

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

## *Joint Meeting of the Medical Imaging Drugs Advisory Committee (MIDAC) and the Oncologic Drugs Advisory Committee (ODAC)*

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

May 3, 2013

### DRAFT AGENDA

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*The committees will discuss the safety and efficacy of currently approved leukocyte growth factors (LGFs) as potential treatments for radiation-induced myelosuppression associated with a radiological/nuclear incident. Current LGF products are licensed under biological license applications (BLAs) and include BLA 103353, NEUPOGEN (filgrastim, Amgen, Inc), BLA 125031, NEULASTA (pegfilgrastim, Amgen, Inc.), BLA 103362, LEUKINE, (sargramostim, Genzyme, Inc.) and BLA 125294, TBOFILGRASTIM (tbo-filgrastim, Sicor Biotech, UAB). The National Institute of Allergy and Infectious Diseases (NIAID) has submitted efficacy data for filgrastim, based on treatment in an animal model of radiation-induced myelosuppression. Safety and other supportive information is available from clinical studies currently described in the labeling for LGFs.*

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| 8:00 a.m. | Call to Order and Introduction of Committee                                                      | <b>Deborah K. Armstrong, MD</b><br>Acting Chairperson                                                                                                                |
| 8:05 a.m. | Conflict of Interest Statement                                                                   | <b>Diane P. Goyette, RPh, JD</b><br>Designated Federal Officer, MIDAC                                                                                                |
| 8:10 a.m. | FDA Introductory Remarks                                                                         | <b>Dwaine Rieves, MD</b><br>Director<br>Division of Medical Imaging Products (DMIP)<br>Office of Drug Evaluation-IV (ODE-IV)<br>Office of New Drugs (OND), CDER, FDA |
| 8:20 a.m. | <b>BIOMEDICAL ADVANCED RESEARCH<br/>AND DEVELOPMENT AUTHORITY<br/>(BARDA) PRESENTATION</b>       |                                                                                                                                                                      |
|           | Radiological/Nuclear Incident Scenario                                                           | <b>Richard J. Hatchett, MD</b><br>Chief Medical Officer and Deputy Director<br>BARDA, Office of the Assistant Secretary for<br>Preparedness and Response             |
| 8:35 a.m. | <b>GUEST SPEAKER PRESENTATION</b>                                                                |                                                                                                                                                                      |
|           | Evidence-Based Recommendations for<br>the Use of Cytokines in a<br>Radiological/Nuclear Incident | <b>Nicholas Dainiak, MD</b><br>Chairman, Department of Medicine<br>Bridgeport Hospital<br>Yale-New Haven Health<br>Bridgeport, CT                                    |

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**DRAFT AGENDA (cont.)**

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9:05 a.m. Clarifying Questions from the Committee

9:15 a.m. **BREAK**

9:30 a.m. **NATIONAL INSTITUTE OF ALLERGY  
AND INFECTIOUS DISEASES (NIAID)  
PRESENTATIONS**

Regulatory Overview of the NIAID  
Filgrastim Program

**Jui Shah, PhD**  
Senior Regulatory Affairs Officer  
Division of Allergy, Immunology and  
Transplantation  
NIAID, National Institutes of Health (NIH)

Characterization of a Rhesus Macaque  
Model of the Hematopoietic Acute  
Radiation Syndrome (H-ARS) and  
Correlation with the Human Syndrome

**Thomas J. MacVittie, PhD**  
Professor and NIAID Principal Investigator  
Departments of Radiation Oncology and Pathology  
University of Maryland School of Medicine

Study AXG 15: Efficacy and Statistical  
Analysis

**Ann Farese, MS, MT (ASCP)**  
Research Associate and Study Director  
Department of Radiation Oncology  
University of Maryland School of Medicine

Summary

**Jui Shah, PhD**

10:20 a.m. Clarifying Questions from the Committee

10:30 a.m. **FDA PRESENTATIONS**

Analytical Review of Study AXG15

**Lan Huang, PhD**  
Mathematical Statistician  
Division of Biostatistics V  
Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

Summary of FDA Reviews

**William E. Dickerson, MD**  
Medical Officer  
DMIP, ODE-IV, OND, CDER, FDA

10:50 a.m. Clarifying Questions from the Committee

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**DRAFT AGENDA (cont.)**

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11:00 a.m. **AMGEN, INC. PRESENTATIONS**

Neupogen/Neulasta – Amgen, Inc.

**Lyndah Dreiling, MD**

Vice President, Global Development

**Steve Galson, MD, MPH**

Vice President, Global Regulatory Affairs

11:20 a.m. **GENZYME CORPORATION, A SANOFI  
COMPANY PRESENTATIONS**

Introduction to Leukine

**Tal Zaks, MD, PhD**

Vice-President, Head of Development  
Sanofi Oncology

Overview of Data Supporting Use of  
Leukine for Treatment of Acute  
Radiation-induced Neutropenia

**Jacob Rowe, MD**

Department of Hematology and BMT  
Rambam Health Care Campus  
Haifa, Israel

11:35 a.m. **TEVA BRANDED PHARMACEUTICAL  
PRODUCTS R&D, INC. PRESENTATION**

Role of Tbo-filgrastim in the  
Management of Neutropenia

**Ashutosh K. Pathak, MD, PhD**

Senior Medical Director  
US Medical Affairs, Oncology

11:50 a.m. Clarifying Questions from the Committee

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing Session

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**