4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 28, 2016, from 8 a.m. to 3:15 p.m., and June 29, 2016, from 8 a.m. to 4:15 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email:

ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On June 28, 2016, information will be presented to gauge investigator interest in exploring potential pediatric development plans for four products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) VENETOCLAX, application sponsored by AbbVie, Inc.; (2) TAZEMETOSTAT, application sponsored by Epizyme, Inc.; and (3) ATEZOLIZUMAB, application sponsored by Roche/Genentech.

On June 29, 2016, during the morning session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric

studies, if appropriate. The products under consideration are: (1) LOXO-101, application sponsored by Loxo Oncology, Inc.; and (2) ENTRECTINIB, application sponsored by Ignyta, Inc.

During the afternoon session, information will be presented on the current unmet clinical need in the nearly uniformly fatal brain tumor, diffuse intrinsic pontine glioma (DIPG), which occurs predominantly in the pediatric age group. The diagnosis of DIPG is typically based on characteristic radiographic and clinical features in lieu of brain biopsy, and histological confirmation. Recent data has demonstrated that the biology and pathophysiology of these tumors differ. There are no approved drugs for this disease. Clinical investigators seek to exploit precision medicine approaches to DIPG and use potentially predictive information from the genomic signature of tumors at either diagnosis or relapse. This information can be used to select specific molecularly targeted drugs based on the genetic aberrations of an individual patient's tumor. The Agency will seek the input of the subcommittee, including an assessment of benefit/risk given the potential for an adverse event associated with a surgical intervention in the brainstem.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before June 21, 2016. Oral presentations from the public will be scheduled between approximately 8:50 a.m. and 9:10 a.m., 11 a.m. and 11:20 a.m., 1:55 p.m. and 2:15 p.m., and 3:50 p.m. and 4:05 p.m. on June 28, 2016, and between approximately 8:50 a.m. and 9:10 a.m., 10:55 a.m. and 11:15 a.m., and 3 p.m. and 3:20 p.m. on June 29, 2016. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before June 16, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 17, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: June 10, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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