Meeting on the Long-term Safety and Efficacy of Extended-release and Long-acting Opioid Analgesics for Chronic Pain

Hosted by the Clinical Trials Transformation Initiative (CTTI)

August 12&13, 2013

Sheraton Silver Spring Hotel
8777 Georgia Avenue · Silver Spring, MD 20910

The purpose of this meeting, hosted by CTTI, is to facilitate a broad scientific discussion about optimal ways to generate additional evidence to help inform the safe and effective use of extended-release and long-acting opioid analgesics.

A public meeting titled, Assessment of Analgesic Treatment of Chronic Pain: A Scientific Workshop, was conducted by the FDA in May 2012. Available data on the efficacy of analgesics in the treatment of chronic non-cancer pain was discussed. The materials from the May 2012 meeting provide useful background and are available at http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm.

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MEETING OBJECTIVES

- Engage multiple stakeholders in discussions around approaches to develop more evidence on the long-term safety and efficacy of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain
- Review and discuss a proposed study to evaluate the long-term efficacy of opioids for the treatment of chronic non-cancer pain
- Discuss strategies to assess the long-term safety of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain
DAY 1 – AUGUST 12, 2013

7:30 – 8:30am  Breakfast · Elm I&II

WELCOMING REMARKS · Cypress Ballroom
8:30 – 8:45am  Introduction to CTTI and Opening Comments
  Pamela Tenaerts, CTTI
  Rachel Sherman, FDA

8:45 – 09:00am  Meeting Goals
  Robert Califf, Duke University

SESSION I: Evidence for the Efficacy of Opioid Analgesics for Chronic Pain
Session Facilitator: Robert Califf
Session Objectives: Review the available evidence on the long-term efficacy of opioid analgesics for the treatment of chronic non-cancer pain

9:00 – 09:30am  Review of the Evidence for the Efficacy and Effectiveness of Opioid Analgesics for Chronic Pain
  Jane Ballantyne, University of Washington

9:30 – 10:00am  Discussion
  All Attendees

10:00 – 10:15am  Break

SESSION II: Review of Proposed Efficacy Study
Session Facilitator: Robert Califf
Session Objectives: Review a proposed study to evaluate the long-term efficacy of opioids

10:15 – 11:00am  Overview of Efficacy Protocol Synopsis
  Robert Califf

11:00 – 12:00pm  Discussion of Efficacy Protocol Overview and Objective
  All Attendees

12:00-1:00pm  Lunch (Provided) · Elm I&II

SESSION III: Continued Discussion of Efficacy Study
Session Facilitator: Robert Califf, All attendees to contribute to discussion
Session Objectives:
  - Discuss study population and inclusion and exclusion criteria
  - Discuss study design, duration, and outcome measures

1:00 - 1:45pm  Discussion of Study Population and Inclusion and Exclusion Criteria

1:45 - 3:15pm  Discussion of Study Design, Duration, and Outcome Measures
3:15 – 3:30pm  Break

3:30 – 5:15pm  What additional studies are needed to evaluate efficacy?  
All attendees

5:15pm  ADJOURN

6:00 - 8:00pm  Reception · Elm I&II

DAY 2 – AUGUST 13, 2012

7:00 – 8:00am  Breakfast · Elm I&II

8:00 – 8:05am  Goals of Safety Discussion  
Robert Califf

SESSION IV: Existing Data Sources to Evaluate Opioid Analgesic Safety  
Session Facilitator: Robert Califf
Session Objectives:

- Review examples of data sources used to assess opioid misuse, abuse, addiction, unintentional overdose, and death
- Discuss the strengths and weaknesses of existing databases and the gaps in data where additional evidence to assess safety is needed

8:05 – 8:25am  Monitoring Opioid Analgesic Abuse and Overdose in the United States  
Christopher M. Jones, Centers for Disease Control and Prevention

8:25 – 8:40am  Postmarketing Surveillance of Prescription Drug Abuse  
Richard Dart, Rocky Mountain Poison and Drug Center

8:40 – 8:55am  Harnessing National Data Sets: National Survey on Drug Use and Health (NSDUH) and VA Data  
William Becker, VA Connecticut Healthcare System

8:55 – 9:10am  Using Integrated Health Plan EMR Data to Evaluate Outcomes Associated with Clinical Services for the Treatment of Non-Malignant Chronic Pain  
Lynn DeBar, Kaiser Permanente Center for Health Research

9:10 – 9:45am  Questions and Discussion

- Are existing data sources sufficient for use in studying safety outcomes, or is new data collection needed?

9:45 – 10:00am  Break
SESSION V: Gathering Additional Evidence on Opioid Analgesic Safety
Session Facilitator: Robert Califf
Session Objectives: Discuss strategies to gather evidence to assess the long-term safety of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain

10:00 – 12:00pm  Topic Discussion: How to Conduct Studies to Assess Long-Term Safety
  ● How is exposure to opioids and other drugs best ascertained?
  ● What comparator groups could/should be used?
  ● What outcomes need to be captured to reflect misuse, abuse, addiction, and overdose?
  ● How do we make sure we have complete ascertainment of death?

12:00 – 1:00pm  Working Lunch and Topic Discussions · Cypress Ballroom

1:00 – 2:00pm  Continue Topic Discussions

2:00 - 2:30pm  Summarize Topic Discussions

2:30pm  ADJOURN