

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

March 29, 2016

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the effectiveness for pimavanserin for the treatment of psychosis associated with Parkinson's disease?
2. **VOTE:** Has the applicant adequately characterized the safety profile of pimavanserin?
3. **VOTE:** Do the benefits of pimavanserin for the treatment of psychosis associated with Parkinson's disease outweigh the risk of treatment?