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.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the American Society of Clinical Oncology, is announcing a public workshop that will provide a forum for discussion of extending the qualification of minimal residual disease (MRD) detection as a prognostic biomarker to that of an efficacy/response biomarker in evaluating new drugs for the treatment of chronic lymphocytic leukemia (CLL). Our objective for the workshop is to provide a venue for an in-depth discussion of potential surrogate endpoints for trials intended to support the approval of new drugs or biologics for the treatment of CLL. Participants in the workshop will examine the advantages and disadvantages of MRD as a surrogate endpoint for approval, identify the preferred technology platform and performance characteristics for the assay of this biomarker, and discuss any issues regarding methodological standardization for the biomarker. The primary focus will be on the biomarkers that are ready for incorporation into clinical trials and the technical and regulatory challenges for use of these markers.

DATES: The public workshop will be held on February 27, 2013, from 8 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through

Building 1 where routine security check procedures will be performed. For parking and security information please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

The Public Workshop on Minimal Residual Disease will be one of a series of FDA workshops to establish processes and procedures necessary to qualify a prognostic biomarker, MRD, as a possible response or efficacy biomarker in a group of hematological malignancies. Evaluation of clinical data suggests that MRD can be established as a potential surrogate endpoint for pivotal clinical trials and drug approval given its prominent role as a prognostic indicator in certain subtypes of acute and chronic leukemia. The Office of Hematology and Oncology Products plans to explore the potential utility of MRD as a surrogate endpoint in acute lymphoblastic leukemia (ALL) (including the relapsed setting), CLL, and acute myeloid

leukemia (AML). Given the diverse pathophysiology and natural history of these diseases, and current practice standards, individualized consideration of MRD as a surrogate endpoint is warranted. The ALL workshop was held on April 18, 2012. The CLL and AML workshops are scheduled for February 27, 2013, and March 4, 2013, respectively.

II. Structure and Scope of the Workshop

The workshop's scope will extend to the use of flow cytometry and the molecular methods used to measure minimal residual disease in patients being treated for CLL. The workshop will consist of formal presentations examining the regulatory, scientific, and clinical basis for use of biomarkers as potential clinical trial endpoints in CLL followed by discussions on issues associated with use of an MRD endpoint.

III. 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. There is no registration fee for the public workshop. To register electronically, please use the following Web site: http://www.zoomerang.com/Survey/WEB22GPA3U95QX (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."

Dated: December 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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