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

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