

Spiriva as good as Serevent in asthma study

September 19 2010, By ALICIA CHANG , AP Science Writer

(AP) -- Researchers say they've found a possible new treatment for adults with hard-to-control asthma. Their discovery, however, came at a price.

Scientists of a U.S. government-funded [asthma](#) study had to spend nearly \$1 million of taxpayers' money after British drugmaker [GlaxoSmithKline](#) PLC declined to donate its asthma drug and look-alike dummy medicine for the study, which compared two other treatments.

Editors of the [New England Journal of Medicine](#), which published the study, chastised Glaxo, saying its actions made the research harder and more expensive to do. [Drug companies](#) aren't required to supply their medicines for study, but they often do.

"In the end, the study results provided the truth" - the drug, Spiriva, was as good as Glaxo's Serevent, they wrote. The study was published online Sunday to coincide with a presentation at a medical meeting in Barcelona, Spain.

About 300 million people worldwide suffer from asthma. In the U.S., 22 million Americans have asthma, which kills about 4,000 a year. For people who can't control their asthma with inhaled steroid medicine, current guidelines call for doubling the dose or adding a different drug that relaxes the muscles to help patients breathe.

Researchers tested three inhaled treatments: doubling the steroid dose, adding Glaxo's Serevent or adding Boehringer Ingelheim's Spiriva,

which is approved for [emphysema](#) and other chronic lung conditions, but not asthma.

The study involved 210 people whose asthma was not well controlled. They took each drug for 14 weeks with two-week breaks in between treatment.

Researchers found Spiriva worked better than a double steroid dose and was as effective as Serevent. When the study first began, patients on average had 77 asthma-free days a year - days in which they had no symptoms and did not have to use their rescue inhaler.

Doubling the steroid medicine gave patients an extra 19 asthma-free days; taking Spiriva gave them an additional 48 days with no symptoms, and taking Serevent gave them an extra 51 days.

Spiriva is a promising alternative asthma treatment and some doctors are already using it in people who don't respond to steroid medicine, but more study on drug safety is needed, Dr. Lewis Smith of Northwestern University wrote in an accompanying editorial.

Two years ago, safety concerns were raised with Spiriva inhalers. But the Food and Drug Administration earlier this year said recent data do not show a connection between a popular inhaler and previously reported risks of stroke, heart attack and death.

The \$5.3 million study was funded by the National Heart, Lung and Blood Institute. Teva Pharmaceutical Industries supplied the inhaled steroid medicine and Boehringer Ingelheim provided Spiriva. Both companies also donated matching placebos. Researchers bought Glaxo's Serevent.

Glaxo declined to participate because Spiriva is not approved for treating

asthma. The company also "lacked adequate information in this case to understand what the impact would be on patients in the trial," said company spokeswoman Mary Anne Rhyne.

The study's leader, Dr. Stephen Peters of Wake Forest University Baptist Medical Center, said that since his team did not have access to Glaxo's drug, they bought it from a third-party supplier and hired another company to make the placebo - at a cost of \$900,000.

Peters said it's harder to get drug companies to donate their medicine for research compared with a decade ago.

"Now more drug companies are more likely to ponder whether a trial could help them in the marketplace" and decline to provide their products for studies, Peter said.

Peters has received lecture fees from Teva. Several other researchers on the team reported ties with Glaxo and other drug companies.

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

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