

Sanofi's SAR402663 earns fast track designation in the US for neovascular age-related macular degeneration

- Designation earned for a one-time intravitreal gene therapy with the potential to eliminate treatment burden for people living with neovascular age-related macular degeneration
- Neovascular or "wet" age-related macular degeneration can lead to significant vision loss and affects more than one million people in the US

Paris, September 11, 2025. The US Food and Drug Administration (FDA) has granted fast track designation to SAR402663, an investigational one-time intravitreal gene therapy for the treatment of neovascular 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.

SAR402663 delivers genetic material encoding soluble FLT01 designed to inhibit vascular endothelial growth factor (VEGF). Sanofi is currently evaluating SAR402663 in a phase 1/2 (clinical study identifier: [NCT06660667](#)), for the treatment of patients with neovascular AMD. The gene therapy aims to address the underlying disease pathology by inhibiting abnormal blood vessel growth, reducing vascular leakage and minimizing retina damage, while significantly reducing treatment burden through the elimination of frequent intravitreal injections.

AMD is an acquired progressive degeneration of the retina that affects approximately 200 million people globally. Neovascular, or "wet", AMD is a severe form of macular degeneration. It is characterized by growth of abnormal blood vessels beneath the retina, which can lead to vision loss, potentially progressing to blindness in advanced cases. Neovascular AMD affects more than one million people in the US and six million people worldwide; it 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 (CIPD), Alzheimer's Disease (AD), Parkinson's disease (PD), AMD and other neurological diseases for the people who need them most. Emerging scientific innovation and investment 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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