Evaluate Vantage

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Glaxo joins the Covid-19 delay queue

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Glaxosmithkline will have to wait a little longer to find out whether dostarlimab can become the industry's seventh anti-PD-(L)1 antibody to reach the market. A US Pdufa date in the second half of 2020 came and went with no statement from the company, but it now emerges that the Covid-19 pandemic is to blame for the delay. A Glaxo spokesperson told *Evaluate Vantage* that approval "requires a site inspection of our manufacturing site, the timing of which is contingent on Covid-19 travel restrictions. The site inspection has not occurred yet, so we are now expecting approval in the first half of 2021." For now Glaxo is not mounting a strong challenge to the leaders, and its filing seeks approval in MSS or MSI-high endometrial cancer, a relatively obscure use in which only Keytruda's label in MSI-high cancers irrespective of tumour type has an overlap.

Selected regulatory casualties of the Covid-19 pandemic

Project	Company	Pdufa date	Outcome
Liso-cel	Bristol Myers Squibb	16 Nov 2020	Covid-19 travel restrictions prevented manufacturing inspection; no CRL, no new Pdufa date
Leqvio	Novartis/Alnylam	23 Dec 2020	CRL, citing unresolved facility inspection-related conditions; Covid-19 travel restrictions will delay in-person inspection
Dostarlimab	Glaxosmithkline/ Anaptysbio	H2 2020	Covid-19 travel restrictions prevented manufacturing inspection; no CRL, no new Pdufa date