



Breast Cancer Public Meeting on Patient-Focused Drug Development



April 2, 2015

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 Amna Ibrahim, MD <i>Deputy Director, Division of Oncology Products 1(DOP 1) Center for Drug Evaluation and Research (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 Suparna Wedam, MD <i>Medical Officer, DOP 1, 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 – 2:45 pm	Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
2:45 – 2:55 pm	Break
2:55 – 3:25 pm	Panel #2 Comments on Topic 2 Topic 2: Patient perspectives on current approaches to treating breast cancer. A panel of patients and patient representatives will provide comments to start the discussion.
3:25 – 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 Amy McKee, MD <i>Team Lead, DOP 1, CDER, FDA</i>

Discussion Questions

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

1. For context, how long ago was your diagnosis of breast cancer? Is your cancer currently in only one area or has it spread to other parts of the breast or lymph nodes or outside of the breast?
2. Of all the symptoms that you experience because of your breast cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include breast pain, swelling, bone pain, and fatigue.)
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 breast cancer? (Examples may include exercise, sexual activity/intimacy, etc.)

Topic 2: Patient perspectives on current approaches to treating breast cancer

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your breast 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 breast cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as pain medication, acupuncture, massage therapy, and dietary supplements).
 - 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 breast cancer?
4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your breast 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 the 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.)

Docket Information

We encourage you to submit your written comments to the docket by June 2, 2015:

<http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-2137-0001> or go to www.regulations.gov and search for: **breast cancer patient-focused drug development**.