

FDA approves MenQuadfi™, the latest innovation in meningococcal (MenACWY) vaccination

- * Latest innovation in quadrivalent meningococcal vaccination designed for use in persons 2 years of age and older in the U.S.
- * Safety and effectiveness studied in five double-blind, randomized clinical trials with nearly 5,000 individuals
- * Helps protect an expanded age group and elicits a high immune response across multiple ages
- * Under regulatory review in Europe and other countries to help support local immunization efforts

PARIS – April 24, 2020 – The U.S. Food and Drug Administration (FDA) has approved a Biologics License Application for MenQuadfi™ Meningococcal (Groups A, C, Y, W) Conjugate Vaccine for the prevention of invasive meningococcal disease in persons 2 years of age and older.

“Meningococcal meningitis remains a major global health challenge because it can strike quickly and with devastating effect, taking a life in less than 24 hours. With the ability to help prevent this disease through vaccination, Sanofi believes one case is one too many,” said David Loew, Executive Vice President, Sanofi Pasteur. “Approval of this new vaccine in the U.S. represents an important milestone in the ongoing fight to help protect as many people as possible from meningococcal disease. It is our ambition to make this vaccine available to further expand protection to individuals worldwide.”

MenQuadfi is Sanofi’s Latest MenACWY Innovation

MenQuadfi was designed to elicit and demonstrated a high immune response across all four serogroups for multiple ages and was well tolerated. MenQuadfi is intended to protect an expanded age group. Licensure marks MenQuadfi as the only U.S. FDA-approved quadrivalent meningococcal vaccine indicated for persons 2 through 56 years of age and older.¹ MenQuadfi is the first and only quadrivalent meningococcal vaccine in the U.S. that uses tetanus toxoid as a protein carrier. It will be available in a ready-to-use liquid formulation allowing healthcare providers to avoid vaccine reconstitution.

The ongoing Phase 3 trials are investigating use in infants as young as 6 weeks of age to better address the worldwide needs for meningococcal disease prevention throughout life.

“Given the severity and unpredictability of meningococcal disease, there is a public health need to ensure immunization across multiple ages, consistent with U.S. recommendations,” said Corey Robertson, MD, Senior Director, Scientific and Medical Affairs at Sanofi Pasteur. “MenQuadfi’s pivotal clinical trials demonstrated a high immune response across all four serogroups and provides a new vaccine option to help protect an expanded age group.”

MenQuadfi’s FDA approval is based on a robust clinical program

The FDA approval is based on clinical data from five double-blind, randomized, multicenter Phase 2 and 3 trials that assessed safety and immune responses following vaccination, with nearly 5,000 persons 2 years of age and older. Based on study objectives, immune responses elicited by MenQuadfi achieved non-inferiority compared to those induced by licensed quadrivalent meningococcal vaccines. Four studies evaluated MenQuadfi in meningococcal-naïve persons; the other study evaluated MenQuadfi in persons previously immunized with a quadrivalent meningococcal vaccine. Against each of the four meningococcal serogroups (A, C, W, Y), the majority (55.4%–97.2%) of meningococcal-naïve trial participants had a vaccine-induced immune response 30 days following vaccination with MenQuadfi. Among adolescents and adults previously vaccinated, 92.2%–98.2% demonstrated an immune response against each serogroup.

The most common side effects following a first dose of MenQuadfi included injection site pain (25.5%–45.2%), muscle ache (20.1%–35.6%), headache (12.5%–30.2%), and tiredness (14.5%–26.0%). In adolescents and adults receiving a MenQuadfi booster, similar rates of these reactions were observed.

Pivotal study results demonstrating MenQuadfi’s safety and effectiveness in inducing an immune response across all four serogroups have been published, including the performance of MenQuadfi in [adolescents](#) when the vaccine was co-administered with other routinely recommended vaccines,² and its performance as a [booster](#).³ Additional data were presented at the 2019 European Society for Paediatric Infectious Diseases Annual Meeting and IDWeek 2019.

MenQuadfi is expected to be available to providers and pharmacies nationwide in the U.S. for immunization efforts in 2021.

Sanofi’s legacy includes more than 45 years at the forefront of meningococcal disease prevention

MenQuadfi builds on Sanofi’s legacy at the forefront of meningococcal disease prevention beginning with the first monovalent vaccine for Africa in 1974. Since then, Sanofi has worked to progressively extend protection against four of the most prevalent meningococcal disease serogroups with the first quadrivalent vaccine registered in the U.S. in 1981, followed by the first quadrivalent conjugate vaccine licensed in 2005.⁴

Meningococcal Disease is a Public Health Concern

In the U.S., the Centers for Disease Control and Prevention recommends vaccination against meningococcal disease at 11-12 years of age and a second dose at 16 years of age.⁵ Despite strong public health recommendations, about half of teens have not received the recommended second dose of MenACWY vaccine by 17 years of age, leaving them vulnerable when they are at increased risk for the disease.⁶ Hundreds of cases of vaccine-preventable meningococcal disease (caused by serogroups B, C, W, Y) still occur annually in the U.S. and, despite treatment, one in five survivors suffer from permanent complications such as hearing loss, organ damage, and limb amputations.⁷

Around the world, meningococcal disease is highly unpredictable, and it varies widely across regions and ages. Accordingly, vaccination recommendations differ from country to country. Disease still occurs in unvaccinated individuals. MenQuadfi's safety and effectiveness data are currently under review though not yet fully evaluated by other health authorities, including those in several other countries and the European Union, to help address their local vaccination recommendations.

What is MenQuadfi?

MenQuadfi is a vaccine given to people 2 years of age and older to help prevent invasive meningococcal disease (including meningitis) caused by serogroups A, C, W, and Y of the bacterium *N meningitidis*. MenQuadfi does not prevent serogroup B disease.

Important Safety Information for MenQuadfi in the U.S.

MenQuadfi should not be given to people who have had a severe allergic reaction after a previous dose of MenQuadfi, any of its ingredients, or another vaccine that contains tetanus toxoid.

If MenQuadfi is given to people with a compromised immune system, including those receiving therapies that suppress the immune system, the immune response may be lower than expected. People with certain complement deficiencies and people taking certain complement inhibitors (for example, eculizumab) may still be at risk for meningococcal disease even if they receive a meningococcal vaccine, including MenQuadfi.

Fainting can occur shortly before or after injecting vaccines, including MenQuadfi.

Tell your health care provider if you ever had Guillain-Barré syndrome (severe muscle weakness) after a previous meningococcal vaccination.

Vaccination with MenQuadfi may not protect all people who receive the vaccine.

The most common side effects after a first dose of MenQuadfi for people 2 years and older include pain where the shot is given; muscle aches, headache, and tiredness. In children 2 through 9 years of age, other common side effects include redness and swelling where the shot is given. In adolescents and adults receiving a booster dose of MenQuadfi, the

most common side effects include those occurring after a first dose. Other side effects may occur.

Please see the full [Prescribing Information](#).

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

¹ MenQuadfi Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc.

² “A Phase II, randomized, immunogenicity and safety study of a quadrivalent meningococcal conjugate vaccine, MenACYW-TT, in healthy adolescents in the United States.” <https://doi.org/10.1016/j.vaccine.2020.03.017>, 23 April 2020

³ “Immunogenicity and safety of a booster dose of a quadrivalent meningococcal tetanus toxoid-conjugate vaccine (MenACYW-TT) in adolescents and adults: a Phase III randomized study.” doi.org/10.1080/21645515.2020.1733867, 25 Mar 2020

⁴ Sanofi Pasteur. Our Vaccines — A History of Innovation. 2016.

⁵ “Meningococcal Vaccination for Preteens and Teens: Information for Parents.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 26 July 2019, www.cdc.gov/vaccines/vpd/mening/public/adolescent-vaccine.html.

⁶ “National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years - United States, 2018.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 22 Aug. 2019, www.cdc.gov/mmwr/volumes/68/wr/mm6833a2.htm.

⁷ “Meningococcal Disease Clinical Information.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 31 May 2019, www.cdc.gov/meningococcal/clinical-info.html