

No hiding from respirageddon for Boehringer



[Jacob Plieth](#)

Given the hammering that US prices of respiratory drugs have taken as payers assaulted GlaxoSmithKline's Advair it might come as a shock that sales of Boehringer Ingelheim's blockbuster Spiriva fell just 8% last year.

The decline was due to discounts and rebates implemented to keep the COPD drug on US formularies, volume having remained pretty constant, Boehringer's chairman, Andreas Barner, told yesterday's annual press conference. The fact that the group expects the business overall to return to moderate growth in 2015 could seem surprising, as might its lifecycle management strategy.

While for some big respiratory players like Glaxo and AstraZeneca an evolving combination plan forms the centrepiece of moves to protect the central franchise, this is not Boehringer's idea. As far as combinations go the group looks – for now at least – to stop at a combo of Spiriva with the LABA olodaterol.

"We are not ... developing a triple combination for the time being," said Mr Barner, adding that the [Wisdom trial](#) had shown the limited benefit of adding a steroid into the LAMA/LABA mix. Still, that trial did not consider the triple in a single inhaler; moreover, cynics would say the point of a triple has more to do with generating a new patentable drug than improving efficacy.

The Boehringer combo, trademarked Spiolto/Stiolto, was filed in the US and EU last October, so approval could see it on the market late this year. Mr Barner had previously also questioned the logic of developing a MABA (muscarinic antagonist/beta agonist), thus apparently ruling out another novel respiratory tactic ([Glaxo tries to turn a triple play, February 10, 2015](#)).

Rebate war

Speaking to *EP Vantage* Allan Hillgrove, who heads up Boehringer's pharma marketing and sales, said the dual combo was the key aspect of the group's Spiriva lifecycle management effort, but accepted that pricing might be tough here, too.

"US payers have become increasingly willing to use price as a lever," he said. Companies have tended to deny that this represents a price war, and Mr Hillgrove said it would be more accurate to call it a "rebate war" ([Welcome to respirageddon, February 9, 2015](#)).

Spiriva sales fell 8.1% to €3.3bn (\$3.5bn) last year, dragging group revenue down 5.3% to €13.3bn – something with which Mr Barner said he was not satisfied. Two novel areas – forays into biosimilars and oncology – could help diversify the group in future, though its 2015 "moderate" sales increase target will presumably rely on a recovery in the underlying business.

Yesterday, Boehringer outlined its push into biosimilars, highlighting the first wave of three assets in late development: versions of AbbVie's Humira, and Roche's Rituxan and Avastin. A second wave comprises four undisclosed products – three in immunology and one in ophthalmology that is assumed to be a Lucentis biosimilar.

Certainly Boehringer will face intense competition initially, the first three products having multiple biosimilar copies waiting in the wings from groups including Sandoz, Momenta and Hospira. But it can at least count on its established expertise in contract biologicals manufacturing.

For obvious commercial reasons the company says it will not develop biosimilars of the products it is manufacturing on a contract basis – something that means it will have to choose which path to pursue with which biological in future.

Clarification of the US approval pathway, with a legal verdict last month on the key issues of the "patent dance" and 180-day notice, is slowly making life easier for biosimilars makers, though Boehringer says it is still very hard to predict how these issues will play out longer term.

Silent on Gilotrif

Meanwhile, the burgeoning oncology field is one in which it has made an entry with the launch in 2013 of

Gilotrif for first-line EGFR-mutated non-small cell lung cancer, pitting it head-to-head against AstraZeneca's Iressa and Roche's Tarceva.

Somewhat remarkably, however, Boehringer would not reveal how much Gilotrif had sold in 2014, its first full year on the market, though Mr Hillgrove said launch had gone "pretty much in line with what we expected". Just getting under way is the next stage in Gilotrif's development - combining it with CV9202.

CV9202 is CureVac's cancer vaccine designed around the revolutionary concept of delivering naked mRNA into immune system cells, and is an asset to which Boehringer got rights under a deal last September. The goal of the combo is to raise the efficacy of both, and initial trials in lung cancer have begun.

Boehringer also revealed for the first time that it had started researching second-generation checkpoint inhibitors. Mr Barner said these looked at targets beyond PD-1/PD-L1, but cautioned that work was very early.

And today's hottest oncology area? T-cell therapies could be something the group looks at in future, said Mr Barner, but there are no plans to do so for now.

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