

Public Meeting on Patient-Focused Drug Development for Sarcopenia

April 6, 2017

12:00 – 1:00 pm	Registration
1:00 – 1:05 pm	Welcome Meghana Chalasani <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i>
1:05 – 1:10 pm	Opening Remarks Jean-Marc Guettier, MD <i>Director, Division of Metabolism and Endocrinology Products (DMEP), CDER, FDA</i>
1:10 – 1:20 pm	Overview of Sarcopenia and Current Treatment Options John Sharretts, MD <i>DMEP, CDER, FDA</i>
1:20 – 1:30 pm	Overview of FDA’s Patient-Focused Drug Development Meeting Sara Eggers, PhD <i>OSP, CDER, FDA</i>
1:30 – 2:00 pm	Setting the Context on Patients’ Experiences and Perspectives A panel of patients and patient representatives will provide comments related to Topic 1 and Topic 2 (next page) to kick-off the facilitated discussions on these topics.
2:00 – 2:30 pm	Large-Group Facilitated Discussion Patients and patient representatives in the audience will be invited to add to the dialogue.
2:30 – 2:45 pm	Break
2:45 – 3:30 pm	Large-Group Facilitated Discussion: Continued Patients and patient representatives in the audience will be invited to add to the dialogue.
3:30 – 3:50 pm	Open Public Comment
3:50 – 4:00 pm	Closing Remarks Jean-Marc Guettier, MD <i>Director, DMEP, CDER, FDA</i>

Discussion Questions

Topic 1: Disease 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 difficulty walking, feeling unsteady and falling frequently, having a decreased level of activity 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 participation in social activities, household chores, daily hygiene, etc.)
- 3) How do your symptoms and their negative impacts affect your daily life on the **best days**? On the **worst days**?
- 4) How have your condition and its symptoms **changed over time**?
 - a) Would you define your condition today as being well managed?
- 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 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) What specific symptoms do your treatments address?
 - b) How has your treatment regimen changed over time, and why?
- 2) **How well** does your current treatment regimen control your condition?
 - a) How well do your treatments address specific activities that are important to you in your daily life?
 - b) How well have these treatments worked for you as your condition has changed over time?
- 3) What are the most significant **downsides to your current treatments**, and how do they affect your daily life? (Examples of downsides may include going to the hospital or clinic for treatment, time devoted to treatment, etc.)
- 4) What specific things would you look for in an **ideal treatment** for your condition?
 - a) What would you consider to be a meaningful improvement (for example symptom improvements or functional improvements) in your condition that a treatment could provide?

Docket Information

We encourage you to submit your written comments to the docket by June 6, 2017:

<https://www.regulations.gov/document?D=FDA-2016-N-4198-0001> or go to www.regulations.gov and search for: **sarcopenia patient-focused drug development**.