

Chlamydia vaccine candidate granted fast track designation by the US FDA

- Chlamydia infection can contribute to pelvic inflammatory diseases in women, which can lead to pregnancy complications or infertility
- A phase 1/2 clinical study evaluating the immunogenicity and safety of the vaccine candidate is due to start in coming days

Paris, March 26, 2025. The US Food and Drug Administration has granted fast track designation to Sanofi's mRNA vaccine candidate for the prevention of chlamydia infection. The decision was based on the potential of the vaccine candidate to address a serious condition and address an unmet public health need.

The chlamydia vaccine candidate has been designed to protect against primary genital tract infection and reinfection by the bacterium *Chlamydia trachomatis*. Following a promising pre-clinical program, Sanofi is planning a phase 1/2 randomized, clinical study designed to evaluate the immunogenicity and safety of the chlamydia vaccine candidate in adults aged 18 to 29 years. The study is due to start in coming days.

Jean-François Toussaint

Global Head of Vaccines R&D

"Millions of people currently live with undiagnosed chlamydia, including asymptomatic infection that can also cause severe long-term health effects if left untreated. Antibiotics to treat chlamydia have not been successful in controlling rising infection rates. With our program we aim to make chlamydia a preventable disease through vaccination."

Chlamydia, caused by the bacterium *Chlamydia trachomatis*, is a common bacterial infection of the reproductive tract with consequences for developing infertility and pregnancy complications. In 2020, there were 129 million worldwide cases of chlamydia among adults (15-49 years old), with the highest rates of infection among adolescents and young adults.

Although chlamydia can be treated with antibiotics when diagnosed, over 80% of chlamydia cases are asymptomatic, meaning there is a significant risk that infections go unrecognized, leading to untreated cases and unintentional transmission. Programs that have been put in place to prevent infection rates from rising have proven insufficient, highlighting the urgent public health need for a vaccine.

The development of this vaccine candidate is part of the Translational Science Hub, a partnership with the Queensland Government, Griffith University, and the University of Queensland, connecting world-class researchers in Queensland, Australia, with Sanofi scientists in France and the US.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com

Nicolas Obrist | +33 6 77 21 27 55 | nicolas.obrist@sanofi.com

Léo Le Bourhis | +33 6 75 06 43 81 | leo.lebourhis@sanofi.com

Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com

Timothy Gilbert | +1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

Thomas Kudsk Larsen | +44 7545 513 693 | thomas.larsen@sanofi.com

Alizé Kaisserian | +33 6 47 04 12 11 | alize.kaisserian@sanofi.com

Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com

Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com

Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com

Tarik Elgoutni | +1 617 710 3587 | tarik.elgoutni@sanofi.com

Thibaud Châtelet | +33 6 80 80 89 90 | thibaud.chatelet@sanofi.com

Yun Li | +33 6 84 00 90 72 | yun.li3@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 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 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 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

All trademarks mentioned in this press release are the property of the Sanofi group.