

BIOBUSINESS BRIEFS

REGULATORY WATCH

FDA new drug approvals in Q3 2018

With one full quarter still to go before the end of the year, 41 novel drugs have already been approved by the FDA, putting 2018 on track to surpass 1996's record 53 new drug approvals. Many of the 21 products approved in Q3 (TABLE 1) were also in areas of unmet need, often with first-in-class mechanisms of action.

Among these, Alnylam's patisiran ensured its place in history as the first FDA-approved RNA interference drug, for the rare disease hereditary transthyretin-mediated amyloidosis. AstraZeneca's first-in-class CD22-directed cytotoxin, moxetumomab, was the first new treatment for relapsed or refractory hairy cell leukaemia in more than 20 years. Agios and Kyowa Hakko Kirin also gained first-in-class oncology approvals with ivosidenib, an isocitrate dehydrogenase 1 inhibitor, and mogamulizumab, a CC-chemokine receptor 4

monoclonal antibody (mAb), respectively, while Sanofi and Regeneron celebrated the approval of the PD1-specific mAb cemiplimab, the first treatment for metastatic cutaneous squamous cell carcinoma (although it is the sixth immune checkpoint inhibitor to be approved).

Completing the six cancer drugs to receive a green light in Q3 were two kinase inhibitors; Pfizer's dacomitinib was approved for metastatic non-small-cell lung cancer and Verastem's duvelisib was approved for several blood cancers.

Outside of oncology, two mAbs targeting calcitonin-gene-related peptide (CGRP) were approved for migraine: Teva's fremanezumab and Eli Lilly's galcanezumab. These follow Amgen/Regeneron's CGRP receptor-targeted mAb erenumab earlier this year, intensifying competition in this new market.

The quarter also saw advances in the women's health area, as TherapeuticsMD won approval for Anovera, a novel birth control product that lasts up to a year. Elagolix, a gonadotropin-releasing hormone antagonist developed by Neurocrine and AbbVie for pain associated with endometriosis, was also approved. However, the women's health space remains underserved, which could underlie the \$1.5 billion of sales forecasted for elagolix in 2024.

Finally, there were several products approved for rare diseases, including Biocodex's GABA reuptake inhibitor stiripentol for Dravet syndrome, Amicus Therapeutics' pharmacological chaperone migalastat for Fabry disease and Shire's kallikrein-specific mAb for hereditary angioedema, lanadelumab, the only other drug approved in this quarter forecasted to be a blockbuster in 2024.

Lisa Urquhart is at Vantage, London, UK.
e-mail: lisau@vantageanalysis.com

doi:10.1038/nrd.2018.194
Published online 30 Oct 2018

Competing interests

The authors declare no competing interests.

Table 1 | Selected FDA new drug approvals in Q3 2018

Date	Drug (brand name; company)	Properties	Indication	2024 global sales forecast
13 Jul	Tecovirimat (TPOXX; SIGA Technologies)	Viral P37 protein inhibitor	Smallpox	NA
20 Jul	Ivosidenib (Tibsovo; Agios Pharmaceuticals)	IDH1 inhibitor	AML	\$926 million
20 Jul	Tafenoquine (Krintafel; MMV/GSK)	NA	Malaria	NA
23 Jul	Elagolix (Orilissa; Neurocrine Biosciences/AbbVie)	GnRH antagonist	Pain associated with endometriosis	\$1,508 million
27 Jul	Fish oil triglycerides (Omegaven; Fresenius)	NA	Malnutrition	NA
31 Jul	Lusutrombopag (Mulpleta; Shionogi)	TPO receptor agonist	Thrombocytopenia	\$38 million
8 Aug	Mogamulizumab (Poteligeo; Kyowa Hakko Kirin)	CCR4 mAb	Cutaneous T cell lymphoma	\$72 million
10 Aug	Segesterone acetate and ethinyl estradiol (Anovera; TherapeuticsMD)	PR agonist and ER agonist	Female contraception	NA
10 Aug	Migalastat (Galafold; Amicus Therapeutics)	α -Galactosidase regulator	Fabry disease	\$546 million
10 Aug	Patisiran (Onpattro; Alnylam Pharmaceuticals)	TTR RNAi	TTR-mediated amyloidosis	\$953 million
20 Aug	Stiripentol (Diacomit; Biocodex)	GABA reuptake inhibitor	Dravet syndrome	NA
22 Aug	Cenegermin (Oxervate; Dompé)	Recombinant NGF	Ocular infections	NA
23 Aug	Lanadelumab (Takhzyro; Shire)	KLK mAb	Hereditary angioedema	\$1,542 million
27 Aug	Eravacycline (Xerava; Tetrphase Pharmaceuticals)	Tetracycline antibiotic	Intra-abdominal infections	\$219 million
30 Aug	Doravirine (Pifeltro; Merck & Co.)	HIV NNRTI	HIV	\$186 million
13 Sep	Moxetumomab pasudotox (Lumoxiti; AstraZeneca)	CD22-directed cytotoxin	Hairy cell leukaemia	\$132 million
14 Sep	Fremanezumab (Ajovy; Teva)	CGRP mAb	Migraine	\$896 million
24 Sep	Duvelisib (Copiktra; Verastem Oncology)	PI3K inhibitor	CLL, FL and SLL	\$326 million
27 Sep	Dacomitinib (Vizimpro; Pfizer)	EGFR inhibitor	EGFR-mutant NSCLC	\$336 million
27 Sep	Galcanezumab (Emgality; Eli Lilly)	CGRP mAb	Migraine	\$944 million
28 Sep	Cemiplimab (Libtayo; Regeneron/Sanofi)	PD1 mAb	CSCC	\$611 million

AML, acute myeloid leukaemia; CCR4, CC-chemokine receptor 4; CGRP; calcitonin gene-related peptide; CLL, chronic lymphocytic leukaemia; CSCC, cutaneous squamous cell carcinoma; EGFR, epidermal growth factor receptor; ER, oestrogen receptor; FL, follicular lymphoma; GnRH; gonadotropin-releasing hormone; GSK, GlaxoSmithKline; IDH, isocitrate dehydrogenase 1; KLK, kallikrein; mAb, monoclonal antibody; MMV, Medicines for Malaria Venture; NA, not available; NGF, nerve growth factor; NNRTI, non-nucleoside reverse transcriptase inhibitor; NSCLC, non-small-cell lung cancer; PI3K, phosphatidylinositol 3-kinase; PR, progesterone receptor; RNAi, RNA interference; SLL, small lymphocytic lymphoma; TPO, thrombopoietin; TTR, transthyretin.