

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**164<sup>th</sup> Meeting of the Vaccines and Related Biological Products**  
**Advisory Committee**  
**February 26, 2021**  
**AGENDA**

**Topic:** The committee will meet in open session to discuss Emergency Use Authorization (EUA) of the Janssen Biotech Inc. COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years and older.

<b>Time</b>	<b>Presentation/Presenter</b>
<b>9:00 a.m.</b>	<p><b><u>Opening Remarks: Call to Order and Welcome</u></b> (10 min)  Arnold Monto, M.D. Acting Chair, VRBPAC  Professor of Public Health and Epidemiology, University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement</u></b> (20 min)  Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC  Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
<b>9:30 a.m.</b>	<p><b><u>FDA Presentation on Emergency Use Authorization</u></b></p> <p>Maria Allende, MD  Branch Chief, Clinical Review Branch 1  Division of Vaccines and Related Products Applications (DVRPA)  Office of Vaccines Research and Review (OVRR)  Center for Biologics Evaluation and Research (CBER), FDA</p> <p>Presentation – 15 Min  Q/A – 5 Min</p>
<b>9:50 a.m.</b>	<p><b><u>Epidemiology of COVID-19 Variants</u></b></p> <p>Adam MacNeil, Ph.D., M.P.H.  Deputy Branch Chief for Epidemiology, Respiratory Viruses Branch  Division of Viral Diseases, National Center for Immunization and Respiratory Diseases  Centers for Disease Control and Prevention (CDC)</p> <p>Presentation - 30 min  Q/A - 10 min</p>
<b>10:30 a.m.</b>	<p><b><u>Postmarketing Surveillance from currently authorized COVID-19 Vaccines</u></b></p> <p>Tom Shimabukuro, M.D., M.P.H., M.B.A. (10 minutes)  Deputy Director Immunization Safety Office  Division of Healthcare Quality Promotion  National Center for Emerging and Zoonotic Infectious Diseases  Centers for Disease Control and Prevention (CDC)</p>

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	<p>Steven Anderson, PhD, MPP (10 minutes)          Director          Office of Biostatistics and Epidemiology          Center for Biologics Evaluation and Research (CBER), FDA</p> <p>Q/A – 10 Min</p>
<b>11:00 a.m.</b>	<b><u>BREAK</u></b>
<b>11:10 a.m.</b>	<p><b><u>Sponsor Presentation: Emergency Use Authorization Application for COVID-19 Vaccine</u></b></p> <p>Janssen - 60 minutes</p> <p>Johan Van Hoof, M.D.          Hanneke Schuitemaker, Ph.D.          Macaya Douoguih, M.D., M.P.H.          Gregory A. Poland, M.D., F.R.C.P.</p>
<b>12:10 p.m.</b>	<b><u>Additional Q &amp; A for Sponsor Presenters</u></b> (30 min)
<b>12:40 p.m.</b>	<b><u>Lunch</u></b> (30 mins)
<b>1:10 p.m.</b>	<b><u>Open Public Hearing</u></b> (60 mins)
<b>2:10 p.m.</b>	<p><b><u>FDA Presentation and Voting Questions</u></b> (50 min)</p> <p>Rachel Zhang, M.D. Yosefa Hefter, M.D.          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>
<b>3:00 p.m.</b>	<b><u>Break</u></b> (10 min)
<b>3:10 p.m.</b>	<b><u>Committee Discussion and Voting</u></b> (140 min)
<b>5:30 p.m.</b>	<b><u>Meeting Adjourned</u></b> - DFO