Evaluate Vantage

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US regulator brings year-end joy for some

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While Astrazeneca celebrated US approval on Friday for Tagrisso in an adjuvant lung cancer setting, it had less luck with its Fibrogen-derived HIF-PH inhibitor roxadustat. The FDA has delayed its decision over roxadustat in anaemia of chronic kidney disease by three months to March 20, pending further clinical data analyses; still, as long as this is the only outstanding issue it probably bodes well for eventual approval. Novartis's cholesterol-lowering RNAi project Leqvio was also knocked back on Friday, with its complete response letter continuing a growing trend seen during the coronavirus pandemic. The group had earlier said that a paper-based inspection of a manufacturing plant in Italy was outstanding, and now cites "unresolved facility inspection-related conditions" as the reason for the CRL. If a physical inspection is required this will clearly be impossible until Covid-19 travel restrictions are eased, possibly causing further delay. For investors the highest-profile Covid-19-related delay remains that over Bristol Myers Squibb's liso-cel, whose Texas manufacturing plant could not be inspected during the pandemic, resulting in the FDA missing its November 16 action date. Curiously, neither a CRL nor a new action date has been issued.

Friday's US FDA decisions			
Product	**Company**	**Indication**	**Action**
Tagrisso	Astrazeneca	Adjuvant EGFR exon 19 del, or exon 21 L858R mut, NSCLC (Adaura study)	Approved
Roxadustat	Astrazeneca/Fibrogen	Anaemia of chronic kidney disease	3-mth delay to 20 Mar 2021 over clinical data analysis issues
Leqvio	Novartis/Alnylam	Hyperlipidaemia with elevated LDL cholesterol	CRL over manufacturing facility inspection-related issues
Xpovio	Karyopharm	2nd-line multiple myeloma (Boston study)	Approved 3 mths early (already had accelerated approval in penta-refractory use)
Orgovyx (relugolix)	Myovant/Sumitomo	Hormone-sensitive prostate cancer (Hero study)	Approved
mRNA-1273	Moderna	Prevention of Covid-19	Emergency use authorisation (1 day after positive adcom vote)