4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-N-2014-0865]

Patient-Focused Drug Development for Idiopathic Pulmonary Fibrosis; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for idiopathic pulmonary fibrosis. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of idiopathic pulmonary fibrosis on daily life as well as patient views on treatment approaches for idiopathic pulmonary fibrosis.

DATES: The public meeting will be held on September 26, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by September 10, 2014 (see SUPPLEMENTARY INFORMATION for instructions). Submit electronic or written comments by November 26, 2014.

ADDRESSES: The public meeting 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. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to

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

Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm395774.htm.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1144, Silver Spring, MD 20993, 301-796-0684, FAX: 301-847-8443, email: Pujita.Vaidya@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has selected idiopathic pulmonary fibrosis as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144). The full set of performance commitments is available on the FDA Web site at http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

FDA committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 08441) in the Federal Register announcing the disease areas for meetings in fiscal years (FY) 2013-2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in the April 11 notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a second public process for determining the disease areas for FY 2016-2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.

II. Purpose and Scope of Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of idiopathic pulmonary fibrosis that matter most to patients, as well as perspectives on current approaches to treating idiopathic pulmonary fibrosis. FDA expects that this information will come directly from patients, caregivers, and patient advocates. Idiopathic pulmonary fibrosis is a rare and life-threatening disease in which lung tissue become

scarred over time. Many people with idiopathic pulmonary fibrosis survive only 3 to 5 years from the time of diagnosis. Symptoms of idiopathic pulmonary fibrosis can include shortness of breath, dry cough, fatigue, and chest pain. There is no cure for idiopathic pulmonary fibrosis; symptomatic treatment options include corticosteroids, oxygen therapy, pulmonary rehabilitation, and lifestyle changes.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES).

Topic 1: Symptoms and daily impacts that matter most to patients:

- Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include shortness of breath, cough, fatigue, etc.)
- Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include household chores, walking up the stairs, etc.)
    - How do your symptoms and their negative impacts affect your daily life on the best days?
    - How do your symptoms and their negative impacts affect your daily life on the worst days?
- How has your condition and its symptoms changed over time?

Topic 2: Patient perspectives on treatment approaches:

- What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification.) How well does your current treatment regimen treat the most significant symptoms of your disease?
- What are the most significant downsides to your current treatments and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital for treatment, etc.)
- Because there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

III. Attendance and Participation

If you wish to attend this meeting, visit http://patientfocusedIPF.eventbrite.com. Please register by September 10, 2014. If you are unable to attend the meeting in person, you can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Pujita Vaidya (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will be asked to send a brief summary of responses to the topic questions to PatientFocused@fda.hhs.gov. Panelists will be notified of their selection a few days after the close of registration on September 10, 2014. FDA will try to accommodate all patients and patient advocate participants who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

IV. Comments

Submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see ADDRESSES) by November 26, 2014. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Transcripts

As soon as a transcript is available, FDA will post it at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm395774.htm.

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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