First-Line Kisqali Shows Overall Survival Benefit for Metastatic Breast Cancer

Adding the CDK 4/6 inhibitor to hormone prolonged survival by a year.

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Adding a CDK 4/6 inhibitor to first-line hormonal treatment prolongs survival by one year for postmenopausal women with hormone receptor (HR) positive, HER2 negative advanced breast cancer, according to late breaking results of the MONALEESA-2 trial presented at the European Society for Medical Oncology (ESMO) Congress 2021.

This is the first report of a statistically significant and clinically meaningful overall survival benefit in this patient population.

Study author Prof. Gabriel N. Hortobagyi, Professor of Medicine, Department of Breast Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, US said: "Previous studies have shown that CDK 4/6 inhibitors in combination with standard hormonal treatment prolong the duration of disease control, also called progression-free survival (PFS), by approximately one year. These drugs were subsequently approved by the regulatory agencies and have been available for patients with HR positive, HER2 negative advanced breast cancer. Today's results add to this by showing that the CDK 4/6 inhibitor ribociclib extends survival by one year."

The trial randomly allocated 668 patients to ribociclib [Kisqali] plus the aromatase inhibitor letrozole or placebo plus letrozole. Patients were excluded if they had previously received a CDK 4/6 inhibitor, chemotherapy or endocrine therapy in the advanced setting.

As already reported, the median PFS was 25.3 months for ribociclib plus letrozole and 16.0 months for placebo plus letrozole. Overall survival was evaluated after 400 deaths and showed a median duration of 63.9 months for ribociclib plus letrozole compared with 51.4 months for placebo plus letrozole.

Hortobagyi commented: "To put these results into perspective, in my 45 years as an oncologist there have been tens of thousands of clinical trials for breast cancer and while a PFS benefit has been shown many, many times, we have rarely observed an improvement in overall survival. It is difficult to show a statistically significant extension in survival for first-line therapy in this type of breast cancer because due to the development of resistance, patients receive four to 15 different

types of treatment over the course of their disease and these dilute the effect of the first therapy."

Commenting on the findings, Prof. Giuseppe Curigliano, Clinical Director, Division of Early Drug Development for Innovative Therapy, European Institute of Oncology, Milan, Italy pointed out: "It is important to note that these data are related to endocrine-sensitive patients who had not previously received endocrine therapy for metastatic disease. The clinical implication is that now we have a clear demonstration that the combination of endocrine therapy plus the CDK 4/6 inhibitor ribociclib prolongs both progression-free survival and overall survival."

"My advice would be to compare the exceptional responders and long-term survivors with the exceptional progressors and short-term survivors," Curigliano said, hinting at the need for further research: "This could identify biological features that may predict which patients benefit the most from this therapy. If a mechanism of resistance is found, then research could be conducted to develop new therapies for the non-responders."

Hortobagyi noted that research is ongoing to examine whether there are any subgroups in the study that benefitted more or less from treatment. "We are also looking for biomarkers, meaning proteins or other substances that could be tested to tell the physician which patients are likely to respond to therapy and which patients are unlikely to respond," he said. "Those are very important decisions because these drugs are enormously expensive and while they are well tolerated, they do produce some side-effects and toxicities."

He added that the findings can be generalized to patients with this type of cancer around the world: "This trial included patients from 29 countries in Western Europe, the Americas and East Asia and the results can be extrapolated to HR positive, HER2 negative metastatic breast cancer regardless of their ethnicity."

Hortobagyi concluded: "While this is the only CDK 4/6 inhibitor to demonstrate an overall survival benefit in this patient population so far, we are still waiting for results of the palbociclib and abemaciclib trials. And of course there are other emerging treatments such as other kinase inhibitors so there is more research to come in this field."

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