema? (**Voting Question**)
 - a. *If not, what further data should be obtained?*
 4. Do the efficacy and safety data provide substantial evidence to support approval of icatibant for the treatment of acute attacks of hereditary angioedema in patients 18 years of age and older? (**Voting Question**)
 - a. *If not, what further data should be obtained?*
 5. Discuss the potential impact of self-administration on the safety and efficacy of icatibant, if any. (**Discussion Question**)
 - 6.* Do the data support the self-administration of icatibant? (**Voting Question**)
 - a. *If not, what further data should be obtained?*
- *Question 6 was created during the meeting due to a favorable consensus by the committee to provide their opinion on self-administration of icatibant through an official vote.