AGENDA

The committee will discuss appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism while preserving or improving testicular function, including spermatogenesis.


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<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter</th>
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<tr>
<td>8:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Vivian Lewis, MD (Chairperson), BRUDAC</td>
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<td>8:10 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>CDR LaToya Bonner, PharmD, NCPS Acting Designated Federal Officer, BRUDAC</td>
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<td>8:15 a.m.</td>
<td>FDA Opening Remarks</td>
<td>Hylton V. Joffe, MD, MMSc Director, Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA</td>
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<td>8:30 a.m.</td>
<td>GUEST SPEAKER PRESENTATION</td>
<td>Sergio Oehninger, MD, PhD Director, Division of Reproductive Endocrinology The Jones Institute for Reproductive Medicine Eastern Virginia Medical School</td>
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<td>9:10 a.m.</td>
<td>Clarifying Questions to the Guest Speaker</td>
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<td>9:25 a.m.</td>
<td>INDUSTRY PRESENTATIONS</td>
<td>Michael Wyllie, PhD Managing Director, Global Pharma Consulting, Ltd. Introduction</td>
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<tr>
<td>Introduction</td>
<td>Mohit Khera, MD Associate Professor of Urology Baylor College of Medicine</td>
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<tr>
<td>Treatment Considerations for Secondary Hypogonadism</td>
<td>Edward Kim, MD Professor of Surgery University of Tennessee Graduate School of Medicine</td>
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<tr>
<td>Sperm Concentration is an Acceptable Endpoint for Demonstrating Clinical Benefit in Men who Have Hypogonadotropic Hypogonadism and Oligozoospermia (Impaired Spermatogenesis) as a Cause of Male Infertility</td>
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INDUSTRY PRESENTATIONS (CONT.)

Human Chorionic Gonadotropin
Mohit Khera, MD

Diagnostic Categories of Hypogonadism and Secondary Hypogonadal Population
Frederick Wu, MD
Professor of Medicine and Endocrinology
University of Manchester

Weight Associated, Secondary Hypogonadism: An acquired Estrogen-Dependent Disorder
Andrew McCullough, MD
Director of Male Sexual Health, Urology Department
Lahey Health and Medical Center

Summary and Conclusions
Michael Wyllie, PhD

10:25 a.m. Clarifying Questions to Industry

10:45 a.m. BREAK

11:00 a.m. FDA PRESENTATIONS

FDA Clinical Perspective on Development of Non-Testosterone Products to Treat Male Secondary Hypogonadism
Olivia Easley, MD
Medical Officer
DBRUP, ODE III, OND, CDER, FDA

Regulatory Approach to Clinical Outcome Assessment Review for Drug Development
Selena Daniels, PharmD, MS
Team Leader, Clinical Outcome Assessments Staff
OND, CDER, FDA

11:40 a.m. Clarifying Questions to the FDA

12:00 p.m. LUNCH

1:00 p.m. OPEN PUBLIC HEARING

2:00 p.m. Clarifying Questions to the Guest Speaker, Industry or FDA

2:30 p.m. BREAK

2:45 p.m. Questions to the Committee/Committee Discussion and Voting

5:00 p.m. ADJOURN