FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 19, 2017

AGENDA

The committee will discuss supplemental new drug application (sNDA) 021938/033 SUTENT (sunitinib malate) oral capsules, submitted by C.P. Pharmaceuticals International C.V., represented by Pfizer, Inc. (authorized U.S. agent). The proposed indication (use) for this product is for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

8:30 a.m.	Call to Order and Introduction of Committee	**Thomas Uldrick, MD, MS** Acting Chairperson, ODAC
8:35 a.m.	Conflict of Interest Statement	**Cindy Chee, PharmD** Acting Designated Federal Officer, ODAC
8:40 a.m.	Opening Remarks	**Julia Beaver, MD** Acting Division Director Division of Oncology Products 1 (DOP1) Office of Hematology & Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	**APPLICANT PRESENTATIONS**	**C.P. Pharmaceuticals International C.V., represented by Pfizer, Inc.**
	Introduction	**Sriram Krishnaswami, PhD** Asset Team Leader Global Product Development Pfizer Inc.
	Non-Metastatic RCC: Unmet Medical Need	**Allan Pantuck, MD** Professor of Urology UCLA Medical Center
	Rationale for Adjuvant Treatment and Efficacy	**Daniel George, MD** Professor of Medicine and Surgery Duke University Medical Center
	Safety and Quality of Life	**Liza DeAnnuntis, MD** Safety Risk Lead/Pharmacovigilance Worldwide Safety and Regulatory Pfizer Inc.
	Benefit/Risk: Clinical Perspective	**Robert A. Figlin, MD, FACP** Steven Spielberg Family Chair in Hematology Oncology Professor of Medicine and Biomedical Sciences Cedar-Sinai Medical Center

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AGENDA (cont.)

9:30 a.m. **FDA PRESENTATIONS**

Sutent - Adjuvant Treatment of Renal Cell Carcinoma	**James Xu, MD** Clinical Reviewer DOP1, OHOP, OND, CDER, FDA
	Laura Fernandes, PhD Statistician Division of Biometrics V Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Sundeep Agrawal, MD Clinical Reviewer DOP1, OHOP, OND, CDER, FDA

10:15 a.m. Clarifying Questions to the Presenters

10:45 a.m. **BREAK**

11:00 a.m. **OPEN PUBLIC HEARING**

12:00 p.m. Questions to the Committee/Committee Discussion

1:00 p.m. **ADJOURNMENT**