NEWS IN BRIEF

FDA approvals for the first 6 months of 2017

The US FDA approved 23 new drugs in the first 6 months of 2017 (TABLE 1). This is more than the agency approved in the entirety of 2016, a lacklustre year with only 22 approvals (*Nat. Rev. Drug Discov.* **16**, 73–76; 2017).

The FDA tends to approve more drugs in the second half of the year than in the first, but this is not always the case. In 2016, it approved 13 in the first half of the year and the other 9 in the second.

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Table 1 | **FDA approvals in the first 6 months of 2017**

Drug name	Lead company	Indication
Plecanatide (Trulance)	Synergy Pharmaceuticals	Chronic idiopathic constipation
Etelcalcetide (Parsabiv)	Amgen	Secondary hyperparathyroidism in patients with chronic kidney disease on haemodialysis
Deflazacort (Emflaza)	PTC Therapeutics	Duchenne muscular dystrophy
Brodalumab (Siliq)	Valeant	Plaque psoriasis
Telotristat etiprate (Xermelo)	Lexicon Pharmaceuticals	Carcinoid syndrome diarrhoea
Avelumab (Bavencio)	Merck KGaA	Merkel cell carcinoma
Ocrelizumab (Ocrevus)	Genentech/Roche	Relapsing and primary progressive forms of multiple sclerosis
Dupilumab (Dupixent)	Regeneron	Atopic dermatitis
Ribociclib (Kisqali)	Novartis	HR-positive, HER2-negative breast cancer
Safinamide (Xadago)	US WorldMeds	Parkinson disease
Naldemedine (Symproic)	Shionogi	Opioid-induced constipation
Niraparib (Zejula)	Tesaro	Epithelial ovarian, fallopian tube or primary peritoneal cancers
Cerliponase alfa (Brineura)	BioMarin	Tripeptidyl peptidase 1 deficiency
Midostaurin (Rydapt)	Novartis	FLT3-positive AML
Deutetrabenazine (Austedo)	Teva	Chorea associated with Huntington disease
Valbenazine (Ingrezza)	Neurocrine Biosciences	Tardive dyskinesia
Brigatinib (Alunbrig)	Ariad Pharmaceuticals	ALK-positive NSCLC
Abaloparatide (Tymlos)	Radius Health	Osteoporosis
Durvalumab (Imfinzi)	AstraZeneca	Urothelial carcinoma
Sarilumab (Kevzara)	Sanofi	Rheumatoid arthritis
Edaravone (Radicava)	Mitsubishi Tanabe Pharma	ALS
Delafloxacin (Baxdela)	Melinta Therapeutics	Acute bacterial skin and skin structure infections
Betrixaban (Bevyxxa)	Portola Pharmaceuticals	Prophylaxis of venous thromboembolism

ALK, anaplastic lymphoma kinase; ALS, amyotrophic lateral sclerosis; AML, acute myeloid leukaemia; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; NSCLC, non-small-cell lung cancer.

FDA approves first new sickle cell drug in 20 years

The US FDA approved Emmaus Medical's L-glutamine for sickle cell anaemia, providing the first new drug for these patients in 20 years.

Emmaus's drug is an oral, pharmaceutical-grade amino acid. The mechanism of action of the drug is not understood, but it is thought to act by exerting antioxidant effects in red blood cells. In a 230-patient phase III trial of the drug, treated patients experienced fewer sickle cell crises, fewer hospital visits for pain and shorter stays in the hospital than placebo-treated patients.

Analysts expect the company to charge US$11,000–18,000 per year for the drug. The amino acid is also available for over-the-counter purchase as a diet supplement.

Around a dozen other sickle cell candidates are in development, including small-molecule anti-sickling agents and stem cell treatments (*Nat. Rev. Drug Discov.* **15**, 593–594; 2016).

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New cancer vaccines show clinical promise

Personalized cancer vaccines can help to stave off melanoma, suggested two phase I clinical trials published in *Nature*. The findings buoyed an emerging field that is using neoantigens — antigens that are unique to each patient's cancer — to prime the immune system to kill cancer cells.

In BioNTech's study, 13 patients with a history of recurrent melanoma received the firm's mRNA-based vaccine. Eight of these patients had no radiologically detectable lesions at vaccination and remained recurrence-free 23 months later. Of the other five patients, who had metastatic disease at vaccination, two experienced vaccine-related objective responses.

Separately, a team that includes co-founders of Neon Therapeutics treated six patients with a peptide-based vaccine. Four of these patients had no disease recurrence at 25 months. In the two patients who had recurrence after vaccination, subsequent treatment with Merck & Co's anti-PD1 antibody pembrolizumab led to complete and ongoing radiographic responses.

Other neoantigen-based cancer vaccine developers include Advaxis, Aduro Biotech and Gritstone Oncology (*Nat. Rev. Drug Discov.* **15**, 663–665; 2016).

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