



PRESS CLIPPING SHEET

| PUBLICATION: | Business Today |
|---------------|---|
| DATE: | July-2019 |
| COUNTRY: | Egypt |
| CIRCULATION: | 10,000 |
| TITLE : | Novartis Global announces unprecedented results for |
| | advanced breast cancer in premenopausal patients. |
| PAGE: | 19 |
| ARTICLE TYPE: | Agency-Generated News |
| REPORTER: | Staff Report |
| AVE: | 3,000 |

Novartis Global announces unprecedented results for advanced breast cancer in premenopausal patients



Novartis Global has announced statistically significant overall survival (OS) results for ribociclib in combination with endocrine therapy at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO). The results offer women with advanced breast cancer a lifeline and hope for a longer life.

"The results announced by Novartis have received great media attention globally, which is a true testament to their significance," said Dr. Mohsen Mokhtar, Professor of Oncology at the Qasr Al Ainy.

"The study, which involved more than 600 cases of advanced premenopausal breast cancer under the age of 59, revealed that patients who received a combined treatment of a daily ribociclib pill and hormone therapy increased their life expectancy after diagnosis compared to women who only received the hormone therapy." Mokhtar said, adding, "Combined therapy works to reduce the growth of cancer cells and slow the progression of the disease. It may not lead to full recovery but offers hope for a longer life.

"Overall Survival represents the length of time patients remain alive, following either their initial diagnosis or the commencement of treatment. It is also one of the ways scientists can determine how effective a new medication or treatment protocol is when tested in clinical trials," Mokhtar explained.

"The MONALEESA-7 trial evaluated ribociclib plus endocrine therapy (goserelin plus either an aromatase inhibitor or tamoxifen) as initial treatment compared to endocrine therapy alone in pre- and perimenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer. The results have been published in The New England Journal of Medicine (NEJM)," he noted. Advanced breast cancer in premenopausal women is an aggressive disease and is the leading cause of cancer-related death in women aged 20-59 years. In Egypt, 50% of new breast cancer cases are diagnosed in premenopausal women. The median age of women diagnosed with breast cancer in the MENA region stands at 48, almost ten years below the median age for breast cancer patients in Western countries.

"Novartis is determined to reimagine medicine by focusing on patient populations that have been previously neglected, and premenopausal women have been an underserved subgroup when it comes to advanced breast cancer research, and as part of our commitment to our patients we have worked on rectifying this imbalance with the development of ribociclib," Dr. Sherif Amin, Novartis Oncology General Manager EMTL- Egypt, Morocco, Tunisia and Libya, "the clinical trial results we are sharing with you today are highly promising.

"As of now ribociclib is the only CDK4/6 inhibitor to achieve statistically significant overall survival benefit in combination with endocrine therapy," Amin said.

"The MONALEESA-7 study has demonstrated that ribociclib is the first drug in the CDK 4/6 inhibitor class to improve overall survival in metastatic breast cancer," Dr. Hamdy Abdel Azim, Professor of Oncology at the Qasr Al Ainy said, "results showed ribociclib significantly extends life in premenopausal women with HR+/HER2- advanced breast cancer. After a median of 42 months follow-up, the survival rate was 70.2% for women who received endocrine therapy alone.

"The MONALEESA-7 data met the efficacy criteria for superior overall survival earlier than anticipated. These results add to the efficacy and safety profile of ribociclib and solidify it as a standard of care for premenopausal women living with HR+/HER2- advanced breast cancer," he added.

Ribociclib is approved for use in more than 75 countries around the world, including the United States and European Union member states. Ribociclib in combination with an aromatase inhibitor was approved for the treatment of pre-, peri- or postmenopausal women as initial endocrine based therapy, and also indicated for use in combination with fulvestrant as both first- or second-line therapy in postmenopausal women by the FDA in July 2018 and by the EC in December 2018. Regulatory filings are underway with other health authorities worldwide.