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

AGENDA

The committee will discuss biologics license application (BLA) 761062, romosozumab injection, submitted by Amgen for the proposed indication of treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

8:15 a.m.	Call to Order and Introduction of Committee	**Vivian Lewis, MD** Chairperson, BRUDAC
8:25 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, BRUDAC
8:30 a.m.	FDA Opening Remarks	**Hylton V. Joffe, MD, MMSc** Director, Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	**APPLICANT PRESENTATIONS**	**Amgen, Inc.**
	Introduction	**Scott Wasserman, MD, FACC** Vice President, Global Development Amgen, Inc.
	Osteoporosis: Unmet Medical Need	**Michael McClung, MD, FACP** Founding Director, Oregon Osteoporosis Center
	Clinical Efficacy	**Rachel Wagman, MD, FACE** Executive Medical Director, Global Development Amgen, Inc.
	Safety – Overall & Cardiovascular	**Scott Wasserman, MD, FACC**
	Benefit/Risk	**Scott Wasserman, MD, FACC**
	Conclusion	**Steven Galson, MD, MPH** Senior Vice President Global Regulatory Affairs & Safety Amgen, Inc.

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinician Perspective	**Felicia Cosman, MD** Professor of Medicine Columbia University College of Physician and Surgeons
9:55 a.m.	Clarifying Questions to Applicant	
10:25 a.m.	**BREAK**	
10:40 a.m.	**FDA PRESENTATIONS**	
	Clinical Efficacy and Safety Assessment	**Jacqueline Karp, MD** Clinical Reviewer DBRUP, ODE III, OND, CDER, FDA
	Cardiovascular Safety – Statistical Assessment	**Tae Hyun Jung, PhD** Statistical Reviewer Division of Biometrics VII Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Cardiovascular Safety Summary	**Theresa Kehoe, MD** Cross Discipline Team Leader DBRUP, ODE III, OND, CDER, FDA
	Feasibility of Using Observational Data to Assess Cardiovascular Risks Associated with Romosozumab	**Wei Liu, PhD, MSc** Reviewer Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology, CDER, FDA
11:40 a.m.	Clarifying Questions to FDA	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Clarifying Questions to Applicant or FDA	
2:30 p.m.	**BREAK**	
2:45 p.m.	Questions to the Committee/Committee Discussion and Voting	
5:00 p.m.	**ADJOURNMENT**	