

New drug regimens may slow advanced breast cancer

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Survival lengthened in studies of two experimental treatments.

(HealthDay)—An experimental cancer drug may delay the progression of some advanced breast cancers, while a double dose of an existing cancer drug could help women live longer, according to separate studies reported Wednesday.

In one study, of nearly 200 women, researchers tested the effects of adding the <u>experimental drug</u> —known for now as PD 0332991—to Femara (<u>letrozole</u>), a hormonal therapy already used to treat certain breast cancers.

They found that women on the combination had a much longer "progression-free survival"—the time a <u>cancer patient</u> lives with the disease without it getting worse. For women on the combination therapy, that period was typically 26 months, versus less than eight months among women given Femara alone.

"That's a dramatic difference," said lead researcher Dr. Richard Finn, associate professor of medicine at the University of California, Los Angeles, Jonsson Comprehensive Cancer Center.

Finn noted that in oncology clinical <u>trials</u>, success is measured in very small steps. A new drug might

extend patients' lives by a matter of a couple of months, for instance.

The women in the trial all had advanced cancer that had spread beyond the breast. Their tumors were also estrogen-receptor positive, which means the cancer depends on estrogen to feed its growth and spread.

"ER-positive <u>breast cancer</u> is the most common form of breast cancer," Finn said. "And while we do have effective therapies for it, we still need to improve upon them."

The experimental drug is made by Pfizer, Inc., which also funded the trial. A larger trial is set to start next year, but Finn said these early results are "encouraging."

He was scheduled to present the findings Wednesday at the 2012 San Antonio Breast Cancer Symposium in Texas. Data and conclusions of studies released at medical meetings are considered preliminary, since they haven't undergone peer review for publication in a medical journal.

In a separate study reported at the meeting, researchers found that doubling the dose of an existing breast cancer drug, Faslodex (fulvestrant), lengthened women's lives by a few months.

Like the other trial, this one focused on older women with advanced ER-positive cancer. Faslodex is an injected form of hormonal therapy that works by blocking the effects of estrogen on breast cancer cells; it's given to postmenopausal women whose cancer has worsened despite antiestrogen therapies such as tamoxifen.

Among more than 700 women in the trial, those randomly assigned to a 500-milligram dose of Faslodex typically lived about four months longer: 26 months versus 22 months among women given



the standard 250-milligram dose.

The higher dose extended lives without increasing validated." <u>side effects</u>, said the researchers, led by Dr. Angelo Di Leo, head of medical oncology at the Hospital of According to the American Cancer Society, the Prato in Italy. average U.S. woman has a 12 percent chance

Faslodex commonly causes side effects such as nausea, vomiting, diarrhea, headaches and hot flashes, and occasionally more serious problems, such as blood clots. In this trial, between 1 percent and 2 percent of <u>women</u> in each group had a serious side effect attributable to the medication.

The trial was sponsored by AstraZeneca Pharmaceuticals, which makes Faslodex.

The higher Faslodex dose has already become the "standard of care," based on earlier findings from the trial, said Dr. Kimberly Blackwell, director of the Duke Breast Cancer Clinic and a professor of medicine at Duke University School of Medicine.

Blackwell, who was not involved in either new study, was more excited about the experimental Pfizer drug.

"We always want to be cautious about a trial that involves fewer than 200 patients," Blackwell said. But, she added, "if this is confirmed in the Phase 3 trial, it could have a big impact on how we treat patients."

What is new about the drug, Finn and Blackwell said, is how it works: It blocks the formation of certain proteins cancer cells need to divide and spread.

Blackwell said the importance of those proteins has long been recognized, but until now, there hasn't been a drug that could safely block them.

"This represents a brand-new way in slowing down breast cancer progression," Blackwell said.

The combination did cause side effects, including fatigue and neutropenia—a decrease in important disease-fighting white blood cells. But these "were manageable side effects," Finn said.

Still, Blackwell said, the safety and ultimate effectiveness of the therapy "remain to be validated."

According to the American Cancer Society, the average U.S. woman has a 12 percent chance of developing breast cancer in her lifetime. Death rates from the disease have dropped in recent decades because of better treatments and earlier detection, experts said.

More information: Learn more about breast cancer from the <u>American Cancer Society</u>.

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