Evaluate Vantage

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US FDA approval tracker: February

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The already crowded migraine space saw two more approvals last month: Lundbeck/Teva's intravenous anti-CGRP MAb Vyepti got the green light in the preventative setting while Biohaven's Nurtec ODT, a fast-acting formulation of the oral CGRP rimegepant, was approved as an acute treatment. Importantly for Biohaven, data in prevention are due before the end of March and could position rimegepant as a more convenient alternative to approved injectable CGRP inhibitors. Esperion received two approvals for its cholesterol-lowering project bempedoic acid, one as a monotherapy and the second in combination with ezetimibe. Being oral, the drug is more convenient than injected PCSK9s, but Esperion will have to wait a couple more years until the Clear Outcomes trial reports to see if it can claim any cardiovascular benefits. Finally, after six previous rejections between them, Twirla, Anjeso and Barhemsys all got approved.

Notable first-time US approval decisions in February			
Project	**Company**	**2024e sales ($m)**	**Outcome**
Nexletol and Nexlizet (bempedoic acid/+ ezetimibe)	Esperion	958	Both approved
Nurtec ODT (rimegepant/Zydis ODT)	Biohaven	868 (rimegepant franchise)	Approved
Ayvakit	Blueprint Medicines	725	Delayed until May 14 (fourth-line GIST)
Vyepti (eptinezumab)	Lundbeck/Teva	404	Approved
Twirla	Agile Therapeutics	216	Approved
Posimir	Durect	134	No decision yet
Barhemsys	Acacia Pharma	103	Approved
Pizensy	Braintree labs	-	Approved
Anjeso (Intravenous meloxicam)	Baudax Bio	-	Approved
Taclantis	Sun Pharma Advanced Research	-	CRL
Sources: EvaluatePharma, Go or no go? Esperion's double whammy and a look to priority reviews.			

Supplementary and other notable approval decisions in February

Product	Company	Event type	Outcome
Keytruda	Merck	sBLA to include every-six-weeks dosing for melanoma and multiple other indications	CRL
Vesicare	Astellas	sNDA for neurogenic detrusor overactivity in paediatric patients	No decision yet
Neratinib	Puma Biotechnology	sNDA in combination with capecitabine in advanced Her2-positive breast cancer	Approved

Sources: EvaluatePharma, Go or no go? Esperion's double whammy and a look to priority reviews.