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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
Food and Drug Administration, White Oak Campus, Building 31, the "Great Room" (Room 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
January 16, 2019

QUESTIONS

1. **DISCUSSION**: Discuss whether the cardiovascular safety of romosozumab has been adequately characterized. If additional safety data are needed, discuss the type(s) of data that are needed and whether these data should be obtained pre-approval or post-approval.

2. **DISCUSSION**: Amgen is seeking an indication for the treatment of osteoporosis in postmenopausal women at high risk of fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

   Discuss whether the benefit/risk profile of romosozumab could be improved by further narrowing the indicated population to patients at low cardiovascular risk, and if so, how to define the narrowed population.

3. **VOTE**: Is the overall benefit/risk profile of romosozumab acceptable to support approval?

   A. Yes, for Amgen's proposed indication (treatment of osteoporosis in postmenopausal women at high risk of fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy)

   B. Yes, but for a different indication

   C. No

   Provide a rationale for your vote. If you voted for (B), describe the patient population in whom the benefits outweigh the risks.