AstraZeneca, Daiichi's breast cancer drug gets FDA nod as first-line treatment

Enhertu originally won U.S. approval in late 2019 as a third-line treatment for HER2-positive breast cancer patients.

The U.S. Food and Drug Administration has approved AstraZeneca and partner Daiichi Sankyo's Enhertu in combination with Roche's drug, Perjeta, for the first-line treatment of patients with a type of breast cancer, the regulator said on Monday.

Enhertu originally won U.S. approval in late 2019 as a third-line treatment for HER2-positive breast cancer patients.

The new approval allows the use of Enhertu with Roche's Perjeta to treat adults with advanced HER2-positive breast cancer confirmed by an FDA-approved test.

Enhertu, already approved for certain breast, gastric and lung cancers, is an antibody-drug conjugate that delivers chemotherapy directly to HER2-positive cancer cells, helping reduce harm to healthy tissue.

Roche's Perjeta, developed by Genentech, was first approved in June 2012 for use with trastuzumab and chemotherapy in previously untreated HER2-positive metastatic breast cancer.

The FDA also cleared two companion diagnostic tests to identify patients with HER2-positive breast cancer eligible for treatment with Enhertu and Perjeta.

The approval is based on the results from a study that enrolled 1,157 patients with advanced HER2-positive breast cancer who had not received prior chemotherapy for metastatic disease.

The combination of Enhertu and Perjeta extended median progression-free survival to 40.7 months, compared with 26.9 months for the standard treatment.

In the study, tumors shrank or disappeared in 87% of patients on the new combination, compared with 81% on standard treatment.

However, overall survival data was not yet mature at the time of analysis, with 16% of patients having died across both study arms. (Reporting by Siddhi Mahatole in Bengaluru; Editing by Alan Barona)

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