Meeting on HIV Patient-Focused Drug Development and HIV Cure Research

June 14, 2013

8:30 – 9:30 am	**Registration**
9:30 – 9:40 am	**Welcome** Edward Cox, MD, MPH *Director, Office of Antimicrobial Products, Center for Drug Evaluation and Research (CDER), FDA*
9:40 – 9:50 am	**Overview of FDA's Patient-Focused Drug Development Initiative** Theresa Mullin, PhD *Director, Office of Strategic Programs (OSP), CDER, FDA*
9:50 – 10:00 am	**Background on Current HIV Treatment** Kimberly Struble, PharmD *Clinical Team Lead, Division of Antiviral Products, CDER, FDA*
10:00 – 10:10 am	**Overview of Discussion Format** Sara Eggers, PhD *Office of Program and Strategic Analysis, OSP, CDER, FDA*

Discussion 1: Patients' Perspectives on Current Approaches to Managing HIV and on Symptoms Experienced Because of HIV or Its Treatment

10:10 – 10:30 am	**Panel #1 Comments on Questions 1 – 3 (See Appendix)** A panel of patients and patient representatives will provide comments to start the discussion.
10:30 – 11:00 am	**Large-Group Facilitated Discussion on Questions 1 – 3** Patients and patient representatives in the audience are invited to add to the dialogue.
11:00 – 11:15 am	**Break**
11:15 – 11:30 am	**Panel # 1 Comments on Questions 4 – 5 (See Appendix)**
11:30 – 12:00 pm	**Large-Group Facilitated Discussion on Questions 4 – 5**
12:00 – 12:15 pm	**Discussion with FDA Panel** An FDA panel will have an opportunity to comment on any points raised in the facilitated discussion or field any relevant questions from the audience.

12:15 – 1:30 pm	**Lunch**
1:30 – 1:35 pm	**Afternoon Opening Comments** Janet Woodcock, MD *Director, CDER, FDA*
1:35 – 1:40 pm	**Summary of Morning Discussion** Richard Klein *Director, Patient Liaison Program, Office of Health and Constituent Affairs, Office of the Commissioner, FDA*
1:40 – 1:50 pm	**Background on HIV Cure Research** Ilan Irony, MD *Chief, General Medicine Branch, Division of Clinical Evaluation and Pharmacology/Toxicology, Center for Biologics Evaluation and Research, FDA*
1:50 – 2:00 pm	**Informed Consent Issues in HIV Cure Research** Sara Goldkind, MD, MA *Senior Bioethicist, Office of Good Clinical Practice, Office of the Commissioner, FDA*
2:00 – 2:05 pm	**Overview of Discussion Format** Sara Eggers, PhD *Office of Program and Strategic Analysis, OSP, CDER, FDA*

Discussion 2: Patients' Perspectives on HIV Cure Research

2:05 – 2:35 pm	**Panel #2 Comments on Questions 1 – 4 (See Appendix)**
2:35 – 3:25 pm	**Large-Group Facilitated Discussion on Questions 1 – 4**
3:25 – 3:40 pm	**Break**
3:40 – 4:00 pm	**Panel #2 Comments on Questions 5 – 6 (See Appendix)**
4:00 – 4:35 pm	**Large-Group Facilitated Discussion on Questions 5 – 6**
4:35 – 4:50 pm	**Discussion with FDA panel**
4:50 – 5:20 pm	**Open Public Comment**
5:20 – 5:30 pm	**Closing Remarks** Theresa Mullin, PhD *Director, OSP, CDER, FDA*

Appendix: Discussion Questions

Topic 1: Patients' perspectives on current approaches to managing HIV and on symptoms experienced because of HIV or its treatment

1. What are you currently doing to help manage your HIV and any symptoms you experience because of your condition? (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 long have you been on treatment and how has your treatment regimen changed over time?
2. How well does your current treatment regimen treat any significant symptoms of your condition?
    a. How well have these treatments worked for you as your condition has changed over time?
    b. Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?
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, physical change to your body because of treatment, adherence to the drug regimen, going to the hospital for treatment, etc.)
4. Of all the symptoms that you experience because of your condition or because of your treatment, which 1-3 symptoms have the most significant impact on your life? (Examples may include diarrhea, insomnia, difficulty concentrating, etc.)
    a. 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 sleeping through the night, daily hygiene, driving, etc.)
5. Assuming there is currently no complete cure for your condition, what specific things would you look for in an ideal treatment to manage your condition?

Topic 2: Patients' perspectives on HIV Cure Research

1. What do you believe are the benefits of participating in an HIV cure research study?
2. What would motivate you to participate or to not participate in an HIV cure research study?
3. What risks would you find unacceptable for participating in an HIV cure research study, and why? (Examples of risks that may be associated with participation in an HIV cure research study include common side effects such as nausea and fatigue, and less common but serious adverse events such as blood clots, infection, seizures and cancer.)
4. In certain HIV cure research studies, you would be asked to stop any other HIV medications that you are currently taking. How would this affect your decision whether to participate in an HIV cure research study?

5. The process of informed consent is an important way for the researchers to communicate the purpose of an HIV research study, as well as its expected benefits and potential risks, so that people can make an informed decision whether to participate in the study.

    a. How should the informed consent clearly communicate to you the purpose of an HIV cure research study, particularly when a study is designed only to provide scientific information that could guide future research and development of treatments?

    b. How should the informed consent clearly communicate to you the potential benefits of an HIV cure research study? In particular, how can the informed consent best describe benefit when we do not know that participants in the study may gain any direct health benefits?

    c. How should informed consent communicate clearly to you that there are potential risks of participating in an HIV cure research study, including unknown risks? In particular, how should the informed consent describe a study if there is very limited understanding about how the medications or interventions may affect participants or what the potential risks of those interventions or medications may be?

    d. Is there any other information that you would find helpful when deciding whether to enter an HIV cure research study?

6. What else do you want FDA to know about HIV cure research from your perspective?