Ribociclib added to endocrine therapy extends survival in postmenopausal patients with metastatic breast cancer

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A study led by researchers from The University of Texas MD Anderson Cancer Center showed a significant overall survival benefit with ribociclib plus endocrine therapy for postmenopausal patients with hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer. This is the first demonstration of a survival advantage with a front-line CDK4/6 inhibitor in postmenopausal patients with HR+/HER 2- advanced breast cancer.

The randomized Phase III MONALEESA-2 trial showed a survival advantage of 63.9 months with front-line ribociclib, a CDK4/6 inhibitor, and the aromatase inhibitor letrozole, compared to 51.4 months with hormone therapy alone. The estimated six-year survival rate was 44.2% with ribociclib, compared with 32% for placebo. Gabriel Hortobagyi, M.D., professor of Breast Medical Oncology, presented the findings at the virtual European Society for Medical Oncology (ESMO) Congress 2021.

"These findings build on previous MONALEESA trials that achieved a survival benefit with the addition of ribociclib," said Hortobagyi. "I am very encouraged that metastatic breast cancer patients may have a treatment option that extends survival, delays chemotherapy treatment and preserves their quality of life."

Previously reported MD Anderson research showed that ribociclib and letrozole improved progression-free survival of postmenopausal women with HR+ metastatic breast cancer in the MONALEESA-2 trial, while the combination reported an improved progression-free and overall survival benefit in premenopausal patients with advanced HR+ breast cancer, according to results of the MONALEESA-7 trial.

The international double-blind study, MONALEESA-2, enrolled 668 postmenopausal women with advanced breast cancer at 223 trial sites in 29 countries. They were randomized to receive either ribociclib and letrozole, or letrozole and placebo. None had been previously treated for their advanced disease. Trial participants were 82.2% white, 7.6% Asian, 2.5% Black and 7.6% other.

The median follow-up was 79.7 months, and the time to first chemotherapy treatment was 50.6 months for patients who received ribociclib, compared to 38.9 months for placebo.

No new safety signals were observed, and adverse events were consistent with earlier reported Phase III MONALEESA trial results.

"Given these results, the combination of a CDK4/6 inhibitor plus an aromatase inhibitor should be the standard first-line treatment for the majority of patients with advanced hormone receptor–positive breast cancer," said Hortobagyi. "These findings have the potential to impact most women diagnosed with metastatic breast cancer."

The study was sponsored by Novartis Pharmaceuticals Corporation, which markets ribociclib (Kisqali). Hortobagyi serves as a paid consultant for Novartis, and MD Anderson received funds from Novartis to conduct this study. A full list of collaborating researchers and their disclosures are included in the abstract.