

US panel backs inhaler drug for lung disease

April 17 2013

A panel of U.S. respiratory experts voted Wednesday in favor of approving an experimental inhaler drug from GlaxoSmithKline and Theravance for treating chronic lung disease.

A majority of [Food and Drug Administration](#) panelists voted that the Breo Ellipta inhaler is safe and effective for long-term use and to control flare ups in patients with chronic obstructive pulmonary disorder or COPD.

The FDA is not required to follow the group's recommendation, though it often does. The agency is expected to make a decision by May 12.

The lung ailment, often called smoker's cough, can cause a number of breathing problems, including [chronic bronchitis](#) and emphysema.

Breo is a combination of two respiratory drugs that can help open lung air passages and reduce swelling. The drug is designed to be used with the Ellipta inhaler device.

The British drugmaker said in a statement following the meeting: "This positive recommendation is a crucial first step toward making Breo Ellipta available for appropriate COPD patients across the U.S."

The drug is also under regulatory review in the European Union.

Glaxo, a leader in respiratory medicine, already sells the [asthma treatment](#) Advair, its best-selling product with more than \$4 billion in

sales per year. Breo Ellipta is one of several experimental respiratory drugs on which the U.K. drugmaker and Theravance are collaborating.

Trading of Theravance Inc. was halted Wednesday morning, ahead of the FDA meeting. [GlaxoSmithKline PLC](#)'s U.S.-listed shares rose 95 cents to close at \$50.33 in trading. The broader markets ended lower.

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