Evaluate Vantage

April 18, 2013

Breo breezes past adcom and affirms GSK's COPD lead

Jonathan Gardner

With a positive FDA panel vote on Breo Ellipta, GlaxoSmithKline and Theravance have nosed ahead again in the race to launch innovative therapies for COPD. Endorsement of the inhaled product, which adds a new long-acting beta agonist to the corticosteroid fluticasone, should lend some confidence that the UK group can guard its mainstay respiratory franchise that is currently led by its blockbuster Advair.

The 9-4 vote in favour of approval came despite uncertainty about how much the steroid contributes to improvement in lung function. Investors appear to be anticipating approval now, as witnessed by Theravance's 17% rise to $32.79 in early trading today; the panel vote also sets the scene for a more pivotal event, a decision on the completely novel combination Anoro Ellipta.

No drama

A positive vote for two compounds in classes well established in respiratory disease should not come as a great surprise. Two of the top-selling drugs in COPD, Advair and AstraZeneca's Symbicort Turbuhaler, are combinations of long-acting beta agonists (LABAs) and corticosteroids; thus Breo was a relatively low-risk product.

There had been concerns raised about the link between fluticasone, the corticosteroid component that is also contained in Advair, and pneumonia (*Event – Theravance awaits respiratory domino effect, February 19, 2013*). This did not come to pass – in any case, the no votes resulted more from a concern that fluticasone played only a minor role in efficacy, according to Seamus Fernandez, an analyst at Leerink Swann.

A more important read-across for GSK comes in the backing for the project's LABA constituent, vilanterol trifenate, an all-new compound. Backing is a good sign for the follow-on compound Anoro, which is poised to become the first combination of a LABA and long-acting muscarinic antagonist (LAMA) to reach the US market should it suffer no hiccups at the regulators.

Spiriva, Boehringer Ingelheim's LAMA monotherapy, is the biggest-selling drug in COPD, and the private German firm is undoubtedly keen to protect its own position. It has no combination products, although in January it gained adcom backing for its once-daily LABA, a dosing schedule that has troubled FDA with similar drugs (*Boehringer breathes more easily after Striverdi adcom vote, January 30, 2013*).

Given that both Spiriva and Striverdi are US-approved for once-daily dosing, there is potential for Boehringer to match up with Anoro, although it could be some time before this happens. Novartis, meanwhile, has been sent back for more US-related trials with its LABA/LAMA combination, although a European decision is nearing.

Rising value

Theravance investors, in particular, appear to be hopeful that the Breo vote is a good sign for the entire GSK respiratory partnership. At intraday share prices, the company is now valued at $3.2bn, exceeding the net present value of Breo and Anoro by 20% as calculated by *EvaluatePharma*.

The franchise, particularly Breo, still has much to prove. Patients and physicians are not likely to switch from a product that is working, and GSK will need to demonstrate that the advantage of once-daily dosing, against Advair's twice daily, is significant enough for payers to adopt it on a favourable coverage tier.

Still, analysts are rather bullish, putting 2018 worldwide sales at $1.37bn and earning Theravance $463m in royalties, according to the consensus forecast.

The commercial battle is one for another day. The signs in favour of regulatory approval are good for Breo in particular and the GSK/Theravance stable in general. Rejection for Breo would be a surprise, and would represent a huge setback.

To contact the writer of this story email Jonathan Gardner in London at JonathanG@EPVantage.com or follow @JonEPVantage on Twitter

More from Evaluate Vantage

Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754