

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

*Meeting of the Oncologic Drugs Advisory Committee (ODAC)*

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)  
White Oak Conference Center, Silver Spring, Maryland

June 25, 2014

**AGENDA**

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*The committee will discuss new drug application (NDA) 206162, olaparib capsules, application submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) for this product is as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed ovarian cancer (including fallopian tube or primary peritoneal) with germline BRCA mutation as detected by an FDA-approved test, who are in response (complete response or partial response) to platinum-based chemotherapy.*

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8:30 a.m.	Call to Order and Introduction of Committee	<b>Mikael Sekeres, MD, MS</b> Chairperson, ODAC
8:40 a.m.	Conflict of Interest Statement	<b>Caleb Briggs, PharmD</b> Designated Federal Officer, ODAC
8:45 a.m.	FDA Introductory Remarks NDA 206162 - Olaparib	<b>Amy McKee, MD</b> Medical Team Leader Breast/Gyn Team Division of Oncology Products 1 (DOP1) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>AstraZeneca Pharmaceuticals LP</b>
	Introduction	<b>Hesham Abdullah, MD, MSc, RAC</b> Vice President, Global Regulatory Affairs Oncology AstraZeneca Pharmaceuticals LP
	Relapsed Ovarian Cancer Unmet Need	<b>Robert Ozols, MD, PhD</b> Consultant
	Olaparib Efficacy	<b>Ursula Matulonis, MD</b> Dana-Farber Cancer Institute

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**AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Olaparib Safety

**Jane Robertson, MD**  
Executive Global Clinical Director  
AstraZeneca Pharmaceuticals LP

Clinical Perspective

**Robert Ozols, MD, PhD**

9:45 a.m. **BREAK**

10:00 a.m. **FDA PRESENTATIONS**

NDA 206162 - Olaparib Capsules

**Geoffrey Kim, MD**  
Medical Officer  
Breast/Gyn Team  
Scientific Liaison – Gynecologic Malignancies  
DOP1, OHOP, OND, CDER, FDA

**Gwynn Ison, MD**  
Medical Officer  
Breast/Gyn Team  
DOP1, OHOP, OND, CDER, FDA

11:00 a.m. Clarifying Questions to the Presenters

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. **ADJOURNMENT**