



Public Meeting on Patient-Focused Drug Development for Neuropathic Pain Associated with Peripheral Neuropathy



June 10, 2016

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 Pamela Horn, MD <i>Medical Officer Team Lead, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), CDER, FDA</i>
1:10 – 1:20 pm	Overview of FDA’s Patient-Focused Drug Development Initiative Sara Eggers, PhD <i>OSP, CDER, FDA</i>
1:20 – 1:30 pm	Background on Pain Neuropathies and Available Treatments Steven Galati, MD <i>Medical Officer, DAAAP, CDER, FDA</i>
1:30 – 1:35 pm	The Road from PFDD Meetings to Clinical Trial Endpoints Nikunj Patel, Pharm.D. <i>Clinical Outcome Assessments Staff, CDER, FDA</i>
1:35 – 1:40 pm	Overview of Discussion Format Soujanya Giambone, MBA <i>OSP, CDER, FDA</i>
1:40 – 2:10 pm	Panel #1 Discussion on Topic 1: Disease Symptoms and Daily Impacts Topic 1: A panel of patients and caregivers will provide comments followed by a large-group facilitated discussion with participants in the audience.
2:10 – 2:45 pm	Large-Group Facilitated Discussion: Topic 1 Patients and patient representatives in the audience will be invited to add to the dialogue.
2:45 – 2:55 pm	Break
2:55 – 3:25 pm	Panel #2 Discussion on Topic 2: Current Approaches to Treatment Topic 2: A panel of patients and caregivers will provide comments to start the discussion on current approaches to treating neuropathic pain associated with peripheral neuropathy
3:25 – 4:25 pm	Large-Group Facilitated Discussion: Topic 2 Patients and patient representatives in the audience will be invited to add to the dialogue.
4:25 – 4:55 pm	Open Public Comment
4:55 – 5:00 pm	Closing Remarks Sharon Hertz, MD <i>Director, DAAAP, CDER, FDA</i>

Discussion Questions

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

- 1) How would you describe your pain associated with peripheral neuropathy? What terms would you use to describe the most bothersome aspects of pain? (Examples may include stabbing sensations, electric shocks, burning or tingling, 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 neuropathic pain? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
- 3) How does your neuropathic pain affect your daily life on the **best days**? On the **worst days**?
- 4) How has your neuropathic pain **changed over time**?
- 5) What **worries you most** about your condition?

Topic 2: Patients' perspectives on current approaches to treatment

- 1) **What are you currently doing** to help treat your neuropathic pain associated with peripheral neuropathy? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as physical therapy).
 - a) How has your treatment regimen changed over time, and why?
- 2) **How well** does your current treatment regimen control your neuropathic pain?
 - a) How well have these treatments worked for you as your condition has changed over time?
 - b) Would you define your condition today as being well managed?
- 3) 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 or clinic for treatment, time devoted to treatment, restrictions on driving, etc.)
- 4) Assuming there is no complete cure for your neuropathic pain, what specific things would you look for in an **ideal treatment** for your neuropathic pain?
 - a) What would you consider to be a meaningful improvement in your condition (for example specific symptom improvements or functional improvements) that a treatment could provide?
- 5) If you had the opportunity to consider participating in a clinical trial studying experimental treatments for neuropathic pain, what things would you consider when deciding whether or not to participate? (Examples may include how severe your neuropathic pain is, how well current treatments are working for you, your concern about risks, etc.)

Docket Information

We encourage you to submit your written comments to the docket by August 10, 2016:

<http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-4166-0001> or go to

www.regulations.gov and search for: **neuropathic pain associated with peripheral neuropathy patient-focused drug development.**