Novartis medicine, ribociclib, prolongs progression-free survival for pre- and perimenopausal patients with aggressive HR+/HER2– metastatic breast cancer compared to chemotherapy

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- RIGHT Choice Phase II trial is the first randomized study in patients with aggressive HR+/HER2– metastatic breast cancer (MBC), including visceral crisis, comparing a CDK4/6 inhibitor (CDK4/6i) plus endocrine therapy (ET) versus combination chemotherapy (CT).
- Ribociclib plus ET demonstrated a statistically significant progression-free survival (PFS) benefit of one year compared to combination CT.
- Ribociclib is a unique CDK4/6i that has consistently shown statistically significant overall survival benefit while preserving or improving quality of life across three Phase III trials in MBC, including in patients with aggressive disease.

In patients with aggressive hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2–) metastatic breast cancer (MBC), including those with visceral crisis, ribociclib plus endocrine therapy (ET) has a statistically significant progression-free survival (PFS) benefit of one year compared to combination chemotherapy (CT).

This was the key finding of RIGHT Choice Phase II trial, the first randomized study comparing a CDK4/6 inhibitor (CDK4/6i) plus ET versus CT in this hard-to-treat patient population.[1]

“Chemotherapy has remained the preferred option for patients with rapidly progressing disease and visceral crisis, despite the widespread adoption of CDK4/6 inhibitors plus ET as first-line treatment for HR+/HER2- MBC. The results of this important study support the superiority of ribociclib plus ET for this patient population whose treatment can be very challenging,” said Dr. Gerardo Cornelio, Director, Cancer Institute, St. Luke’s Medical Center-Bonifacio Global City.

“Ribociclib is a unique CDK4/6 inhibitor with the most robust evidence demonstrating overall survival and quality of life benefits for a wide spectrum of patients, including those with aggressive disease. RIGHT Choice adds to the breadth of data that supports ribociclib as the first-line treatment of choice for patients with MBC, including those with visceral crisis,” said Dr. Giovell Barangan, Chief Scientific Officer, Novartis Healthcare Philippines, Inc.

“Novartis aims to tackle breast cancer with bold science, collaboration, and a passion for transforming patient care. We take a bold approach to our research by including patient populations who are often neglected in clinical trials, identifying new pathways or mutations that may play a role in disease progression, and developing therapies to help extend and improve the lives of patients. Chemotherapy is an effective treatment option however with clear disadvantages from having severe side effects which impact quality of life. Our goal is to elevate current standards of care by providing patients with options that are safer and more convenient while being just as effective,” said Mr. Joel Chong, Country President, Novartis Healthcare Philippines, Inc.

About RIGHT Choice Phase II trial

The study enrolled 222 patients with aggressive forms of HR+/HER2– MBC (i.e., with symptomatic visceral metastases, rapid disease progression or markedly symptomatic non-visceral metastases), including more than 50% of patients with visceral crisis as determined by investigators; ribociclib plus ET doubled the median PFS vs. combination CT at 24.0 months compared to 12.3 months (HR=0.54; 95% CI: 0.36-0.79; p=.0007) in the first-line setting.

Median time to treatment failure with ribociclib plus ET was 18.6 months compared to 8.5 months with combination CT (HR=0.45; 95% CI: 0.32-0.63). Furthermore, patients in the ribociclib plus ET arm of the trial reported lower rates of treatment-related serious adverse events (AEs) and lower rates of discontinuation due to treatment-related AEs, compared to patients in the combination CT trial arm. Overall, the ribociclib safety profile was consistent with previously reported data.

About ribociclib

Ribociclib belongs to a newer class of medicines called CDK4/6 inhibitors. A targeted therapy, ribociclib targets specific proteins known as cyclin-dependent kinases 4 and 6 (CDK4/6) thereby interrupting the process through which breast cancer cells divide and multiply.

Ribociclib is the only CDK4/6 inhibitor with proven overall survival benefit across all its three pivotal Phase III advanced breast cancer trials, and is recognized by the National Comprehensive Cancer Network (NCCN) guidelines as the only CDK4/6 inhibitor with overall survival benefit in first-line HR+/HER2- advanced breast cancer. Additionally, ribociclib has the highest rating of any CDK4/6 inhibitor on the European Society of Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale, achieving a score of five out of five for first-line premenopausal patients with HR+/HER2- advanced breast cancer. Further, ribociclib in combination with either letrozole or fulvestrant has uniquely, among other CDK4/6 inhibitors, received a score of four out of five for postmenopausal patients with HR+/HER2- advanced breast cancer treated in the first line.[2]

References:

1. https://www.novartis.com/news/media-releases/novartis-kisqali-prolonged-pfs-benefit-pre-and-perimenopausal-patients-aggressive-hrher2-metastatic-breast-cancer-compared-chemotherapy
2. https://www.novartis.com/news/media-releases/novartis-kisqali-adds-one-more-year-survival-benefit-broadest-set-patients-including-those-aggressive-hrher2-advanced-breast-cancer

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