FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Gastrointestinal Drugs Advisory Committee

Holiday Inn Washington DC/College Park
10000 Baltimore Avenue, College Park, Maryland
November 17, 2011

DRAFT AGENDA

The committee will provide recommendations to the Agency on the design and size of premarketing cardiovascular safety development programs necessary to support approval of products in the class of serotonin (5-hydroxytryptamine) receptor 4 agonists for the proposed indications of chronic idiopathic (of unknown cause) constipation, constipation predominant irritable bowel syndrome, gastroparesis, and gastroesophageal reflux disease that does not respond to a proton pump inhibitor.

8:00 a.m.	Call to Order and Introduction of Committee	**Jean-Pierre Raufman, M.D.** Committee Chairperson, Gastrointestinal Drugs Advisory Committee (GIDAC)
	Conflict of Interest Statement	**Minh Doan, Pharm.D.** Acting Designated Federal Officer
	FDA Presentations	
8:15 a.m.	Introductions/Opening Remarks	**Joyce Korvick, M.D., M.P.H.** Deputy Director for Safety, Division of Gastroenterology and Inborn Errors Products (DGIEP), Office of Drug Evaluation III (ODE III), Office of New Drugs (OND), CDER, FDA
8:35 a.m.	Background and Historical Overview	**Aisha Peterson-Johnson, M.D., M.P.H.** Medical Officer, DGIEP, ODE III, OND, CDER, FDA
	Sponsor's Presentations	**Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), LLC**
8:45 a.m.	General Overview	**Sheldon Sloan, M.D., M.Bioethics** Internal Medicine Portfolio Leader Established Products, J&JPRD
	Non-clinical Cardiovascular Safety	**Rob Towart, B.Sc., Ph.D., MRQA** Director Licensing and Brand Support Center of Excellence for Cardiovascular Safety, J&JPRD

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DRAFT AGENDA (cont.)

	Sponsor's Presentations (cont.)	**Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), LLC**
	Clinical Pharmacology	**Erik Mannaert, Ph.D.** Senior Director, Clinical Pharmacology Therapeutic Area Head, Established Products J&JPRD
	Clinical and Post Marketing Safety	**Sheldon Sloan, M.D., M.Bioethics** Internal Medicine Portfolio Leader, Established Products, J&JPRD
9:15 a.m.	Questions from the Committee	
	FDA Presentations (cont.)	
9:25 a.m.	Tegaserod: Nonclinical	**Ke Zhang, Ph.D.** Pharmacologist, DGIEP, ODE III OND, CDER, FDA
	Tegaserod: Clinical Pharmacology	**Insook Kim, Ph.D.** Clinical Pharmacology Reviewer Division of Clinical Pharmacology III (DCP III), Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), CDER FDA
	Tegaserod: Clinical	**Aisha Peterson-Johnson, M.D., M.P.H.** Medical Officer, DGIEP, ODE III OND, CDER, FDA
9:45 a.m.	Questions from the Committee	
10:00 a.m.	**BREAK**	
	Sponsor's Presentations	**Theravance, Inc.**
10:15 a.m.	Preclinical Properties of Velusetrag (TD-5108) and TD-8954, Selective 5-HT_4 Receptor Agonists	**David Beattie, Ph.D.** Senior Director, Pharmacology Theravance, Inc.
10:45 a.m.	Questions from the Committee	

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DRAFT AGENDA (cont.)

	FDA Presentations (cont.)	
11:00 a.m.	ATI-7505 (Naronapride): Nonclinical	**Sushanta Chakder, Ph.D.** Pharmacologist, DGIEP, ODE III OND, CDER, FDA
	ATI-7505 (Naronapride): Clinical Pharmacology	**Insook Kim, Ph.D.** Clinical Pharmacology Reviewer DCP III, OCP, OTS, CDER, FDA
	ATI-7505 (Naronapride): Clinical	**Aisha Peterson-Johnson, M.D., M.P.H.** Medical Officer, DGIEP, ODE III OND, CDER, FDA
11:30 a.m.	Questions from the Committee	
	FDA Presentations (cont.)	
11:45 a.m.	Summary	**Rob Fiorentino, M.D., M.P.H.** Medical Team Leader, DGIEP ODE III, OND, CDER, FDA
11:55 a.m.	Statistical Considerations	**Eugenio Andraca-Carrera, Ph.D.** Mathematical Statistician, Division of Biostatistics VII, Office of Biostatistics OTS, CDER, FDA
12:05 p.m.	**LUNCH**	
1:15 p.m.	Open Public Hearing	
2:15 p.m.	Committee Discussion and Questions to the Committee	
3:15 p.m.	**BREAK**	
3:30 p.m.	Committee Discussion and Questions to the Committee (cont.)	
5:00 p.m.	**ADJOURNMENT**	

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