

Food and Drug Administration  
Center for Biologics Evaluation and Research

SUMMARY MINUTES  
148<sup>th</sup> VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY  
COMMITTEE

September 13, 2017

**Committee Members**

Kathryn Edwards, M.D., Chair  
Hana El Sahly, M.D.  
Janet Englund, M.D.  
Holly Janes, Ph.D.  
Karen Kotloff, M.D.  
Ofer Levy, M.D., Ph.D. +  
Sarah Long, M.D.  
Ruth Lynfield, M.D.  
Pamela McInnes, D.D.S., M.Sc. +  
Arnold Monto, M.D. +  
Patrick Moore, M.D.  
M.P.H.+  
Mark Sawyer, M.D.  
Melinda Wharton, M.D., M.P.H.

**Temporary Voting Members**

Karin Bok, M.S., Ph.D.

**Consumer Representative\*\***

Sheldon Toubman, J.D.

**Industry Representative\***

David Greenberg, M.D.

**FDA Speakers**

Carmen Collazo-Custodio, Ph.D.  
Paula Agger, M.D., M.P.H.  
Jeffrey I. Cohen, M.D. (NIH)

**FDA Participants**

Marion Gruber, Ph.D.  
Wellington Sun, M.D.

**GlaxoSmithKline Speakers**

Arnaud Didierlaurent, Ph.D.  
Jacqueline Miller, M.D., F.A.A.P.  
Kimber Poffenberger, Ph.D.  
Jens-Ulrich Stegmann, R.N., M.D.  
Barbara Yawn, M.D., M.Sc., F.A.A.F.P.

**Administrative Team**

**Designated Federal Officer**

Serina Hunter-Thomas, M.S.A., R.N.

**Committee Management Specialists**

Rosanna Harvey

Joanne Lipkind

**Director**

Prabhakara Atreya, Ph.D.

Division of Scientific Advisors and Consultants

+ Not in attendance

\* Industry Representative

\*\* Consumer Representative

These summary minutes for the September 13, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on October 20, 2017.

I certify that I participated on the September 13, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/S/  
Serina Hunter-Thomas  
Designated Federal Officer

/S/  
Kathryn Edwards, M.D.  
Chair

On September 13, 2017 at 8:30 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 148th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss and make recommendations on the safety and effectiveness of Zoster Vaccine Recombinant (Adjuvanted) [Shingrix] manufactured by GlaxoSmithKline Biologicals. The meeting was held in an open session in its entirety. The Chair invited the members, temporary members, and the participants seated at the table to introduce themselves. The Designated Federal Officer (DFO) made administrative remarks and read the Conflict of Interest statement into the public record. There were no waivers issued for conflicts of interest for this meeting. After the Conflict of Interest statement was read for the public record by the DFO, the FDA and non-FDA speaker presentations began.

An introduction and overview of the topic along with the three discussion topics were presented by Dr. Carmen Collazo-Custodio from the Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). The FDA overview was followed by presentation from Dr. Jeffrey Cohen from the National Institutes of Health on the “Epidemiology and Disease Burden of Herpes Zoster in Adults aged 50 Years and Older.” Following Dr. Cohen’s presentation, the sponsor presentations by GlaxoSmithKline (GSK) staff began. Dr. Kimber Poffenberger provided an introduction presentation, followed by Dr. Barbara Yawn, whose presentation was titled “HZ Epidemiology and Burden of Disease.” The next GSK presentation was from Dr. Didierlaurent, who presented on “Vaccine Design and Scientific Rationale” followed by Dr. Jacqueline Miller, who presented on “HZ/su Clinical Efficacy Data and HZ/su Immunogenicity.” The next GSK presentation was from Dr. Jens-Ulrich Stegmann, who presented on “HZ/su Safety.” Dr. Jacqueline Miller returned to give the final GSK presentation, which was titled “Conclusions.” After the GlaxoSmithKline presentations, the committee took a break for lunch. After lunch, Dr. Paula Agger from OVR, CBER made a presentation entitled, “Herpes Zoster Vaccine (Recombinant), Adjuvanted (Shingrix): Review of Efficacy and Safety.” This was followed by the Open

Public Hearing (OPH) session during which Dr. Megan Polanin from the National Center for Health Research made her oral comment.

Following the OPH, the committee proceeded with the discussion and subsequent voting portion of the meeting. Committee discussion began with a review of the following questions previously presented during the first presentation:

1. Are the available data adequate to support the efficacy of SHINGRIX for the prevention of herpes zoster (shingles) in adults 50 years of age and older? Please vote “Yes” or “No”
2. Are the available data adequate to support the safety of SHINGRIX when administered to adults 50 years of age and older? Please vote “Yes” or “No”

For the committee discussion portion of the meeting, the committee stated that they were impressed with the efficacy data presented, and encouraged the sponsor wherever possible to broaden future clinical trials to include a more diversified population or group (i.e. people of color).

In addition, the committee was also satisfied with the comprehensive analysis of the safety data presented, and also supported that the Sponsor is to pursue a post licensure pharmacovigilance plan.

The Committee (10 regular voting members plus 1 temporary voting member, total 11) voted the following:

1. Are the available data adequate to support the efficacy of SHINGRIX for the prevention of herpes zoster (shingles) in adults 50 years of age and older? Please vote “Yes” or “No”

The committee voting results are: 11 Yes, 0 Abstention, 0 No.

2. Are the available data adequate to support the safety of SHINGRIX when administered to adults 50 years of age and older? Please vote “Yes” or “No”

The committee voting results are: 11 Yes, 0 Abstention, 0 No.

The meeting was adjourned at 2:14 p.m. on September 13, 2017.

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

Part 1: <https://collaboration.fda.gov/p3kodrwmd9b/>

Part 2: <https://collaboration.fda.gov/p1rt4qhp605/>