Evaluate Vantage

November 27, 2018

Bayer wants top dollar for larotrectinib

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Bayer tests what the market will bear for its newly approved therapy for cancers with NTRK mutations.

Yesterday's US approval of Loxo and Bayer's tumour-agnostic small-molecule TRK inhibitor larotrectinib might have been expected – but the price tag was not. Bayer has set the list price at nearly $33,000 per month, around twice as much as forecast.

The company highlighted a patient-assistance programme promising refunds for non-responders, but this looks unlikely to have a big impact on sales. Bayer obviously wants to make the most of one of the few bright spots in its pipeline, and must have decided that payers will bear the cost in return for the admittedly impressive responses seen with laro, now trademarked Vitrakvi.

Yesterday the drug became the first small molecule to be approved for cancer patients with a particular mutation – in this case *NTRK* gene fusions – regardless of tumour type. Merck & Co's anti-PD-1 MAb Keytruda is the only other product to get a cancer-type agnostic FDA nod, in tumours with microsatellite instability or DNA mismatch repair deficiency.

No gain, no pay

Bayer estimates that TRK fusion cancers affect just 2,500-3,000 new patients in the US each year, so it is no wonder that it wants to make the most of Vitrakvi, for which it paid $400m up front in a licensing deal last year (*Loxo's Bayer deal falls short of bullish expectations, 14 November 2017*).

Still, like many other companies recently debuting pricey new therapies, Bayer has offered a money-back guarantee for patients who do not respond.

The approval announcement was light on details about what constituted a non-response, but a Bayer spokesperson told *Vantage* that payers would be eligible for a refund if the patient did not achieve at least stable disease within 90 days.

Stifel analysts were scathing about whether this would make much difference to those footing the bill, however. They pointed out that just two patients in the registrational dataset, equivalent to 4%, experienced disease progression.

Bayer was also keen to point out that, as well as the pricier oral capsules for adults, it was launching a paediatric liquid formulation of Vitrakvi, which will cost around $11,000 per month; the dose is calculated based on the patient's body surface area, so presumably this could vary.

The cost of TRK testing is another factor. Bayer previously told *Vantage* that this was around $600, but would come down as testing became routine and TRK was incorporated into commercial panels; whether testing for such a rare mutation actually becomes routine is a separate question (*Interview – Bayer's need for deals grows, 1 March 2018*).

The spokesperson did not give a post-rebate price for Vitrakvi, only saying: "Depending on the dose formulation and the size of the patient, the cost will range between $11,000 and $32,800 per month."

She added that for most patients, monthly out-of-pocket costs should be $20 or less – and that for patients without insurance or who "can't afford the medicine" Bayer would provide Vitrakvi at no cost.

High hopes

Bayer has a lot riding on Vitrakvi: it counts as the company's second-most valuable pipeline hope, behind the prostate cancer candidate darolutamide. The drug is forecast to bring in $770m in 2024 sales, according to *EvaluatePharma* sellside consensus, a number that is likely to rise based on the much higher than expected price tag.

Bayer's most promising late-stage pipeline prospects

Project	Mechanism of action	Indication(s)	2024e sales ($m)
Approved			
Larotrectinib*	TRK inhibitor	Tumours with TRK gene fusions	770
Phase III			
Darolutamide	Androgen receptor antagonist	Prostate cancer	810
Finerenone	Mineralocorticoid receptor antagonist	Diabetic nephropathy	466
Vilaprisan	Selective progesterone receptor regulator	Uterine fibroids, endometriosis	275
Molidustat	Hypoxia inducible factor inhibitor	Anaemia in chronic kidney disease	163
Vericiguat	Guanylate cyclase receptor agonist	Congestive heart failure	129

**Loxo co-promotes in US on 50:50 basis and receives double digit royalties ex-US. Source: EvaluatePharma.*

The German company will have to hope that it has struck the right balance to maximise sales without driving payers away.

Bayer and Loxo are also working on a follow-on TRK inhibitor, LOXO-195, designed to treat patients who develop resistance to Vitrakvi. *EvaluatePharma* puts total 2024 sales at $130m, but Leerink analysts think they could peak at $375m.

These projects are less important for Loxo, whose hopes instead hinge on its wholly owned Ret-targeted kinase inhibitor, Loxo-292. This might help explain why the company's shares, after initially trading up 12% in the premarket, opened down 1% this morning and continued to fall.

Vitrakvi's approval shows that the FDA, at least, is receptive to a tumour-agnostic approach. Now it is up to the payers.

Stay tuned for a new Vantage report on the first-line treatment of non-small cell lung cancer, being published later this week.

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