

Boehringer plays catch-up on multiple fronts



[Lisa Urquhart](#)

Usually the announcement of two FDA approvals in one week is a cause to celebrate – and given the setbacks Boehringer Ingelheim has had with manufacturing issues there is bound to be relief that two of its products are finally out the door and on the market.

But the German group's SGLT2 diabetes treatment Jardiance and COPD product Striverdi Respimat are very late to some big parties so there will be little time to revel. The measure of success for both drugs will be Boehringer's ability to carve out decent sales.

Second time of asking

Jardiance's launch is five months late after receiving a complete response letter in March, due to the manufacturing issues at Boehringer's Ingelheim am Rhein plant ([Empagliflozin exposes cracks in Lilly/Boehringer venture, March 6, 2014](#)). While turnaround has been fast since the drug was refilled in June, it still leaves Jardiance third to market. Rival products Johnson & Johnson's Invokana and AstraZeneca's Farxiga will have capitalised on Jardiance's absence.

With little to differentiate the drugs, as all have genitourinary infection side effects, analyst forecasts appear to be based on first-mover advantage. Sales for Jardiance are forecast to hit \$1.03bn in 2020, with partner Eli Lilly getting \$470m in royalties, compared with \$2.58bn of sales for Invokana and \$1.36bn for Farxiga in the same year.

Top five sodium-glucose cotransporter-2 (SGLT2) inhibitors

Rank	Product	Generic Name	Company	WW Phase (Current)	2020 sales (\$m)
1	Invokana	canagliflozin	Johnson & Johnson/Mitsubishi Tanabe Pharma	Marketed	2,575
2	Farxiga	dapagliflozin	AstraZeneca/Ono Pharmaceutical	Marketed	1,358
3	Jardiance	empagliflozin	Boehringer Ingelheim	Approved	1,033
4	Ertugliflozin	ertugliflozin	Pfizer	Phase III	322
5	Suglat	ipragliflozin	Astellas Pharma	Marketed	259
				Total	5,547

While some more positive analysts have speculated that Lilly's sales force could grow the entire class, there are so many competing oral diabetes products now on the market it is hard to see how that growth could be significant.

No breathing space

The situation in COPD is just as challenging. Although Striverdi is behind combination products Anoro and Breo in the US, both Glaxo drugs have failed to achieve the expectations heaped on their shoulders at launch and were partially behind the recent fall in the UK drug maker's share price ([Glaxo's breath quickens after assault on several fronts, July 29, 2014](#)).

But perhaps the biggest hurdle Striverdi will face will be from generic forms of Spiriva. Boehringer's cash cow is set to lose patent protection in 2018. As such Boehringer has been working on a combination of Spiriva and Striverdi, and last month filed the combination product in Europe, following encouraging phase III results in May.

The move was a sign that the company was confident about Striverdi's approval as a single agent, but also

pointed to its unwillingness to be left too far behind in the new LAMA/LABA combination space.

The growth in combination therapy as a way of more effectively treating COPD has also been reflected in recent moves in the industry including AstraZeneca's bid for Almirall's respiratory business, even after paying \$560m to acquire Pearl Therapeutics ([Astra's bargain basement move sends competition a message, July 30, 2014](#)).

The triple

But ultimately the prize in the space could go to the company that comes up with an effective triple combination including a steroid, something that Glaxo is working on with Theravance ([Glaxo and Theravance raise the respiratory stakes, July 16, 2014](#)).

With the likes of Astra and Chiesi also exploring this new frontier Boehringer, which is thought to be working on a triple combination, needs to keep both its R&D efforts and manufacturing plants in good working order if it is not to fall behind again.

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