

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
170th Meeting of the Vaccines and Related Biological Products
Advisory Committee
October 14-15, 2021
DRAFT AGENDA

October 15, 2021: Topic II: The committee will meet in open session to discuss the EUA of the Janssen Biotech Inc. COVID-19 vaccine for the administration of a booster dose, to individuals 18 years of age and older

| Time | Presentation/Presenter |
|------------------|--|
| 8:30 a.m. | <p><u>Opening Remarks: Call to Order and Welcome (10 min)</u> Arnold Monto, M.D. Acting Chair, VRBPAC Professor of Public Health and Epidemiology, University of Michigan</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u> Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA</p> |
| 9:00 a.m. | <p><u>FDA Introduction (15 min)</u></p> <p><u>Introduction of the Topic (5 Min)</u></p> <ul style="list-style-type: none"> • Peter Marks, M.D. Ph.D. Center Director CBER, FDA <p><u>Janssen COVID-19 Vaccine Application for Emergency Use Authorization of a booster dose (5 Min)</u></p> <ul style="list-style-type: none"> • Sudhakar Agnihothram, Ph.D. Division of Vaccines and Related Product Applications (DVRPA), OVRP, CBER, FDA • Q/A – 5 Min |
| 9:15 am | <p><u>Sponsor Presentation (45 Min)</u></p> <p>Emergency Use Authorization (EUA) Amendment for a Booster Dose for the Janssen COVID-19 Vaccine (Ad26.COV2.S)</p> <ul style="list-style-type: none"> • Penny Heaton, M.D. Global Therapeutic Area Head, Vaccines, Janssen Research & Development, Johnson & Johnson • Johan Van Hoof, M.D., Managing Director, Janssen Vaccines & Prevention B.V., Johnson & Johnson • Dan Barouch, M.D., Ph.D. William Bosworth Castle Professor of Medicine Harvard Medical School; Ragon Institute of MGH, MIT, and Harvard; |

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
170th Meeting of the Vaccines and Related Biological Products
Advisory Committee
October 14-15, 2021
DRAFT AGENDA

| | |
|-----------------|---|
| | <p>Director, Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center</p> <ul style="list-style-type: none"> • Sebastian Schneeweiss, M.D., Sc.D., Co-founder and Science Lead, Aetion Inc. • Macaya Douoguih, M.D., M.P.H. Head, Janssen Clinical Development and Medical Affairs, Janssen Vaccines & Prevention B.V., Johnson & Johnson |
| 10:00 am | <p><u>FDA Presentation (50 min)</u></p> <p><u>FDA Review of Effectiveness and Safety of Janssen COVID-19 Vaccine (Ad26.COV2.S) Booster Dose Emergency Use Authorization Amendment</u></p> <ul style="list-style-type: none"> • Rachel Zhang, M.D. & Timothy Brennan, Ph.D., M.D., M.S. Medical Officers Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRP) Center for Biologics Evaluation and Research (CBER), FDA <p><u>Review of RWE to Assess the Effectiveness of a single dose of Janssen COVID-19 Vaccine (Ad26.COV2.S)</u></p> <ul style="list-style-type: none"> • Artur Belov, Ph.D. Operations Research Analyst Immediate Office of the Director (IOD) Office of Biostatistics and Epidemiology (OBE), CBER, FDA <p><u>Review of Post Authorization Safety Data for Janssen COVID-19 Vaccine</u></p> <ul style="list-style-type: none"> • Narayan Nair, M.D. Director Division of Epidemiology Office of Biostatistics and Epidemiology (OBE), CBER, FDA • Q/A – 5 min |
| 10:50 am | <u>BREAK (10 min)</u> |
| 11:00 am | <u>OPEN PUBLIC HEARING (60 min)</u> |

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
170th Meeting of the Vaccines and Related Biological Products
Advisory Committee
October 14-15, 2021
DRAFT AGENDA

| | |
|----------|---|
| 11:30 am | <u>Additional Q & A regarding Sponsor and FDA presentations (45 Min)</u> |
| 12:15 pm | <u>Lunch (30 Min)</u> |
| 12:45 pm | <u>Committee Discussion and Voting (120 min)</u> |
| 1:30 pm | <u>Break (15 Min)</u> |
| 1:45 pm | <u>DMID 21-0012 – Heterologous Platform Boost Study Mix and Match (45 min)</u> <ul style="list-style-type: none">• Kirsten Lyke, M.D. Professor of Medicine University of Maryland• Q/A – 10 min |
| 2:15 pm | <u>Committee Discussion of FDA Questions (45 min)</u> |
| 3:30 pm | <u>Meeting Adjourned</u> |