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

Joint Meeting of the Arthritis Advisory Committee (AAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
March 24-25, 2021

AGENDA

The committees will discuss Biologics License Application (BLA) 761130, tanezumab subcutaneous injection, submitted by Pfizer Inc., for the proposed indication of relief of signs and symptoms of moderate to severe osteoarthritis in adult patients for whom use of other analgesics is ineffective or not appropriate.

Day 1: Wednesday, March 24, 2021

9:00 a.m.	Call to Order	**Maria Suarez-Almazor, MD, PhD** Acting Chairperson, AAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Acting Designated Federal Officer, AAC
9:10 a.m.	FDA Opening Remarks	**Rigoberto Roca, MD** Director Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP), Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:15 a.m.	**GUEST SPEAKER PRESENTATION**	
	Brief Overview of Patient Preference Information (PPI)	**Deborah A. Marshall, PhD** Professor, Cumming School of Medicine Arthur J.E. Child Chair in Rheumatology, Outcomes Research
9:35 a.m.	Clarifying Questions	
9:50 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer Inc.**
	Introduction	**Ken Verburg, PhD** Senior Vice President, Medicine Team Lead Global Product Development, Internal Medicine Pfizer Inc.
	Osteoarthritis: Current Therapeutic Context	**Thomas J. Schnitzer, MD, PhD** Professor of Medicine Northwestern University Feinberg School of Medicine Chicago, IL

	APPLICANT PRESENTATIONS (CONT.)	
	Efficacy of Tanezumab in Osteoarthritis	**Ken Verburg, PhD**
	Safety of Tanezumab in Osteoarthritis	**Christine West, PhD** Senior Director, Global Clinical Lead Global Product Development Pfizer Inc.
	Risk Management Plan	**Anne Hickman, DVM, PhD** Senior Director Global Safety and Risk Management Lead Worldwide Research and Development Pfizer Inc.
	Utility of Tanezumab in Clinical Practice and Patient Selection and Monitoring Considerations	**Alan Kivitz, MD, FACR** President Altoona Center for Clinical Research & Altoona Arthritis and Osteoporosis Center
	Benefit-Risk and Conclusions	**Ken Verburg, PhD**
11:35 a.m.	Clarifying Questions	
12:20 p.m.	**LUNCH**	
1:20 p.m.	**FDA PRESENTATIONS**	
	Tanezumab: FDA Efficacy Review	**Mary Therese O'Donnell, MD, MPH** Medical Officer DAAP, OND, ON, CDER, FDA
	Tanezumab: FDA Safety Review	**Anjelina Pokrovnichka, MD** Medical Officer DAAP, OND, ON, CDER, FDA
	Tanezumab: FDA Patient Preference Study Review	**Martin Ho, MS** Associate Director Office of Biostatistics and Epidemiology Center for Biologics Evaluation and Research, FDA

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FDA PRESENTATIONS (CONT.)

	Risk Management	**Somya Dunn, MD** CDR, U.S. Public Health Service Risk Management Analyst Division of Risk Management Office of Medication Error Prevention and Risk Office of Surveillance and Epidemiology CDER, FDA
	Tanezumab: FDA Summary	**Robert Shibuya, MD** Medical Officer DAAP, OND, ON, CDER, FDA
2:35 p.m.	Clarifying Questions	
3:20 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
4:30 p.m.	**ADJOURNMENT**	

Day 2: Thursday, March 25, 2021

10:00 a.m.	Call to Order	**Maria Suarez-Almazor, MD, PhD** Acting Chairperson, AAC
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Acting Designated Federal Officer, AAC
10:10 a.m.	Charge to the Committee	**Rigoberto Roca, MD**
10:15 a.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	**ADJOURNMENT**	