

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 7, 2017

QUESTIONS

1. **DISCUSSION:** Discuss the key inclusion and exclusion criteria, including diagnostic procedures, for trials evaluating drugs intended to treat interstitial cystitis.
2. **DISCUSSION:** Discuss the key inclusion and exclusion criteria, including diagnostic procedures, for trials evaluating drugs intended to treat bladder pain syndrome.
3. **DISCUSSION:** For drugs intended to treat patients with interstitial cystitis, discuss:
 - a. How the key symptoms and signs should be defined and assessed.
 - b. Acceptable endpoints for demonstrating clinical benefit.
 - c. Other key trial design features that should be considered.
4. **DISCUSSION:** For drugs intended to treat patients with bladder pain syndrome, discuss:
 - a. How the key symptoms and signs should be defined and assessed.
 - b. Acceptable endpoints for demonstrating clinical benefit.
 - c. Other key trial design features that should be considered.
5. **DISCUSSION:** When assessing efficacy for drugs intended to treat patients with interstitial cystitis and bladder pain syndrome, discuss whether clinical trials should use:
 - a. One set of patient reported outcome (PRO) instruments for patients with interstitial cystitis and a different set of PRO instruments for those with bladder pain syndrome, or
 - b. One set of PRO instruments used both for patients with interstitial cystitis and those with bladder pain syndrome.

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QUESTIONS (cont.)

6. **DISCUSSION:** When assessing efficacy for drugs intended to treat patients with interstitial cystitis and bladder pain syndrome, discuss:
- a. The advantages of enrolling patients with interstitial cystitis and bladder pain syndrome in the same trial.
 - b. The disadvantages of enrolling patients with interstitial cystitis and bladder pain syndrome in the same trial.
7. **VOTE:** Should patients with interstitial cystitis and those with bladder pain syndrome be combined in clinical trials?

Discuss the rationale for your vote.