Evaluate Vantage

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US FDA approval tracker: March

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March proved to be a busy month at the FDA, with success for Novartis's second radioligand product and the ushering in of three first-in-class drugs: Marinus's Ztalmy, CTI Biopharma's Vonjo, and Bristol Myers Squibb's Opdualag. The final product on the list is a combination of Opdivo and relatlimab, the first Lag3 inhibitor to pass the regulator. Bristol might be hoping that relatlimab's reduced toxicity will allow it in time to swap out Yervoy in combination treatments. Meanwhile, approval of Novartis's Pluvicto in patients with metastatic castration-resistant prostate cancer after androgen receptor blockade plus chemo looks to have provided some justification of the Swiss group's $2.1bn acquisition of Endocyte in 2018. On the other side of the coin, those facing disappointment last month included Akebia, and Lilly and its Chinese partner Innovent. Akebia fell foul of FDA concerns around thromboembolic events and toxicity, which have hit others in the HIF-PH inhibitor space, while Lilly/Innovent's chances of approval for the PD-1 antibody Tyvyt were doomed after a 14-1 advisory committee vote against.

Notable first-time US approval decisions in March

Project	Company	Indication(s)	2026e sales by indication ($m)	Outcome
Pluvicto (177Lu-PSMA-617)	Novartis	Radioligand therapy for mCRPC	851	Approved
U2 combination (Ukoniq + ublituximab)	TG Therapeutics	Chronic lymphocytic leukaemia and small lymphocytic lymphoma	691	Adcom Apr 22, Pdufa extended to Jun 25
Vadadustat	Akebia/ Vifor/ Otsuka	Anaemia due to CKD in adult patients on/not on dialysis	–	CRL (toxicity concerns, new pivotal study required)
Vonjo (pacritinib)	CTI Biopharma	Myelofibrosis	469	Approved
Opdualag (relatlimab + Opdivo)	Bristol Myers Squibb	1L melanoma	437	Approved
Ztalmy (ganaxolone)	Marinus	Seizures associated with CDKL5 deficiency disorder (rare form of genetic epilepsy)	384*	Approved
Botulax (LetibotulinumtoxinA)	Hugel America	Moderate to severe glabellar lines	245	CRL
Tyvyt (sintilimab)	Lilly/ Innovent	1L nonsquamous NSCLC	–	CRL (mutliregional study required, non-inferiority design against SoC)

*Source: Evaluate Pharma & company releases. *SBI as general epilepsy.*

Advisory committee meetings in March				
Project	**Company**	**Indication**	**Peak sales (non-risk adjusted, $m)**	**Outcome**
AMX0035 (sodium phenylbutyrate + taurursodiol)	Amylyx	ALS	1,820	6-4 against approval
Source: broker reports (pre adcom) & FDA adcom calendar.				

Supplementary and other notable approval decisions in March			
Product	**Company**	**Indication (clinical trial)**	**Outcome**
Cabenuva	Glaxo/Viiv/ J&J	Treatment of HIV-1 in virologically suppressed adolescents who are 12 years of age or older and weigh at least 35kg (Mocha)	Approved
Triumeq PD	Glaxo/Viiv	Dispersible tablet formulation for the treatment of paediatric patients with HIV, and minimum weight required for tablet form lowered to 25kgs	Approved
Adlarity (donepezil transdermal system)	Corium	Dementia due to mild, moderate, or severe Alzheimer's disease	Approved
Fintepla	Zogenix/ UCB	Seizures associated with Lennox-Gastaut Syndrome	Approved
Reblozyl	Bristol/ Merck & Co	Anaemia in adults with non-transfusion-dependent beta-thalassemia (ph2 Beyond)	Delayed to Jun 27 (information request)
Keytruda	Merck	2nd-line MSI-H/dMMR endometrial cancer (Keynote-158, cohorts D & K)	Approved
Tlando	Lipocine/ Antares	Oral testosterone replacement therapy	Approved (final approval, received tentative decision in December)
Lynparza	Astrazeneca	Adjuvant BRCA-mutated Her2 -ve breast cancer (OlympiA)	Approved
Ozempic (2.0mg)	Novo Nordisk	Type 2 diabetes (Sustain Forte)	Approved
Fasenra	Astrazeneca	Inadequately controlled chronic rhinosinusitis with nasal polyps (Ostro)	CRL (additional data requested)
Rinvoq	Abbvie	Ankylosing spondylitis and ulcerative colitis	Approved in UC
Opdivo + chemo	Bristol	Neoadjuvant stage IB-IIIA NSCLC all-comers (Checkmate-816)	Approved (~4 months early)
Releuko (filgrastim biosimilar)	Kashiv/ Amneal	Treatment and prevention of febrile neutropenia	Approved (third filgrastim biosim approved by the FDA)
Source: Evaluate Pharma & company releases.			

US EUAs to treat Covid-19			
Project	**Company**	**Setting**	**Outcome**
Covaxin	Ocugen/ Bharat Biotech	Prevent Covid-19 in individuals aged 2-18 years old	Declined
Spikevax (mRNA-1273)	Moderna	Second booster dose in adults aged 50 and older, and ≥18 if immunocompromised	Approved
Comirnaty	Pfizer	Second booster dose in adults aged 50 and older, and ≥12 if immunocompromised	Approved
Source: company releases.			