Press Release

Sanofi's SAR446597 earns fast track designation in the US for geographic atrophy due to age-related macular degeneration

- Designation earned for a one-time intravitreal gene therapy designed to inhibit two key complement cascade pathways
- Geographic atrophy is an advanced form of dry age-related macular degeneration, that can lead to permanent vision loss

Paris, July 16, 2025. The US Food and Drug Administration (FDA) has granted fast track designation to SAR446597, a one-time intravitreal gene therapy for the treatment of geographic atrophy (GA) due to age-related macular degeneration (AMD). The fast track designation process aims to facilitate the development and expedite the review of medicines to treat serious conditions and fill unmet medical need. The FDA created this process to help deliver important new drugs to patients earlier and it covers a broad range of serious illnesses.

SAR446597 delivers genetic material encoding two therapeutic antibody fragments that target and inhibit two critical components of the complement pathway: C1s in the classical pathway and factor Bb in the alternative pathway. This dual-targeting approach potentially offers clinical advantages by providing sustained complement suppression within the retinal microenvironment while significantly reducing treatment burden through elimination of frequent intravitreal injections. The therapy aims to address the underlying pathophysiology of complement-mediated retinal diseases through long-term expression of therapeutic proteins following a single intervention.

Sanofi plans to start a phase 1/2 study to evaluate the safety, tolerability, and efficacy of SAR446597.

Sanofi is also currently evaluating SAR402663, a one-time intravitreal gene therapy, in a phase 1/2 study (clinical study identifier: NCT06660667), for the treatment of patients with neovascular wet age-related macular degeneration.

About age-related macular degeneration and geographic atrophy

AMD is an acquired progressive degeneration of the retina that affects approximately 200 million people globally. Geographic atrophy is an advanced form of dry AMD. It is characterized by enlarging irreversible atrophic lesions due to degeneration of retinal cells leading to permanent vision loss in many patients. GA affects approximately 1 million people in the US, more than 2.5 million in Europe, and over 5 million people worldwide and has a profound impact on quality of life, including ability to read, drive and perform other daily activities.

About Sanofi in neurology

Our goal is to improve the lives of people with serious neuroinflammatory and neurodegenerative diseases. We are testing the bounds of clinical possibility to research therapies that may address multiple sclerosis (MS), chronic inflammatory demyelinating polyneuropathy (CIDP), Alzheimer's Disease (AD), Parkinson's disease (PD), Age-Related Macular Degeneration (AMD) and other neurological diseases for the people who need them most. Emerging scientific innovations and investments in ophthalmology have the potential to drive a new phase of growth for Sanofi. We are exploring innovative therapies in retinal diseases with unmet need especially where they connect with immune system conditions.

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 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.