Press Release

Sanofi provides update on Phase 2 study evaluating amcenestrant in ER+/HER2- advanced or metastatic breast cancer

- AMEERA-3 trial did not meet primary endpoint of improving progression-free survival
- Ongoing trials continue as planned, including AMEERA-5 and AMEERA-6

Paris, March 14, 2022. The Phase 2 AMEERA-3 clinical trial evaluating amcenestrant, an investigational optimized oral selective estrogen receptor degrader (SERD), did not meet its primary endpoint of improving progression-free survival (PFS) as assessed by an independent central review. The trial evaluated amcenestrant as monotherapy compared to endocrine treatment of physician's choice in patients with locally advanced or metastatic estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) breast cancer who progressed on or after hormonal therapies. No new safety signals were identified and the safety profile of amcenestrant in AMEERA-3 was consistent with earlier studies.

> ***John Reed, MD, PhD***
> Head of Research and Development at Sanofi
> *"This Phase 2 trial evaluated amcenestrant as a monotherapy in a patient population with advanced disease where limited treatment options remain. While we are disappointed with the AMEERA-3 results, we continue to investigate amcenestrant in patients with earlier stages of breast cancer with different tumor profiles and where different standard of care treatments are used."*

Sanofi will continue to assess data from the AMEERA-3 trial and work with investigators on the publication of the full results. The ongoing clinical trial program for amcenestrant continues as planned, including AMEERA-5 and AMEERA-6.

Amcenestrant is an optimized oral SERD that binds to the estrogen receptors (ER) in breast cancer cells to inhibit their normal function and trigger degradation so they can no longer be used by tumor cells to grow. Amcenestrant is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

About the AMEERA-3 trial

AMEERA-3 was an open-label, Phase 2 randomized trial evaluating the efficacy and safety of amcenestrant as a monotherapy compared to single-agent endocrine treatment of the physician's choice in patients with ER+, HER2- locally advanced or metastatic breast cancer with prior exposure to hormonal therapies. The primary objective of AMEERA-3 was to determine whether amcenestrant improved PFS assessed by an independent central review compared to endocrine monotherapy. The key secondary efficacy endpoint was overall survival and other secondary endpoints were objective response rate, disease control rate, clinical benefit rate and duration of response. The study also compared the overall safety profile in the two treatment arms and evaluated health-related quality of life in the two treatment arms based on patient-reported outcomes.

About the amcenestrant clinical program

The comprehensive development program for amcenestrant has been designed to evaluate its potential as an oral endocrine backbone therapy across treatment lines, including: as a single agent in second-line or later lines of treatment of ER+/HER2- metastatic breast cancer (MBC) (AMEERA-3), in combination with palbociclib in the first-line treatment of ER+/HER2- MBC (AMEERA-5), and to explore its potential in early-stage breast cancer patients in the adjuvant setting (AMEERA-6). Initiated in late 2020, the Phase 3 AMEERA-5 clinical trial is now fully

enrolled. The Phase 3 AMEERA-6 trial, in partnership with the Breast International Group (BIG), the European Organization for Research and Treatment of Cancer (EORTC), and the Alliance Foundation Trials (AFT) is now enrolling.

For more information on amcenestrant clinical trials, please visit www.clinicaltrials.gov.

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

Media Relations
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com
Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

Investor Relations
Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Priya Nanduri | +1 908 981 5560 | priya.nanduri@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

---

Disclaimers or 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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.