

# Cancer research Breast cancer drug cuts risk of most common form returning by 25%

Trial results presented at US oncology conference suggest ribociclib could be gamechanging and boost survival rate significantly

#### Andrew Gregory Health editor in Chicago

@andrewgregory
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Thousands of women with the world's most common form of breast cancer could benefit from a blockbuster drug that helps them live longer and cuts the risk of the disease returning by a quarter.

More than 2 million people globally are diagnosed each year with the disease, which is the world's most prevalent cancer. Although treatments have improved in recent decades, many patients will later experience the cancer returning. If a recurrence does occur, it is often at a more advanced stage.

Now, "very promising" research presented at the American Society of Clinical Oncology (Asco) annual meeting, the world's largest cancer conference, suggests a new targeted therapy drug, ribociclib, could be gamechanging. Trial results show it can boost survival and significantly slash the chances of cancer coming back.

Ribociclib has previously shown survival benefits in breast cancer patients whose disease has spread. But in the new study, researchers discovered it may also boost outcomes for patients with much earlier-stage disease, including those with cancer that has not yet spread to the lymph nodes.

The findings excited researchers and oncologists at Asco's annual meeting in Chicago because the data suggests the drug, also known as Kisqali, could ward off the threat of cancer returning in a broad population, and change global practice.

Ribociclib is a targeted therapy called a small molecule inhibitor. It works by targeting proteins in breast cancer cells called CDK4 and CDK6, which modulate cell growth, including the growth of cancer cells.

### CDK4/6 inhibitors and the cell cycle

The cell cycle - Steps a cell undergoes to make two new daughter cells



1 Cell prepares for division.

2 Genetic material replicates.

3 Further growth in preparation for division. 4 Nuclear division, followed by cell division, creates daughter cells.

The late-stage trial of the drug showed it cut the risk of recurrence by 25% when used with standard hormone therapy, rather than hormone therapy alone, after traditional treatments.

It has already been approved by regulators, including in the UK and US, to treat breast cancer that has spread to other body parts. But the earlier-stage setting, when tumours can still be surgically removed, is seen as a much bigger breakthrough due to the huge numbers of patients it could help.

Breast cancer patients are typically offered surgery and chemotherapy or radiation treatment before taking hormone blocking drugs to try to stop the disease recurring.

Adding ribociclib to hormone therapy showed a "significant improvement" in disease-free survival times for patients with hormone receptor-positive, HER2-negative early-stage breast cancer, the study found.

Hormone receptor-positive, HER2-negative breast cancer is the most common subtype of the disease, making up nearly 70% of all breast cancer cases in the US.

"Currently, approved targeted treatments can only be used in a small population of patients diagnosed with hormone receptorpositive, HER2-negative early breast cancer, leaving many without an effective treatment option for reducing risk of the cancer returning," said lead author Dr Dennis Slamon, the director of clinical and translational research at the UCLA Jonsson Comprehensive Cancer Center in Los Angeles.

About one-third of those with stage two hormone receptor-positive, HER2-negative disease experience a recurrence after standard treatment and more than half of people with stage three disease will see their cancer return, said Slamon.

"Thus, there is a significant unmet need for both reducing the risk of recurrence and providing a tolerable treatment option that keeps patients cancer-free without disrupting their daily life."

The Natalee study involved 5,101 patients who were given either ribociclib for three years alongside five years of hormonal therapy or the hormonal therapy alone.

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After three years, 90.4% of those taking ribociclib remained free of disease, compared with 87.1% in the hormonal therapy alone group. Ribociclib also showed more favourable outcomes in overall survival, recurrence-free survival, and distant disease-free survival, according to the researchers.

"While early, these results are very promising and suggest that there will be a role for adjuvant ribociclib for stage two and higher hormone receptor-positive, HER2-negative breast cancer," said Dr Rita Nanda, an Asco expert in Chicago, who was not involved with the study.

Dr Kotryna Temcinaite, the head of research communications at Breast Cancer Now, hailed the results as positive news for patients. "Researchers found that when combined with hormone therapy, ribociclib significantly reduced the chances of the disease returning in women with oestrogen receptor-positive, HER2-negative primary breast cancer.

"We know many women and their loved ones worry about breast cancer returning after treatment so new treatments like ribociclib, which can reduce this risk, are incredibly welcome.

"This treatment must now be swiftly submitted for licensing, and assessed for use on the NHS, so this group of primary breast cancer patients have the chance to benefit from it as soon as possible."

Dr Catherine Elliott, director of research and partnerships at Cancer Research UK, said: "While more research is required, the initial early results from the ongoing Natalee trial are promising.

"The combination of ribociclib and hormonal therapy could provide a new treatment option for people with this type of early-stage breast cancer, reducing the risk of the disease coming back and improving survival."

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