

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

May 9, 2007

8:00 a.m. Call to Order **Maha Hussain, M.D.**
Introduction of Committee Chair, ODAC

Conflict of Interest Statement **Johanna Clifford, M.Sc., RN**
Designated Federal Officer (DFO), ODAC

8:15 a.m. Opening Remarks **Richard Pazdur, M.D., Director**
Office of Oncology Drug Products (OODP), FDA

The committee will discuss new drug application (NDA) 022-092, proposed trade name JUNOVAN (mifamurtide), IDM Pharma, Inc., proposed indication for the treatment of newly diagnosed resectable high grade osteosarcoma following surgical resection in combination with multiple agent chemotherapy.

8:25 a.m. **Sponsor Presentation** **IDM Pharma, Incorporated**
Unmet Need Ian J. Lewis, M.D.
Pediatric and Adolescent Oncologist
St. James University Hospital, Leeds, UK

Efficacy/Safety Paul Meyers, M.D.
Vice-Chairman, Department of Pediatrics
Memorial Sloan-Kettering Cancer Center, NY

Tolerability and Benefit/Risk Eugenie S. Kleinerman, M.D.
Professor and Head, Division of Pediatrics
MD Anderson Cancer Center, TX

9:10 a.m. **FDA Presentation** **NDA 22-092**
Medical Review Patricia Dinndorf, M.D.
Medical Officer, DODP, OODP, CDER, FDA

Statistical Review Laura Lu, Ph.D.
Statistical Reviewer, Office of Biostatistics, CDER, FDA

9:45 a.m. Questions from the Committee

10:15 p.m. Break

10:30 p.m. Open Public Hearing

11:00 a.m. Questions to the ODAC and ODAC Discussion

12:00 p.m. *Lunch*

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The committee will discuss NDA 022-062, proposed trade name ORBEC (beclomethasone dipropionate), DOR BioPharma, Inc., proposed indication for the treatment of graft vs. host disease (GvHD) involving the gastrointestinal tract in conjunction with an induction course of high-dose prednisone or prednisolone.

1:00 p.m.	Call to Order Introduction of Committee	Maha Hussain, M.D. Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.Sc., RN Designated Federal Officer (DFO), ODAC
1:15 p.m.	Opening Remarks	Richard Pazdur, M.D., Director Office of Oncology Drug Products (OODP), FDA
1:25 p.m.	<u>Sponsor Presentation</u> Introduction and Background	<u>DOR Bio Pharma, Incorporated</u> Christopher J. Schaber, PhD President & Chief Executive Officer
	orBec for the Treatment of Graft-Versus-Host Disease involving the GI Tract in Conjunction with an Induction Course of High-dose Prednisone or Prednisolone	George B. McDonald, MD Professor of Medicine University of Washington and Head, Gastroenterology/Hepatology Section Fred Hutchinson Cancer Research Center
2:10 p.m.	<u>FDA Presentation</u> Clinical Review	<u>NDA 22-062</u> Nancy S. Scher, M.D. Medical Officer, DODP, OODP, FDA
	Statistical Considerations	Shan Sun-Mitchell, Ph.D. Statistical Reviewer, Office of Biostatistics, CDER, FDA
2:45 p.m.	Open Public Hearing	
3:15 p.m.	Break	
3:30 p.m.	Questions from the Committee	
4:00 a.m.	<i>Questions to the ODAC and ODAC Discussion</i>	
5:00 p.m.	<i>Adjourn</i>	