



Public Meeting on Idiopathic Pulmonary Fibrosis Patient-Focused Drug Development



September 26, 2014

12:00 – 1:00 pm	Registration
1:00 – 1:05 pm	Welcome Soujanya Giambone, MBA <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i>
1:05 – 1:10 pm	Opening Remarks Lydia Gilbert McClain, MD, FCCP <i>Deputy Director, Division of Pulmonary, Allergy and Rheumatology (DPARP), CDER, FDA</i>
1:10 – 1:20 pm	Overview of FDA’s Patient-Focused Drug Development Initiative Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i>
1:20 – 1:30 pm	Background on Disease Area and Treatment Banu Karimi-Shah, MD <i>Team Lead, DPARP, CDER, FDA</i>
1:30 – 1:40 pm	Overview of Discussion Format Soujanya Giambone, MBA <i>OSP, CDER, FDA</i>
1:40 – 2:10 pm	Panel #1 Comments on Topic 1 Topic 1: Disease symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion.
2:10 – 2:55 pm	Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
2:55 – 3:10 pm	Break
3:10 – 3:40 pm	Panel #2 Comments on Topic 2 Topic 2: Patient perspectives on current approaches to treating IPF. A panel of patients and patient representatives will provide comments to start the discussion.
3:40 – 4:25 pm	Large-Group Facilitated Discussion on Topic 2 Patients and patient representatives in the audience are invited to add to the dialogue.
4:25 – 4:55 pm	Open Public Comment
4:55 – 5:00 pm	Closing Remarks Banu Karimi-Shah, MD <i>DPARP, CDER, FDA</i>

Discussion Questions

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

- 1) Of all the symptoms that you experience because of your condition, which 1-3 symptoms have the most significant impact on your life? (Examples may include shortness of breath, cough, fatigue, etc.)
- 2) 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.)
 - a) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- 3) How has your condition and its symptoms changed over time?

Topic 2: Patient perspectives on treatment approaches

- 1) 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.)
 - a) How well does your current treatment regimen treat the most significant symptoms of your disease?
- 2) 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.)
- 3) Because there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?