

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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting

Sheraton Silver Spring Hotel, Cypress Ballroom
8777 Georgia Avenue, Silver Spring, Maryland
November 13, 2013

AGENDA

The committee will discuss supplemental biologics license application (sBLA) 103948-5139, alemtuzumab injection, proposed trade name LEMTRADA, submitted by Genzyme Corporation, a Sanofi Company. The proposed indication is for the treatment of patients with relapsing forms of multiple sclerosis to slow or reverse the accumulation of physical disability and reduce the frequency of clinical exacerbations.

8:00 a.m.	Call to Order and Introduction of Committee	Nathan Fountain, MD Chairperson, PCNS
8:10 a.m.	Conflict of Interest Statement	Glendolynn S. Johnson, PharmD Designated Federal Officer, PCNS
8:15 a.m.	FDA Introductory Remarks	Eric Bastings, MD Acting Director Division of Neurology Products (DNP) Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	SPONSOR PRESENTATIONS	Genzyme Corporation, a Sanofi Company
	Introduction	Jennifer Panagoulis, RAC Senior Director, Regulatory Affairs, Genzyme
	Current Medical Needs in MS	Richard Rudick, MD Professor of Neurology, Case Western Reserve University Director, Mellen Center for MS Cleveland Clinic Foundation
	Pharmacology, Efficacy Data and Analysis of Primary Endpoints from Phase 3 Clinical Program	David Margolin, MD, PhD Senior Medical Director, Clinical Research Genzyme Stephen Lake, ScD Senior Director, Biostatistics, Genzyme Gary Cutter, PhD Professor of Biostatistics, School of Public Health University of Alabama at Birmingham Douglas Arnold, MD Professor of Neurology, Montreal Neurological Institute, McGill University President and CEO, NeuroRx Research Inc.

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AGENDA (cont.)

SPONSOR PRESENTATIONS (CONT.)

Integrated Analysis of Safety	Michael Panzara, MD, MPH Group VP, Therapeutic Area Head Multiple Sclerosis & Neurology, Genzyme
Proposed Risk Evaluation and Mitigation Strategy	Jennifer Panagoulis, RAC Senior Director, Regulatory Affairs, Genzyme
Overall Summary of Benefit/Risk	Edward Fox, MD, PhD Director, Central Texas Neurology Consultants Clinical Assistant Professor of Neurology University of Texas

9:50 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:10 a.m. **FDA PRESENTATIONS**

Clinical Review of Effectiveness	John Marler, MD Clinical Reviewer, DNP ODE-I, OND, CDER, FDA
Statistical Review of Alemtuzumab Efficacy	Sharon Yan, PhD Statistics Reviewer Division of Biostatistics I Office of Biostatistics Office of Translational Sciences, CDER, FDA
Clinical Review of Alemtuzumab Safety	Evelyn Mentari, MD Clinical Safety Reviewer, DNP ODE-I, OND, CDER, FDA
Alemtuzumab Risk Management Considerations	Nyedra W. Booker, Pharm.D., M.P.H Risk Management Analyst Division of Risk Management Office of Medication Error and Risk Management Office of Surveillance and Epidemiology CDER, FDA

12:00 p.m. Clarifying Questions

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AGENDA (cont.)

12:10 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**
