

Studies find new drugs boost skin cancer survival

June 6 2011, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- They're not cures, but two novel drugs produced unprecedented gains in survival in separate studies of people with melanoma, the deadliest form of skin cancer, doctors reported Sunday.

In one study, an experimental drug showed so much benefit so quickly in people with advanced disease that those getting a comparison drug were allowed to switch after just a few months.

The drug, vemurafenib, targets a gene mutation found in about half of all [melanomas](#). The drug is being developed by Genentech, part of Swiss-based Roche, and Plexxikon Inc., part of the Daiichi Sankyo Group of Japan.

The second study tested Bristol-Myers Squibb Co.'s Yervoy, a just-approved medicine for newly diagnosed melanoma patients, and found it nearly doubled the number who survived at least three years.

"Melanoma has just seen a renaissance of new agents," and more are being tested, said Dr. Allen Lichter, chief executive of the American Society of Clinical Oncology.

The new studies were presented Sunday at the oncology group's annual meeting in Chicago and published online by the [New England Journal of Medicine](#).

"This is really an unprecedented time of celebration for our patients,"

said Dr. Lynn Schuchter, of the University of Pennsylvania's Abramson [Cancer Center](#). The [new drugs](#) are not by themselves cures, but "the future is going to be to build upon the success" by testing combinations of these newer drugs, she said.

Melanoma is on the rise. There were 68,000 new cases and 8,700 deaths from it in the United States last year, the [American Cancer Society](#) estimates. Only two drugs had been approved to treat it, with limited effectiveness, until Yervoy, an immune-system therapy, won approval in March.

The [experimental drug](#), vemurafenib, (vem-yoo-RAF-eh-nib), is aimed at a specific gene mutation, making it the first so-called targeted therapy for the disease. The drug got attention when a whopping 70 percent of those with the mutation responded to it in early safety testing.

The new study, led by Dr. Paul Chapman of Memorial Sloan-Kettering Cancer Center in New York, was the key test of its safety and effectiveness. It involved 675 patients around the world with inoperable, advanced melanoma and the gene mutation. They received vemurafenib pills twice a day or infusions every three weeks of the chemotherapy drug dacarbazine.

After six months, 84 percent of people on vemurafenib were alive versus 64 percent of the others.

Less than 10 percent on the drug suffered serious side effects - mostly skin rashes, joint pain, fatigue, diarrhea and hair loss. About 18 percent of patients developed a less serious form of [skin cancer](#). More than a third needed their dose adjusted because of side effects.

The study is continuing, and many remain on the drug, including one of Schuchter's patients: Brian Frantz, a 50-year-old former firefighter from

Springfield, Va.

Within a week or two of starting on the drug in September, "we noticed an improvement" and shrinkage in his many tumors, he said. "It was just a miracle."

Schuchter said that's typical of how patients have responded to the drug.

"Within 72 hours, their symptoms improve, pain medicines can be reduced," she said.

The study is a landmark and the results are "very impressive" in people who historically have not fared very well, said Dr. April Salama, a Duke University melanoma specialist.

The study was sponsored by the drug's makers, and many of the researchers consult or work for them. The companies are seeking approval to sell the drug and a companion test for the [gene mutation](#) in the U.S. and Europe. A Genentech spokeswoman said the price has not yet been determined.

The other new drug, Yervoy, is not a chemotherapy but a treatment to stimulate the immune system to fight cancer. Dr. Jedd Wolchok of Memorial Sloan-Kettering led the first test of it in newly diagnosed melanoma patients.

About 502 of them received dacarbazine and half also got Yervoy. After one year, 47 percent of those on Yervoy were alive versus 36 percent of the others. At three years, survival was 21 percent with Yervoy versus 12 percent for chemotherapy alone.

Side effects included diarrhea, rash and fatigue. More than half on the new [drug](#) had major side effects versus one quarter of those on

chemotherapy alone.

[Bristol-Myers Squibb](#) paid for the study and many researchers consult or work for the company. Treatment with Yervoy includes four infusions over three months and costs \$30,000 per infusion.

More information: Melanoma: <http://bit.ly/mBR8XA>

New England Journal of Medicine: <http://www.nejm.org>

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