TODAY, IN 1925
Walter Percy Chrysler founded the Chrysler Corp.

Breast-cancer position is questioned

Tamoxifen now gets renewed backing

By Marilynn Marchione
Associated Press

ATLANTA — Final results from a big study comparing two drugs for preventing breast cancer in high-risk women challenge the government's claim that raloxifene is better than the old standby, tamoxifen.

At a news conference in April, the National Cancer Institute, which paid for the $88 million study, said the two drugs were equally effective at lowering the risk of serious forms of breast cancer.

But users of raloxifene, the newer drug, had 36 percent fewer uterine cancers and 29 percent fewer blood clots, making it a safer choice, government researchers said.

However, data made public yesterday show that the uterine-cancer results were not statistically significant. That means the actual number of cases differed so little that they could have happened by chance.

Scientific standards have long held that such results only suggest trends and are not definitive, certainly not to the extent that government scientists portrayed them to be.

The study tested the drugs in nearly 20,000 postmenopausal women at high risk of breast cancer because of gene mutations, family history or other reasons. Raloxifene is sold as Evista by Eli Lilly & Co. for osteoporosis.

Results were released yesterday at a meeting of the American Society of Clinical Oncology and will be in the June 21 issue of the Journal of the American Medical Association.

Furthermore, so few blood clots occurred in the study that some doctors don't believe that result proves raloxifene is better.

Also, it isn't known whether raloxifene's cancer-prevention benefit will last years after women stop taking the pills, as tamoxifen's is known to do. And so far, raloxifene is approved for only preventing osteoporosis, the bone problem.

"There is some genuine controversy here," said Dr. Len Lichtenfeld, deputy chief medical officer of the American Cancer Society. Not everyone agrees "that there was a clear winner in this study," he said.

The news generated heated discussions at the cancer meeting, where the study's results were to have been first reported so experts could review them as they were released to the public. Instead, the cancer institute hastily called the news conference and didn't disclose in materials sent to reporters that some key results were not statistically significant.

"It needs to be publicly vetted because it's not clear either way" which drug is better, said Dr. Roy Herbst, a University of Texas M.D. Anderson Cancer Center doctor who helped run the oncology meeting, the world's largest cancer conference.

The cancer institute's prevention chief, Dr. Leslie Ford, defended her characterization of raloxifene as a clear winner and the way the news came out. The news conference was called to give women in the study the first word of its results without its "leaking out," as happened with two earlier high-profile women's health studies, Ford said.

Other doctors questioned the urgency, because these drugs are taken for five years to prevent long-term breast-cancer risks — a very different situation from a drug to treat a disease that could have an immediate life-or-death impact.

Tamoxifen has been used for decades to treat and prevent breast cancer. It blunts estrogen, which fuels the growth of most tumors that occur after menopause, but also acts like estrogen elsewhere in the body and has previously been shown to raise the risk of blood clots and uterine cancer. Raloxifene is believed less likely to cause these problems. The safety of raloxifene in premenopausal women is unknown.