Press Release

Sanofi provides update on amcenestrant clinical development program

PARIS, August 17, 2022. Sanofi is discontinuing the global clinical development program of amcenestrant, an investigational oral selective estrogen receptor degrader (SERD). The decision is based on the outcome of a prespecified interim analysis of the Phase 3 AMEERA-5 trial evaluating amcenestrant in combination with palbociclib compared with letrozole in combination with palbociclib in patients with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer.

An Independent Data Monitoring Committee (IDMC) found that amcenestrant in combination with palbociclib did not meet the prespecified boundary for continuation in comparison with the control arm and recommended stopping the trial. No new safety signals were observed. Trial participants will be transitioned to letrozole in combination with palbociclib or another appropriate standard of care therapy, as determined by their physician.

The company will continue to review the data and plans to share the results with the scientific community in the future. All other studies of amcenestrant, including in early-stage breast cancer (AMEERA-6), will be discontinued.

John Reed, MD, PhD
Global Head of Research and Development at Sanofi

"While we are disappointed by this outcome, our research will further the scientific understanding of endocrine therapies in people with breast cancer. Our sincere gratitude goes to the patients, families and healthcare professionals involved in the amcenestrant clinical development program. Oncology remains a priority area for Sanofi, and we will continue to pursue transformative research to develop new medicines for people living with cancer."

In March, Sanofi announced that the Phase 2 AMEERA-3 trial had not met the primary endpoint of improving progression-free survival in patients with ER+/HER2- advanced or metastatic breast cancer.

About AMEERA-5
AMEERA-5 is a randomized, double-blind Phase 3 trial evaluating the efficacy and safety of amcenestrant in combination with palbociclib, a CDK4/6 inhibitor, in the first-line treatment of patients with ER+/HER2- advanced breast cancer. A total of 1068 patients who had not received any prior systemic anticancer therapies for advanced disease were randomized 1:1 to receive either amcenestrant or letrozole in combination with palbociclib.

About AMEERA-6
AMEERA-6 is a randomized, double-blind Phase 3 trial evaluating the efficacy and safety of amcenestrant compared with tamoxifen in patients with hormone receptor-positive early breast cancer who have discontinued adjuvant aromatase inhibitor (AI) therapy due to treatment related toxicity. The trial was initiated in partnership with the Breast International Group (BIG), the European Organization for Research and Treatment of Cancer (EORTC), and the Alliance Foundation Trials (AFT).

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**
Evan Berland | + 1 215 432 0234 | evan.berland@sanofi.com
Kate Conway | +1 508 364 4931 | kate.conway@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 | + 1 617 764 6418 | 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.