

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Oncologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held September 13, 2005, from 8 a.m. to 5 p.m. and on September 14, 2005, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, The Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [cliffordj@cder.fda.gov](mailto:cliffordj@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's

Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to Oncologic Drugs Advisory Committee.)

*Agenda:* On September 13, 2005, the committee will discuss the following:

(1) New drug application (NDA) 21-491, proposed trade name XINLAY (atrasentan hydrochloride) Capsules, Abbott Laboratories, proposed indication for the treatment of men with metastatic hormone-refractory prostate cancer; and (2) NDA 21-743, S003, TARCEVA (erlotinib) Tablets, OSI Pharmaceuticals Inc., proposed indication for the first-line treatment, in combination with gemcitabine, of patients with locally advanced, unresectable or metastatic pancreatic cancer. On September 14, 2005, the committee will discuss the following: (1) NDA 21-880, proposed trade name REVLIMID (lenalidomide), Celgene Corp., proposed indication for the treatment of patients with transfusion-dependent anemia due to low-or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; and (2) NDA 21-877, proposed trade name ARRANON (nelarabine) Injection, GlaxoSmithKline, proposed indication for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to, or has relapsed with, at least two chemotherapy regimens.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 2, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations

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should notify the contact person before September 2, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Johanna Clifford at 301-827-7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated: August 10, 2005.

**Scott Gottlieb,**

*Deputy Commissioner for Policy.*

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