

Food and Drug Administration
Center for Drug Evaluation and Research
Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee Meeting
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD
November 1, 2011

AGENDA

The subcommittee will hear about pediatric development plans for four products that were either recently approved by the FDA or are in late stage development for an adult oncology indication. Based on the information presented, the subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of Written Requests for pediatric studies, if appropriate. The four products under consideration are: (1) sodium thiosulfate, manufactured by Adherex Technologies, Inc., (2) vismodegib(GDC-0449), manufactured by Genentech, Inc. (3) pazopanib, manufactured by GlaxoSmithKline, and (4) medi-573, manufactured by MedImmune, LLC.

8:00 a.m.	Call to Order Introduction of Subcommittee	Frank Balis, M.D. Acting Chairperson, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee
8:10 a.m.	FDA Presentation Overview of Pediatric Regulations	Melissa S. Tassinari, Ph.D., DABT Senior Clinical Analyst Pediatric and Maternal Health Staff Office of New Drugs, FDA
8:30 a.m.	Clarifying Questions from Subcommittee	
8:40 a.m.	Topic 1: Sodium thiosulfate- Adherex Technologies, Inc. Conflict of Interest Statement	Caleb Briggs, Pharm.D. Designated Federal Officer, Oncologic Drugs Advisory Committee (ODAC)
	Introduction of New Participants	Frank Balis, M.D.
8:45 a.m.	<u>Industry Presentation</u> Introduction	<u>Adherex Technologies, Inc. – sodium thiosulfate</u> Franck Rousseau, M.D. Consultant, Medical Affairs Adherex Technologies, Inc.
	Pediatric Ototoxicity	Kristin Knight, M.S., CCC-A Assistant Professor, Director of Pediatric Audiology Oregon Health and Science University

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	STS Data Demonstrating Lack of Tumor Protection	Edward Neuwelt, M.D. Director of the Blood Brain Barrier Program, and Director of the Head and Spinal Cord Injury Prevention Program Professor Neurology and Neurosurgery Oregon Health and Science University
	COG and SIOPEL Clinical Studies	David R. Freyer, D.O., M.S. Chair of the ACCL0431 Study, Director, LIFE Cancer Survivorship & Transition Program Children's Center for Cancer & Blood Diseases Children's Hospital Los Angeles University of Southern California Keck School of Medicine
	Challenges in Development and Q&A	Franck Rousseau, M.D.
9:05 a.m.	Clarifying Questions from Subcommittee	
9:15 a.m.	Open Public Hearing	
9:30 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
10:30 a.m.	BREAK	
10:40 a.m.	Topic 2: Vismodegib-Genentech, Inc.	
	Conflict of Interest Statement	Caleb Briggs, Pharm.D.
	Introduction of New Participants	Frank Balis, M.D.
10:45 a.m.	<u>Industry Presentation</u> Vismodegib Hedgehog Pathway Inhibitor	<u>Genentech, Inc. - vismodegib</u> Jennifer Low, M.D., Ph.D. Group Medical Director and Global Development Leader, Product Development Oncology Genentech, Inc.

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- 11:05 a.m. Clarifying Questions from Subcommittee
- 11:15 a.m. Open Public Hearing
- 11:30 a.m. Questions to the Subcommittee and Subcommittee Discussion
- 12:30 p.m. **LUNCH**

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5:20 p.m.	<u>FDA Presentation</u>	Closing Remarks
5:30 p.m.	ADJOURN	