# Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

## Sanofi partnering with leading academic cooperative groups to study amcenestrant in the adjuvant setting for patients with estrogen receptor positive breast cancer

- Sanofi partnering with the Breast International Group (BIG), the European Organization for Research and Treatment of Cancer (EORTC) and Alliance Foundation Trials (AFT), which are world-leading academic groups delivering practice-changing breast cancer clinical research
- Collaborating on the Phase 3 AMEERA-6 study expected to be the first pivotal trial of an oral selective estrogen receptor degrader (SERD) in the adjuvant setting and will evaluate the safety and efficacy of Sanofi's investigational amcenestrant in estrogen receptor-positive (ER+) patients who prematurely discontinue standard therapy and have high risk of disease recurrence
- Parties to finalize full terms of this cooperative effort
- Additional treatment options in early breast cancer are needed to help prevent patients from developing advanced, incurable disease and would represent a significant treatment advance

**PARIS – June 4, 2021** – Sanofi is partnering with leading groups delivering practice-changing breast cancer research, the Breast International Group (BIG), the European Organization for Research and Treatment of Cancer (EORTC) and the Alliance Foundation Trials (AFT), to initiate a pivotal trial of an oral selective estrogen receptor degrader (SERD) in the adjuvant setting. The Phase 3 AMEERA-6 study will evaluate the efficacy and safety of Sanofi's amcenestrant vs tamoxifen for women with estrogen receptor-positive (ER+) breast cancer who were unable to continue their adjuvant aromatase inhibitor (AI) therapy.

> "*Together with our research partners, BIG conducts landmark, practice-changing trials that can have a significant impact on the lives of women with breast cancer," said David Cameron, Chair of the BIG Executive Board. "Adjuvant therapy helps prevent and delay the progression of disease into the later setting. However, current adjuvant therapies, like AIs, can have side effects for some women, which may cause them to discontinue the medication prematurely. Amcenestrant may be a potential option for women in this setting and we look forward to working with Sanofi, EORTC and AFT to investigate this further."*

*"We look forward to collaborating with these leading academic networks to investigate amcenestrant in the adjuvant setting through AMEERA-6. Based on encouraging data emerging from our ongoing clinical program, we believe that amcenestrant, an investigational oral SERD, has the potential to become a best-in-class oral endocrine backbone therapy," said Peter Adamson, M.D., Global Development Head, Oncology at Sanofi. "Additional treatment options for patients with breast cancer are needed to allow women to remain on adjuvant therapy and decrease their risk of progressive disease."*

Amcenestrant is an oral SERD that antagonizes and degrades the estrogen receptor (ER), resulting in inhibition of the ER signaling pathway. Amcenestrant is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

Despite the established clinical efficacy of tamoxifen and AIs in early breast cancer, many patients experience disease recurrence because of resistance to therapy, non-adherence or premature discontinuation of their adjuvant therapy.[1] Additional treatment options in the adjuvant setting in early breast cancer are needed to prevent women from developing advanced, incurable disease and could represent a significant treatment advance.

As per the terms of the Pre-Study Agreement, Sanofi will be the sponsor and will provide funding and investigational drug product for the global study. BIG will conduct the study within the BIG network, EORTC will oversee study management and data analysis, as well as the medical management, and AFT will conduct the United States portion of the study. Sanofi will conduct this global study in selected countries outside the geographical scope of the academic networks, as further described in a follow-on agreement under negotiation among the four parties. The protocol is being developed in collaboration with all four parties, including AFT, BIG, EORTC and Sanofi.

## About Alliance Foundation Trials

Alliance Foundation Trials, LLC (AFT) is a research organization that develops and conducts cancer clinical trials, working closely with the Alliance for Clinical Trials in Oncology scientific investigators and institutional member network, research collaborators, and non-NCI funding sources. AFT seeks to fulfil the vision of the Alliance for Clinical Trials in Oncology to reduce the impact of cancer on people by uniting a broad community of scientists and clinicians from many disciplines committed to discovering, validating, and disseminating effective strategies for the prevention and treatment of cancer. Current AFT studies are funded by a number of pharmaceutical company collaborators and the Patient-Centered Outcomes Research Institute (PCORI).

To learn more about AFT studies, visit www.AllianceFoundationTrials.org.

[1] Murphy CC, Bartholomew LK, Carpentier MY, Bluethmann SM, Vernon SW. Adherence to adjuvant hormonal therapy among breast cancer survivors in clinical practice: a systematic review. Breast Cancer Res Treat. 2012;134(2):459-78.

## About European Organization for Research and Treatment of Cancer

European Organization for the Research and Treatment of Cancer (EORTC) is an academic clinical research organisation which unites clinical cancer research experts across the globe to define better treatments for cancer patients to prolong survival and improve quality of life. Both international and multidisciplinary, EORTC's Network comprises over 2800 collaborators involved in cancer treatment and research in more than 740 institutions across 30 countries. Conducting translational research, phase 2 and 3 trials, EORTC offers an integrated approach to therapeutic strategies and quality of life. EORTC Headquarters, a unique international clinical research infrastructure, is based in Brussels, Belgium, from where its various activities are coordinated and run.

For further information, please visit the EORTC website: www.eortc.org.

## About Breast International Group

The Breast International Group (BIG) is an international not-for-profit organization for academic breast cancer research groups from around the world, based in Brussels, Belgium.

Global collaboration is crucial to make significant advances in breast cancer research, reduce unnecessary duplication of effort, share data, contribute to the faster development of better treatments, and increase the likelihood of cures for patients. Therefore, BIG facilitates breast cancer research at the international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

In 1999, BIG was founded by leading European opinion leaders with the aim to address fragmentation in European breast cancer research. Research groups from other parts of the world rapidly expressed interest in joining BIG and, two decades later, BIG represents a network of over 50 like-minded research groups from around the world. These entities are tied to several thousand specialized hospitals, research centres and world class breast cancer experts across approximately 70 countries on 6 continents. More than 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the NCI National Clinical Trials Network (NCTN), so that together they act as a strong integrating force in the breast cancer research arena.

BIG's research is supported in part by its philanthropy unit, known as *BIG against breast cancer*. This denomination is used to interact with the general public and donors, and to raise funds for BIG's purely academic breast cancer trials and research programs. BIG against breast cancer conducts vital fundraising to help finance academic clinical trials and research programs that have no commercial interest but are crucial for patients with breast cancer. The funds raised provide the means for BIG's member groups (made up of breast cancer experts across the globe), and their affiliated hospitals, to finance their efforts and patients' participation in one or more BIG studies. Between 2012 and 2020, 94.4% of all funds BIG received, including from BIG against breast cancer's philanthropic activity, were spent directly on BIG's research.

For further information, please visit the BIG website: www.bigagainstbc.org, or contact Oriana Spagnolo, Communications Manager (Tel: +32 479 814831, Email: communications@bigagainstbc.org).

**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


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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 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*