FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 10, 2019

QUESTIONS

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1. **DISCUSSION**: Please discuss whether the safety profile of vernakalant for rapid conversion of recent onset atrial fibrillation has been adequately *characterized*. If so, please comment on the sources upon which you relied—randomized studies, SPECTRUM, others.

2. **DISCUSSION**: Please discuss whether the efficacy and safety profiles of alternative approaches to cardioversion are *relevant* to assessment of vernakalant's benefit-risk assessment. If so, given the indirect comparisons, how do vernakalant and alternatives compare…

    a. … for effectiveness?

    b. … for safety?

3. **VOTE**: Do you recommend approval of vernakalant for the rapid conversion of recent onset atrial fibrillation?

4. **DISCUSSION**: If vernakalant was approved, what restrictions would you place on patients or on the conditions of use?