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

***Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting***
FDA White Oak Campus, 10903 New Hampshire Avenue Building 31 Conference Center
The Great Room (Rm. 1503), Silver Spring, Maryland
February 3, 2016

# AGENDA

*During the morning session, the committee will discuss cognitive dysfunction in major depressive disorder (MDD). This is an evolving concept and experts in the field have not yet reached consensus as to whether cognitive dysfunction in MDD is a distinct entity. The committee will consider the clinical presentation of cognitive dysfunction in MDD, as well as methods for assessing this condition.*

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| 8:00 a.m. | Call to Order and Introduction of Committee | **David Pickar, MD**<br>Acting Chair Chairperson, PDAC |
| 8:05 a.m. | Conflict of Interest Statement | **Kalyani Bhatt, BS, MS**<br>Designated Federal Officer, PDAC |
| 8:10 a.m. | **FDA PRESENTATIONS** | |
| | FDA Introductory Remarks | **Mitchell Mathis, MD**<br>Director<br>Division of Psychiatry Products (DPP)<br>Office of Drug Evaluation I (ODE-I)<br>Office of New Drugs (OND), CDER, FDA |
| 8:20 a.m. | Cognitive Dysfunction in Major Depressive Disorder: FDA's Perspective, Past and Present | **Tiffany R. Farchione, MD**<br>Deputy Director<br>DPP, ODE-I, OND, CDER, FDA |
| 8:35 a.m. | **NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH) PRESENTATION** | |
| | Cognition and Neuroimaging in Depression | **Carlos A. Zarate, Jr., MD**<br>Chief, Experimental Therapeutics and Pathophysiology Branch<br>NIMH, Office of the Director<br>National Institutes of Health (NIH) |
| 9:15 a.m. | **GUEST SPEAKER PRESENTATION** | |
| | Cognitive Dysfunction and MDD | **Madhukar Trivedi, MD**<br>Director<br>Center for Depression Research Clinical Care<br>UT Southwestern Medical Center |

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**AGENDA (cont.)**

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| 10:00 a.m. | **NIMH PRESENTATION** | |
| | Assessing Cognitive Function | **Jenni Pacheco, PhD**<br>Scientific Program Manager<br>NIMH, Office of the Director<br>NIH |
| 10:20 a.m. | Clarifying Questions | |
| 10:40 a.m. | **BREAK** | |
| 10:50 a.m. | Open Public Hearing | |
| 11:20 a.m. | Questions to the Committee/Committee Discussion | |
| 12:00 p.m. | **LUNCH** | |

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**AGENDA (cont.)**

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*During the afternoon session, the committee will discuss new drug application 204447/supplemental new drug application 006, for the effectiveness of vortioxetine for the treatment of cognitive dysfunction in MDD, submitted by Takeda Development Center Americas, Inc.*

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| 1:00 p.m. | Call to Order and Introduction of Committee | **David Pickar, MD**<br>Acting Chairperson, PDAC |
| 1:05 p.m. | Conflict of Interest Statement | **Kalyani Bhatt, BS, MS**<br>Designated Federal Officer, PDAC |
| 1:10 p.m. | FDA Introductory Remarks | **Tiffany R. Farchione, MD**<br>Deputy Director<br>Division of Psychiatry Products (DPP)<br>Office of Drug Evaluation-I (ODE-I)<br>Office of New Drugs (OND), CDER, FDA |
| 1:15 p.m. | **INDUSTRY PRESENTATIONS** | **Takeda Development Center Americas, Inc.** |
| | Introduction | **Jonathon M. Parker, RPh, MS, PhD**<br>Vice President, Global Regulatory Affairs<br>Takeda Pharmaceuticals |
| | Measuring Change in Cognition with Digit Symbol Substitution Test (DSST) | **Judith Jaeger, MPA, PhD**<br>Professor of Psychiatry and Behavioral Sciences<br>Albert Einstein College of Medicine<br>President and Principal Scientist<br>Cognition Metrics, LLC |
| | Study Design and Results | **Christina Kurre Olsen, PhD**<br>Senior Specialist, Clinical Science<br>Lundbeck |
| | Clinical Perspective | **Maurizio Fava, MD**<br>Executive Vice Chair, Department of Psychiatry<br>Massachusetts General Hospital<br>Executive Director, Clinical Trials Network and Institute |
| | Conclusion | **Louis Mini, MD**<br>Vice President, Global Medical Head, Medical Affairs<br>Takeda Pharmaceuticals |

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## AGENDA (cont.)

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| 2:15 p.m. | Clarifying Questions | |
| 2:25 p.m. | **BREAK** | |
| 2:35 p.m. | **FDA PRESENTATIONS** | |
| | Regulatory History of Vortioxetine for the Treatment of Cognitive Dysfunction in MDD | **Tiffany R. Farchione, MD** |
| | Clinical Outcome Assessment Review of Digit Symbol Substitution Test (DSST): Vortioxetine for Cognitive Dysfunction in MDD | **Wen-Hung Chen, PhD**<br>Acting Team Leader<br>Clinical Outcome Assessments Staff<br>Immediate Office<br>OND, CDER, FDA |
| | Clinical, Safety, and Efficacy Data | **Aeva Gaymon-Doomes, MD**<br>Medical Officer<br>DPP, ODE-I, OND, CDER, FDA |
| 3:20 p.m. | Clarifying Questions | |
| 3:30 p.m. | Open Public Hearing | |
| 4:00 p.m. | Charge to the Committee | **Tiffany R. Farchione, MD** |
| 4:10 p.m. | Questions to the Committee/Committee Discussion | |
| 5:00 p.m. | **ADJOURNMENT** | |