Evaluate Vantage

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Corporate and regulatory developments over the Christmas period

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Myovant and Pfizer showed that deal-making was not taking a Christmas break, but for Celgene CVR holders the dream is almost over. And vaccine approvals gained pace.

While the US FDA managed an approval flurry just before Christmas, for holders of **Bristol Myers Squibb's** Celgene-related contingent value right this could have marked the end of a dream. Liso-cel was not among the approved drugs, and as the clock ticks down to New Year's Day the CVR looks set to expire; the security's value now surely rests with any successful litigation.

The big positive news over the holiday period came courtesy of **Myovant** and **Pfizer**. On December 28 the groups struck a deal covering relugolix, a drug that did feature in the US regulator's approval flurry just a few days earlier.

Myovant's relugolix, an LHRH antagonist, carries sellside consensus 2026 revenue estimates of just $156m, according to *EvaluatePharma*. But Pfizer has paid Myovant $650m for North America rights, and has the option to buy rights to oncology use outside North America for a further $50m.

In oncology the deal driver seems to be Pfizer's prostate cancer franchise, which currently comprises the blockbuster Xtandi in the castration-resistant setting. Relugolix has been approved as Orgovyx on the basis of the Hero study, effectively meaning that it can be used in hormone-sensitive prostate cancer instead of Lupron.

Relugolix has also been developed for endometriosis, where an FDA decision is due on June 1, 2021, and uterine fibroids, where a US filing is imminent. The deal's total biodollar value is $4.2bn, including $200m for approvals in women's health and tiered sales milestones.

Other biopharma developments over the Christmas break included the following.

31 December:

Sinopharm gained provisional approval for its Covid-19 vaccine for domestic use, but questions remained about the product's real ability to prevent Covid-19 infections following mixed data readouts from China and the United Arab Emirates respectively claiming 79% and 86% efficacy. Sinopharm has promised full data "soon".

30 December:

The other big Covid regulatory news was the emergency authorisation in the UK of Astrazeneca's Covid-19 vaccine, AZD1222. However, there are still questions about the ideal dosing schedule and whether the project will get the nod elsewhere.

Osmotica's second attempt to get Ontinua ER approved failed when the US FDA issued a complete response letter for its resubmitted filing in multiple sclerosis spasticity. The CRL, announced after market close the previous day, cited an unjustified change of co-primary endpoint, and called for the company to conduct another study. Osmotica's stock fell 24%.

29 December:

Bristol Myers Squibb's Opdivo became the first anti-PD-(L)1 drug to have an indication pulled from the US market when the company withdrew its use in small-cell lung cancer. A third-line SCLC label got accelerated US approval in 2018, but then two potentially confirmatory trials, Checkmate-331 and 451, failed. Bristol had little to gain from Opdivo's continued use in SCLC given that **Merck & Co's** Keytruda and **Roche's** Tecentriq respectively carry third and first-line SCLC labels.

Anti-PD-(L)1 drugs with accelerated US approvals and failed confirmatory trials

Drug (company)	Indication	Failed potentially confirmatory trial(s)	Regulatory outcome
Keytruda (Merck & Co)	Urothelial bladder cancer (2L/1L)	Keynote-361 (1L)	US label narrowed
	Liver cancer (2L)	Keynote-240 (2L)	None
	Gastric/GEJ adenocarcinoma (3L)	Keynote-061 (2L) & 062 (1L, inconclusive)	None
	SCLC (3L)	Keynote-604 (1L)	None
Tecentriq (Roche)	Urothelial bladder cancer (1L)	Imvigor-211 (2L)	US label narrowed
	TNBC (1L)	Impassion-131 (1L)	None
Opdivo (BMS)	Liver cancer (2L)	Checkmate-459 (1L)	None
	SCLC (3L)	Checkmate-331 (2L) & 451 (1L)	Voluntarily withdrawn
Imfinzi (Astrazeneca)	Urothelial bladder cancer (2L)	Danube (1L, tremelimumab combo)	None

Source: company information.

Celltrion applied to have its anti-Covid-19 MAb CT-P59 approved for conditional marketing in South Korea. Data from a 327-subject phase II trial of the project should come shortly, and a global phase III programme is planned.

28 December:

Y-mabs got $105m from **United Therapeutics** for a priority review voucher it had received on US approval of Danyelza, an anti-GD2 MAb, in second-line neuroblastoma. United, which also has a marketed anti-GD2 MAb, Unituxin, says it will redeem the voucher with Tyvaso DPI, which it wants to file by mid-2021. $42m of Y-mabs' windfall is due to Memorial Sloan Kettering, Danyelza's academic originator.

A week after closing a $131m series C round the private US biotech **Cullinan Oncology** licensed China rights to its lead project, CLN-081, to **Zai Lab** for $20m up front. CLN-081 is an EGFR inhibitor targeting NSCLC driven by exon 20 insertions, a highly intractable setting. Competitors include **Spectrum's** poziotinib, which recently failed first line, and Takeda's TAK-788.

However, the front-runner in exon 20 mutated NSCLC is **Johnson & Johnson's** amivantamab, an EGFR/cMet-targeted bispecific that on the same day was filed in the EU, four weeks after J&J sought a US green light. Amivantamab yielded impressive data at Esmo, and its filings are based on the phase I Chrysalis trial.