# **Meningococcal Vaccines Session**

David S. Stephens, M.D. Chair, Meningococcal Work Group

Advisory Committee on Immunization Practices February 28, 2019

# Two serogroup B meningococcal (MenB) vaccines licensed for persons aged 10-25 years in 2014 and 2015

- MenB-FHbp (Trumenba<sup>®</sup>, Pfizer):
  - Persons at increased risk for serogroup B meningococcal disease: 3-dose series administered at 0, 1-2, 6 months
  - Healthy adolescents: 2-dose series administered at 0 and 6 months
- MenB-4C (Bexsero<sup>®</sup>, GlaxoSmithKline):
  - 2-dose series administered at 0 and ≥1 month

# ACIP MenB recommendations for persons at increased risk for serogroup B meningococcal disease

- In February 2015, ACIP recommended that persons aged ≥10 years at increased risk for serogroup B meningococcal disease receive a MenB primary series:
  - Persons with complement component deficiency (including complement inhibitor use)
  - Persons with functional or anatomic asplenia
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
  - Persons exposed during an outbreak
- These groups are also recommended to receive a quadrivalent meningococcal conjugate (MenACWY) primary dose or series.
  - Booster dose every 5 years thereafter for as long as increased risk remains.

## **ACIP MenB recommendations for adolescents**

In June 2015, ACIP recommended that adolescents aged 16-23 years may be vaccinated with a MenB primary series based on individual clinical decision-making (preferred age of 16-18 years).

### MenB booster doses

- ACIP does not currently recommend MenB booster doses for persons at increased risk for serogroup B meningococcal disease.
  - Recommendation would be off-label; booster vaccination currently not licensed.
- Data and considerations for MenB booster doses were presented at the February, 2017 ACIP meeting.
  - ACIP requested further data to inform policy options.
- Additional data on immune persistence following a MenB primary series and immunogenicity, safety, and persistence of a MenB booster dose have been generated.
  - Manufacturers have indicated that no further data are forthcoming.

## **Meningococcal Vaccines Work Group Activities**

- Reviewed data on persistence of the immune response following a MenB primary series and immunogenicity, persistence, and safety of a MenB booster dose.
- Formulated policy questions and evaluated quality of evidence for MenB booster doses.
- Summarized Work Group perspectives and developed potential MenB booster policy options for ACIP feedback.

## Agenda

- Summary of data on the immune persistence following a MenB-FHbp primary series and immunogenicity and safety of a MenB-FHbp booster dose: Dr. Paul Balmer (Pfizer)
- Summary of data on the immune persistence following a MenB-4C primary series and immunogenicity and safety of a MenB-4C booster dose: Dr. Phil Watson (GSK)
- GRADE and Evidence to Recommendations Framework for MenB booster doses: Dr. Catherine Bozio (CDC/NCIRD)
- Work Group interpretation of data, considerations, and next steps: Dr. Sarah Mbaeyi (CDC/NCIRD)

## **Work Group Members**

#### **ACIP Members**

- David Stephens (Chair)
- Kelly Moore
- Hank Bernstein
- Veronica McNally

#### Ex Officio Members

- Lucia Lee (FDA)
- Anuja Rastogi (FDA)
- Ruth Brenner (DOD)

#### **CDC Work Group Lead**

Sarah Mbaeyi (CDC/NCIRD)

#### **Liaison Representatives**

- Nina Ahmad (AAFP)
- Oliver Baclic (NACI)
- Carol Baker (IDSA)
- Susan Even (ACHA)
- Rachel Herlihy (IAC)
- Nneka Holder (SAHM)
- Martin Luta (CSTE)
- Ruth Lynfield (AAP)
- Paul McKinney (APTR)
- William Schaffner (NFID)

#### Consultants

- Mike Brady
- Kathleen Harriman
- Mary Healy
- Cody Meissner
- Paul Offit
- Lorry Rubin

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

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