

## CHMP recommends approval of MenQuadfi® for active immunization of individuals from the age of 12 months and older against invasive meningococcal ACWY disease

- \* Positive opinion based on a large, international clinical program demonstrating a good safety profile and a high immune response against all four serogroups (A, C, W and Y)
- \* The European Commission final decision is expected by the end of this year

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The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for 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.<sup>1</sup>

The recommendation is supported by seven double-blind, randomized, multicenter Phase 2 and 3 clinical studies<sup>2,3,4,5,6,7,8</sup> that assessed safety and immune responses following vaccination, with nearly 6,300 persons from toddlers 12 month and older to older adults. These studies compared MenQuadfi with other licensed combination vaccines, demonstrating a good safety profile and high immune response against all four serogroups (A, C, W and Y).

Meningococcal meningitis can take one's life in as little as one day and leave survivors with severe permanent disabilities.<sup>9,10</sup> While most cases are vaccine-preventable, in 2018 there were more than 3,000 cases of invasive Meningococcal Disease in Europe, half of them caused by serogroups C, W, and Y.<sup>11</sup>

Following this CHMP positive opinion, a final decision is anticipated by the end of this year. MenQuadfi is expected to be gradually available in Europe starting in 2021.

MenQuadfi has been registered in April 2020 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. It is currently under review by several health authorities across the world to help meet local immunization efforts.

**Editor's Note:** MenQuadfi builds on Sanofi's legacy of leading meningococcal vaccine innovation, 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 polysaccharide vaccine. in 1981, followed by the first FDA approved quadrivalent conjugate vaccine in 2005.

## 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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<sup>1</sup> MenQuadfi Summary of Product Characteristics (SmPC).

<sup>2</sup> 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].

<sup>3</sup> 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].

<sup>4</sup> 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].

<sup>5</sup> 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].

<sup>6</sup> 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].

<sup>7</sup> Clinicaltrials.gov. NCT02842866 (MET49). results summary . February 2020. Available at: <https://clinicaltrials.gov/ct2/show/results/NCT02842866> [accessed September 2020]

<sup>8</sup> Clinicaltrials.gov. NCT02752906 (MET56). results summary. June 2020. Available at: <https://clinicaltrials.gov/ct2/show/results/NCT02752906> [accessed September 2020].

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<sup>9</sup> 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].

<sup>10</sup> 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].

<sup>11</sup> 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].