FDA panel backs drug for early-stage breast cancer

WASHINGTON (AP) — Government cancer experts say a Rocha drug has shown effectiveness in a new option for treating advanced breast cancer before tumor metastasizes.

The Food and Drug Administration panel voted 15-0, with one abstention, that the benefit of Perjeta to be an initial treatment for breast cancer outweighs its risks.

The recommendation is not binding, but could clear the way for the FDA to approve the drug as the first pharmaceutical option to shrink or delay metastases in women whose tumors have spread.

A study by Rocha's Genentech showed women who received Perjeta as initial treatment were 31 percent more likely to be cancer-free after 12 weeks than women who received other drug combinations.

Perjeta is already approved to treat breast cancer that has spread to other parts of the body, known as metastatic cancer.

But Genentech is seeking approval to market the drug as the first step in treating the disease.

The proposed treatment approach could help shrink tumors, making it easier to remove them. In some cases, that could allow women to keep their breasts rather than having a full mastectomy.

Cancer specialists already use some drugs as initial treatments for breast cancer, but are not formally approved for the use.

Panel chairman Dr. Michael Meeker of the University of Washington said, "We are supporting the movement for a drug for metastatic breast cancer to the clinic, with the hope that women who suffer from breast cancer will live longer and better," said Sibilia, associate professor of medicine at the Cleveland Clinic.

The FDA is considering granting Perjeta accelerated approval, a step used to speed up the introduction of drugs that have shown groundbreaking results in clinical trials.

The panel added that Genentech must continue to study the drug in ongoing trials.

"Today, Genentech must continue to ensure that Perjeta's early promise is confirmed in the earliest stages of the disease, heathier lives for patients," the panel said.

While Genentech backed the drug's benefits, it pointed to ongoing clinical trials with the suggestion that it might not work.

The study was based on a 417-woman study, including a large number of patients with lung metastases. When Perjeta was combined with another Genentech drug, and hormone therapy, 39 percent of women saw their cancer reach undetectable levels. Only 21 percent of women experienced the same result after treatment with chemotherapy alone.

"The other side of the equation is you have to look at the benefit, that is the additional benefit of not killing many more women," said Dr. Richard Pazdur, director of the FDA's office of new drugs.

Early next week, FDA scientists published a very favorable opinion, including that it met the criteria for approval. The FDA is scheduled to make a decision on the drug by Oct. 31.

FDA officials also heard from a group of women whose loved ones benefited from the experimental treatment. But, like Pazdur, said the drug is "too early.""""

Released time before treating the disease is an important and dramatic effect on the financial, emotional, and psychological impact of breast cancer, she said, "for our lives.""

FDA leaders acknowledged the issues, but upheld the panel to consider the potential advantages of getting the drug to market.

Woman featured in stark CDC anti-smoking ads dies of cancer

ATLANTA (AP) — A North Carolina woman featured in a national anti-smoking campaign died Monday of cancer.

Dr. Terrie Hall died at a hospital in Roosevelt, Wash., a spokesman for the Centers for Disease Control and Prevention confirmed Tuesday.

"It was the public health hero," said Dr. Tom Frieden, director of the CDC, who helped campaign against smoking. "For Disease Control and Prevention, Terrie Hall was the Goldilocks, the perfect fit," he said.

A smoker whose voice remains, she was a co-president of BHM-UC Medical Group, a nonprofit public benefit organization in Memphis, Tenn.

"We are encouraged by the news of Terrie's passing," said Terrie Hall's daughter, Jennifer Hall. "She dedicated her life to public health and helping others to make life-saving and lasting changes.""""

A spokesman for the CDC said Hall was a "true leader" who "was a driving force in the fight against smoking."

"We are heartbroken about Terrie's passing," said Hall's son, Dr. Louis Caruso, Cardiologist, Stern Cardiovascular Associates, BHM-UC Medical Group. "We wanted so much for her to be well."

"We Recognize Benefits for Blue Cross Blue Shield, BHM-UC Medical Group," the spokesman said. "From what is being said, she had been in treatment."

"We are encouraged by her work and knew she was being treated."

"We are heartbroken by the news of the death," said Hall's husband, John Caruso. "She was a true pioneer in the public health arena."

"Terrie Hall died at a hospital in Roosevelt, Wash. Of her life, she is being of our lives," said Judy Bridges, who was diagnosed with breast cancer in 2006.

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"What's said, is said."

"What's said, is said."

"What's said, is said."

Baptist's HeartScore test helps in making accurate treatment choice

September 18, 2013

"As a cardiologist, the HeartScore test helps me in making accurate treatment choice in heart disease patients," said Dr. Debra Gerson. "I am able to get the right therapy for my patients with the new HeartScore test and I am able to give them the best possible treatment for their heart disease patients."

"Baptist's HeartScore test is a simple 10-minute scan that can help determine whether patients are at risk for heart disease or heart attack. We use the HeartScore test to help determine whether patients are at risk for heart disease."

"HeartScore is an easy, quick and reliable test."