

Public Meeting on Patient-Focused Drug Development for Alopecia Areata

September 11, 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 Tatiana Oussova, MD <i>Deputy Director for Safety, Division of Dermatology and Dental Products (DDDP), 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	Overview of Alopecia Areata and Current Treatment Options Melissa Reyes, MD <i>DDDP, CDER, FDA</i>
1:30 – 1:35 pm	The Road from PFDD Meetings to Clinical Trial Endpoints Michelle Campbell, PhD <i>Clinical Outcome Assessments Staff, OND, CDER, FDA</i>
1:35 – 1:40 pm	Overview of Discussion Format Meghana Chalasani <i>OSP, CDER, FDA</i>
1:40 – 2:00 pm	Panel #1 Discussion on Topic 1: Health Effects and Daily Impacts Topic 1: A panel will provide comments to start the discussion on health effects and daily impacts of alopecia areata
2:00 – 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 – 3:00 pm	Break
3:00 – 3:20 pm	Panel #2 Discussion on Topic 2: Current Approaches to Treatment Topic 2: A panel will provide comments to start the discussion on current approaches to treating alopecia areata
3:20 – 4:30 pm	Large-Group Facilitated Discussion: Topic 2 Patients and patient representatives in the audience will be invited to add to the dialogue
4:30 – 4:55 pm	Open Public Comment
4:55 – 5:00 pm	Closing Remarks Tatiana Oussova, MD <i>DDDP, CDER, FDA</i>

Docket Information

We encourage you to submit your written comments to the docket by November 13, 2017:

<https://www.regulations.gov/document?D=FDA-2017-N-3067-0001> or go to www.regulations.gov and search for: **alopecia areata patient-focused drug development**.

Discussion Questions

Topic 1: Health effects and daily impacts that matter most to patients

- 1) Of all the symptoms or disease manifestations that you experience because of your condition, which **1-3 symptoms or manifestations** have the most significant impact on your life? (Examples may include location or type of hair loss [i.e. loss of hair on scalp, loss of eyebrows, loss of all hair on body patchy hair loss], nail changes, hair quality upon regrowth)
- 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 daily hygiene, engagement in personal relationships, participation in sports or social activities, completion of school or work activities, etc.)
- 3) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- 4) How has your condition **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 non-drug therapies such as diet modification)
 - a) How has your treatment regimen changed over time, and why?
- 2) **How well** does your current treatment regimen control your condition?
 - a) 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 clinic for treatment, time devoted to treatment, side effects of treatment, route of administration, 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 in your condition that a treatment could provide?
- 5) What factors do you take into account when making decisions about selecting a course of treatment?