SANOFI

Press Release

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Sanofi provides update on venglustat clinical program

PARIS – JUNE 1, 2021 – A pivotal Phase 2/3 study of venglustat in autosomal dominant polycystic kidney disease (ADPKD) did not meet futility criteria, and the company has halted the clinical program in ADPKD. The safety profile of venglustat remains consistent with previously reported results with more than 500 patients treated to date over a period of up to four years across all clinical programs. Biomarker data from the study confirmed venglustat effectively inhibits the glycosphingolipid (GSL) pathway by demonstrating a reduction in GL-1, a lipid that accumulates in certain cells.

The STAGED-PKD study was stopped for futility following an independent analysis of the annualized rate of change in total kidney volume (TKV) in patients receiving venglustat compared to placebo. Trends from the analysis showed venglustat did not provide a meaningful reduction in TKV growth rate, the primary endpoint of stage 1 of the Phase 2/3 study. This interim analysis suggests the reduction of GSLs may not play a significant role in the prevention of kidney cyst growth, and as such, may not be a primary pathway associated with the progression of ADPKD. The investigational research of venglustat in ADPKD was an attempt to explore a novel biological role for GSLs beyond the established role of these lipids in lysosomal storage diseases (LSDs).

> *"The venglustat development program started with our confidence in the promise of a potential breakthrough treatment to address the unmet needs of people living with lysosomal storage disorders,"* said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *"In parallel, we set out to evaluate venglustat in autosomal dominant polycystic kidney disease, a leading cause of kidney transplant. This outcome is not what we hoped for, especially for these patients. However, our research has furthered the scientific understanding of ADPKD by demonstrating that modulating the GSL pathway is insufficient to restore kidney function in adults affected by this disease."*

Sanofi has both completed and active studies evaluating venglustat in Gaucher disease type 3, Fabry disease and GM2 Gangliosidosis. These diseases are LSDs caused by inherited genetic abnormalities. The abnormal accumulation of GSLs is central to certain LSDs and therapeutics promoting the clearing of these accumulated lipids have been validated in Fabry disease and Gaucher disease through clinical research. In this context, venglustat operates as a Substrate Reduction Therapy (SRT), which is a concept that has also been previously validated for certain LSDs.

About venglustat

GSLs are cellular building blocks whose abnormal accumulation is implicated in several rare diseases, responsible for both cell dysfunction and disease progression. Venglustat is a novel, oral investigational therapy that has the potential to slow the progression of certain diseases by inhibiting abnormal GSL accumulation. Venglustat is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

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

Sanofi Media Relations Contact
Ashleigh Koss
Tel.: +1 (908) 205-2572
Ashleigh.Koss@sanofi.com

Sally Bain
Tel.: +1 (781) 264-1091
Sally.Bain@sanofi.com

Sanofi Investor Relations Contacts Paris
Eva Schaefer-Jansen
Arnaud Delepine
Nathalie Pham

Sanofi Investor Relations Contacts North America
Felix Lauscher
Fara Berkowitz
Suzanne Greco

Sanofi IR main line:
Tel.: +33 (0)1 53 77 45 45
investor.relations@sanofi.com
https://www.sanofi.com/en/investors/contact

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 COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.