Evaluate Vantage

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US FDA approval tracker: July

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Last month saw plenty of setbacks for companies gunning for US approvals, with four complete response letters as well as a number of delays to Pdufa dates. One group that has been held up is Chemocentryx, which will now have to wait until October for the decision on Vynpenta for ANCA-associated vasculitis. The new date was given after Chemocentryx submitted a filing amendment intended to address issues raised during an earlier panel meeting. Having already been delayed to the third quarter, decisions on Jak inhibitors from Pfizer, Lilly and Abbvie have been pushed back again as the US regulators continue to review the safety profile of Pfizer's Xeljanz. The FDA has not given any guidance as to when the reviews might be completed. On a more positive note, Merck & Co’s Keytruda added more indications to its armoury, including neoadjuvant and adjuvant use in triple-negative breast cancer. However, the drug's accelerated approval in third-line gastric cancer was voluntarily withdrawn following an FDA-backed panel meeting in April.

Notable first-time US approval decisions in July				
Project	**Company**	**Indication(s)**	**2026e sales by indication ($m)**	**Outcome**
Kerendia (finerenone)	Bayer	CKD and type 2 diabetes	896	Approved
Rezurock (belumosudil/ KD025)	Kadmon	Chronic graft vs host disease	863	Approved (~6wks early)
Vaxneuvance (V114)	Merck & Co/Ligand	Pneumococcal infection vaccine (adults)	786	Approved
Ibsrela (tenapanor)	Ardelyx	Control of serum phosphorus in adult patients with CKD	701	CRL
Vynpenta (avacopan)	Chemocentryx	ANCA-associated vasculitis	639	Delayed to October 7
Saphnelo (anifrolumab)	Astrazeneca	Moderate to severe SLE	488	Approved
Bylvay (odevixibat)	Albireo	Progressive familial intrahepatic cholestasis	299	Approved
Sulopenem etzadroxil/probenecid (oral sulopenem)	Iterum	uUTIs	220	CRL
Retifanlimab	Incyte	Squamous cell carcinoma of the anal canal	80	CRL
Dalvance	Abbvie	Acute bacterial skin and skin structure infections in paediatric patients	40	Approved
Teplizumab (PRV-031)	Provention Bio	Delay or prevention of type 1 diabetes in at-risk individuals	-	CRL
Leukotac (inolimomab)	Gruppo Mediolanum farmaceutici	Acute steroid-resistant graft vs host disease	-	No decision yet
Twyneo	Sol-Gel	Acne	-	Approved
Fexinidazole	Sanofi/Drugs for Neglected Diseases initiative	All-oral treatment for sleeping sickness	-	Approved
Source: Evaluate Pharma & company releases.				

Advisory committee meeting in July				
Project	**Company**	**Indication**	**2026e sales by indication ($bn)**	**Outcome**
Evrenzo (roxadustat)	Astrazeneca/ Fibrogen/Astellas	Anaemia due to CKD in adult patients not on dialysis and on dialysis	2.6*	The committee voted 12-2 against approval in pts on dialysis and 13-1 against approval for pts not on dialysis
Source: Evaluate Pharma & company releases. *Forecasts prior to adcom.				

Supplementary and other notable approval decisions in July			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Abrocitinib	Pfizer	Atopic dermatitis	Delayed
Xeljanz	Pfizer	Ankylosing spondylitis	Delayed
Olumiant	Lilly	Atopic dermatitis	Delayed
Rinvoq	Abbvie	Atopic dermatitis	Delayed
Keytruda	Merck & Co	Locally advanced cutaneous squamous cell carcinoma that is not curable by surgery or radiation (Keynote-629)	Approved
Keytruda + Lenvima	Merck & Co/Eisai	Advanced endometrial carcinoma that is not MSI-H or dMMR (Confirmatory study Keynote-775)	Approved (~6wks early)
Keytruda	Merck & Co	High-risk early-stage triple-negative breast cancer plus chemo as neoadjuvant treatment and then as a single agent as adjuvant treatment after surgery (Keynote-522)	Approved
Keytruda	Merck & Co	Full approval triple-negative breast cancer (≥10% PD-L1 expressers) (Confirmatory study Keynote-522, originally granted in Nov 2020 based on Keynote-355)	Approved
Padcev	Seagen/Astellas	Regular approval and expanded indication in adult patients with locally advanced or met urothelial cancer who are ineligible for cisplatin-containing chemo (EV-301, EV-201)	Approved (~1mo early)
Darzalex Faspro + pomalidomide + dexamethasone	J&J	Adult multiple myeloma patients who have received at least one prior line of therapy (Apollo)	Approved
Octagram 10%	Octapharma	Dermatomyositis in adults (Proderm)	Approved
Prograf	Astellas	Prevention of organ rejection in adult and paediatric lung transplant recipients.	Approved
Bydureon BCise (exenatide extended-release)	Astrazeneca	Once-weekly injectable suspension for type 2 diabetes in paediatric patients ages 10 years and older (BCB114)	Approved
Shingrix	Glaxosmithkline	Prevention of shingles in immunocompromised adults	Approved
Semglee (Lantus biosimilar)	Viatris	Improve glycaemic control in adults and children with Type 1 diabetes and in adults with Type 2 diabetes (interchangeable label)	Approved
Botox	Abbvie	Label to include eight new muscles for the treatment of upper limb spasticity in adults	Approved
Nucala	Glaxosmithkline	Chronic rhinosinusitis with nasal polyps (Synapse)	Approved
Source: Evaluate Pharma & company releases.			

Voluntarily withdrawn accelerated approvals		
Product	**Company**	**Withdrawn indication**
Keytruda	Merck & Co	3L (PD-L1 ≥1%) gastric/GEJ adenocarcinoma
Opdivo	Bristol Myers Squibb	2L hepatocellular
Source: Company releases.		