Pfizer Logo

FDA Approves PENBRAYA™, the First and Only Vaccine for the Prevention of the Five Most Common Serogroups Causing Meningococcal Disease in Adolescents

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Media Contact:
PfizerMediaRelations@Pfizer.com
+1 (212) 733-1226

Investor Contact:
IR@Pfizer.com
+1 (212) 733-4848

- *PENBRAYAÔ provides the broadest serogroup coverage (meningococcal groups A, B, C, W and Y) of any meningococcal vaccine available in the U.S. and has the potential to help simplify complex vaccination schedule in the U.S.*
- *The FDA's decision is based on data from Phase 2 and Phase 3 trials, which demonstrated that PENBRAYA has robust immunogenicity non-inferior to Trumenba® + Menveo® for all serogroups and was well-tolerated with a favorable safety profile*
- *The vaccine further advances Pfizer's vaccine portfolio and builds on more than 20 years of expertise and knowledge in the prevention of meningococcal disease*

NEW YORK, October 20, 2023 — Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved PENBRAYA? (meningococcal groups A, B, C, W and Y vaccine), the first and only pentavalent vaccine that provides coverage against the most common serogroups causing meningococcal disease in adolescents and young adults 10 through 25 years of age. PENBRAYA combines the components from two meningococcal vaccines, Trumenba® (meningococcal group B vaccine) and Nimenrix® (meningococcal groups A, C, W-135, and Y conjugate vaccine) to help protect against the five most common meningococcal serogroups that cause the majority of invasive meningococcal disease (IMD) globally.

"As a pioneer in vaccines, one of our goals is to deliver vaccines that evolve the paradigm and help simplify the standard of care in the U.S.," said Annaliesa Anderson, Ph.D., Senior Vice President and Head, Vaccine

Research and Development, Pfizer. “Today marks an important step forward in the prevention of meningococcal disease in the U.S. In a single vaccine, PENBRAYA has the potential to protect more adolescents and young adults from this severe and unpredictable disease by providing the broadest meningococcal coverage in the fewest shots.”

Meningococcal disease is an uncommon but serious illness that can lead to death within 24 hours and, for survivors, can result in life-altering, significant long-term disabilities. PENBRAYA reduces the total number of doses needed for individuals to be fully vaccinated against the five most common serogroups, thereby streamlining the standard of care and potentially increasing the number of adolescents and young adults vaccinated. According to the U.S. Centers for Disease Control and Prevention (CDC), combining vaccines into fewer shots may mean that more adolescents and young adults get their recommended vaccines on time, resulting in fewer delays in protection against serious diseases. Routine use of PENBRAYA could also reduce IMD cases and associated mortality, the rate of long-term consequences of infection (sequelae) in survivors and costs associated with controlling outbreaks.

“Nearly 9 out of 10 adolescents have incomplete protection against invasive meningococcal disease caused by the leading serogroups ,” said Jana Shaw, MD, Pediatrics Infectious Disease Specialist, Upstate Golisano Children's Hospital in Syracuse, NY. “For the first time, we have a single vaccine that helps protect against the five most common serogroups and has the potential to improve coverage and increase protection among adolescents and young adults.”

The FDA’s decision is based on the positive results from the Phase 2 and Phase 3 trials, including a randomized, active-controlled and observer-blinded Phase 3 trial assessing the safety, tolerability, and immunogenicity of the pentavalent vaccine candidate compared to currently U.S. licensed meningococcal vaccines, with the goal of determining immunologic noninferiority. The Phase 3 trial (NCT04440163) evaluated more than 2,400 patients from the U.S. and Europe.

The CDC Advisory Committee on Immunization Practices (ACIP) will meet on October 25, 2023, to discuss recommendations for the appropriate use of PENBRAYA in adolescents and young adults.

About PENBRAYA Regulatory Review
In September 2022, Pfizer announced positive results from a randomized, active-controlled and observer-blinded Phase 3 trial assessing the safety, tolerability, and immunogenicity of the PENBRAYA compared to currently licensed meningococcal vaccines, with the goal of determining immunologic noninferiority. The Phase 3 trial (NCT04440163) evaluated more than 2,400 patients from the U.S. and Europe. This trial was followed by the FDA’s acceptance of PENBRAYA’s Biologics License Application (BLA) in December 2022.

Indication for PENBRAYA
PENBRAYA is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y. PENBRAYA is approved for use in individuals 10 through 25 years of age.

PENBRAYA is administered as a two-dose series given six months apart.

Important Safety Information for PENBRAYA

- PENBRAYA should not be given to anyone with a history of a severe allergic reaction to any component of PENBRAYA
- Fainting may happen after getting injectable vaccines, including PENBRAYA. Precautions should be taken to avoid falling and injury due to fainting
- Some individuals with weakened immune system may have reduced immune responses to PENBRAYA

- Individuals with certain complement deficiencies and individuals receiving treatment that inhibits terminal complement activation are at increased risk for invasive disease caused by N. meningitidis groups A, B, C, W, and Y, even if they develop antibodies following vaccination with PENBRAYA
- Vaccination with PENBRAYA may not protect all who receive the vaccine against N. meningitidis group A, B, C, W, and Y infections
- Vaccination with PENBRAYA does not substitute for vaccination with a tetanus toxoid–containing vaccine to prevent tetanus
- Guillain-Barré syndrome (GBS) has been reported following administration of other meningococcal vaccines. Ask your healthcare provider about the risks and benefits of PENBRAYA if you have a history of GBS
- The most common adverse reactions were pain at the injection site, fatigue, headache, injection site redness, muscle pain, injection site swelling, joint pain, and chills.

- Tell your healthcare provider if you are pregnant or plan to become pregnant
- Ask your healthcare provider about the risks and benefits of PENBRAYA. Only a healthcare provider can decide if PENBRAYA is right for you or your child

View the full Prescribing Information. There may be a delay as the document is updated with the latest information. It will be available as soon as possible. Please check back for the updated full information shortly.

U.S. Indication for TRUMENBA® (meningococcal group B vaccine)

TRUMENBA® (meningococcal group B vaccine) is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B in individuals aged 10 through 25 years of age..

Important Safety Information

- TRUMENBA® should not be given to anyone with a history of a severe allergic reaction after a previous dose of TRUMENBA®.
- Individuals with weakened immune systems may have a reduced immune response.
- The most common adverse reactions were pain at the injection site, fatigue, headache, muscle pain, and chills.
- Data are not available on the safety and effectiveness of using TRUMENBA® and other meningococcal group B vaccines interchangeably to complete the vaccination series.
- Tell your healthcare provider if you are pregnant, or plan to become pregnant.
- Ask your healthcare provider about the risks and benefits of TRUMENBA®. Only a healthcare provider can decide if TRUMENBA® is right for you or your child.

You are encouraged to report negative side effects of vaccines to the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit www.vaers.hhs.gov or call 1-800-822-7967. For the full prescribing information for TRUMENBA, please visit www.pfizer.com.

Indication for Nimenrix® in the European Union
Nimenrix® is indicated for active immunization of individuals from the age of six weeks and above against invasive meningococcal disease caused by Neisseria meningitidis group A, C, W-135, and Y. Nimenrix® is not licenced in the U.S.

Important Safety Information
Nimenrix® (meningococcal group A, C, W-135, and Y conjugate vaccine) should not be given to anyone with a history of a severe allergic reaction after a previous dose of Nimenrix®.

Individuals with weakened immune systems may have a reduced immune response.
The most common adverse reactions were loss of appetite, irritability, drowsiness, pain at the injection site, fatigue, redness at the injection site, and swelling at injection site.

Tell your healthcare provider if you are pregnant, or plan to become pregnant.

Ask your healthcare provider about the risks and benefits of Nimenrix®. Only a healthcare provider can decide if Nimenrix® is right for you or your child.

You are encouraged to report negative side effects of vaccines to Pfizer. In the United States, to report suspected adverse reactions, contact Pfizer Inc. at 1-800-438-1985 or VAERS at 1-800-822-7967 or http://vaers.hhs.gov

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of October 20, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about PENBRAYA, including its potential benefits, an approval in the U.S. for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y. PENBRAYA is approved for use in individuals 10 through 25 years of age. and its potential recommendation, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of PENBRAYA; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologic license applications may be filed in particular jurisdictions for PENBRAYA; whether and when any such applications that may be pending or filed for PENBRAYA may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether such product candidate will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of

PENBRAYA; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding PENBRAYA and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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