

June 2020

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Dojolvi™ (trihexanoin) [†] Ultragenyx	Medium chain fatty acid	As a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders	July 2020
Dupixent® (dupilumab) single-dose prefilled pen Regeneron	Interleukin-4/13 inhibitor	Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.	June 24, 2020
Fintepla® (fenfluramine) [†] Zogenix	Serotonin receptor agonist	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older	June 29, 2020
Gimoti™ (metoclopramide) Evoke Pharma	Antidopaminergics	For the relief of symptoms in adults with acute and recurrent diabetic gastroparesis	4th quarter of 2020

Lyumjev™ (insulin lispro-aabc) Eli Lilly	Insulins	To improve glycemic control in adults with diabetes mellitus	June 18, 2020
Mycapssa® (octreotide) [†] Chiasma	Somatostatin analog	Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide	4 th quarter of 2020
Nyvepria™ (pegfilgrastim-apgf) ^{*§} Pfizer	Colony-stimulating factor	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	2 nd half of 2020
Phesgo™ (pertuzumab/trastuzumab/hyaluronidase-zzxf) Genentech	HER2/neu receptor antagonist	In combination with chemotherapy for: the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence; in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease	July 1, 2020
Semglee® (insulin glargine) Mylan and Biocon	Long-acting insulin	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	TBD
Tivicay® PD (dolutegravir) tablets for oral suspension ViiV Healthcare	Integrase inhibitor	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but integrase strand	June 16, 2020

		transfer inhibitor [INSTI]-naïve) aged at least 4 weeks and weighing at least 3 kg	
Uplizna™ (inebilizumab-cdon)*† Viela Bio	CD-19 antagonist	Treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive	June 22, 2020
Zepzelca™ (lurbinectedin)*† Jazz Pharmaceuticals and PharmaMar	Alkylating agent	Treatment of adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy	June 23, 2020

*New molecular entity †Orphan Drug §Biosimilar TBD: To be determined

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Desonate® (desonide) LEO Pharma	Cintex†	0.05% topical gel	Atopic dermatitis	June 15, 2020

†A-rated generic manufacturer

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Bavencio® (avelumab) Pfizer and EMD Serono	Expanded indication	Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy

Cosentyx® (secukinumab) Novartis	New indication	Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
Crysvita® (burosumab-twza) Kyowa Kirin and Ultragenyx	New indication	Treatment of fibroblast growth factor 23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older
Gardasil® 9 (human papillomavirus 9-valent vaccine, recombinant) Merck	Expanded indication	Prevention of oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58 in males and females 9 through 45 years of age
Ilaris® (canakinumab) Novartis	Expanded indication	Treatment of active Still's disease, including Adult-Onset Still's Disease in patients aged 2 years and older
Inlyta® (axitinib) Pfizer	New indications	First-line treatment of patients with advanced renal cell carcinoma (RCC); in combination with pembrolizumab is for the first-line treatment of patients with advanced RCC
Keytruda® (pembrolizumab) Merck	New indications	Treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (≥ 10 mutations/megabase) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options; treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation; treatment of patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer
Lialda® (mesalamine) Takeda	Expanded indication	Treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg
Mylotarg™ (gemtuzumab ozogamicin) Pfizer	Expanded indication	Treatment of newly-diagnosed CD33-positive acute myeloid leukemia in adults and pediatric patients 1 month and older
Opdivo® (nivolumab) Bristol Myers Squibb	New indication	Treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy
Recarbrio® (imipenem/cilastatin/relebactam) Merck	New indication	Treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by susceptible gram-negative microorganisms

Sivextro® (tedizolid) Merck	Expanded indication	In adult and pediatric patients 12 years of age and older, for the treatment of acute bacterial skin and skin structure infections caused by susceptible isolates of Gram-positive microorganisms
Tazverik™ (tazemetostat) Epizyme	New indications	Treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an enhancer of zeste homolog 2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and adult patients with R/R FL who have no satisfactory alternative treatment options
Taltz® (ixekizumab) Eli Lilly	New indication	Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
Tivicay® (dolutegravir) and Tivicay PD (dolutegravir) ViiV Healthcare's	Expanded indication	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor-naïve) aged at least 4 weeks and weighing at least 3 kg
Xpovio® (selinexor) Karyopharm Therapeutics	New indication	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy

Drug safety news

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Drug name Manufacturer(s)	Description
Epinephrine auto-injector Amneal and Impax	The FDA alerted patients, caregivers and health care professionals to immediately inspect certain lots of Amneal and Impax epinephrine 0.3 mg auto-injectors to ensure the yellow “stop collar” in the device is present. If the auto-injector is missing the yellow “stop collar” component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Amoxapine Teva	25 mg, 50 mg, 100 mg, and 150 mg tablets	Shortage	The drug shortage of Teva's amoxapine is ongoing. Amoxapine has been unavailable due to manufacturing delays from capacity constraints. Per Teva, amoxapine is backordered until the end of July 2020.
Metformin extended-release (ER) Amneal, Apotex, AvKare, Lupin, Marksans, and Teva	Amneal, Apotex, AvKare, Lupin, Marksans, and Teva: 500 mg tablets Amneal, AvKare, Teva: 750 mg tablets	Recall	Several manufacturers announced voluntary, consumer-level recalls of metformin ER tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit. Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.

Key guideline/literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma.</i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 4.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</i> June 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 4.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 6.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 6.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u></i> June 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections - Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u></i> June 2020



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