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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 26, 2020

DRAFT QUESTIONS

NDA 212578
padeliporfin di-potassium powder for solution for injection
Proposed Trade Name: Tookad
Applicant: STEBA Biotech, S.A.

PROPOSED INDICATION: For the treatment of patients with localized prostate cancer, meeting the following criteria: Stage T1-T2a and prostate specific antigen less than or equal to 10 ng/mL and Gleason Grade Group 1 based on transrectal ultrasound guided biopsy or unilateral Gleason Grade Group 2 based on multiparametric magnetic resonance imaging-targeted biopsy with less than 50 percent of cores positive.

1. **VOTE:** Do the results of PCM301 represent a favorable benefit/risk profile for TOOKAD in patients with low-risk early stage prostate cancer?