Press Release

Sanofi's SAR446268 earns US fast track designation for the treatment of non-congenital myotonic dystrophy type 1

- Designation earned for one-time AAV gene therapy SAR446268, designed to silence DMPK expression
- Myotonic dystrophy type 1 (DM1) is a rare, genetic disorder that causes progressive muscle weakness and wasting, with no currently approved medicines

Paris, September 23, 2025. The US Food and Drug Administration (FDA) has granted fast track designation to SAR446268, Sanofi's one-time AAV gene therapy for the treatment of non-congenital (juvenile and adult onset) DM1 myotonic dystrophy type 1 (DM1). This designation process aims to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need. The FDA created this process to help deliver important new medicine to patients earlier and it covers a broad range of serious illnesses.

SAR446268 employs a vectorized RNA interference (RNAi) approach to silence *DMPK* expression through a single administration. By reducing *DMPK* transcripts, the gene therapy aims to eliminate the abnormal and toxic RNA foci responsible for splicing defects in muscle tissue, thereby restoring normal splicing and improving muscular function. This approach has the potential to address key symptoms of the disease, including progressive muscle weakness, difficulty relaxing muscles (myotonia), and effects on multiple body systems including heart, lungs, and endocrine functions. SAR446268 is the only investigational therapy in clinical development for this disease, and there are no currently approved therapies for DM1.

SAR446268 is currently under investigation in a first-in-human, phase 1-2 study to evaluate the safety, tolerability, and efficacy (clinical study identifier: NCT06844214). The first patient is planned for enrolment in late 2025. Sanofi has already been granted orphan designations for SAR446268 in both the US (July 2024) and EU (October 2024).

About myotonic dystrophy type 1

Myotonic dystrophy type 1, also known as Steinert's disease, is an inherited, progressive, rare disorder affecting approximately 1 in 2,300 people worldwide. The condition is caused by mutations in the DMPK gene and is characterized by progressive muscle weakness, difficulty relaxing muscles (myotonia), and effects on multiple body systems including heart, lungs, and endocrine functions. DM1 can manifest at any age with varying severity, from mild adult cases to severe congenital forms, and has a profound impact on quality of life, affecting patients' ability to perform daily activities, maintain independence, and in severe cases, sustain vital functions. There are no currently approved treatments for DM1.

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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