

# Philippine FDA approves Novartis drug, ribociclib, for advanced breast cancer in males

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The Philippine Food and Drug Administration (FDA) has approved ribociclib for the treatment of metastatic breast cancer. Ribociclib in combination with an aromatase inhibitor or fulvestrant can be used to treat postmenopausal women and men with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer after disease progression following an endocrine-based regimen. In pre or peri-menopausal women or in men, endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.<sup>1</sup>

## Breast Cancer in Males

Breast cancer is the most common cancer among Filipino women.<sup>2</sup> While often thought as a disease that only affects women, breast cancer can develop in men in rare cases. Paguirigan et al looked at medical records involving male breast cancer patients who underwent surgery and treatment at the Philippine General Hospital (PGH) from January 2008 to December 2017. They found that male breast cancer accounted for 15 (0.26%) of 5,777 resected breast specimens for breast cancer patients with a 1:384 male to female ratio. The average age of the male patients when they were diagnosed with breast cancer at PGH was 60 years. Sixty-seven percent were Stage II and 20% Stage III breast cancer.<sup>3</sup>

“Breast cancer is rare among Filipino men and often diagnosed at a later age and at an advanced stage. Because of its rarity, awareness [on breast cancer in males] is necessary not only in the community but also among healthcare providers to identify and treat the problem earlier. Further investigation and prospective studies are recommended,” Paguirigan et al concluded.

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## Ribociclib in the Treatment of Breast Cancer

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.<sup>4</sup>

“The study by Paguirigan et al showed that breast cancer in Filipino men is often diagnosed at a later age and at an advanced stage. As such, the Philippine FDA approval of ribociclib for male breast cancer patients is a welcome development. Ribociclib has demonstrated significant survival benefit in the first line setting in patients with more aggressive disease. It is the only CDK4/6 inhibitor to show a consistent overall survival benefit in combination with endocrine therapy, while also maintaining quality of life across the Phase III program,” said Dr. Arnold John B. Uson, President, Philippine Society of Medical Oncology (PSMO).

“Novartis is pleased with the Philippine FDA approval of the indication extension of ribociclib to include male breast cancer patients. We've taken a bold approach to our research by including patient populations often neglected in clinical trials, identifying new pathways or mutations that may play a role in disease progression and developing therapies that not only maintain, but also improve, quality of life for patients. Our priority over the past 30 years and today is to deliver treatments proven to improve and extend lives for women and men diagnosed with metastatic breast cancer<sup>4</sup>,” said Mr. Joel Chong, President and Managing Director, Novartis Healthcare Philippines, Inc.

## References:

1. Safety Label Changes Form on file
2. 2015 Philippine Cancer Facts and Estimates
3. Paguirigan et al. Male Breast Cancer: The Philippine General Hospital Experience. Philippine Journal of Surgical Specialties. Vol. 76, No. 2, July-December, 2021. <https://pcs.org.ph/wp-content/uploads/2022/03/1PCS-Journal-76-2-Male-Breast-Cancer.pdf>
4. <https://www.novartis.com/news/media-releases/novartis-kisqali-adds-one-...>

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