Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
179th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
February 28- March 1, 2023

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

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

Consumer Representative
Jay Portnoy, M.D.*

Designated Federal Officers (DFO)
Sussan Paydar, Ph.D.
Prabhakara Atreya, Ph.D.; Director, DSAC

Committee Management Staff
Joanne Lipkind
Karen Thomas
Lisa Johnson

Temporary Voting Members
Daniel Feikin, M.D., M.S.P.H
James Hildreth, Sr., Ph.D., M.D.
Marie Griffin, M.D., M.P.H.

Speakers and Guest Speakers
Alejandra Gurtman, M.D. CDC
Fiona Havers, M.D., MHS. CDC
H. Keipp Talbot, M.D., MPH, FIDSA
Natalie Thornburg, Ph.D. CDC

FDA Participants
David C. Kaslow, M.D. - Speaker
Sudhakar Agnihothram, B. Pharm., Ph.D.
Joseph Toerner, M.D., M.P.H.
Lucia Lee, M.D.
Nadine Peart Akindele, M.D. (Speaker)
Goutam Sen, Ph.D. (Speaker)

≥+Not Attending
*Consumer Representative
*>Acting Consumer Rep
***Industry Representative

These summary minutes for the February 28, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on March 31st, 2023.

I certify that I participated in the February 28 – March 1, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Sussan Paydar, Ph.D.
Designated Federal Officer

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Hana El Sahly, M.D.
Acting Chair

There were two topics discussed during the February 28 – March 1, 2023, VRBPAC meeting.

On February 28, 2023, at 8:30 a.m. Eastern Standard Time (EST), the 179th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss Topic 1 to 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 # 125769 (STN 125769/0), for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

Dr. Hana El Sahly, VRBPAC Chair called the meeting to order and made introductory remarks. The DFO, Dr. Sussan Paydar made administrative remarks, conducted a roll call, and invited the committee members to introduce themselves. She read the Conflict 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 from OVRR gave a 15-minute presentation titled "Biologics License Application for ABRYSVO (Respiratory Syncytial Virus Vaccine) in adults 60 years of age and older" which was followed by 5 minutes of Q&A. Starting at 9:20 a.m. Dr. Natalie Thornburg from the Center 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. Fiona Havers titled "RSV Epidemiology and Disease Burden in Older Adults" and a 5-minute Q&A. Next was a 15-minute presentation by Dr. H. Keipp Talbot, 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 11:30 a.m. EST for a 50-minute presentation given by Alejandra Gurtman from Pfizer titled "Safety and Efficacy of Bivalent RSV Prefusion F Vaccine in Adults ≥60 Years of Age" which was followed by a 10-minute Q&A. Dr. Nadine

Peart Akindele from CBER, OVRR, gave a 50-minute presentation titled "FDA Review of Efficacy and Safety of ABRYSVO (Respiratory Syncytial Virus Vaccine) in Adults 60 years of age and older". A 10-minute Q&A followed before the Committee was released for a 40-minute lunch break.

The Committee reconvened for the Open Public Hearing (OPH) Session at 1:10 pm EST. The Chair, Dr. El Sahly read the Chair's Conflict of Interest statement before turning the meeting over to Dr. Paydar who provided further OPH instructions. Six participants made 4-minute remarks. After the OPH session concluded, at approximately 1:35 pm, Dr. Paydar returned the meeting back to Dr. El Sahly for the next 30-minutes session for Additional Q&A in which Committee members asked clarifying questions regarding presentations from FDA, CDC, and Pfizer, Inc speakers.

Following this session, the committee was released for about a 15-minute break. At 2:25 pm Dr. El Sahly opened the committee discussion by reading Voting Question #1, after which Dr. Paydar conducted the voting. The following Voting Question #1 was presented to the Committee of 12 voting members:

Voting Question # 1:
• Are the available data adequate to support the safety of ABRYSVO (RSVPreF) when administered to individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV?

The voting results were as follows: 7 Yes, 4 No, 1 Abstain

Dr. Paydar 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.

Discussion Summary: While the majority of the committee members agreed that the available evidence supported the safety of ABRYSVO, committee members also emphasized the need for robust postmarketing surveillance in assessing the Guillain-Barré syndrome (GBS) safety signal and the atrial fibrillation imbalance. The committee highlighted the incomplete safety information on potential repeat vaccination and concomitant use with other vaccines. There was broad consensus across the committee that if ABRYSVO were approved, postmarketing evaluation would be critical to further define the benefits and risks of the product.

Dr. El Sahly then allowed the Committee to discuss Voting question #2 after which she requested Dr. Paydar to conduct the voting. The following voting question # 2 was presented to the Committee of 12 voting members:

Voting Question # 2:
• Are the available data adequate to support the effectiveness of ABRYSVO (RSVPreF) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older?

The voting results were as follows: 7 Yes, 4 No, 1 Abstain

Dr. Paydar 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.

Discussion Summary: Committee members generally agreed that the primary efficacy endpoint demonstrated the effectiveness of ABRYSVO in preventing lower respiratory tract disease caused by RSV; however, several committee members noted that there was a paucity of evidence of the effectiveness in preventing severe outcomes, such as hospitalization, particularly in the highest at-risk populations. Committee members also noted that additional first season efficacy and the second season efficacy data are forthcoming, and again there was broad consensus across the committee that if ABRYSVO were approved, postmarketing evaluation would be critical to further define the benefits and risks of the product.

At the conclusion of the voting and vote explanations by individual committee members, Dr. El Sahly handed the meeting over to Dr. Paydar who in turn asked Dr. Kaslow for his concluding remarks. Dr. Kaslow thanked the Members of the Committee, the speakers, Advisory Committee staff, and the AV team for all their efforts. Dr. Paydar then officially adjourned the meeting on February 28, 2023, at 4:14p.m. EST.

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

Vaccines and Related Biological Products Advisory Committee February 28 - March 1, 2023 Meeting Announcement - 02/28/2023 | FDA