Evaluate Vantage

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Veklury boosts Gilead, yet disappoints too

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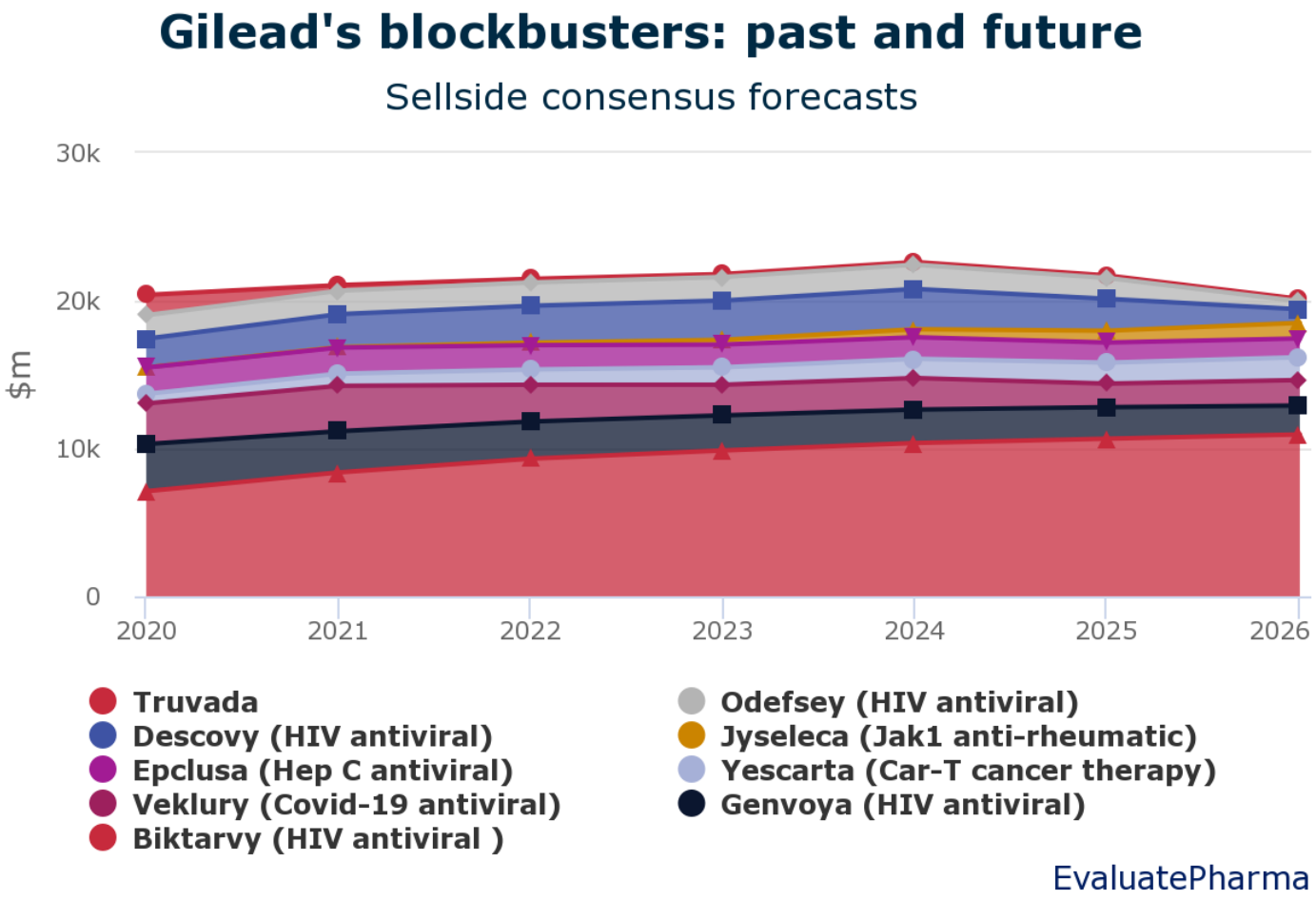
With Gilead's big sellers forecast to drift, investors turn to its newer projects but find little comfort.

Gilead has Veklury to thank for its 17% third-quarter revenue growth, reported after market yesterday. But the newly approved Covid-19 antiviral was also responsible for Gilead trimming its 2020 revenue guidance, since the disease is increasingly affecting younger, healthier patients, decreasing the hospitalisation rate and thus limiting the population in whom Veklury can be used.

And, with sales of all but one of its current blockbusters forecast to wane over the next six years, the group will have to rely on newer products to bring in growth. And that will not be easy.

The graph below, which is interactive, looks at the nine Gilead drugs that are either blockbusters now or forecast to become so in 2026, according to sellside consensus compiled by *EvaluatePharma*. The HIV therapy Biktarvy is the only one of Gilead’s current billion-dollar babies whose sales are forecast to increase out to 2026, by which time it will bring in a highly respectable $11bn.



The other two growth stories in this cohort are Veklury and filgotinib, the group's Jak1, newly branded Jyseleca. And both of these projects are, arguably, turning out to be disappointments.

As management stated on Gilead's third-quarter conference call yesterday, owing to an overambitious ramping up of production, supply of Veklury now exceeds global demand. The nucleotide inhibitor brought in $873m in the past quarter, but during that period hospitalisation rates for Covid-19 patients were around 5%, down from 12-15% in the second quarter.

The group also noted that Veklury was not being stockpiled at the level it had projected, possibly owing to contradictory evidence of its efficacy. On the call management took issue with the WHO-funded Solidarity study, results of which, released as a preprint mid-month, suggested that Veklury had "little or no effect on hospitalised Covid-19" patients.

Gilead's chief medical officer, Merdad Parsey, said issues with Solidarity included lack of PCR confirmation of Covid-19 at time of enrolment, failure to distinguish between patients requiring low or high levels of oxygen, and "20% of the data being reported as missing from the preliminary analysis".

The effect of the Solidarity results on Veklury sales will become apparent when Gilead reports its year-end results – but the company cited Veklury's volatile sales trends as the reason for cutting full-year guidance from $23-25bn to $23-23.5bn.

Manta-Ray of hope

Jyseleca has its problems too. Its filing in rheumatoid arthritis having met with an FDA complete response letter in August, some investors had questioned what the drug's future in the US might look like – or whether it has one at all.

Gilead is to discuss with the FDA by the end of the year what might be done with Jyseleca in RA. If this suggests that it is a no-go, Mr Persay said two options were on the table: abandoning Jyseleca in RA but moving forward in Crohn's disease and ulcerative colitis, or giving up any attempt to get the drug to the US market in any indication.

The company is awaiting data from the Manta and Manta-Ray studies looking at the testicular safety of filgotinib in inflammatory bowel disease and various arthritic conditions respectively. It will decide once these are out at the start of next year.

As for another programme that originated with Galapagos, Gilead said it would decide whether to opt in to the

"Toledo" assets once they are “de-risked to the appropriate level”. Gilead has the option to buy ex-Europe rights to these candidates, now confirmed to target SIK1, 2 and 3 kinases, for $150m per programme plus royalties.

“If you saw, hypothetically, a huge response in one indication that was really unexpected and blew it out of the water, we might opt in more early,” Mr Parsey said. Clinical successes on that scale are exactly what Gilead needs; time for investors to cross their fingers.