

# Study finds key GSK-Theravance lung drug didn't extend lives

September 8 2015, by Linda A. Johnson

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A closely watched study of GlaxoSmithKline plc's Breo Ellipta respiratory treatment failed to prove that it extends patients' lives, denying the drugmaker a much-needed marketing edge in its most lucrative—but declining—medicine category.

It was a disappointing *déjà vu* for the British drugmaker, which previously failed to prove the same benefit for its much older respiratory treatment Advair, long the company's top seller with revenue of \$8.3 billion as recently as 2013.

GlaxoSmithKline and partner Theravance Inc. of South San Francisco, California, had hoped their study, called SUMMIT, would show that Breo Ellipta, a once-a-day inhaled medicine for controlling asthma and chronic obstructive pulmonary disease, reduced the risk of patients dying and rate of lung function decline. The study included 16,485 patients in 43 countries with both heart disease and chronic obstructive pulmonary disease, which includes chronic bronchitis and emphysema.

The SUMMIT results, released Tuesday, indicated a trend toward reduced rates of lung function decline, death from any cause and death from heart attack or stroke, but the results weren't statistically significant, meaning they could have occurred by chance.

Had the results shown a strong reduction in those risks, the companies would have been able to promote Breo Ellipta as the first drug shown to extend lives of this high-risk group—patients who generally take

respiratory medicines for years and often land in hospital ERs due to scary flare-ups when it's difficult to breathe.

Sanford Bernstein analyst Dr. Tim Anderson noted that unlike Glaxo's earlier study of Advair, called TORCH, SUMMIT had better odds of succeeding because it focused on cardiac patients with increased risk of death.

"Unfortunately, SUMMIT did not deliver the goods," Anderson wrote to investors, adding, "Even if results had been positive, it was never clear how impactful they would be because physicians largely view Breo and Advair as interchangeable, and Advair is very well-entrenched."

GlaxoSmithKline has been trying to bolster revenue from its respiratory drug portfolio because Advair has seen sales tumble in recent years, including a 14 percent first-half decline to about \$2.9 billion. Multiple brand-name rivals have forced price cuts and generic competition has slashed sales in several foreign countries.

In the U.S., the patent for Advair expires in August 2016, though generic competition likely won't be immediate because the drug comes inside a special inhaler-like device. Anderson predicts that competition will hit in the U.S. in 2017.

Breo Ellipta, first approved in the U.S. in May 2013, is one of four respiratory medicines approved since then as GlaxoSmithKline tries to build up its respiratory franchise.

Sales of all four have been minimal, though, at less than \$200 million in the first half of this year.

U.S.-traded shares of Glaxo fell about 2 percent after the study results were released, but ended the day up 2.2 percent at \$40.57. Shares of

much-smaller Theravance plunged 15.4 percent to \$13.53.

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