4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2452]

Endpoints for Drug Development in Heart Failure; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled "Endpoints for Drug Development in Heart Failure." The purpose of this public meeting is to bring the stakeholder community together to discuss clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. The workshop will focus on endpoints related to symptoms and physical function. In addition, there will be discussion of the need to assess mortality effects of drugs under development for heart failure.

DATES: The public workshop will be held on Friday, July 26, 2019, from 9 a.m. to 4 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD, 20993. 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

https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Meg Pease-Fye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4115, Silver Spring, MD, 20993-0002, 301-796-1130, Meg.PeaseFye@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. FDA is convening this public workshop to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

FDA is interested in soliciting feedback on a number of topics:

1. Consider and discuss endpoints related to symptoms and physical function, e.g., patient-reported outcome instruments, exercise tests, data from electronic monitors;
2. Consider the best ways to count multiple hospitalizations;
3. Discuss when the nature and clinical importance of a treatment effect for a particular endpoint may justify deferral or omission of outcomes studies;
4. In setting an upper bound for a mortality risk to be ruled out, discuss how the boundary may be influenced by a drug's demonstrated benefits and risks;
5. Discuss the advantages and disadvantages of all-cause vs. cardiovascular-specific endpoints, e.g., hospitalizations and deaths;
6. Discuss the advantages and disadvantages of adjudicating causes of deaths and hospitalizations.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website https://fdaheartfailureendpointsindrugdev.eventbrite.com. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public workshop must register by July 24, 2019, at 3 p.m., Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Meg Pease-Fye at 301-796-2240 no later than July 1, 2019.

Requests for Oral Comment: On the day of the meeting, a signup sheet will be made available for those who wish to speak during the public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments. On the day of the meeting, based on demand, we will determine the amount of time allotted to each presenter and the approximate time each comment is to begin. Please note this will be oral comment only; no slides or other presentation material is permitted. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast via https://collaboration.fda.gov/thf072519/.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at https://www.fda.gov.

Dated: June 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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