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Go or no go? Vaccine panel upstages US approval decisions

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October brings US approval decisions for Eysuvis and Brilinta, while a panel meeting sets up a discussion around Covid-19 vaccines.

Heading into the last quarter of the year a number of valuable US drug approval decisions are pending, including for Kala's Eysuvis, whose fate will be decided by the end of October *(Another strong year for novel drug approvals is in the making, September 25, 2020).*

But perhaps the most important event due this month will be a panel meeting on October 22 to discuss the general development of Covid-19 vaccines. Though this is not expected to cover any one particular project it will provide additional insight into the FDA's expectations and requirements for a vaccine. Readouts from ongoing phase III studies are due in the coming months *(J&J and Novavax push Covid-19 vaccine candidates into late-stage testing, September 25, 2020).*

Of the approval decisions, though, that for Eysuvis will be critical for Kala since the dry eye asset is the group's biggest growth driver. Despite Kala having to run three clinical studies before getting the result it needed, approval is likely. With a green light, and the status of the Covid-19 pandemic permitting, Kala plans to double its sales force to 100-125 reps.

The biggest hurdle could be meeting sellside expectations. According to *EvaluatePharma* consensus, 2026 sales are forecast to reach $1.1bn, making Eysuvis the biggest-selling dry eye therapy that year. But generic steroids and versions of Allergan's artificial tear treatment Restasis are major obstacles.

Eysuvis has an NPV of $2.2bn. Given that Kala has a market cap of just $436m investors apparently do not share the sellside's enthusiasm.

Cocktail hour

Regeneron, meanwhile, is awaiting a decision for its Ebola project REGN-EB3, a three-antibody cocktail developed using similar technologies to the company's Covid-19 asset REGN-Cov2, on which encouraging data were released this week (*Regeneron joins Lilly in validating the Covid antibody approach, September 30, 2020*).

A study run by the NIAID testing four different Ebola therapies showed that REGN-EB3 was superior to ZMapp, a triple MAb used as control, in reducing mortality from Ebola. REGN-EB3 also showed a mortality rate of 34%,

versus 53% with Gilead's Veklury. REGN-EB3 also achieved faster viral clearance than ZMapp and Veklury.

Notably the study also tested MAb114, now called ansuvimab, a single treatment that showed similar efficacy to Regeneron's therapy. Ansuvimab, developed by Ridgeback Biotherapeutics, is also filed in the US, with a decision expected early next year.

Money down the drain?

A notable supplemental decision due in the fourth quarter is for Astrazeneca's Brilinta in stroke. Sales of the blood thinner have long disappointed, and with patent expiry in 2024 Astra needs to wring the most it can out of the product.

The decision will be based on the Thales study, where Brilinta plus aspirin showed a statistically significant and clinically meaningful reduction in its primary endpoint, a composite of the risk of stroke and death, at 30 days.

However, the benefit came at the expense of an increased bleeding rate, including fatal haemorrhages. Jefferies analysts note that Sanofi's Plavix could remain favoured given its lower bleeding risk.

Astra has invested huge sums on label extension for Brilinta, but has so far only managed to add two studies of its substantial Parthenon programme to the label *(The cost to Astrazeneca of building Brilinta, January 28, 2020)*.

The tables below list first-time and supplementary US approvals, as well as panel meetings due in October, with consensus forecasts from *EvaluatePharma*.

Advisory committee meetings in October

Project	Company	Adcom date	2026e sales by indication ($m)	Note
AR19 (immediate-release amphetamine)	Arbor	Oct 8	-	ADHD treatment, abuse deterrant version, Pdufa Nov 15
ALKS 3831	Alkermes	Oct 9	262	Schizophrenia and bipolar disorder, Pdufa Nov 15, issues around weight gain
Vaccines and related biological products	Various	Oct 22	NA	To discuss vaccines to prevent Covid-19

Source: FDA ad com calendar, EvaluatePharma & company releases

Notable first-time US approval decisions due in October

Project	Company	PDUFA date	2026e sales by indication ($m)	Note
IV Tramadol	Avenue Therapeutics	Oct 9	281	Acute pain treatment
Qtrypta	Zosano	Oct 20	286	Migraine treatment, received a discipline review letter, approval unlikely
Rolontis/ eflapegrastim	Spectrum	Oct 23 (resubmitted)	314	FDA requested additional manufacturing-related information, Spectrum withdrew original BLA
REGN-EB3	Regeneron	Oct 23	-	Ebola treatment
Eysuvis	Kala Pharmaceuticals	Oct 30 (resubmitted)	1,118	Stride 2 missed one co-primary endpoint, subsequently met in Stride 3

Sources: EvaluatePharma & company releases.

Supplementary and other notable approval decisions in October

Product	Company	Indication (clinical trial)	Date
Keytruda	Merck & Co	2nd-line r/r classical Hodgkin's lymphoma (Keynote-204, vs Seattle's Adcetris)	Oct 30
Brilinta	Astrazeneca/ Merck & Co	Acute ischaemic stroke or transient ischaemic attack (Thales)	Q4
Imfinzi	Astrazeneca	Four-week fixed-dose regimen for NSCLC and bladder cancer (several trials, incl Caspian)	Q4
Ocrevus	Roche	Two-hour infusion time, dosed twice yearly for relapsing or primary progressive MS (Ensemble Plus)	Q4

Sources: EvaluatePharma & company releases.