Evaluate Vantage

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US FDA approval tracker: March 2021

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Fibrogen and Astrazeneca had been gearing up for an approval decision on their chronic kidney disease project roxadustat last month, but a surprise advisory panel meeting is now in the works, at a date yet to be determined. Experts will play close attention to cardiac safety issues with the oral HIF-PH inhibitor. Akebia, which recently filed vadadustat, a similarly acting project with its own toxicity problems, will be watching the adcom with interest. Elsewhere, Keytruda got knocked back in neoadjuvant/adjuvant triple-negative breast cancer after a negative vote from an earlier panel meeting. Merck & Co will likely have to wait for data on event-free survival from the Keynote-522 study to get another shot here; these are due in the third quarter. Merck also voluntarily withdrew Keytruda's use in small-cell lung cancer. The anti-PD-1 antibody, alongside Roche's Tecentriq and Bristol's Opdivo, will be the subject of a panel towards the end of April looking at accelerated approvals for six indications in which confirmatory studies have failed *(Go or no go? The FDA plays hardball, March 30, 2021).*

Notable first-time US approval decisions in March

Project	Company	2026e sales by indication ($m)	Outcome
Evrenzo (roxadustat)	Astrazeneca/Fibrogen/ Astellas	2,656	Adcom planned, no date disclosed
Abecma (ide-cel)	Bristol Myers Squibb/ Bluebird	1,198	Approved
Mirabegron oral suspension	Astellas	579*	Approved
Dostarlimab	Glaxosmithkline	537	No decision yet
DaxibotulinumtoxinA	Revance	356	No decision yet
Rolontis	Spectrum	344	Pre-approval inspection scheduled for May
Zegalogue (Dasiglucagon HypoPal Rescue Pen)	Zealand Pharma	268	Approved
Fotivda	Aveo	155	Approved (~3 weeks early)
Trevyent	United Therapeutics	41	Company discontinued development after receiving FDA comments; CRL in Apr 2020
Azstarys (KP145)	Kempharm/ Aquestive	-	Approved
Ponvory (ponesimod)	J&J/Idorsia	-	Approved
Besremi (ropeginterferon alfa-2b)	AOP/PharmaEssentia	-	CRL (manufacturing inspection delay)

**Includes sales for tablet version (Myrbetriq). Source: EvaluatePharma & company releases.*

Advisory committee meetings in March			
Project	**Company**	**2026e sales by indication ($m)**	**Note**
Tanezumab	Lilly/Pfizer	179	Negative, Pdufa estimated in Apr
Source: EvaluatePharma & FDA adcom calendar.			

Supplementary and other notable approval decisions in March			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Sarclisa	Sanofi	R/r multiple myeloma, combo with Kyprolis & dexamethasone (Ikema)	Approved (~3mth early)
Yescarta	Gilead	R/r follicular lymphoma & marginal zone lymphoma after ≥2 systemics (Zuma-5)	Approved
Arcalyst (rilonacept)	Kiniksa	Recurrent pericarditis (Rhapsody)	Approved
Exparel	Pacira	Postsurgical analgesia in children aged ≥6 (Play)	Approved
Myrbetriq (mirabegron tablets)	Astellas	Neurogenic detrusor overactivity in patients aged ≥3 (NCT02751931)	Approved
Keytruda	Merck & Co	TNBC in combo with chemo as neoadjuvant, also single agent as adjuvant (Keynote-522)	CRL (negative adcom in Feb)
Keytruda	Merck & Co	1L oesophageal/gastroesophageal junction carcinoma (Keynote-590)	Approved
Xolair	Roche/Novartis	Self-administration option across all approved US indications	No decision yet
Vazalore	Plx Pharma	Liquid-filled aspirin capsule (325mg and 81mg doses)	Approved
Lorbrena	Pfizer	1L Alk +ve NSCLC (Crown)	Approved
Kimyrsa/ Orbactiv	Melinta	Acute bacterial skin and skin structure infections, single one-hour infusion	Approved
Source: EvaluatePharma & company releases.			

Voluntarily withdrawn accelerated approvals in March		
Product	**Company**	**Setting (failed confirmatory study)**
Keytruda	Merck & Co	3L SCLC (Keynote-604)
Tecentriq	Roche	1L urothelial bladder cancer (Imvigor-211)
Source: company releases.		

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