Evaluate Vantage

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US FDA approval tracker: May 2022

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The most valuable approval of the year was bestowed in May − that of Lilly's Mounjaro in type 2 diabetes. According to *Evaluate Pharma* its consensus 2028 forecasts are over $8bn, and the product is gearing up to take market share from Novo's diabetes franchise. Elsewhere it was good news for Dupixent as the anti-IL-4/1L-13 MAb became the first FDA-approved drug for the chronic inflammatory disease eosinophilic oesophagitis (EoE). The decision for Sanofi/Regeneron's product came over two months early. Competing data from Astrazeneca's phase 3 Messina study testing the anti-IL-5 MAb Fasenra in EoE are expected in the second half of the year. It was not all good news last month: UCB and Verrica both received knockbacks, while Avadel, Amicus and Pfizer/Myovant all had their Pdufas extended. On the theme of delays, TG Therapeutics became the latest to suffer a three-month extension, announcing yesterday that the Pdufa for ublituximab in relapsing multiple sclerosis had been pushed out to the end of December. This came after a long list of setbacks for the company.

Notable first-time US approval decisions in May				
Project	**Company**	**Indication(s)**	**2028e sales by indication (SBI) ($m)**	**Outcome**
Mounjaro (tirzepatide)	Lilly	Type 2 diabetes	8,132	Approved
Bimzelx	UCB	Plaque psoriasis	1,191	CRL (pre-approval inspections)
AXS-05	Axsome	Major depressive disorder	787	Pending (Q2)
FT218	Avadel	Treatment of excessive daytime sleepiness or cataplexy in adults with narcolepsy	361	Full approval not expected until mid-2023, when Jazz's '963 REMS patent expires
VP-102	Verrica	Molluscum contagiosum	359	CRL (deficiencies at CMO)
Miglustat	Amicus	Pompe disease	266*	Delayed to Aug 29 (cipaglucosidase Pdufa also delayed to Oct 29, combination product known as AT-GAA)
Vtama (tapinarof)	Dermavant	Plaque psoriasis	-	Approved
Annik (penpulimab)	Akeso/Sino	3L nasopharyngeal carcinoma	-	Pending (H1)
Voquenza triple pak, Voquenza dual pak (vonoprazan)	Phathom	Adults with H pylori infection	-	Approved
Radicava ORS (MT-1186, oral edaravone)	Mitsubishi Tanabe	ALS	-	Approved
Lamotrigine (ET-105) for supspension	Eton/Azurity	Epilepsy	-	CRL

**Forecasts for AT-GAA. Source: Evaluate Pharma & company releases.*

Supplementary and other notable approval decisions in May			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Myfembree	Pfizer/Myovant	Moderate to severe pain associated with endometriosis (Spirit 1, Spirit 2)	Delayed to Aug 6 (FDA needs more time to review bone mineral density information)
Tyvaso DPI	Mannkind/United Therapeutics	PAH and pulmonary hypertension-associated interstitial lung disease	Approved
Evrysdi	Roche/PTC	Pre-symptomatic infants under 2 months old with spinal muscular atrophy (Rainbowfish)	Approved
Opdivo + Yervoy, Opdivo + chemo	Bristol Myers Squibb	1L unresected advanced, recurrent or metastatic oesophageal squamous cell carcinoma (Checkmate-648)	Approved
Enhertu	Astra/Daiichi	Her2+ve breast cancer after anti-Her2-therapy (Destiny-Breast 03)	Approved
Olumiant	Lilly	Treatment of certain hospitalised patients with Covid-19	Approved
Kymriah	Novartis	3L follicular lymphoma (ph2 Elara)	Approved
Tpoxx IV	Siga	Smallpox	Approved
Dupixent	Sanofi/Regeneron	Eosinophilic oesophagitis, 12 years and older (NCT03633617)	Approved (over 2mth early)
Annovera	Therapeutics MD	Birth control, revisions to in vitro release testing specification	Approved
Vidaza	Bristol Myers Squibb	Paediatric patients with newly diagnosed juvenile myelomonocytic leukaemia (AZA-JMML-001)	Approved
Tibsovo + Vidaza	Servier	Newly diagnosed IDH1-mutated AML in adults 75 years or older (Agile)	Approved
Fylnetra (Neulasta biosimilar)	Amneal	Neutropenia	Approved
Beovu	Novartis	Diabetic macular oedema (Kestrel, Kite)	Approved
Source: Evaluate Pharma & company releases.			

FDA Covid-19 EUAs		
Product	**Company**	**Outcome**
Janssen Covid-19 vaccine (Ad26.COV2-S)	J&J	Authorised use limited to individuals aged 18+ for whom other authorised or approved vaccines are not accessible or clinically appropriate, and to individuals aged 18+ who elect to receive the J&J vaccine because they would otherwise not receive a vaccine (received EUA in Feb 21)
Comirnaty	Pfizer/ Biontech	Single booster dose authorised for individuals aged 5-11
Source: company releases.		

The supplementary table has been updated to include Beovu's approval.