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Go or no go? Roche, Jazz and Camarus await crucial regulatory readouts

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The final month of 2018 will see FDA verdicts on Roche's bid to play in the first-line lung cancer space, and what Jazz hopes will be its next big narcolepsy product.

As the US regulator seeks to clear desks ahead of the festive period, several companies will be hoping for a marketing license for Christmas. The biggest FDA decision due in December is actually a supplementary approval for Roche's checkpoint inhibitor, but several smaller companies are also awaiting important news.

Camurus and Ocular Therapeutix have already tried and failed to get their respective projects to market, and getting a green light this time around will be crucial. Meanwhile Servier will hear on a newly acquired leukaemia product. Novo is awaiting news on an extension to its haemophilia franchise, while Shire will be hoping to launch its bowel disease agent Resolor in the US, almost a decade after the FDA stopped work on safety grounds.

Notable December first time approval decisions			
Product	**Company**	**PDUFA date**	**Product NPV ($m)**
XaraColl	Innocoll	Dec 2	n/a
Solriamfetol	Jazz Pharmaceuticals	Dec 20	864
Resolor	Shire	Dec 21	614
Calaspargase Pegol	Les Laboratoires Servier	Dec 22	n/a
Buvidal	Camurus/Braeburn	Dec 26 (2nd review)	n/a
Dextenza	Ocular Therapeutix	Dec 28 (3rd review)	584
N8-GP	Novo Nordisk	December (estimate)	1,180
VivaGel BV	Starpharma	December (estimate)	319
Source: EvaluatePharma.			

The first to hear on a pending first-time approval in December should be Innocoll, though since confirming that XaraColl had been accepted for review back in February, the company has remained silent. The product is a surgically implantable and bioresorbable collagen matrix to treat post-surgical pain, which received a refuse to file letter back in 2016. A few months ago Innocoll was bought by Gurnet Point, a private equity group that pledged to help support the launch and find partners. Both groups will soon find out whether they have a product to sell, and some fairly big reputations are on the line: Innocoll is led by former Astrazeneca executive Tony Zook, while Gurnet Point is headed by Sanofi's former chief executive Christopher Viehbacher.

Camurus and partner Braeburn will be hoping for approval second time round for opioid dependence therapy Buvidal. A complete response letter was handed down back in January, which was not a big surprise after an advisory panel raised questions about data integrity. The delay allowed Indivior to launch its rival long-acting buprenorphine injection Sublocade without competition, so the partners will have some catching up to do, assuming the FDA is finally in agreement.

Jazz will be hoping for a green light for its most important sales growth driver, solriamfetol, a "wakefulness" product that is projected to be selling $500m by 2024, according to *EvaluatePharma*. Trials suggested that the project, a selective dopamine and norepinephrine reuptake inhibitor, gets to work faster and is more effective than former blockbuster narcolepsy drugs Provigil and Nuvigil; an absence of cardiovascular safety signals could also give it an edge. Jazz will be launching into a highly genericised market, so it will need all the differentiation it can offer.

After being backed unanimously by an FDA advisory panel in October Shire's prucalopride should receive a nod next month. Concerns about cardiovascular risk has kept the chronic idiopathic constipation drug from the US market, despite having been available in Europe for the past nine years under the name Resolor. The sellside apparently believes its novel mechanism of action for this space will drive demand: despite generating annual sales of only $13-14m in the last few years, *EvaluatePharma's* consensus has sales soaring to a comparatively lofty $124m by 2024 in the wake of a US launch.

Servier is awaiting news on approval of what is essentially a follow-on version of Oncaspar, a treatment for acute lymphoblastic leukemia, which has been pegylated for longer shelf life. The French company gained calaspargase pegol when it acquired Shire's oncology division in September.

Ocular Therapeutics will be hoping for third time lucky with its ocular pain project, Dextenza, which has been rejected twice by the FDA on manufacturing concerns. The ever-optimistic sellside has pencilled in a 2019 launch and sales of $263m by 2024, but the company is no stranger to regulatory upsets – a couple of months ago the FDA warned executives about shoddy data collection and reporting obligations related to another product. A green light for Dextenza looks far from assured.

Novo Nordisk filed its extended half-life factor VIII with US and EU regulators at the beginning of the year, and should hear on their verdicts next month. The product, a treatment for haemophilia A, was tested as a prophylactic treatment; patients dosed every fourth day experienced a significant decrease in bleeds compared to those treated on-demand. As a glyopegylated version of NovoEight approval should be

straightforward, and sales of $230m by 2024 have been pencilled in by sellside analysts, according to *EvaluatePharma*.

Starpharma, an Australia-listed drug maker, might see approval of VivaGel BV sneak in this year. The exact PDUFA date is unclear but the application has fast track status and was accepted sometime in the first half of the year. The project, described by Starpharma as an antiviral and bacterial blocker, is a mucoadhesive gel; approval is being sought to treat and protect against recurrence of bacterial vaginosis. Analysts consider it the company's most valuable product.

Finally to Roche, which will hear the FDA's decision on Tecentriq plus Avastin and chemo in first-line NSCLC, a decision that was pushed back by three months. Details of the filing, based on the Impower-150 trial, are still sketchy. It is not clear, for instance, whether this could result in a broad non-squamous label, or whether it might be limited by PD-L1 expression or other biomarkers. Any move to limit the label would be a huge blow to the Swiss pharma giant, and severely limit its chances of loosening Merck & Co's grip on this market with its rival checkpoint inhibitor Keytruda.

Supplementary approvals and other notable regulatory decisions for December

Product	Company	Event Type	Date
Tecentriq	Roche	sNDA/BLA for Tecentriq & Avastin & chemotherapy to treat 1st-line NSCLC.	Dec 5
Keytruda	Merck & Co	sBLA for acclerated approval of merkel cell carcinoma.	Dec 28
Bivigam	ADMA Biologics	Decision to allow the company to relaunch the IVIG product.	PDUFA Dec 18
Herzuma	Celltrion	Herceptin biosimilar resubmitted in June 2018, decision expected within six months.	December?
Ontruzant	Biogen	Herceptin biosimilar accepted for review in December 2017.	December?
Ravicti	Horizon Pharma	sNDA to extend approval of Ravicti to infants under two months of age.	December?
Truxima	Celltrion	Rituxan biosimilar; FDA panel voted in favour of approval in October.	Approved Nov 28

Source: EvaluatePharma.