Work Group Interpretation of Pfizer's MenABCWY Vaccine Clinical Trials Data

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Policy Questions for Each Pentavalent Vaccine

- Should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?
  - For example, 16 year olds[1]
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?
  - For example, 11–12 year olds
- Should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only?
  - For example, during a serogroup B outbreak

[1] 16 year olds who decide to receive the MenB vaccine based on shared clinical decision-making

Pfizer MenABCWY Vaccine and Trials Overview

- Comprised of Nimenrix (serogroups ACWY) and Trumenba (serogroup B)
  - Trumenba currently licensed and available in US, 10y through 25y
  - Nimenrix not licensed in US but used extensively elsewhere, 6w and older
- Two clinical trials completed (NCT03135834, NCT04440163)
  - Assessed safety and immunogenicity of pentavalent vaccine
  - Compared to Trumenba (MenB) and Menveo (MenACWY)
  - Included participants 10 through 25 years of age
  - Studied single and two dose (0, 6m) schedules
  - 4-year persistence and booster dose were evaluated
- Extended interval study underway (NCT04440176)
  - Study arm 1 — 0, 12m (data available)
  - Study arm 2 — 0, 36m

Safety

- Assessed by monitoring for and comparing local reactions, systemic events, medically attended adverse events, serious adverse events, and newly diagnosed chronic medical conditions

- Local reactions within 7 days after vaccination
  - Includes pain, redness, swelling
  - Comparison between pentavalent and MenB vaccine only
  - Slightly higher percentage of participants had a local reaction to pentavalent vaccine for both 1st and 2nd doses

- Systemic events within 7 days after vaccination
  - Includes fatigue, headache, muscle pain, joint pain, chills, diarrhea, vomiting, fever
  - Similar percentage of participants experienced systemic events in pentavalent vaccine group and in MenACWY+MenB group
  - Percentage varied slightly between groups by systemic event and by dose

Safety, Continued

- Medically attended adverse events
  - Similar percentages between study groups (both <15%)
- Serious adverse events
  - More reported for pentavalent group (0.4% vs. 0%)
  - None assessed to be related to pentavalent vaccine (e.g., hospitalization due to other medical conditions)
- Newly diagnosed chronic medical conditions (NDCMC)
  - More reported for pentavalent group (1.1% vs. 0.3%)
  - Higher number of participants with attention-deficit/hyperactivity disorder (ADHD) in pentavalent group – most with related symptoms before entering study
- Higher risk patients (e.g., complement deficiency) not included in trials

Immunogenicity Standards

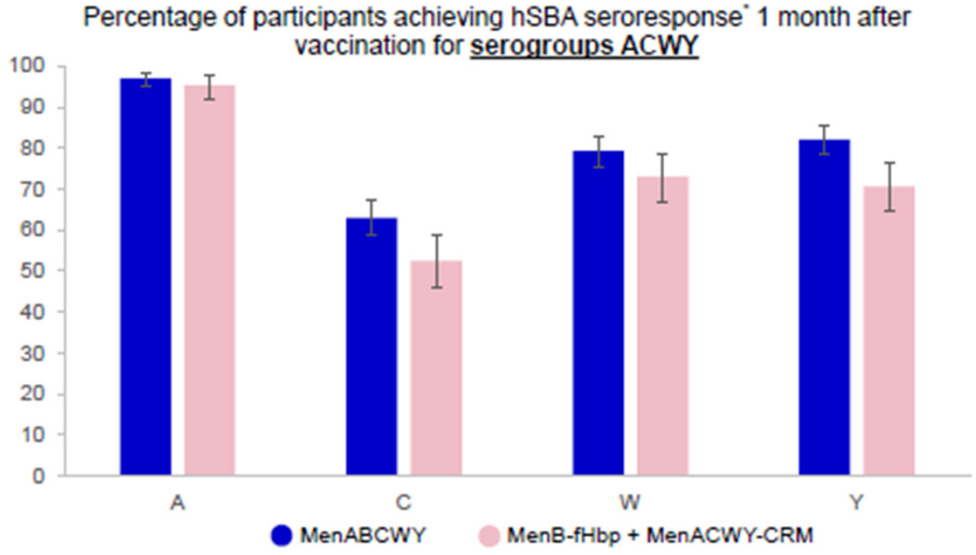
- Serogroups A, C, W, and Y
  - Percentage of participants achieving MenACWY seroresponse in hSBA titer 1 month after 1 dose and 1 month after 2 doses
  - Seroresponse is defined as a 4-fold increase in titer over baseline

- Serogroup B
  - Percentage of participants achieving MenB seroresponse in hSBA 1 month after 2 doses
  - Composite response provided
  - Seroresponse is defined as a 4-fold increase in titer over baseline

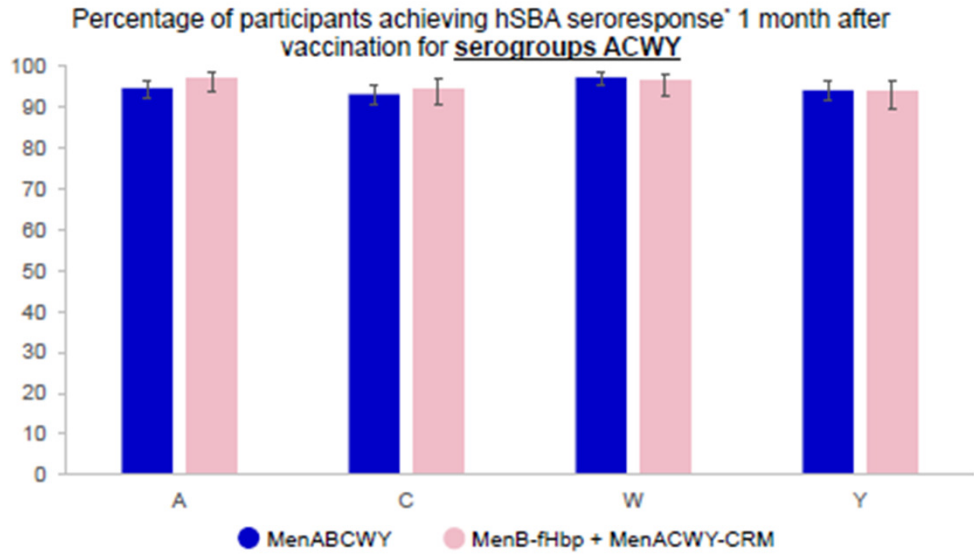
Immunogenicity for Serogroups A, C, W, Y

- 1 dose of the pentavalent vaccine is noninferior to 1 dose of MenACWY in both ACWY-naïve and ACWY-primed participants 1 month after administration

ACWY-Naive



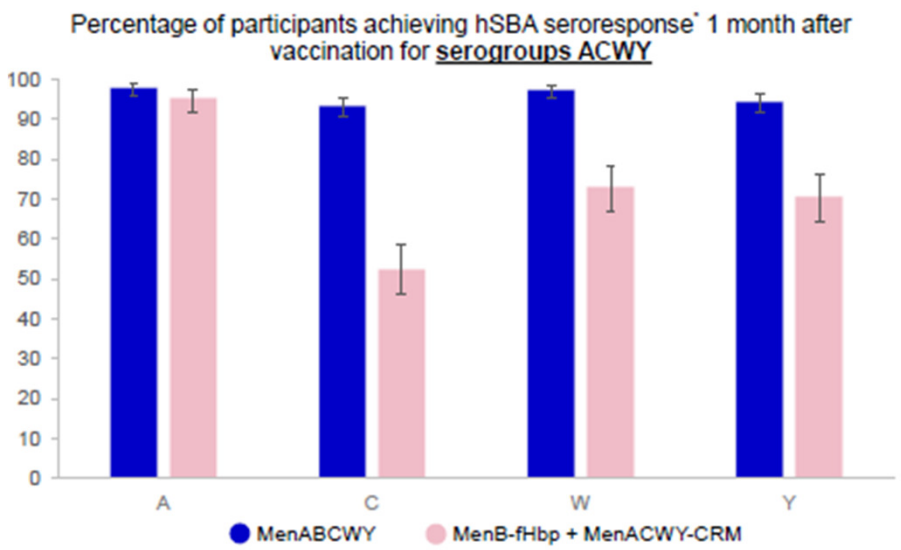
ACWY-Primed



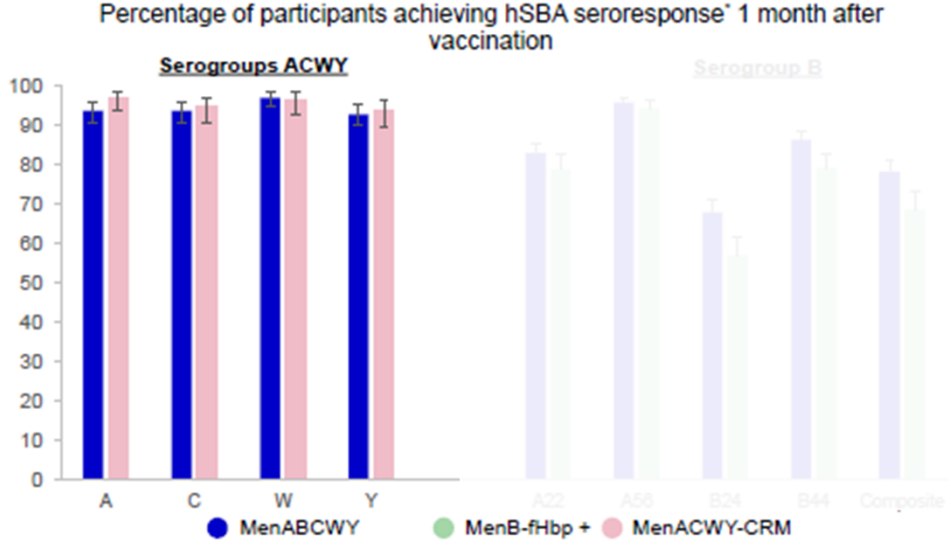
Immunogenicity for Serogroups A, C, W, Y

- 2 doses of the pentavalent vaccine given 6 months apart are noninferior to 1 dose of MenACWY in both naïve and primed participants 1 month after administration

ACWY-Naive

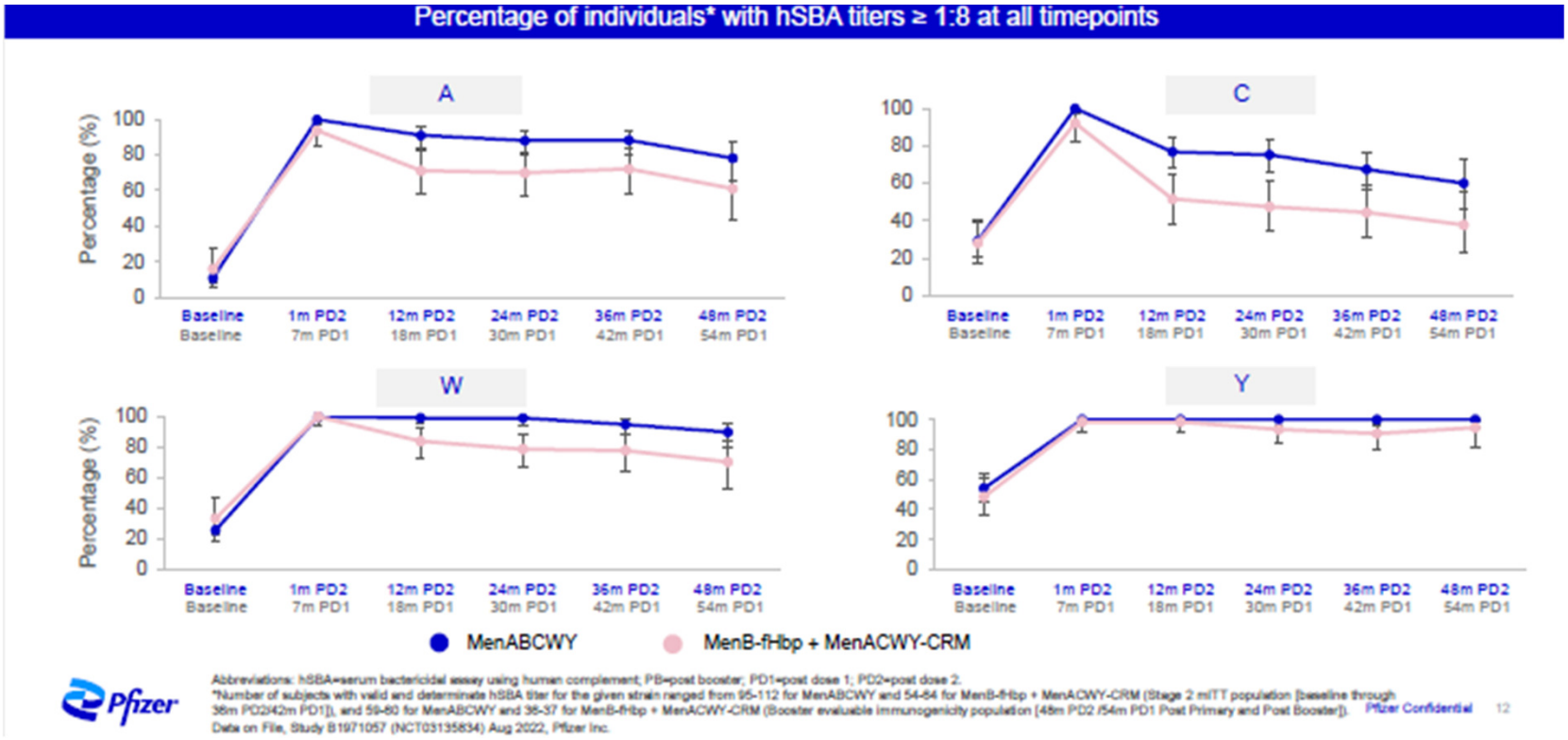


ACWY-Primed



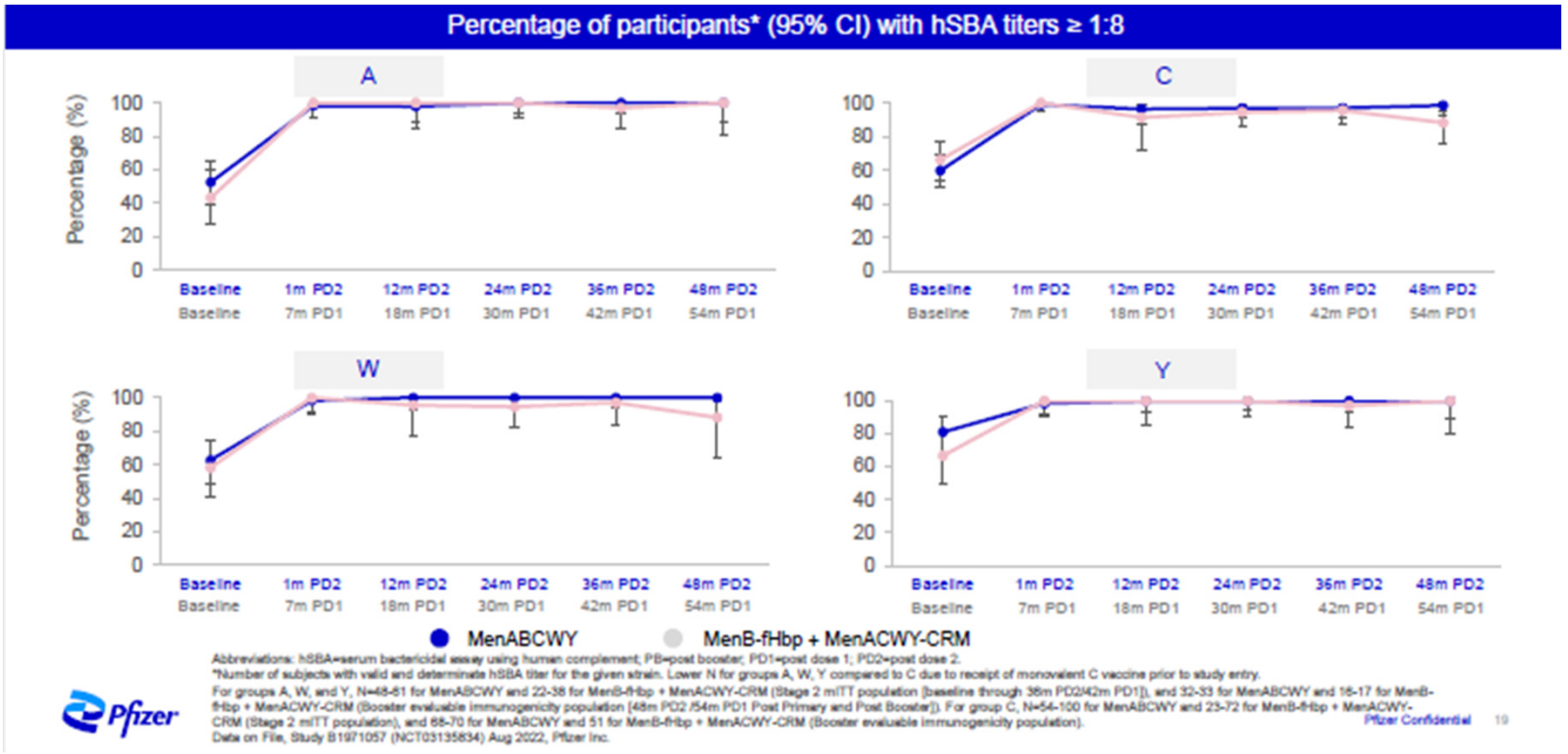
Seroprotection for ACWY-Naïve Participants after 4 Years

- Seroprotection persists up to 4 years in naïve participants after a 2-dose series



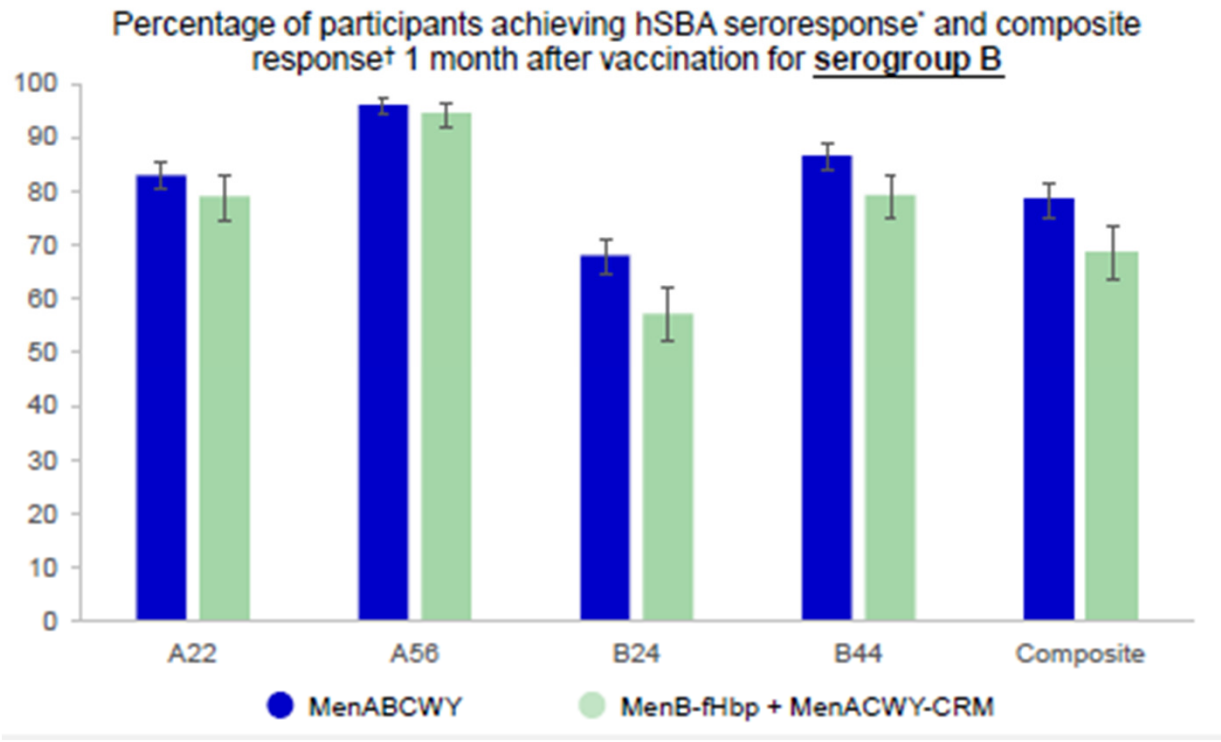
Seroprotection for ACWY-Primed Participants after 4 Years

- Seroprotection persists up to 4 years in primed participants after a 2-dose series



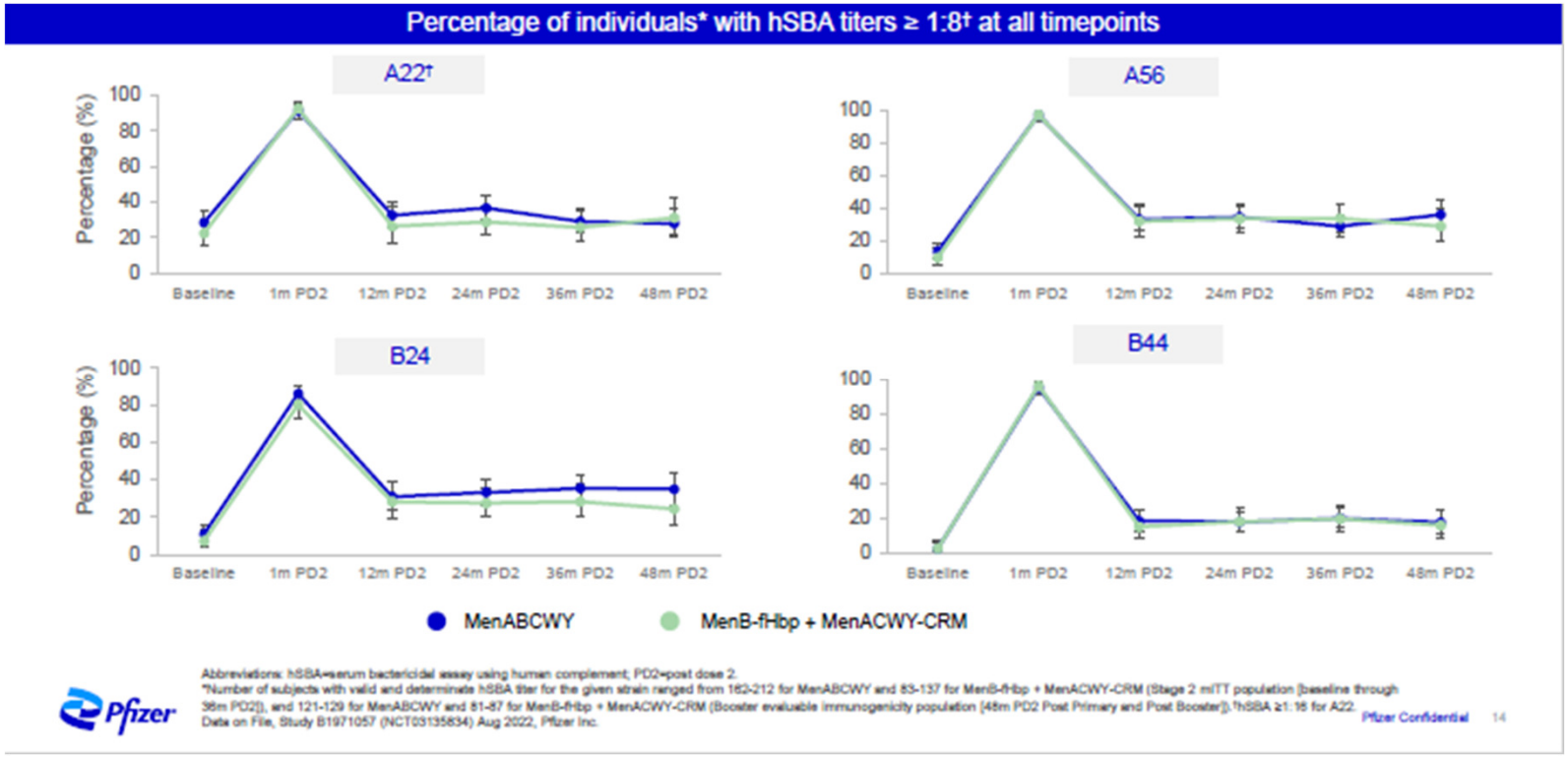
Immunogenicity for Serogroup B

- 2 doses of the pentavalent vaccine given 6 months apart are noninferior to 2 doses of MenB in naïve participants (primed not assessed)



Seroprotection for Serogroup B-Naïve Participants

- Waning of immunity for the pentavalent vaccine is very similar to that observed with MenB, dropping substantially by 12 months post-dose 2



Additional Work Group Reflections

- Data not presented on 3-dose schedule of pentavalent vaccine
  - 3-dose schedule of Trumenba currently recommended for certain high-risk groups (e.g., people affected by a serogroup B outbreak)

- Data not available in people older than 25 years
  - MenB vaccines licensed for 10–25 years
  - MenACWY vaccines licensed up to 55 years or older depending on vaccine

Final Reflections and Next Steps

- Pfizer's MenABCWY vaccine appears to be noninferior to MenACWY+MenB based on clinical trial data presented

- Data gaps
  - 3-dose schedule for high-risk populations
  - Adults older than 25 years

- Next steps
  - Reviewing additional immunologic persistence data for a single dose
  - GRADE and EtR — will focus on pentavalent vaccine studies
  - Cost effectiveness study will be conducted

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