Evaluate Vantage

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US FDA approval tracker: September 2021

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While there were FDA setbacks for Calliditas and Verrica last month there were also a couple of early oncology approvals. One such win was for Tivdak, Seagen/Genmab's treatment for recurrent or metastatic cervical cancer. However, expected sales of Tivdak could be hit by an unexpected black box warning regarding ocular toxicity. An early approval for Takeda's Exkivity also came with safety implications. The oral therapy, used to treat lung cancer driven by EGFR exon 20 insertions, has a black box warning for QTc prolongation. J&J's competing project Rybrevant does not come with a warning, but is less convenient as it is an infused antibody. Separately, Takeda investors are still holding out for FDA news on Eohilia after the FDA's action date was missed in April. Takeda says Eohilia could become the first treatment for eosinophilia oesophagitis, but with a filing for Sanofi/Regeneron's Dupixent expected next year Takeda will want the regulators to hurry.

Notable first-time US approval decisions in September				
Project	**Company**	**Indication(s)**	**2026e sales by indication ($m)**	**Outcome**
Qulipta (atogepant)	Abbvie	Episodic migraine prevention	954	Approved
Tivdak (tisotumab vedotin)	Seagen/Genmab	Previously treated recurrent or metastatic cervical cancer	629*	Accelerated approval (over 2 weeks early)
Nefecon	Calliditas	IgA nephropathy	629**	Extended to Dec 15
Exkivity (moborcertinib)	Takeda	EGFR exon 20 Insertion+ NSCLC	436	Accelerated approved (over a month early)
Livmarli (maralixibat)	Mirum	Cholestatic pruritus in Alagille syndrome	432	Approved
VP-102	Verrica	Molluscum contagiosum	271*	Second CRL (deficiencies at contract manufacturer)
Eohilia (TAK-721)	Takeda	Eosinophilic esophagitis	187	No decision yet (April Pdufa missed)
Illuccix	Telix	Prostate cancer imaging	42	Extended to December 23
Reltecimod	Atox Bio	Resolution of organ dysfunction in necrotising soft tissue infections	-	Supposed to have been Sep 30, no news released
Epsolay	Sol-Gel	Papulopustular rosacea	-	No decision yet (delayed in Apr)

**Sales by indication not split out, **includes undisclosed partner sales. Source: Evaluate Pharma & company releases*

Supplementary and other notable approval decisions in September			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
AVT02 (Humira biosimilar)	Alvotech/Teva	Inflammatory conditions, PK study AVT02-GL-101, efficacy study AVT02-GL-301	Delayed (facility inspection)
Repatha	Amgen	Paediatric patients with heterozygous familial hypercholesterolemia (Hauser-RCT)	Approved
Invega Hafyera (Paliperidone palmitate 6-month, PP6M)	J&J	Adults with schizophrenia (Route 6)	Approved
INP104/ Trudhesa	Impel	505(b)(2) application acute treatment of migraine (dihydroergotamine mesylate with olfactory delivery)	Approved
Brukinsa	Beigene	Marginal zone lymphoma who have received at least one prior anti-CD20-based therapy (Magnolia, Ph1/2)	Approved
Brukinsa	Beigene	Waldenström's macroglobulinemia (Aspen)	Approved
Opzelura (ruxolitinib cream)	Incyte	Atopic dermatitis (TruE-AD1, TruE-AD2)	Approved
Jakafi	Incyte/Novartis	Paediatric patients with steroid-refractory GvHD (Reach3)	Approved
Byooviz (Lucentis biosimilar)	Biogen/ Samsung Bioepis	Wet AMD, myopic choroidal neovascularisation and macular oedema following retinal vein occlusion	Approved
Erbitux + Braftovi	Lilly/Pfizer	Adult patients with metastatic colorectal cancer with a BRAF V600E mutation (Beacon CRC)	Approved
Cabometyx	Exelixis	Previously treated radioactive iodine-refractory differentiated thyroid cancer (Cosmic-311)	Approved (~ 3 months early)
Source: Evaluate Pharma, company releases & clinicaltrials.gov			

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