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

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 19, 2016

AGENDA

The committee will discuss biologics license application (BLA) 761032, brodalumab injection, a human monoclonal antibody, submitted by Valeant Pharmaceuticals Luxembourg S.a.r.l., proposed for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

8:00 a.m.	Call to Order and Introduction of Committee	**Michael Bigby, MD** Chairperson, DODAC
8:10 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Designated Federal Officer, DODAC
8:15 a.m.	FDA Introductory Remarks	**Kendall A. Marcus, MD** Director Division of Dermatology and Dental Products (DDDP), Office of Drug Evaluation III (ODE-III) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**GUEST SPEAKER PRESENTATION**	
	Suicidal Behavior, Inflammation and Cytokine Antagonism	**Ebrahim Haroon, MD** Medical Director Emory Behavioral Immunology Program Emory University, Assistant Professor Department of Psychiatry and Behavioral Sciences Emory School of Medicine
8:45 a.m.	**APPLICANT PRESENTATIONS**	**Valeant Pharmaceuticals Luxembourg S.a.r.l.**
	Introduction	**Tage Ramakrishna, MD** Chief Medical Officer President of Research and Development, Quality Valeant Pharmaceuticals
	Medical Landscape	**Mark Lebwohl, MD** Professor and Chairman Kimberly and Eric J Waldman Department of Dermatology Icahn School of Medicine at Mount Sinai

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Efficacy	**RK Pillai, PhD** Vice President, Head of Dermatology Valeant Pharmaceuticals
	Safety	**Robert Israel, MD** Vice President, Clinical and Medical Affairs Valeant Pharmaceuticals
	Suicidal Ideation and Behavior (SIB)	**Lauren B. Marangell, MD** Psychiatrist and President Brain Health Consultants
	IL-17 Signaling and Safety	**James B. Trager, PhD** Vice President, Research Valeant Pharmaceuticals
	Risk Management Overview	**Tage Ramakrishna, MD**
	Benefit-Risk	**Kim A. Papp, MD, PhD, FRCPC** Founder and President Probity Medical Research
	Closing	**Tage Ramakrishna, MD**
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology, Efficacy Overview, and Safety Assessment	**Gary Chiang, MD, MPH** Medical Officer DDDP, ODE-III, OND, CDER, FDA
	Biostatistical Analysis of SIB	**Ling Lan, PhD** Biostatistics Reviewer Division of Biostatistics VII Office of Biostatistics Office of Translational Sciences, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	Division of Pharmacovigilance: Review of SIB	**Robert L. Levin, MD** Director Division of Pharmacovigilance I (DPV-I) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Division of Epidemiology-I: Review of SIB	**Andrew Mosholder, MD, MPH** Medical Officer Division of Epidemiology I (DEPI-I) OPE, OSE, CDER, FDA
	Division of Psychiatric Products: Review of SIB	**Jean Kim, MD, MA** Medical Officer Division of Psychiatry Products ODE-I, OND, CDER, FDA
	Biostatistical Analysis of Major Adverse Cardiovascular Events (MACE)	**Gary Chiang , MD, MPH**
	Division of Epidemiology-I: Review of MACE	**Andrew Mosholder, MD, MPH**
	Risk Management Options for Brodalumab	**Jasminder Kumar, PharmD** Risk Management Analyst Division of Risk Management (DRISK) Office of Medication Error Prevention and Risk Management (OMEPRM) OSE, CDER, FDA
11:45 p.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Kendall A. Marcus, MD**
2:05 p.m.	Questions to the Committee/Committee Discussion	

AGENDA (cont.)

3:00 p.m.	**BREAK**
3:15 p.m.	Questions to the Committee/Committee Discussion
5:00 p.m.	**ADJOURNMENT**