

**FOOD AND DRUG ADMINISTRATION**

Center for Drug Evaluation and Research

***Oncologic Drugs Advisory Committee (ODAC) Meeting***

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

White Oak Conference Center, Silver Spring, Maryland

December 7, 2011

**AGENDA**

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*During the **morning session**, the committee will discuss new drug application (NDA) 202324, with the proposed trade name INLYTA (axitinib) tablets, application submitted by Pfizer Inc. The proposed indication (use) for this product is for the treatment of patients with advanced renal cell carcinoma (RCC, kidney cancer).*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Wyndham Wilson, M.D., Ph.D.</b> Chair, ODAC
8:05 a.m.	Conflict of Interest Statement	<b>Yvette Waples, Pharm.D.</b> Acting Designated Federal Officer, ODAC
8:15 a.m.	<b>SPONSOR PRESENTATION</b>	<b>Pfizer, Inc.</b>
	Introduction	<b>Mace Rothenberg, M.D.</b> Senior Vice President Clinical Development and Medical Affairs Pfizer Oncology
	Axitinib Background	<b>Glen Andrews, M.S.</b> Axitinib Team Leader, Pfizer Oncology
	Summary of Clinical Efficacy	<b>Brian Rini, M.D.</b> Associate Professor of Medicine Cleveland Clinic
	Summary of Clinical Safety	<b>Sinil Kim, M.D.</b> Clinical Lead for Axitinib Development Program, Pfizer Oncology
	Clinical Perspective on Axitinib and Benefit/Risk in Patients with RCC	<b>Robert Motzer, M.D.</b> Attending Physician Memorial Sloan Kettering Cancer Center
	Concluding Remarks	<b>Mace Rothenberg, M.D.</b> Senior Vice President Clinical Development and Medical Affairs Pfizer Oncology

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**AGENDA (cont.)**

9:00 a.m. **FDA PRESENTATION**

NDA 202324: Inlyta (axitinib)

**Amy McKee, M.D.**

Medical Officer

Division of Oncology Products 1 (DOP1)

Office of Hematology & Oncology Products  
(OHOP), Office of New Drugs (OND), CDER,  
FDA

9:45 a.m. Clarifying Questions from the Committee

10:15 a.m. **BREAK**

10:30 a.m. Open Public Hearing Session

11:00 a.m. Questions to the Committee/Committee Discussion

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

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### AGENDA (cont.)

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*During the **afternoon session**, the committee will discuss new drug application (NDA) 202799, with the established name peginesatide injection, application submitted by Affymax, Inc. The proposed indication (use) for this product is for the treatment of anemia associated with chronic renal failure (CRF) in adult patients on dialysis.*

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12:30 p.m.	Call to Order and Introduction of Committee	<b>Wyndham Wilson, M.D., Ph.D.</b> Chair, ODAC
12:35 p.m.	Conflict of Interest Statement	<b>Yvette Waples, Pharm.D.</b> Acting Designated Federal Officer, ODAC
12:40 p.m.	Introduction/Background	<b>Kathy Robie-Suh, M.D., Ph.D.</b> Medical Team Leader Division of Hematology Products (DHP), OHOP, OND, CDER, FDA
12:45 p.m.	<b>SPONSOR PRESENTATION</b>	<b>Affymax, Inc.</b>
	Introduction	<b>Christine Conroy, Pharm.D.</b> Vice President, Regulatory Affairs Affymax, Inc.
	Anemia of Chronic Kidney Disease (CKD)	<b>Anatole Besarab, M.D.</b> Director of Clinical Research Division of Nephrology and Hypertension Henry Ford Health System
	Efficacy and Safety of Peginesatide	<b>Anne-Marie Duliege, M.D., M.S.</b> Chief Medical Officer Affymax, Inc
	Risk Benefit Summary	<b>Krishna Polu, M.D.</b> Vice President, Clinical Development Affymax, Inc.
1:30 p.m.	<b>FDA PRESENTATION</b>	
	NDA 202799 - Peginesatide Injection	<b>Andrew Dmytrijuk, M.D.</b> Medical Officer DHP, OHOP, OND, CDER, FDA

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**AGENDA (cont.)**

- 2:15 p.m. Clarifying Questions from the Committee
- 2:45 p.m. **BREAK**
- 3:00 p.m. Open Public Hearing Session
- 4:00 p.m. Questions to the Committee/Committee Discussion
- 5:00 p.m. **ADJOURNMENT**