

Accelerating Drug Development for Sickle Cell Disease

Washington Plaza Hotel • Washington, DC Thursday, October 9, 2014

- 9:00 a.m. Welcome, Overview, and Meeting Objectives Mark McClellan, Engelberg Center for Health Care Reform Gregory Daniel, Engelberg Center for Health Care Reform
- 9:15 a.m. **Opening Remarks** Ann Farrell, US Food and Drug Administration
- 9:30 a.m. Facilitating Drug Development for Sickle Cell Disease Nicole Verdun, US Food and Drug Administration
- 9:45 a.m. Session I: Clinical Trial Endpoint Selection: Drug development for Chronic Prevention versus Acute Management Mark McClellan, Moderator

Opening presentation: Wally R. Smith, Virginia Commonwealth University

11:00 a.m. Break

11:15 a.m. Session II: Special Considerations for Adult Clinical Trials Gregory Daniel, Moderator

Opening presentation: Ken Ataga, University of North Carolina-Chapel Hill

12:15 p.m. Lunch

1:15 p.m.Session III: Special Considerations for Pediatric Clinical Trials
Mark McClellan, Moderator

Opening presentation: Carlton Dampier, Emory University

2:15 p.m. Session IV: Development of Patient Reported Outcomes Mark McClellan, Moderator

Opening presentation: Carlton Haywood, Johns Hopkins University

- 3:00 p.m. Break
- 3:15 p.m. Session V: Identifying Next Steps
- 3:45 p.m. **FDA Wrap-Up of Today's Discussion** Kathy Robie-Suh, US Food and Drug Administration



4:00 p.m. Closing Remarks Mark McClellan

4:15 p.m. Adjournment

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