

## **Patient-Focused Drug Development Consultation Meeting**

February 27, 2013, 10:00 – 11:00 am

FDA White Oak Campus, Silver Spring, MD

Building 51, Room 1300

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### **Participants**

#### FDA

Mark Ascione	Center for Drug Evaluation and Research (CDER)
Sara Eggers	CDER
Ray Ford	CDER
Patrick Frey	CDER
Andrea Furia-Helms	Office of Special Health Issues (OSHI)
Georgiann Ienzi	CDER
Richard Klein	OSHI
Theresa Mullin	CDER
Anne Pariser	CDER
Gayatri Rao	Office of Orphan Products Development
Andrea Tan	CDER
Graham Thompson	CDER
Robert Yetter	Center for Biologics Evaluation and Research

#### Patient Stakeholders

Theresa Barnes	Coalition for Pulmonary Fibrosis
Ronald Bartek	Friedreich's Ataxia Research Alliance
Cynthia Bens	Alliance for Aging Research/Accelerate Cure/Treatments for Alzheimer's Disease
Julie Block	National Eczema Foundation
Marc Boutin	National Health Council
Sarah Buchanan	Interstitial Cystitis Foundation/Nephcure Foundation
Dane Christiansen	Health and Medicine Counsel of Washington/Pulmonary Hypertension Association
Lee Claassen	Health and Medicine Counsel of Washington/Pulmonary Hypertension Association
Mary Cathy Collet	Individual patient stakeholder
Diane Dorman	National Organization for Rare Disorders
Ryan Fischer	Parent Project Muscular Dystrophy
Julie Flygare	Individual patient stakeholder
Richard Gelula	National Alopecia Areata Foundation
Steve Gibson	ALS Association
Joshua Griffis	Pulmonary Hypertension Association
Allison Kassir	Muscular Dystrophy Association/King & Spalding LLP
Annie Kennedy	Muscular Dystrophy Association
Dolly Kervitsky	Pulmonary Fibrosis Foundation

Janet Long	U.S. Hereditary Angioedema Association/Health and Medicine Counsel of Washington
Kimberly McCleary	CFIDS Association of America
Kristen Mizzi	Children's Cause for Cancer Advocacy
Thomas Murphy	Individual patient stakeholder
Martha Nolan	Society for Women's Health Research
Maureen Rigney	Lung Cancer Alliance
Cynthia Rothblum	A-T Children's Project
Lisa Schlager	FORCE (Facing Our Risk of Cancer Empowered)
Mary Schweitzer	Wisconsin ME/CFS Association
Charles Swindell	Sturge-Weber Foundation
Mark Velleca	Leukemia and Lymphoma Society
Patrick Wildman	ALS Association

### **Discussion Summary**

FDA began the meeting with an update on the proposed questions for gathering patients' perspective during the Patient-Focused Drug Development meetings. FDA described the changes made to the original set of questions based on input from the patient community and FDA review staff. The patients and patient advocates provided additional input on these questions.

Several attendees stated the questions should capture issues relevant to individual diseases. Patients and advocates noted the importance of obtaining input from patients at different stages of a disease as well as from pediatric and caregiver populations. FDA stated that the general set of questions would be tailored to allow specific questions for each disease area.

The group discussed potential options for the structure of the disease-specific Patient-Focused Drug Development meetings, including facilitated panel discussions, small group discussions, and structured comment periods. FDA noted several considerations that needed to be taken into account in determining the most appropriate meeting structure for each disease area. Several attendees emphasized the importance of obtaining input from a wide range of stakeholders, including caregivers and advocates.