During the morning session, the committee will discuss new drug application (NDA) 206333, deoxycholic acid injection, a cytolytic drug, submitted by Kythera Biopharmaceuticals, proposed for the improvement in the appearance of moderate-to-severe convexity or fullness associated with submental fat in adults.

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<tr>
<th>Time</th>
<th>Item</th>
<th>Presenter</th>
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| 8:00 a.m. | Call to Order and Introduction of Committee | Lynn A. Drake, MD  
Chairperson, DODAC       |
| 8:15 a.m. | Conflict of Interest Statement | Jennifer Shepherd, RPh  
Acting Designated Federal Officer, DODAC |
| 8:20 a.m. | FDA Introductory Remarks | Kendall A. Marcus, MD  
Director  
Division of Dermatology and Dental Products (DDDP)  
Office of Drug Evaluation III (ODE III)  
Office of New Drugs (OND), CDER, FDA |
| 8:30 a.m. | SPONSOR PRESENTATIONS | Kythera Biopharmaceuticals, Inc. |
|        | Introduction | Frederick C. Beddingfield, III, MD, PhD, FAAD  
Chief Medical Officer, Kythera  
Clinical Associate Professor of Medicine  
Division of Dermatology  
University of California at Los Angeles |
|        | ATX-101 Administration | Derek H. Jones, MD, FAAD  
Founder and Director  
Skincare & Laser Physicians  
Clinical Associate Professor of Medicine  
Division of Dermatology  
University of California at Los Angeles |
|        | Pivotal Clinical Study Design | Todd M. Gross, PhD  
Vice President of Clinical Development, Biostatistics, and Data Management, Kythera  
Associate Professor, Department of Statistics and Applied Probability  
University of California, Santa Barbara |
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
March 9, 2015

AGENDA (cont.)

SPONSOR PRESENTATIONS (CONT.)

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<thead>
<tr>
<th>Time</th>
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<tr>
<td>9:15 a.m.</td>
<td>Clarifying Questions</td>
<td>Frederick C. Beddingfield, III, MD, PhD, FAAD</td>
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<td>9:30 a.m.</td>
<td>BREAK</td>
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<td>9:45 a.m.</td>
<td>FDA PRESENTATIONS</td>
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<td>Background</td>
<td>Milena Lolic, MD, MS</td>
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<td>Efficacy Endpoints</td>
<td>Elektra Papadopoulos, MD, MPH</td>
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<td>Summary of Efficacy</td>
<td>Kathleen Fritsch, PhD</td>
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<td>Summary of Safety</td>
<td>Milena Lolic, MD, MS</td>
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<td>10:15 a.m.</td>
<td>Clarifying Questions</td>
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<td>10:30 a.m.</td>
<td>Open Public Hearing</td>
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<td>11:00 a.m.</td>
<td>Questions to the Committee/Committee Discussion</td>
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<td>12:00 p.m.</td>
<td>LUNCH</td>
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During the afternoon session, the committee will discuss pediatric development of systemic products for the treatment of atopic dermatitis with inadequate response to topical prescription therapy.

1:00 p.m. Call to Order and Introduction of Committee
Lynn A. Drake, MD
Chairperson, DODAC

1:05 p.m. Conflict of Interest Statement
Jennifer Shepherd, RPh
Acting Designated Federal Officer, DODAC

1:10 p.m. FDA Introductory Remarks
Kendall A. Marcus, MD
Director
DDDP, ODE III, OND, CDER, FDA

1:15 p.m. FDA PRESENTATIONS
Atopic Dermatitis Inadequately Responsive to Topical Therapy—Overview and Available Therapy
Jill Lindstrom, MD, FAAD
Clinical Team Leader
DDDP, ODE III, OND, CDER, FDA

Dupilumab as an Example of a Product in Development for Atopic Dermatitis Inadequately Responsive to Topical Therapy
Jane Liedtka, MD, FAAD
Medical Officer
DDDP, ODE III, OND, CDER, FDA

1:45 p.m. Clarifying Questions

1:55 p.m. BREAK

2:05 p.m. INDUSTRY PRESENTATIONS
Pediatric Development of Systemic Products for the Treatment of Atopic Dermatitis with Inadequate Response to Topical Prescription Therapy
Dr. René van der Merwe MBChB, MSc, FFPM
Senior Director - Clinical Development
Respiratory and Inflammation
MedImmune, Ltd.

Dr. Athos Gianella-Borradori, MD
Chief Medical Officer
Chugai Pharma USA, LLC

2:45 p.m. Clarifying Questions
3:00 p.m. **FDA Presentation – Ethicist**

Ethical Considerations in the Development of Products for Use in Pediatric Patients with Atopic Dermatitis

Michelle Roth-Cline, MD, PhD
Pediatric Ethicist
Office of Pediatric Therapeutics
Office of the Commissioner, FDA

3:15 p.m. Clarifying question

3:30 p.m. Open Public Hearing

4:00 p.m. **Break**

4:10 p.m. Charge to the Committee

Kendall A. Marcus, MD
Director
DDDP, ODE III, OND, CDER, FDA

4:15 p.m. Questions to the Committee/Committee Discussion

5:15 p.m. **Adjournment**