

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Oncologic Drugs Advisory Committee*

## AGENDA

May 29, 2009

8:00 a.m. Call to Order  
Introduction of Committee Chair, ODAC

Conflict of Interest Statement **Nicole Vesely, Pharm.D.**  
Designated Federal Official, ODAC

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*The committee will discuss biologic license application (BLA) 125326, proposed trade name Arzerra (ofatumumab), GlaxoSmithKline, proposed indication for treatment of patients with chronic lymphocytic leukemia who have received prior therapy.*

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8:15 a.m. **Sponsor Presentation** GlaxoSmithKline

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

9:45 a.m. Questions to the Presenters

10:15 a.m. *Break*

10:30 a.m. Open Public Hearing

11:30 a.m. Questions to ODAC and ODAC Discussion

12:30 p.m. Adjourn