Press Release

Sanofi's MenQuadfi approved in the EU for use in infants from age six weeks against invasive meningococcal disease

Paris, August 4, 2026. Sanofi today announced that the European Commission (EC) has approved an extension of the indication for MenQuadfi (Meningococcal Group A, C, W and Y conjugate vaccine) to include infants from six weeks of age to help protect against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi was previously approved in the EU for use in individuals aged 12 months and older. The expanded indication follows the positive opinion adopted by the Committee for Medicinal Products for Human Use on June 25, 2026.

Invasive meningococcal disease is a life-threatening bacterial infection that can progress rapidly, with patients potentially deteriorating from the onset of symptoms to death within 24 hours. Infants are among the populations at highest risk for invasive meningococcal disease, facing high rates of mortality and severe long-term complications, including limb amputation, hearing loss, and neurological damage. Even with appropriate treatment, invasive meningococcal disease carries a case fatality rate of approximately 10–15%, and up to 20% of survivors experience permanent complications. Although serogroup A is now rarely reported in the EU, serogroups C, W, and Y remain responsible for a significant share of invasive meningococcal disease cases across Europe, reinforcing the importance for broad protection against these four serogroups from an early age.

> *"Meningococcal disease moves fast and strikes the hardest in younger children. Having a product indicated across a broad age range is key to meeting public health needs — giving healthcare providers the flexibility to help protect infants within routine immunization schedules and increase vaccine coverage. The immunogenicity data for MenQuadfi in infants is robust and supports the usage with confidence in the EU,"* said **Federico Martinon-Torres**, Pediatrician and Clinical Researcher, Head of Pediatrics and Vaccine Research Unit at Hospital Clínico Universitario de Santiago in Spain and Principal Investigator of MET58.

With this approval, MenQuadfi provides healthcare professionals in the EU with an additional option for vaccinating infants against invasive meningococcal disease from as early as six weeks of age. This expanded indication, aligned with routine infant immunization schedules, is supported by MenQuadfi's demonstrated immunogenicity data.

> *"Offering protection for the EU's youngest children is at the heart of what we do — and this approval is a direct expression of that commitment. It reflects the scientific rigor behind this work, and it means healthcare providers now have an additional option to help protect infants against invasive meningococcal disease from the early weeks of life,"* said **Bogdana Coudsy**, Global Head of Medical, Vaccines, Sanofi.

This milestone embodies Sanofi's contribution, fighting against invasive meningococcal disease, a devastating disease, by expanding vaccine access to the most vulnerable populations across the EU.

About the MET58 pivotal study

The EU approval is supported by comprehensive data from the MET58 pivotal clinical study, which evaluated the immunogenicity, safety, and tolerability of MenQuadfi in infants from six weeks of age.

About MenQuadfi

MenQuadfi (Meningococcal Group A, C, W and Y conjugate vaccine) is indicated for active immunization of individuals six weeks of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y.

MenQuadfi benefits from a strong track record of clinical data in infants with more than 6,000 infants studied across 11 countries and multiple immunization schedules.

The new dose regimen approved for those starting vaccination from six weeks of age is aligned with routine pediatric vaccination schedules.

The approved dosing regimens include:

- 2+1 schedule for infants from six weeks of age, aligned with standard EU immunization schedules. Two doses (each 0.5mL) should be administered with an interval of at least two months. One dose (booster) should be given in the second year of life (from 12 months of age) and at least two months from the last dose.
- For infants expected to be at increased risk of invasive meningococcal disease due to serogroup A exposure, a 3+1 schedule may be considered. Three doses primary series at two, four and six months followed by one booster dose from 12 months of age.
- Single dose for individuals 12 months of age and older.

In infants, MenQuadfi can be co-administered with combined diphtheria - tetanus - acellular pertussis (DTaP) - inactivated poliovirus (IPV) - hepatitis B (HepB) - *Haemophilus influenzae* type b (Hib) vaccine (DTaP-IPV-HepB-Hib), rotavirus vaccine (live attenuated) and with 10-valent pneumococcal conjugate vaccine (PCV10).

The safety and immunogenicity profile have been established across a broad age range, from six weeks of age through adulthood. MenQuadfi is well tolerated, with a safety profile comparable to other MenACWY vaccines currently licensed.

The Paediatric Investigation Plan compliance statement has been received from the European Medicines Agency, marking the completion of all pediatric post-licensure commitments linked to MenQuadfi's initial marketing authorization.

MenQuadfi is approved in the EU, US, and multiple other countries.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi forward-looking statements

This press release contains forward-looking statements within the meaning of applicable securities laws, including 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 regarding the marketing and other potential of the product; regarding potential future events and revenues from the product. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these and similar expressions are intended to identify forward-looking statements. 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, uncertainties and assumptions 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; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; 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 pending or future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that global crises may 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. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the French Markets Authority (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, 2025, or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.