4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Public Workshop on Minimal Residual Disease; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to provide a forum for discussion of the use of minimal residual disease (MRD) as a biomarker for evaluating new drugs for the treatment of acute lymphoblastic leukemia (ALL). The meeting is cosponsored with the American Society of Clinical Oncology and will be the first in a series of workshops intended to bring together scientific and advocacy communities and the pharmaceutical and in vitro diagnostic device industries to help develop processes and procedures to qualify MRD as a biomarker of efficacy and/or response to treatment in a group of hematological malignancies.

Date and Time: The public workshop will be held on April 18, 2012, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

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SUPPLEMENTARY INFORMATION:

I. Background

Clinical data from patients with certain subtypes of acute and chronic leukemia suggest that MRD can be established as a surrogate endpoint for clinical trials and drug approval. This public workshop will provide a forum for discussion among scientific and advocacy communities and the pharmaceutical and in vitro diagnostic device industries of issues related to the qualification (validation) of MRD as a biomarker (i.e., a measurable characteristic that is predictive of disease outcome) that can be used to determine efficacy and/or response in evaluation of new drugs for the treatment of ALL. Although the data related to the prognostic significance of MRD are most extensive in the pediatric population, and are currently used to stratify patients for risk-adjusted therapy, MRD may also be pertinent to subtypes of adult ALL; hematologists who treat adult patients have been invited to participate, as well as hematologists who treat pediatric patients. Topics to be discussed at the workshop include: (1) Evaluation of the prognostic biomarker data that is currently available to support the qualification of MRD as a marker of response and/or efficacy in both pediatric and adult ALL; (2) the specificity, sensitivity, and comparability of techniques that might be used in a standardized fashion to measure MRD; (3) the performance characteristics and proficiency assessment of current technology platforms; and (4) the design and analysis of the clinical trials needed to establish the use of postinduction MRD as an alternative endpoint for approval of new drugs to treat ALL.

This workshop is part of a series in which FDA's Office of Hematology and Oncology Products will explore the utility of MRD as a surrogate endpoint in ALL (including ALL that has recurred), chronic lymphocytic leukemia (CLL), and acute myeloid leukemia (AML). Given the diverse etiologies, pathophysiologies, and natural histories of these diseases and current practice standards, separate consideration of MRD as a surrogate endpoint in each disease is warranted. FDA is seeking representation from both North American and European academic investigators as well as cooperative groups at the workshops. The workshops for CLL and AML are tentatively scheduled for October 10 and 11, 2012, respectively.

II. Attendance and Registration

FDA encourages patient advocates, representatives from industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Registration: There is no registration fee for the public workshop. To register electronically, please use the following Web site: http://www.zoomerang.com/Survey/WEB22EJ4HRZLW9. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

Seats are limited and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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