

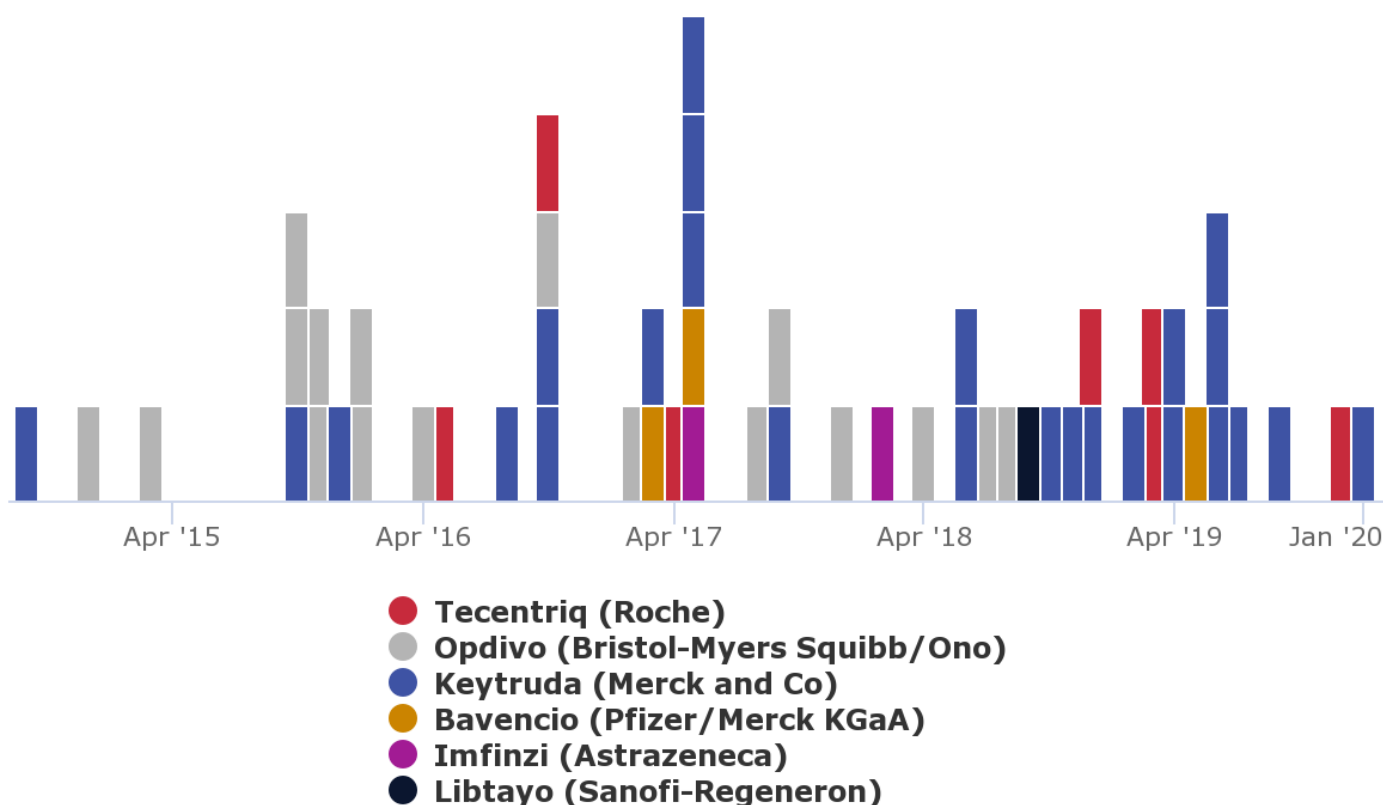
## Keytruda stumbles, but remains dominant



Edwin Elmhirst

The mere fact that Merck & Co's mighty Keytruda received a US complete response is reason enough for surprise, but in reality it amounts to little. The slapdown, issued after market close yesterday, concerned an every six weeks dosing regimen (rather than the current three-week schedule) for monotherapy use only, and Mizuho analysts reckon it will have had no effect on the drug's two biggest growth areas, non-small cell lung cancer and renal cell carcinoma. As the chart below shows, Keytruda is well entrenched, with global sales estimated to total an incredible \$22.3bn in 2024, according to *EvaluatePharma* sellside consensus. Still, this has not deterred challengers, as evidenced by Roche's pursuit of Tecentriq monotherapy for first-line NSCLC; a US filing for this was yesterday accepted, with the FDA setting a June 19 action date. This is backed by the [Impower-110](#) study that read out positively for overall survival versus chemo alone in patients whose tumours expressed PD-L1 at  $\geq 1\%$ . Keytruda monotherapy is already available in this precise setting, thanks to the [Keynote-042](#) trial, and in all-comers as part of a chemo combo, so the Roche threat looks relatively minor for now.

### US PD(L)-1 approvals



Vantage