

**Food and Drug Administration**  
**Center for Drug Evaluation and Research**  
*Oncologic Drugs Advisory Committee Meeting*  
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center  
(Rm. 1503), Silver Spring, MD  
**June 20, 2012**

**AGENDA**

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*During the morning session, the committee will discuss new drug application (NDA) 203213, with the established name semuloparin sodium injection, application submitted by sanofi-aventis U.S. LLC. The proposed indication (use) for this product is for the prophylaxis of venous thromboembolism (VTE) in patients receiving chemotherapy for locally advanced or metastatic pancreatic or lung cancer or for locally advanced or metastatic solid tumors with a VTE risk score  $\geq 3$ .*

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8:00 a.m.	Call to Order Introduction of Committee	<b>Wyndham Wilson, M.D., Ph.D.</b> Chairperson, Oncologic Drugs Advisory Committee
	Conflict of Interest Statement	<b>Caleb Briggs, Pharm.D.</b> Designated Federal Officer, Oncologic Drugs Advisory Committee
	Member Appreciation	<b>Richard Pazdur, M.D.</b> Director, Office of Hematology and Oncology Products Office of New Drugs, CDER, FDA
8:15 a.m.	<b><u>Sponsor Presentation</u></b> Introduction	<b><u>sanofi-aventis U.S. LLC</u></b> <b>Richard Gural, Ph.D.</b> Sanofi
	Medical Need	<b>Alok Khorana, M.D.</b> University of Rochester
	Semuloparin Efficacy and Safety	<b>Francesca Lawson, M.D.</b> Sanofi
	Proposed Indication: Rationale, Efficacy, Safety and Benefit/Risk	<b>Tal Zaks, M.D., Ph.D.</b> Sanofi
	Impact of SAVE-ONCO Results On Clinical Practice	<b>Paul Bunn, M.D.</b> University of Colorado

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**AGENDA (cont.)**

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9:00 a.m.	<b><u>FDA Presentation</u></b> NDA 203213 Semuloparin sodium	<b>Jeanne Herndon, M.D.</b> Medical Officer Division of Hematology Products, Office of Hematology and Oncology Products, Office of New Drugs, CDER, FDA  <b>Kyung Yul Lee, Ph.D.</b> Statistical Reviewer Division of Biostatistics V, Office of Biostatistics, Office of Translational Science, CDER, FDA
9:45 a.m.	Clarifying Questions from Committee	
10:15 a.m.	<b>BREAK</b>	
10:30 a.m.	Open Public Hearing	
11:00 a.m.	Questions to the Committee and Committee Discussion	
12:00 p.m.	<b>LUNCH</b>	

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**AGENDA (cont.)**

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*During the afternoon session, the committee will discuss NDA 202714, with the proposed trade name Kyprolis (carfilzomib) for injection, application submitted by Onyx Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of patients with relapsed and refractory (recurring and/or not responsive to other treatments) multiple myeloma who have received at least 2 prior lines of therapy that included a proteasome inhibitor and an immunomodulatory agent.*

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1:00 p.m.	Call to Order Introduction of Committee	<b>Wyndham Wilson, M.D., Ph.D.</b> Chairperson, Oncologic Drugs Advisory Committee
	Conflict of Interest Statement	<b>Caleb Briggs, Pharm.D.</b> Designated Federal Officer, Oncologic Drugs Advisory Committee
1:15 p.m.	<b><u>Sponsor Presentation</u></b> Introduction	<b><u>Onyx Pharmaceuticals, Inc.</u></b> <b>Ted W. Love, M.D.</b> EVP, Research & Development and Technical Operations Onyx Pharmaceuticals, Inc.
	Multiple Myeloma Unmet Need	<b>Kenneth C. Anderson, M.D.</b> Program Director and Chief, Division of Hematologic Neoplasias Kraft Family Professor of Medicine Harvard Medical School
	Clinical Efficacy	<b>Barbara Klencke, M.D.</b> Sr. VP, Clinical Development Onyx Pharmaceuticals, Inc.
	Clinical Safety	<b>Natalie Sacks, M.D.</b> VP, Clinical Science & Biometrics Onyx Pharmaceuticals, Inc.
	Benefit/Risk Summary	<b>Sagar Lonial, M.D.</b> Professor and Vice Chair of Clinical Affairs Department of Hematology and Medical Oncology Emory University School of Medicine

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| 2:00 p.m. | <b><u>FDA Presentation</u></b><br>NDA 202714<br>Carfilzomib (Kyprolis™) | <b>Thomas Herndon, M.D.</b><br>Medical Officer<br>Division of Hematology Products,<br>Office of Hematology and Oncology<br>Products,<br>Office of New Drugs, CDER, FDA |
| 2:45 p.m. | Clarifying Questions from Committee                                     |  |
| 3:15 p.m. | <b>BREAK</b>  |  |
| 3:30 p.m. | Open Public Hearing   |  |
| 4:00 p.m. | Questions to the Committee and Committee Discussion                     |  |
| 5:00 p.m. | <b>ADJOURN</b>  |  |