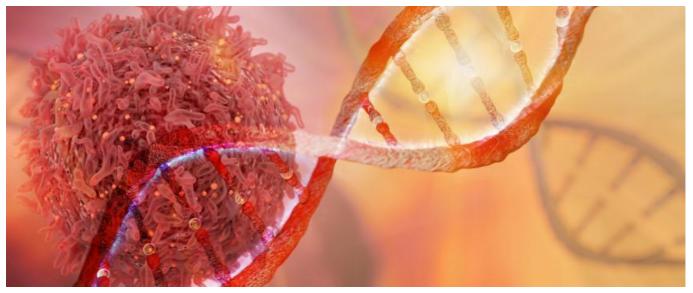


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## Bayer could become the latest casualty of Roche's targeted pricing



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## Roche's lower price tag for its targeted cancer therapy Rozlytrek could - intentionally or not - hit one of Bayer's big hopes hard.

Roche has proven itself a canny pricing strategist in recent years during the launches of Ocrevus and Hemlibra. And now, by setting the price for its targeted cancer therapy, Rozlytrek, at \$17,000 per month, the Swiss group could have Bayer looking over its shoulder.

Bayer has a similar, but slightly different, targeted drug in Vitrakvi, but it costs nearly twice as much, \$33,000 per month. Roche might not be setting out to destroy Vitrakvi – it has other reasons for its pricing decision – but the end result could end up being much the same.

Rozlytrek just got US FDA approval for NTRK fusion cancers, regardless of the tumour type – the same population in which Vitrakvi received the nod last November (<u>Bayer wants top dollar for larotrectinib</u>, 27 November 2018).

But Rozlytrek, which Roche gained via its \$1.7bn purchase of Ignyta, also got the go-ahead in Ros1-positive non-small cell lung cancer, and it is here that Roche has so far focused its attention.

So perhaps it is no wonder that Rozlytrek's price tag is more in line with Pfizer's Xalkori, which had previously been the only approved therapy for NSCLC patients with Ros1 mutations; these occur in around 1-2% of cases.

However, this does not help Bayer. The company took on full rights to Vitrakvi just after Lilly closed its purchase of the product's originator, Loxo Oncology, and sorely needs it to be a success. The drug is currently forecast to bring in \$688m in 2024, according to *EvaluatePharma* sellside consensus, making it Bayer's sixth biggest product that year and its most important recent launch. If anything could dent this estimate it would be a price war with one of oncology's top players.

Rozlytrek versus Vitrakvi								
					Sales (\$m)			
Product	Company/ies	Approval date	Indication	List price	2019e	2020e	2022e	2
Vitrakvi	Bayer	Nov 2018	Solid tumors with NTRK gene fusion	\$33,000 per month	64	179	446	6
Rozlytrek	Roche/Chugai	Aug 2019	Solid tumors with NTRK gene fusion; ROS1- positive metastatic NSCLC	\$17,000 per month	5	78	263	4
Source: EvaluatePharma.								

As well as hoping that Roche will be too focused on Ros1 NSCLC to pay too much attention to NTRK fusion cancers – which seems like wishful thinking – Bayer has a few other straws to cling to.

For one, in NTRK fusion tumours, Vitrakvi looks like it has better efficacy, although the usual caution about cross-trial comparisons applies. <u>The Bayer drug's label</u> outlines an overall response rate (ORR) of 75%, versus <u>57% with Rozlytrek</u> in this setting. However, Bernstein analysts noted that Roche's trials enrolled a sicker patient population and included more patients with brain metastases, which are harder to treat.

Vitrakvi could also be safer, but this might be a double edged sword, as this appears to relate to its inability to penetrate the blood-brain barrier. This is another way it differs to Rozlytrek, and is likely the reason why Vitrakvi looks less effective in brain metastases.

Bayer has had a head start with Vitrakvi since its launch last November, but it is unclear how much the company has been able to capitalise on this. During its second-quarter earnings call Bayer's head of pharma, Stefan Oelrich, declined to disclose how many patients had been treated with the drug so far, only saying that the launch was going "according to plan".

Given that NTRK gene fusion cancers affect only around 2,500-3,000 new patients in the US each year, Vitrakvi was probably always going to get off to a slow start. And finding these patients can be difficult: NTRK gene fusions are not routinely tested for, and there are technical challenges when trying to detect them via next-generation sequencing, the Bernstein analysts noted.

Roche plans to launch a dedicated companion diagnostic for Rozlytrek via its Foundation Medicine subsidiary, but this has not yet been approved by the FDA.

Carving out a decent chunk of the market will only get harder for Bayer now Roche is on the scene. And another contender, Turning Point Therapeutics, is also approaching the market with repotrectinib (<u>Which direction for Turning Point?</u>, June 24, 2019).

Roche's latest pricing gambit looks akin to <u>the one it took with its haemophilia A therapy Hemlibra</u>, when it undercut rivals in its initial market, patients with inhibitors, in order compete in the bigger non-inhibitor population. The drug is now storming both markets.

History suggests that Bayer should be worried, whatever Roche's motivations are for Rozlytrek's price.