

New breast cancer drug may benefit younger women, too

6 December 2017, by Amy Norton, Healthday Reporter



(HealthDay)—Adding a new drug to standard treatment can slow the progression of advanced breast cancer in younger women, a new clinical trial has found.

The drug, called ribociclib (Kisqali), was approved by the U.S. Food and Drug Administration in March for the treatment of postmenopausal [women](#) with advanced [breast](#) cancer.

Now, experts say, the drug is just as effective for premenopausal women.

In the trial, the treatment typically doubled the time a woman remained free of cancer progression—from roughly one year to two years.

That benefit is "strikingly similar" to what's been seen in postmenopausal women, said Dr. Neil Iyengar, who specializes in treating breast cancer at Memorial Sloan Kettering Cancer Center in New York City.

Breast cancer occurs most often in older women,

and tumors that develop before menopause tend to be more aggressive, explained Iyengar.

"This is an important study because it addresses the question of whether a treatment is as effective for premenopausal women as it is for postmenopausal women," he said. Iyengar was not involved in the research.

Kisqali is one of several new drugs called CDK4/6 inhibitors. They work by blocking two proteins that help cancer cells grow and divide.

The drug was specifically approved as a first-line treatment for postmenopausal women with advanced breast cancer that is hormone receptor-positive—which means estrogen fuels the cancer's growth.

It is meant to be used along with an [aromatase inhibitor](#), a drug that blocks estrogen production in [postmenopausal women](#). Aromatase inhibitors can be given to premenopausal women if they're used with medication that shuts down the ovaries' production of estrogen.

The new trial involved 672 women with [advanced breast cancer](#), aged 25 to 58, who were premenopausal or going through menopause.

All of the women were given standard hormonal therapy—an aromatase inhibitor or the drug tamoxifen—plus ovary-suppressing medication. Half were randomly assigned to take Kisqali in addition. The other half took inactive placebo tablets.

The main focus of the trial was "progression-free survival"—how long a patient lives without the cancer getting worse.

Overall, women taking Kisqali were typically progression-free for two years, versus 13 months for women on standard treatment only.

The findings offer "clear proof" that the drug can work just as well for [younger women](#), said the trial's lead researcher, Dr. Debu Tripathy. He's a professor of medicine and chairman of the breast medical oncology department at the University of Texas M.D. Anderson Cancer Center, in Houston.

Tripathy cautioned, though, that Kisqali is not yet approved for [premenopausal women](#).

Last month, Kisqali's maker Novartis said it would "begin discussions" with drug regulators based on these trial results.

Tripathy, who is a paid consultant to Novartis, was scheduled to present the findings Wednesday at the San Antonio Breast Cancer Symposium. Research presented at medical meetings should be viewed as preliminary until published in a peer-reviewed journal.

Kisqali does have downsides. For instance, it's known to often cause a drop in certain white blood cells that help fight off infections.

In this study, three-quarters of the women who took Kisqali had a decline in blood cells called neutrophils, though most didn't have symptoms, according to Tripathy.

A small number of women had what's called a QT prolongation—a change in the heart's electrical activity that can trigger an abnormal heart rhythm. Novartis says that as a "precaution," Kisqali patients should have their heart activity checked before and during treatment.

The study does not answer the question of whether the [drug](#) ultimately extends women's lives, Tripathy said.

But, he added, that's a tough question, because once a woman's [cancer](#) progresses, she'll typically try other treatments—like chemotherapy or newer "targeted" drugs.

Iyengar agreed. And, he said, researchers are still trying to figure out the best course of treatment once patients do have a progression.

For now, Iyengar said, "this study gives us new and convincing evidence that a lot of doctors and patients will want to consider."

Cost, and what insurance will cover, is another issue. Kisqali, like other CDK4/6 inhibitors, costs thousands of dollars for one 28-day cycle of [treatment](#).

More information: Debu Tripathy, M.D., professor of medicine and chairman, Breast Medical Oncology Department, University of Texas M.D. Anderson Cancer Center, Houston; Neil Iyengar, M.D., medical oncologist, Memorial Sloan Kettering Cancer Center, New York City; presentation, San Antonio Breast Cancer Symposium, San Antonio, Texas, Dec. 6, 2017

The U.S. Centers for Disease Control and Prevention has more on [breast cancer in younger women](#).

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