

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland 20903
September 14, 2016

DRAFT AGENDA

The committee will discuss new drug application 208714, apaziquone for intravesical instillation, application submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for immediate intravesical instillation post-transurethral resection of bladder tumors in patients with non-muscle invasive bladder cancer.

8:00 a.m.	Call to Order and Introduction of Committee	Bruce J. Roth, MD Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	Lauren Tesh, PharmD, BCPS Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	Chana Weinstock, MD Medical Officer, Genitourinary Cancers Team Division of Oncology Products 1 (DOP1) Office of Hematology & Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	GUEST SPEAKER PRESENTATION Overview of Diagnosis and Management of Non-Muscle Invasive Bladder Cancer	Seth P. Lerner, MD, FACS Professor, Scott Department of Urology Beth and Dave Swalm Chair in Urologic Oncology Director of Urologic Oncology Director of the Multidisciplinary Bladder Cancer Program Baylor College of Medicine Medical Center Houston, Texas
8:30 a.m.	APPLICANT PRESENTATIONS Introduction Post-Operative Intravesical Therapy	Spectrum Pharmaceuticals, Inc. Anil K. Hiteshi, RAC Global Regulatory Affairs Spectrum Pharmaceuticals, Inc. Neal Shore, MD Medical Director Carolina Urologic Research Center

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Efficacy and Safety

Gajanan Bhat, PhD

Vice President, Biostatistics, Data Management
and Medical Writing
Spectrum Pharmaceuticals, Inc.

Benefit-Risk and Clinical Utility of
Apaziquone

Alfred Witjes, MD

Professor of Urologic Oncology
Radboud University Nijmegen Medical Centre

Clinical Perspective

Mark Soloway, MD

Chief of Urological Oncology
Memorial Cancer Institute, Miami

Concluding Remarks

Rajesh Shrotriya, MD

Chairman and Chief Executive Officer
Spectrum Pharmaceuticals, Inc.

9:15 a.m.

FDA PRESENTATIONS

NDA 208714 - Apaziquone

Gwynn Ison, MD

Medical Officer
DOP1, OHOP, OND, CDER, FDA

FDA Statistical Analysis

Erik Bloomquist, PhD

Statistical Reviewer
Division of Biometrics V (DBV)
Office of Biometrics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

10:00 a.m. Clarifying Questions to the Presenters

10:30 a.m. **BREAK**

10:45 a.m. Open Public Hearing

11:45 a.m. Questions to the Committee/Committee Discussion

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