

MenQuadfi® demonstrates superior immune response against serogroup C meningococcal disease in toddlers

- * Phase 3 study met primary and secondary endpoints demonstrating MenQuadfi® induced superior immune responses to serogroup C compared to a standard-of-care vaccine in healthy toddlers
- * MenQuadfi is the first and only quadrivalent ACWY vaccine to demonstrate superior immune response against serogroup C in toddlers

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Results from a head-to-head Phase 3 study, evaluating the immune response of MenQuadfi® to serogroup C, one of the main serogroups of invasive meningococcal disease (IMD), compared to Nimenrix® (quadrivalent ACWY vaccine) and NeisVac-C® (monovalent C vaccine) in healthy toddlers, were presented today in an oral session at the 2021 European Congress of Clinical Microbiology and Infectious Disease.

The Phase 3 study met all primary and secondary endpoints, demonstrating that MenQuadfi induced superior immune responses to serogroup C based on geometric mean antibody titers (GMTs*) compared to NeisVac-C - a standard-of-care vaccine - in healthy toddlers. The study shows that a switch from monovalent C to MenQuadfi in toddlers can be achieved without compromising serogroup C protection. The data also showed superior immune responses to serogroup C based on seroprotection rates and GMTs compared to Nimenrix in this population. The safety profiles were comparable between all three vaccines.

“In the last decade there has been an increase in the incidence of invasive meningococcal disease due to serogroups W & Y in Europe,¹ demonstrating a need for routine MenACWY vaccination.” said Prof. Markus Knuf, Head of Department for Pediatric and Adolescent Medicine, Worms Clinic, Worms, Germany, *“Now that we know that we can help protect against A,C,W and Y serogroups with no compromise on C serogroup protection, I have great hope that routine ACWY vaccination will soon become the standard helping to protect European children from this potentially devastating disease.”*

Children under five and adolescents are most at risk from IMD, a rare but potentially deadly disease which can have devastating consequences.² Up to 20% of survivors of IMD suffer from serious complications such as brain damage or loss of limbs.²⁻³

Data has shown IMD has an unpredictable and evolving epidemiology.¹ Recent trends in Europe suggest a decreasing incidence of IMD cases caused by serogroup B and an

increase in serogroups Y and W.¹ There has also been a significant increase in the incidence of IMD caused by hypervirulent serogroup W, with a case fatality rate more than twice that of IMD caused by other serogroups.¹

“The results of our head-to-head Phase 3 study are clear and add to our robust evidence demonstrating the strong profile of MenQuadfi against meningococcal disease caused by serogroups A, C, W and Y from toddlers to adults,” said Dr. Su-Peing Ng, Global Medical Head, Sanofi Pasteur. *“These data represent an important public health milestone in our efforts to advance protection against meningococcal meningitis and in support of the World Health Organization’s ambition to defeat this disease by 2030.”*

About the Phase 3 study^{4,5}

MEQ00065 is a head-to-head comparative, multi-center, Phase 3 study conducted in Germany, Finland and Denmark to compare the immune response against meningococcal serogroup C and describe the safety following a single dose of MenQuadfi in healthy meningococcal vaccine-naïve toddlers 12 to 23 months of age compared to Nimenrix or NeisVac-C.

The full results of the Phase 3 MEQ00065 data will be submitted for publication in a peer-reviewed journal Q4 2021.

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 injection, 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.⁶

MenQuadfi is approved by the European Commission, Iceland, Liechtenstein, Norway, Australia, Canada, UK, Brazil and Argentina for use as a single dose in individuals 12 months of age and older for the prevention of invasive meningococcal ACWY disease and is currently under review by several health authorities across the world to help meet local immunization efforts. It is licensed by the Food and Drug Administration in the United States for the prevention of invasive meningococcal disease in individuals 2 years of age and older.

** GMT is the criteria that enables to measure the immune response compared to NeisVac-C*

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.

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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 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

¹ Surveillance Atlas of Infectious Diseases. European Centre for Disease Prevention and Control (ECDC). Available at: <https://www.ecdc.europa.eu/en/meningococcal-disease/surveillance-and-disease-data/atlas> [accessed June 2021].

² Factsheet about meningococcal disease. European Centre for Disease Prevention and Control (ECDC), [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 June 2021].

³ Beebejaun, 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 June 2021].

⁴ EU Clinical Trials register. 2018-003790-10 (MEQ0065) <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-003790-10/results> [accessed June 2021].

⁵ Clinicaltrials.gov. NCT03890367 (MEQ65) study record Available at: <https://clinicaltrials.gov/ct2/show/NCT03890367> [accessed June 2021].

⁶ MenQuadfi Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/menquadfi-epar-product-information_en.pdf. [accessed June 2021].