Clinical trial: Adding ribociclib to hormone therapy improves outcomes in patients with early breast cancer

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A study involving UCLA Jonsson Comprehensive Cancer Center researchers found when ribociclib, a targeted therapy drug, is added to hormone therapy there are a significant invasive disease-free survival benefit in patients with early hormone-receptor (HR) positive/HER2 negative breast cancer.

Researchers found that patients who took the combination therapy had substantially longer invasive disease-free survival compared to those who were treated with the hormone therapy alone, regardless of whether the cancer has spread to the lymph nodes. The addition of the targeted therapy reduced the risk of recurrence by 25%.

The results were shared today during the American Society of Clinical Oncology Annual Meeting by Dr. Dennis Slamon, chair of hematology-oncology and director of clinical and translational research at the UCLA Jonsson Comprehensive Cancer Center.

"The results from the clinical trial have immediate implications for patients," said Slamon. "The findings show this combination is a treatment of choice for patients with stage 2 or stage 3 HR positive/HER2 negative breast cancer."

HR positive/HER2 negative breast cancer is the most common subtype of the disease and accounts for nearly 70% of breast cancer cases in the Unites States.

Previously, Slamon and researchers at the Jonsson Cancer Center demonstrated that adding ribociclib, a cyclin-dependent kinase inhibitor, to the standard hormone therapy improves overall survival in both premenopausal and postmenopausal women with metastatic HR positive/HER2 negative breast cancer.

Slamon also led the discovery program that found that cyclin-dependent

kinase inhibitors are effective in treating hormone receptor positive breast cancer. These drugs work by blocking the activity of cyclin-dependent kinase 4/6 enzymes, which promote cell division and cancer growth.

This work ultimately helped lead to the FDA approval of ribociclib and other related drugs to treat metastatic breast cancer. There are now three CDK4/6 inhibitors that have been approved by the FDA for combination treatment with standard hormone therapies in the metastatic setting.

Building on this past research, the team assessed whether the treatment combination could also improve outcomes in early breast cancer.

The clinical trial, called NATALEE, involved 5101 patients with stage 2 or stage 3 early HR positive/HER2 negative breast cancer. Patients were randomized into two arms: 2549 were randomized to the combination treatment and 2552 to the hormone therapy alone. Invasive disease-free survival was the primary endpoint of the study.

The median duration on study follow-up was 34 months, with three-year and two-year duration of ribociclib completed by 20% and 57% patients respectively. Invasive disease-free survival was evaluated after 426 events.

At the time of this analysis, 189 people in the ribociclib group (7.4% of patients) experienced an invasive disease-free survival event, compared to 237 people in the hormone therapy alone group (9.3% of patients). The data showed a statistically significant improvement in the risk of invasive disease in favor of the combination arm.

The invasive disease-free survival rates at three years were 90.4%, compared to 87.1% for women who were treated with only hormone therapy.

Ribociclib at 400 mg had a favorable safety profile with no new signals.

"Overall, the combination therapy showed more favorable outcomes, significantly reducing the risk of the cancer returning," Slamon said. "These results should change how we evaluate and treat patients."

The study was sponsored by Novartis, which developed ribociclib at the Novartis Institutes for BioMedical Research under a research collaboration with Astex Pharmaceuticals.

More information: Conference: conferences.asco.org/am/attend

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