

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

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