Evaluate Vantage

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Go or no go? Vascepa’s finale and Allergan's pain relief

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Amarin’s Vascepa and Allergan’s migraine project ubrogepant are the high-profile pending FDA approval decisions as the sector heads into the last month of the year.

No one could have predicted that November would see such a wave of early approvals by the FDA. Two sickle cell drugs – Adakveo and Oxbryta – the BTK inhibitor Brukinsa and RNAi therapy Givlaari all won through months ahead of schedule.

Whether the streak continues is questionable and December is often a quiet month. Some of the more interesting upcoming decisions are supplemental approvals, the most highly anticipated of which is Amarin’s Vascepa. The purified fish-oil product is looking for a broader label, mentioning cardiovascular risk reduction, after gaining a unanimous vote by an FDA advisory panel in November.

Just how broad a label it might get is a big question. Restriction to a secondary prevention setting, namely only those patients with established cardiovascular disease, is possible. A benefit was seen in a primary prevention setting – those considered at risk of future cardiac problems – but this was much less pronounced.

For now, consensus from *EvaluatePharma* shows 2024 sales at $2.2bn, giving an NPV of $5.9bn; if Vascepa obtains a cardiovascular risk reduction label analysts believe that its sales could peak at double that figure.

Another notable supplemental approval expected this month is that of Lynparza in a maintenance setting in pancreatic cancer. Results from the Polo trial strongly favoured the Astrazeneca/Merck & Co Parp on progression-free survival, but this was overshadowed by the absence of an overall survival benefit. Few successes have been seen in pancreatic cancer, and as current therapies involve toxic platinum chemotherapies the regulator might look favourably on Lynparza’s offering.

Meanwhile Pfizer will hope to gain ground on its prostate cancer rival J&J: it is due an approval decision on Xtandi in metastatic hormone-sensitive disease, for which J&J’s Erleada was approved in September.

Supplementary and other notable approval decisions due in December			
Product	**Company**	**Event type**	**Date**
Tecentriq	Roche	sBLA + Abraxane for first-line non-squamous NSCLC (Impower-130)	Dec 2
ABP 710	Amgen	Biosimilar Remicade	Dec 14
Vascepa	Amarin	sNDA for Cardiovascular outcomes (Reduce-It)	Dec 28
Xtandi	Pfizer/Astellas Pharma	sNDA for metastatic hormone sensitive prostate cancer (Arches)	Q4
Lynparza	Astrazeneca	sNDA for BRCAm pancreatic cancer (Polo)	Q4
Source: EvaluatePharma.			

First-timers

Allergans's oral CGRP antagonist ubrogepant will likely gain approval in an acute migraine setting by the end of the year. The product is backed by positive late-stage trials and has a clean safety profile. Ubrogepant is Allergan's most valuable pipeline project with 2024 sales forecast to reach $302m, according to *EvaluatePharma* consensus.

Hot on ubrogepant's heels is Biohaven's orally dissolving tablet formulation of rimegepant, also known as Zydis ODT, with a PDUFA date in the first quarter of next year.

A decision is due for Shionogi/GSK's HIV doublet cabotegravir and rilpivirine, a long-acting injectable treatment dosed monthly. Concerns about drug resistance mean that many remain to be convinced by the doublet strategy; three-drug regimens represent the current standard of care and Gilead's oral once-daily triplet Biktarvy dominates the market with forecasts of $9.1bn by 2024, according to *EvaluatePharma* consensus.

Enzyvant's RVT-802 is a one-off treatment for the severe immune deficiency that results from rare childhood diseases, such as complete DiGeorge anomaly. The regenerative therapy could be the first approval for Vivek Ramaswamy's Roivant stable of companies. A strategic alliance with Sumitomo Dainippon that includes Enzyvant was announced in September.

Less likely to receive the FDA's backing will be Intra-Cellular's lumateperone in schizophrenia. A decision is now due after a three-month delay to a previous PDUFA date after the FDA cancelled an advisory meeting and requested further preclinical data to address toxicity findings in previous animal studies; phase III results have also been mixed.

Notable first-time US approval decisions due in December			
Project	**Company**	**PDUFA date**	**Product NPV ($m)**
Ubrogepant	Allergan	December	701
RVT-802	Enzyvant	December	-
AV001	Avadel	Dec 15	6
IDP-123/tazarotene	Bausch Health Companies	Dec 22	3
Brinavess	Correvio Pharma	Dec 24 (advisory committee Dec 10)	504
Lumateperone	Intra-Cellular Therapeutics	Dec 27	2,046
Lemborexant	Eisai	Dec 27	617
Cabotegravir & rilpivirine	Shionogi/GSK	Dec 29	1,792
Source: EvaluatePharma.			

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