



Lung Cancer Public Meeting on Patient-Focused Drug Development



June 28, 2013

7:30 – 8:30 am	Registration
8:30 – 8:40 am	Welcome Patricia Keegan, MD <i>Director, Division of Oncology Products II, Center for Drug Evaluation and Research (CDER), FDA</i>
8:40 – 8:50 am	Overview of FDA’s Patient-Focused Drug Development Initiative Theresa Mullin, PhD <i>Director, Office of Strategic Programs (OSP), CDER, FDA</i>
8:50 – 9:00 am	Background on Lung Cancer and Treatment Options Sean Khozin, MD, MPH <i>Division of Oncology Products II, CDER, FDA</i>
9:00 – 9:10 am	Overview of Discussion Format Sara Eggers, PhD <i>Office of Program and Strategic Analysis, OSP, CDER, FDA</i>
9:10 – 9:40 am	Panel #1 Comments: Topic 1 (see Appendix) A panel of patients and patient representatives will provide comments to start the discussion.
9:40 – 10:10 am	Large-Group Facilitated Discussion: Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
10:10 – 10:25 am	Break
10:25 – 10:55 am	Panel #2 Comments: Topic 2 (see Appendix)
10:55 – 11:45 am	Large-Group Facilitated Discussion: Topic 2
11:45 – 12:15 pm	Open Public Comment
12:15 – 12:30 pm	Closing Remarks Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i>

Appendix: Discussion Questions

Topic 1: Disease symptoms and daily impacts that matter most to patients

- 1) For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?
- 2) Of all the symptoms that you experience because of your lung cancer, which 1 to 3 symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)
- 3) 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 lung cancer? (Examples may include sleeping through the night, climbing stairs, household activities.)

Topic 2: Patients' perspectives on current approaches to treating lung cancer

- 1) Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.
 - a) What do you consider to be the most significant downsides of these treatments? (Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)
 - b) How do these downsides affect your daily life?
- 2) What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).
 - a) What specific symptoms do your treatments address?
 - b) How well do these treatments manage these symptoms?
 - c) Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?
- 3) When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?
- 4) What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:
 - a) What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)
 - b) How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)
 - c) How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)