

European Commission approves MenQuadfi[®], the latest innovation in meningococcal (MenACWY) vaccination for individuals 12 months of age and older

- EC approval based on robust data from seven pivotal Phase 2 and 3 trials^{1,2,3,4,5,6,7} involving more than 6,300 individuals aged 12 months and older
- First quadrivalent meningococcal conjugate vaccine available in Europe in a fully liquid presentation, avoiding the need for vaccine reconstitution
- Meningococcal disease is a rare but highly unpredictable deadly bacterial infection, with more than 3,000 cases per year in Europe⁸

PARIS – November 23 – The European Commission (EC) has approved MenQuadfi[®] for active immunization of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y.⁹

“Meningococcal meningitis can take one’s life in as little as one day and leave survivors with severe permanent disabilities.^{10,11} In Europe, there were more than 3,000 cases of Invasive Meningococcal Disease in 2018, half of them caused by serogroups C, W and Y,”⁸ says Thomas Triomphe, Head of Sanofi Pasteur. “One case is one too many. It is our ambition to make this vaccine available worldwide to further expand protection to as many people as possible. The European Commission’s approval of MenQuadfi takes us one step closer to achieving this goal.”

Efficacy and safety profiles for MenQuadfi confirmed in robust clinical program

The European Commission’s decision is based upon results from a robust and comprehensive international clinical program, including seven pivotal Phase 2 and 3 randomized, active-controlled, multi-center studies. The immunogenicity and safety of MenQuadfi were evaluated in over 6,300 healthy individuals aged 12 months and older, who received a single dose of MenQuadfi.^{1,2,3,4,5,6,7}

MenQuadfi was compared with other licensed combination vaccines across all age groups. It demonstrated a good safety profile and induced a high immune response against all four serogroups (A, C, W and Y) consistently across all studies.^{1,2,3,4,5,6,7}

“The introduction of a new vaccine against four of the major serogroups of meningococcal disease is very welcome news. The disease is unpredictable and remains the biggest cause of sepsis and septic shock in children across Europe today,¹²” says Professor Federico Martín-Torres, Pediatrician and Clinical Researcher, Head of Pediatrics and Vaccine Research Unit at Hospital Clínico Universitario de Santiago in Spain. “Meningococcal disease is vaccine-

preventable but, in spite of its threat, there is currently no common immunization schedule for it in Europe. The approval of MenQuadfi in Europe will contribute to our efforts to protect against, and help defeat, this truly devastating disease.”

In order to better address the global need for meningococcal disease prevention over the life course, Phase 3 studies are ongoing to investigate the vaccine in infants from 6 weeks of age.^{13,14,15,16,17,18}

Invasive meningococcal disease remains a major public health challenge

Invasive meningococcal disease (IMD) epidemiology is highly unpredictable and varies widely across geographies and over time. In Europe, with the increase in incidence of IMD caused by hypervirulent serogroup W, several countries have introduced MenACWY conjugate vaccination into their routine vaccination schedules. However, considerable variation remains between European countries, leaving room for outbreaks in unprotected and vulnerable populations.¹⁹

In 2018, 3,233 individuals contracted invasive meningococcal disease in Europe, and approximately 1 in 10 did not survive. Of the total number of cases, 2,911 were reported to be serogroups B, C, W or Y, of which almost half (47%) were serogroup C, W or Y.⁸ Rates were highest in infants, followed by children under 5 years, with a second peak in those aged 15–24 years.⁸

About MenQuadfi

MenQuadfi benefits from Sanofi’s latest advancements in chemical design and delivers optimized stability while maintaining the vaccine in a convenient, fully liquid presentation. The vaccine can be administered as a single dose, supporting primary and booster vaccination to a wide age group, ranging from 12-month-old toddlers to children, adolescents, adults and the elderly. It can also be co-administered with multiple routine pediatric and adolescent vaccines.^{2,4}

The safety of a single dose of MenQuadfi was evaluated in 6,308 individuals 12 months of age and older. The most frequently reported adverse reactions in toddlers 12–23 months of age were irritability and injection site tenderness. Those in vaccine recipients aged 2 years and above were myalgia and injection site pain. These adverse reactions were mostly mild or moderate in intensity. Immune non-inferiority was consistently demonstrated across all age groups for all four serogroups and versus all comparator vaccines.

Following EC approval, MenQuadfi is expected to be available in several European countries from 2021 to help protect individuals 12 months of age and older.

MenQuadfi is licensed by the Food and Drug Administration (FDA) in the United States for the prevention of Invasive Meningococcal Disease in individuals 2 years of age and older, and is currently under review by several health authorities across the world to help meet local immunization efforts.

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

Media Relations Contact

Nicolas Kressmann
Tel.: +1 (732) 532-5318
Nicolas.Kressmann@sanofi.com

Investor Relations Contacts Paris

Eva Schaefer-Jansen
Arnaud Delepine
Yvonne Naughton

Investor Relations Contacts North America

Felix Lauscher
Fara Berkowitz
Suzanne Greco

IR main line:
Tel.: +33 (0)1 53 77 45 45
investor.relations@sanofi.com

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, 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 EU Clinical Trials Register. 2016-000749-30 (MET51) results summary. November 2018. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-000749-30/results> [accessed September 2020].

² EU Clinical Trials Register. 2018-001472-38 (MET57) results summary. August 2019. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-001472-38/results> [accessed September 2020].

³ EU Clinical Trials Register. 2018-001471-20 (MET35) results summary. December 2018. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-001471-20/results> [accessed September 2020].

⁴ EU Clinical Trials Register. 2016-001963-35 (MET50) results summary. January 2019. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-001963-35/results> [accessed September 2020].

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- ⁵ EU Clinical Trials Register. 2018-001468-48 (MET43) results summary. December 2018. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-001468-48/results> [accessed September 2020].
- ⁶ Clinicaltrials.gov. NCT02842866 (MET49) results summary. February 2020. Available at: <https://clinicaltrials.gov/ct2/show/results/NCT02842866> [accessed September 2020]
- ⁷ Clinicaltrials.gov. NCT02752906 (MET56) results summary. June 2020. Available at: <https://clinicaltrials.gov/ct2/show/results/NCT02752906> [accessed September 2020].
- ⁸ European Centre for Disease Prevention and Control (ECDC). Surveillance Atlas of Infectious Diseases. Available at: <https://www.ecdc.europa.eu/en/meningococcal-disease/surveillance-and-disease-data/atlas> [accessed September 2020].
- ⁹ MenQuadfi Summary of Product Characteristics.
- ¹⁰ Beebeejaun, K et al. (2020). Invasive meningococcal disease: Timing and cause of death in England, 2008–2015. *Journal of Infection*. Available at: <https://doi.org/10.1016/j.jinf.2019.12.008> [accessed September 2020].
- ¹¹ European Centre for Disease Prevention and Control (ECDC). Factsheet about meningococcal disease. Available at: [https://www.ecdc.europa.eu/en/meningococcal-disease/factsheet#:~:text=In%202016%2C%203%20280%20confirmed,Member%20States%20\(Figure%201\)](https://www.ecdc.europa.eu/en/meningococcal-disease/factsheet#:~:text=In%202016%2C%203%20280%20confirmed,Member%20States%20(Figure%201)) [accessed September 2020].
- ¹² Martín-Torres, F et al. (2018). Life-threatening infections in children in Europe: a prospective cohort study. *The Lancet Child & Adolescent Health* 2(6):404–414.
- ¹³ Clinicaltrials.gov. NCT03632720 (MET52) results summary. August 2018. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT03632720?term=MET&cond=Meningococcal+Disease&lead=Sanofi+Pasteur&draw=2&rank=1> [accessed September 2020].
- ¹⁴ Clinicaltrials.gov. NCT03673462 (MET41) results summary. September 2018. Available at: <https://clinicaltrials.gov/ct2/show/NCT03673462?term=MET41&draw=2&rank=1> [accessed September 2020].
- ¹⁵ Clinicaltrials.gov. NCT03691610 (MET61) results summary. October 2018. Available at: <https://clinicaltrials.gov/ct2/show/NCT03691610> [accessed September 2020].
- ¹⁶ Clinicaltrials.gov. NCT03547271 (MET58) results summary. June 2018. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT03547271?term=MET&cond=Meningococcal+Disease&lead=Sanofi+Pasteur&draw=2> [accessed September 2020].
- ¹⁷ Clinicaltrials.gov. NCT03630705 (MET33) results summary. August 2018. Available at: <https://www.clinicaltrials.gov/ct2/show/record/NCT03630705?term=MET&cond=Meningococcal+Disease&lead=Sanofi+Pasteur&draw=2&rank=4> [accessed September 2020].
- ¹⁸ Clinicaltrials.gov. NCT03537508 (MET42) results summary. May 2018. Available at: <https://www.clinicaltrials.gov/ct2/show/record/NCT03537508?term=MET&cond=Meningococcal+Disease&lead=Sanofi+Pasteur&draw=2> [accessed September 2020].
- ¹⁹ Sanofi Pasteur (2020). Meningococcal Disease in Europe: A Rare but Devastating Disease.