Evaluate Vantage

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US approval tracker: December 2022

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The FDA granted a flurry of end-of-year approvals, including green lights for Mirati, Gilead and TG Therapeutics. A handful of surprises were also thrown in for good measure, including an early decision for Rigel and Forma's Rezlidhia in relapsed/refractory IDH1-mutated AML. Grabbing a share of this tiny market will be tough as Servier's Tibsovo dominates the space. Another surprise was the approval of Adstiladrin, the first gene therapy for bladder cancer, handed to the private group Ferring. Two years ago the project was knocked back by manufacturing issues. Merck & Co's Keytruda is on the market in the same setting − high-risk BCG-unresponsive non-muscle-invasive bladder cancer. The big pharma also had an early hand in Adstiladrin. In 2011 the project, alongside Merck's gene therapy portfolio, was handed over to FKD Therapies, with Merck taking an equity stake in the private Finnish company. FKD then signed over Adstiladrin's global commercialisation rights to Ferring in 2018. The approval of Adstiladrin follows other gene therapy thumbs ups in 2022, including those of Skysona and Zynteglo from Bluebird and CSL/Uniqure's Hemgenix.

Notable first-time US approval decisions in December				
Project	**Company**	**Indication(s)**	**2028e SBI ($m)**	**Outcome**
Sunlenca (lenacapavir)	Gilead	HIV-1 infection in heavily treatment-experienced people with multidrug-resistant infection	1,602	Approved
Krazati (adagrasib)	Mirati/Zai Lab	2L Kras G12C-mutated NSCLC	1,474	Approved (accelerated)
Briumvi (ublituximab)	TG Therapeutics	Relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	842	Approved
Tuoyi (toripalimab)	Coherus	Nasopharyngeal carcinoma	468	Delayed (China facility inspections pending owing to Covid-19 related travel restrictions)
Lunsumio (mosunetuzumab)	Roche/Biogen	3L follicular lymphoma	251*	Approved (accelerated)
Sohonos (palovarotene)	Ipsen	Fibrodysplasia ossificans progressiva	152	CRL (additional info on clinical trial data)
Nexobrid	Mediwound/Vericel/ Kaken	Eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns	78	Approved
Tislelizumab	Beigene/Novartis	2L oesophageal squamous cell carcinoma	83	Pending (Chinese facility inspections)
Olpruva (ACER-001)	Acer/Relief	Urea cycle disorder	73	Approved
Annik/Anniko (penpulimab)	Akeso/Sino	3L nasopharyngeal carcinoma	-	Pending (Chinese facility inspections)
Rezlidhia (olutasidenib)	Rigel/Forma	R/r AML with a IDH1 mutation	-	Approved (2 months early)
Adstiladrin (nadofaragene firadenovec)	Ferring (private)	Adults with high-risk BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ with or without papillary tumors	-	Approved
Xenoview (hyperpolarised Xe-129)	Polarean Imaging	Drug/device combination to evaluate pulmonary function and imaging	-	Approved

*SBI = sales by indication. *SBI not split out. Source: Evaluate Pharma & company releases.*

Advisory committee meetings in December				
Project	**Company**	**Indication**	**2028e SBI ($m)**	**Outcome**
Omecamtiv	Cytokinetics	Reduce the risk of CV death and heart failure events in patients with symptomatic chronic HFrEF	326*	8-3 against
**Forecasts pre-adcom. HFrEF: heart failure with reduced ejection fraction. Source: Evaluate Pharma, company releases, FDA adcom calendar.*				

Supplementary and other notable approval decisions in December			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Wegovy	Novo Nordisk	Chronic weight management in paediatric patients aged 12 years and older with obesity (Step Teens)	Approved
Vraylar	Abbvie	Adjunctive treatment of major depressive disorder (NCT03738215)	Approved
Tymlos (abaloparatide)	Radius	Men with osteoporosis at high risk for fracture (Atom)	Approved
Actemra	Roche	Hospitalised Covid patients (EUA in Jun 2021; Empacta, Covacta, Remdacta, Recovery)	Approved
Tecentriq	Roche	Adult and paediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (Study ML39345)	Approved
Idacio (Humira biosimilar)	Fresenius Kabi	Chronic autoimmune diseases for all eligible indications of the reference product, Humira	Approved
Cytalux	On Target Laboratories	Injectable imaging agent for adults with lung cancer (Elucidate)	Approved
Moderna and Pfizer/Biontech bivalent Covid-19 vaccines	Moderna, Pfizer/Biontech	Covid 19, include use in children down to 6 months of age	EUA amended
Abrilada (Humira biosimilar)	Pfizer	Interchangeability designation	Pending
Lynparza + Zytiga + prednisone/prednisolone	Astrazeneca	Metastatic castration-resistant prostate cancer (Propel)	Delayed by 3 months
AVT02 (Humira biosimilar)	Alvotech/Teva	Interchangeability designation	CRL (facility reinspection, Pdufa set for April)
Pepaxto	Oncopeptides	R/r multiple myeloma after at least 4 lines of therapy	FDA requested withdrawal of NDA (failed confirmatory Ocean study)
Source: Evaluate Pharma, company releases.			

The tables have been updated to include approvals for Olpruva and Wegovy.

For a look at January's upcoming Pdufa decisions, including Eisai's lecanemab see here: Go or no go? Lecanemab's destiny approaches.

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