Press Release

Sanofi announces end of program evaluating tusamitamab ravtansine after a 2L NSCLC Phase 3 trial did not meet a primary endpoint

- CARMEN-LC03 trial did not meet dual primary endpoint of improving progression-free survival; tusamitamab ravtansine clinical development program will be discontinued
- Sanofi reinforces commitment to broader oncology development program including CEACAM5-directed antibody drug conjugates (ADC) with additional anticipated trials

PARIS, December 21, 2023. Sanofi is discontinuing the global clinical development program of tusamitamab ravtansine. The decision is based on the outcome of a prespecified interim analysis of the Phase 3 CARMEN-LC03 trial evaluating tusamitamab ravtansine as monotherapy compared to docetaxel in previously treated patients with metastatic non-squamous (NSq) non-small cell lung cancer (NSCLC) whose tumors express high levels of carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5).

An Independent Data Monitoring Committee (IDMC) found that tusamitamab ravtansine as a monotherapy did not meet its dual primary endpoint of progression-free survival (PFS) compared to docetaxel. Despite an improved overall survival (OS) trend, termination of the program was based on non-improvement in PFS at the final analysis. Tusamitamab ravtansine had a similar safety profile as previously presented with a lower incidence of various important clinical categories of adverse events versus docetaxel. Trial participants will have the option to stay on their current therapy if they are benefitting, as deemed by their provider, or to transition to an appropriate standard-of-care therapy.

Sanofi will continue exploring the potential of antibody tusamitamab-based ADCs and CEACAM5 research in several types of cancer.

> ***Dietmar Berger***
> Chief Medical Officer and Head of Development
> *"Our team is grateful to the patients, families and healthcare professionals involved in the tusamitamab ravtansine development program. Although the results are not what we hoped for, our research and work to advance potentially transformative therapies in areas of high unmet need for people living with cancer will not stop. We will continue to explore the potential of CEACAM5 as a biomarker in cancer types where it is highly expressed."*

CEACAM5 is a member of the CEACAM family of 12 glycoproteins and may drive cell adhesion and migration, as well as inhibit apoptosis, and may be overexpressed in many different cancer types.

About the CARMEN-LC03 Trial

CARMEN-LC03 was a randomized, open-label Phase 3 study evaluating tusamitamab ravtansine as monotherapy compared to docetaxel in patients with metastatic NSq NSCLC and high CEACAM5 expression. The dual primary endpoints of CARMEN-LC03 were progression-free survival and overall survival. Secondary endpoints included objective response rate, health-related quality of life, safety and duration of response.

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 some 100 countries, 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

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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 pandemics or other 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.