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One chance for Glaxo’s triple

Jacob Plieth

The UK company's triple combo just got US approval, and now the group must meet rising analyst expectations.

With US approval of Trelegy Ellipta, the first closed triple for chronic obstructive pulmonary disease, Glaxosmithkline must make the most of the opportunity it now has to get this drug accepted by US payers.

The window creaked open thanks to generics players’ ongoing problems challenging Glaxo’s Advair on the one hand, and the UK company’s shrewd move to accelerate Trelegy’s timeline by 12 months on the other. Baird analysts reckon Glaxo now has significant bargaining power with payers heading into 2018 contract negotiations, and sellside consensus forecast have crept up accordingly.

EvaluatePharma figures show Trelegy selling $780m in 2022. This is an advance on the $672m consensus that existed last November, and the $75m just five months before that.

Meanwhile, there is still no sign of US generic versions of Advair, despite this blockbuster having lost its patent. Generics will come sooner or later – current analyst thinking is that they are 12-18 months away – and Advair has of course already been hit by extreme pricing pressure.

Thus, while Glaxo’s opportunity is bigger than it was not long ago, the COPD triple is destined to become little more than an interesting addition. It too will face price pressure eventually, and Glaxo’s task is now to convince payers that a once-daily single inhaler improves compliance versus the triples many COPD patients already take – Advair plus Spiriva, for instance.

Innoviva hit?

If Trelegy manages to offset some of Advair’s expected decline it is also likely to eat into sales of Glaxo’s follow-ons, the forecast blockbuster combos Breo Ellipta and Anoro Ellipta. This will hit Innoviva, which receives royalties on Breo and Anoro, but will only receive 15% of the 6.5-10% tiered royalty on Trelegy sales, with the rest accruing to Theravance Biopharma.

Still, Glaxo has never scientifically demonstrated the superiority of Trelegy over multiple inhalers; the single pivotal trial supporting Trelegy’s US approval only compared the triple against Symbicort. The company’s stroke of genius was to recognise that this would suffice for approval without awaiting data from a COPD exacerbations study due to read out by the end of 2017.

A trial that did compare a closed triple versus an open combo involved Chiesi’s rival Trimbow, but all this comparison showed was non-inferiority. Trimbow became the first closed triple to get a regulatory green light

in July, but this was in the EU – US development is apparently not being pursued; moreover this is a twice-daily inhaler.

Other competitors include Astrazeneca's PT010, which is in several phase III COPD trials; Novartis recently entered phase III with QVM149 – albeit in asthma – and Boehringer Ingelheim has occasionally been rumoured to be involved too.

However much of the respiratory market opportunity has shrunk over recent years, it must be comforting that there are companies beyond Glaxo that still think that it is worth trying to turn a triple play in this market.

The inhaled triple combination players

Project	Company	Status	Indication	2022e sales ($m)	Trial ID	Completion
Trimbow	Chiesi	EU approved; US not being pursued	COPD	No forecast	NCT01911364 (Trinity; ex-US)	Completed
Trelegy Ellipta	Glaxosmithkline	US approved; EU recommended	COPD	780	NCT02345161 (Fulfil)	Completed
PT010	Astrazeneca	Phase III	COPD	236	NCT02465567	Dec 2018
QVM149	Novartis	Phase III	Asthma	139	NCT02571777	Apr 2019

Source: EvaluatePharma

To contact the writer of this story email Jacob Plieth in London at jacobp@epvantage.com or follow @JacobPlieth on Twitter