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
Fiona Havers, M.D., MHS., FIDSA
H. Keipp Talbot, M.D., MPD, FIDSA
Natalie Thornburg, Ph.D.

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.
Santosh Nanda, DVM, Ph.D. (Speaker)
Nicholas Geagan, D.O., STN (Speaker)

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

These summary minutes for the March 1, 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

On March 1, 2023 starting at 9:00 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 and make recommendations on the safety and effectiveness of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted), manufactured by GSK, with a requested indication, in Biologics License Application # 125775 (STN 125775/0), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes 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 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. Santosh Nanda from OVRR gave a 15-minute presentation titled “Biologics License Application for AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted) in adults 60 years of age and older”. His presentation was followed by 5 minutes of Q&A.

Starting at 9:50 a.m. there was a 50-minute series of presentations by the Sponsor, GSK. An introduction presentation was given by Dr. Bishoy Rizkalla’s titled “RSVPreF3 Vaccine for Respiratory Syncytial Virus (RSV) in Older Adults”. Dr. Ann Falsey gave a presentation on “Burden of Respiratory Disease in the Older Adult Population” followed by Dr. Rizkalla’s second presentation on “Efficacy & Immunogenicity”. Dr. Peggy Webster gave the final Sponsor presentation on “Safety / Benefit Risk” before a 10-minute Q&A session was held.

Dr. Nicholas Geagan from Division of Vaccines and Related Products Applications (DVRPA), OVRR, CBER gave a presentation titled “FDA Review of Efficacy and Safety of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted) in Adults 60 Years of Age and

Older". A 10-minute Q&A followed to answer several questions before the Committee was released for a 40-minute lunch.

The Committee reconvened at 12:30 pm for an OPH session. However, since there were no OPH registered speakers, Dr. El Sahly moved the Committee to the next session for the Additional Q&A for FDA and Sponsor Presenters. However, before the start of the session, Dr. Kaslow brought up two topics for clarification: 1) a further breakdown of the nervous system disorders (pIMDs) by Dr. Geagan; and 2) the definition of "effectiveness" by Dr. Toerner. Dr. Geagan gave brief explanations and invited GSK to provide further clarifications on the Nervous System Disorder topic. Dr. Toerner, Acting Deputy Director at OVRR provided context and further clarification on the use of the term "effectiveness". GSK also provided further clarifications on various topics previously discussed such as severe LRTD, clinical perspectives and diagnosis, etc. The Committee was then invited to ask additional questions in the Q&A session.

At approximately 1:30 pm, Dr. El Sahly read the Voting Question #1 and allowed discussion for 30 minutes by the Committee before requesting that Dr. Paydar conduct the voting. The following voting question was presented to the Committee of 12 voting members:

Voting Question #1:
Are the available data adequate to support the safety of AREXVY (RSVPreF3+AS01E) 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: 10 Yes, 2 No, 0 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: The committee members generally agreed that the available evidence supported the safety of AREXVY. Committee members emphasized the need for robust postmarketing surveillance in assessing the Guillain Barre Syndrome (GBS) and potential immune-mediated diseases (pIMDs) safety signals and the atrial fibrillation imbalance. The committee highlighted the incomplete safety information on repeat vaccination and concomitant use with other vaccines. Committee members highlighted that if AREXVY were approved, postmarketing evaluation would be critical to further define the benefits and risks of the product.

Dr. El Sahly then proceeded to the Second Voting question and allowed the Committee to discuss Voting question #2. She then requested that Dr. Paydar conduct the voting. The following voting question was presented to the Committee of 12 voting members:

Voting Question #2:
Are the available data adequate to support the effectiveness of AREXVY (RSVPreF3+AS01E) 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: 12 Yes, 0 No, 0 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: Committee members agreed that the primary efficacy endpoint demonstrated the effectiveness of AREXVY in preventing lower respiratory tract disease caused by RSV; however, several committee members noted that second season efficacy data are forthcoming and the need for additional studies on prevention of severe outcomes in at-risk populations and for repeat vaccination evidence. Again, there was broad consensus across the committee that if AREXVY 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 2:42 p.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:

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