Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
181st VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
May 18, 2023

Committee Members
Hana El Sahly, M.D., Chair
Adam Berger, Ph.D.
Henry Bernstein, D.O., MHCM, FAAP
Archana Chatterjee, M.D., Ph.D.+
CAPT Amanda Cohn, M.D.
Hayley Gans, M.D.+
Holly Janes, Ph.D.
CAPT David Kim, M.D.
Arnold Monto, M.D.
Paul Offit, M.D.
Steven Pergam, M.D., M.P.H., FIDSA
Stanley Perlman, M.D., Ph.D.+
Jay Portnoy, M.D.* (Consumer Representative)
Eric Rubin, M.D. Ph.D.+
Andrea Shane, M.D., M.P.H., M.Sc.+

Industry Representative
Paula Annunziato, M.D. ***+
Gregg Sylvester, M.D., M.PH. (Alt.)

Designated Federal Officers (DFO)
Prabhakara Atreya, Ph.D.
Valerie Vashio, B.Pharm.

Committee Management Staff
Joanne Lipkind, M.S.
Lisa Johnson

Temporary Voting Members
Kevin Ault, M.D.
Daniel Feikin, M.D., M.S.P.H.
CAPT Meredith McMorrow, M.D., M.P.H., FAAP
Saad Omer, M.B.B.S., M.P.H., Ph.D., FIDSA

Speakers and Guest Speakers
Helen Chu, M.D., M.P.H. (University of Washington)
Katherine Fleming-Dutra, M.D. (CDC)
Natalie Thornburg, Ph.D. (CDC)

FDA Participants
Peter Marks, M.D., Ph.D. (CBER/Director)
David C. Kaslow, M.D. (Speaker) (OVRR/Director)
Joseph Toerner, M.D., M.P.H. (OVRR)
Sudhakar Agnihothram, B. Pharm., Ph.D.
Goutam Sen, Ph.D. (Speaker)
Yugenia Hong-Nguyen, M.D. (Speaker)

+Not Attending
*Consumer Representative
***Industry Representative

These summary minutes for the May 18, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on June 13, 2023.

I certify that I participated in the May 18, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Prabhakara Atreya, Ph.D.
Designated Federal Officer

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Hana El Sahly, M.D.
Chair

Topic below was discussed during the May 18, 2023, VRBPAC meeting.

On May 18, 2023, at 8:30 a.m. Eastern Time (ET), the 181st meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on the safety and effectiveness of ABRYSVO (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication, in Biologics License Application # 125768 (STN 125768/0), for the prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age by active immunization of pregnant individuals.

Dr. Hana El Sahly, VRBPAC Chair called the meeting to order and made introductory remarks. The DFO, Dr. Prabhakara Atreya made administrative remarks, conducted a roll call, and invited the committee members to introduce themselves. The Alternate DFO, Ms. Valerie Vashio read the Conflicts of Interest (COI) statement for the public record.

The meeting kicked off at 8:55 a.m. with a 5-minute introduction by Dr. David C. Kaslow, Director of the Office of Vaccines Research and Review (OVRR) in the Center for Biologics Evaluation and Research (CBER). Dr. Goutam Sen, the BLA review committee Chair from OVRR gave a 15-minute presentation titled "Biologics License Application for Respiratory Syncytial Virus Vaccine (ABRYSVO) Immunization During Pregnancy to Prevent RSV Lower Respiratory Tract Disease [LRTD] and Severe RSV LRTD in Infants," which was followed by 5 minutes of Q&A. Starting at 9:20 a.m. Dr. Natalie Thornburg from the Centers for Disease Control and Prevention (CDC) gave a 15-minute presentation titled "RSV Virology, Strain Variation, and Surveillance Measures," which was followed by another 15-minute presentation also from CDC by Dr. Katherine Fleming-Dutra titled "RSV Epidemiology and Disease Burden in Infants from birth through 6 months of age," and a 10-minute Q&A. Next was a 15-minute presentation by Dr. Helen Chu, titled "Durability of Naturally Acquired Immunity and Susceptibility to Repeated RSV Infections." A 5-minute Q&A followed to answer several questions before the Committee took a 10-minute break.

The Committee reconvened at approximately 10:30 a.m. ET for a 50-minute presentation given by Dr. William Gruber, Dr. Iona Munjal, and Dr. Jamie Wilkins from Pfizer; and Dr. Eric Simoes from University of Colorado School of Medicine, titled "Bivalent RSV Prefusion F Vaccine for Maternal Immunization to Protect Infants" which was followed by a 10-minute Q&A. Next, Dr. Yugenia Hong-Nguyen from CBER, OVRR, gave a 50-minute presentation titled "Review of Efficacy and Safety of Respiratory Syncytial Virus Vaccine (ABRYSVO) Immunization During the Second or Third Trimester of Pregnancy (24-36 weeks gestational age) to Prevent RSV Lower Respiratory Tract Disease [LRTD] and Severe RSV LRTD in Infants,

From Birth Through 6 Months of Age." A 10-minute Q&A followed before the Committee was released for a 45-minute lunch break.

The Committee reconvened for the Open Public Hearing (OPH) Session at 1:15 p.m. ET. The Chair, Dr. El Sahly read the Chair's Conflicts of Interest statement before turning the meeting over to Ms. Vashio who provided further OPH instructions. Five participants made 4-minute remarks each. After the OPH session concluded, at approximately 1:38 p.m., Ms. Vashio returned the meeting back to Dr. El Sahly for the next 60-minute session of additional Q&A in which Committee members asked clarifying questions regarding presentations from FDA, CDC, and Pfizer speakers.

Following this extended Q&A session, the committee was released for about a 10-minute break. At 3:37 p.m. Dr. El Sahly opened the committee discussion.

The committee discussed the balance between the convincing vaccine efficacy, including against severe lower respiratory tract disease, and adverse events, particularly premature delivery/birth. The committee also discussed duration of vaccine protection, gestational age at time of vaccination, concomitant administration of other vaccines during pregnancy, and considerations for postmarketing studies.

At the conclusion of Committee Discussion, Dr. Atreya conducted the voting process.

The following Voting Question #1 was presented to the Committee of 14 voting members:

Voting Question #1:

Are the available data adequate to support the effectiveness of immunization with ABRYSVO during the second or third trimester of pregnancy (24-36 weeks gestational age) to prevent RSV lower respiratory tract disease [LRTD] and severe RSV LRTD in infants, from birth through 6 months of age?

The voting results were as follows: **14 Yes, 0 No, 0 Abstain**

Dr. Atreya read the voting results for the public record and then handed over the meeting to Dr. El Sahly to ask the Committee for their Vote explanation. Dr. El Sahly called upon each Committee Member to explain their votes.

After Committee Vote explanations for Question #1, Dr. El Sahly then allowed the Committee to discuss Voting Question #2 after which she requested Dr. Atreya to conduct the voting.

The following Voting Question #2 was presented to the Committee of 14 voting members:

Voting Question #2:

Are the available data adequate to support the safety of immunization with ABRYSVO during the second or third trimester of pregnancy (24-36 weeks gestational age) to prevent RSV LRTD and severe RSV LRTD in infants, from birth through 6 months of age?

The voting results were as follows: **10 Yes, 4 No, 0 Abstain**
Dr. Atreya read the voting results for the public record and then turned over the meeting to Dr. El Sahly to ask the Committee for their Vote explanation. Dr. El Sahly called upon each Committee Member to explain their votes.

At the conclusion of the voting and vote explanations by individual committee members, Dr. El Sahly handed the meeting over to the DFO, Dr. Atreya, who in turn asked Dr. Marks for his concluding remarks. Both Dr. Marks and Dr. Kaslow thanked the Members of the Committee, the speakers, Advisory Committee staff, and the AV team for all their efforts. Dr. Atreya then officially adjourned the meeting on May 18, 2023, at 5:10 p.m. ET.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

FDA Vaccines and Related Biological Products Advisory Committee May 18, 2023 Meeting Announcement