

## New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Dengvaxia</b> <sup>®</sup> (dengue tetravalent vaccine, live)* Sanofi Pasteur	Vaccine	For the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4. Dengvaxia is approved for use in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.	TBD
<b>Ingrezza</b> <sup>®</sup> (valbenazine) initiation pack Neurocrine Biosciences	Vesicular monoamine transporter-2 inhibitor	Treatment of adults with tardive dyskinesia	April 22, 2019
<b>Nayzilam</b> <sup>®</sup> (midazolam)+ single-dose nasal spray UCB	Benzodiazepine	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older	TBD
<b>Piqray</b> <sup>®</sup> (alpelisib)* Novartis	Phosphoinositide 3-kinase CA inhibitor	In combination with Faslodex <sup>®</sup> (fulvestrant) for the treatment of postmenopausal women, and men, with hormone receptor-positive, human epidermal growth factor receptor 2-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen	May 30, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Qternmet<sup>®</sup> XR</b> (dapagliflozin/saxagliptin/ metformin) AstraZeneca	Sodium-glucose cotransporter 2 inhibitor/dipeptidyl peptidase-4 inhibitor/biguanide	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	TBD
<b>Ruzurgi<sup>™</sup></b> (amifampridine)*† Jacobus Pharmaceuticals	Potassium channel blocker	Treatment of Lambert-Eaton myasthenic syndrome in patients 6 to less than 17 years of age	June 6, 2019
<b>Slynd<sup>®</sup></b> (drospirenone) Exeltis	Progesterone	For use by females of reproductive potential to prevent pregnancy	TBD
<b>Vyndaqel<sup>®</sup></b> (tafamidis meglumine)*, <b>Vyndamax<sup>™</sup></b> (tafamidis)* Pfizer	Transthyretin stabilizer	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization	May 13, 2019 <sup>Δ</sup>
<b>Zolgensma<sup>®</sup></b> (onasemnogene abeparvovec- xioi)*† Novartis/AveXis	Gene therapy	Treatment of pediatric patients less than 2 years of age with spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 gene	May 29, 2019

\*New molecular entity †Orphan Drug §Biosimilar ΔVyndaqel; Vyndamax 2H2019 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
<b>Cuprimine</b> <sup>®</sup> (penicillamine) Bausch Health	Amerigen <sup>†</sup> , Oceanside	250 mg capsules	Wilson's disease, cystinuria, and rheumatoid arthritis	May 8, 2019 <sup>¥</sup>
<b>Delzicol</b> <sup>®</sup> (mesalamine) Allergan	Teva <sup>†</sup> , Greenstone <sup>*</sup>	400 mg delayed release capsules	Ulcerative colitis	May 10, 2019 <sup>#</sup>
<b>Faslodex</b> <sup>®</sup> (fulvestrant) AstraZeneca	Sandoz <sup>†</sup> , Amneal <sup>†</sup>	250 mg/mL injection	Breast cancer	May 31, 2019 <sup>^</sup>
<b>Lotemax</b> <sup>®</sup> (loteprednol etabonate) Bausch Health	Akorn <sup>†</sup>	0.5% ophthalmic suspension	Post-operative inflammation and pain following ocular surgery	May 6, 2019
<b>Suprax</b> <sup>®</sup> (cefixime) Lupin	Ascend Laboratories <sup>†</sup> , Lupin <sup>*</sup>	400 mg capsules	Urinary tract infections, otitis media, pharyngitis/tonsillitis, acute exacerbations of chronic bronchitis, and gonorrhea	May 16, 2019
<b>Tracleer</b> <sup>®</sup> (bosentan) Actelion	Amneal <sup>†</sup> , Par/Endo <sup>†</sup> , Alvogen <sup>†</sup> , Lupin/Natco <sup>†</sup> , Sun <sup>†</sup> , Teva/Watson <sup>†</sup> , West- Ward/Hikma <sup>†</sup> , Zydus <sup>†</sup>	62.5 mg and 125 mg tablets	Pulmonary arterial hypertension	May 5, 2019 <sup>Δ</sup>
<b>Tarceva</b> <sup>®</sup> (erlotinib) Genentech	Teva <sup>†</sup> , Mylan <sup>†</sup>	25 mg, 100 mg, and 150 mg tablets	Non-small cell lung cancer and pancreatic cancer	May 9, 2019 <sup>§</sup>
<b>Yosprala</b> <sup>®</sup> (aspirin/omeprazole) Aralez	Basim <sup>*</sup>	aspirin/omeprazole: 81/40 mg, 325/40 mg tablets	Secondary prevention of cardiovascular and cerebrovascular events	April 19, 2019

†A-rated generic manufacturer \*Authorized generic

¥ Oceanside launch May 10, 2019

#Greenstone launch May 13, 2019

ΔAmneal, Par/Endo, Alvogen, Lupin/Natco, Sun, West-Ward/Hikma; Teva/Watson and Zydus TBD

§Mylan launched 25 mg, 100 mg and 150 mg tablets; Teva launched 100 mg and 150 mg tablets

^Amneal TBD

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Bavencio</b> <sup>®</sup> (avelumab) EMD Serono, Pfizer	New indication	In combination with Inlyta <sup>®</sup> (axitinib) for the first-line treatment of advanced renal cell carcinoma
<b>Cyramza</b> <sup>®</sup> (ramucirumab) Eli Lilly	New indication, removal of boxed warning	Treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of $\geq 400$ ng/mL and have been treated with Nexavar <sup>®</sup> (sorafenib)  The <i>Boxed Warning</i> for hemorrhage, gastrointestinal perforation, and impaired wound healing was removed from the Cyramza drug label.
<b>Eylea</b> <sup>®</sup> (afibercept) Regeneron	Expanded indication	Treatment of diabetic retinopathy
<b>Fragmin</b> <sup>®</sup> (dalteparin) Pfizer	New indication	Treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence of VTE in patients $\geq 1$ month of age
<b>Gattex</b> <sup>®</sup> (teduglutide) Takeda Pharmaceuticals	Expanded indication	Treatment of patients $\geq 1$ year of age with short bowel syndrome who are dependent on parenteral support
<b>Herzuma</b> <sup>®</sup> (trastuzumab-pkrb) Teva, Celltrion	New and expanded indications	Treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease, and for adjuvant treatment of HER2 overexpressing node positive or node negative breast cancer as a single agent following multi-modality anthracycline based therapy
<b>Jakafi</b> <sup>®</sup> (ruxolitinib) Incyte	New orphan indication	Treatment of steroid-refractory acute graft-versus-host disease in patients $\geq 12$ years of age
<b>Kadcyla</b> <sup>®</sup> (ado-trastuzumab emtansine) Genentech	New indication	As a single agent, for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and Herceptin <sup>®</sup> (trastuzumab)-based treatment

<b>Livalo</b> <sup>®</sup> (pitavastatin) Kowa Pharmaceuticals	Expanded indication	An adjunctive therapy to diet in patients ≥ 8 years of age with heterozygous familial hypercholesterolemia to reduce elevated total cholesterol, low-density lipoprotein cholesterol, and apolipoprotein B
<b>Lyrica</b> <sup>®</sup> (pregabalin) capsules and oral solution Pfizer	Expanded indication	Adjunctive therapy for the treatment of partial-onset seizures in patients ≥ 1 month of age
<b>Qtern</b> <sup>®</sup> (dapagliflozin/saxagliptin) AstraZeneca	Expanded indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
<b>Revlimid</b> <sup>®</sup> (lenalidomide) Celgene	New indications	In combination with a rituximab product for the treatment of adult patients with previously treated follicular lymphoma and marginal zone lymphoma
<b>Sorilux</b> <sup>®</sup> (calcipotriene) foam Mayne Pharma	Expanded indication	Topical treatment of plaque psoriasis of the scalp and body in patients ≥ 12 years of age
<b>Tibsovo</b> <sup>®</sup> (ivosidenib) Agiros	Expanded indication	Treatment of newly-diagnosed acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation in adults ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy
<b>Truxima</b> <sup>®</sup> (rituximab-abbs) Teva, Celltrion	New and expanded indications	Treatment of adult patients with previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone or other anthracycline-based chemotherapy regimens; and with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide
<b>Venclexta</b> <sup>®</sup> (venetoclax) Roche	Expanded indication	Treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma
<b>Vraylar</b> <sup>®</sup> (cariprazine) Allergan, Gedeon Richter	New indication	Treatment of depressive episodes associated with bipolar I disorder
<b>Xeomin</b> <sup>®</sup> (incobotulinumtoxinA) Merz Pharmaceuticals	Expanded indication	Treatment of blepharospasm

## Drug safety news

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Drug name Manufacturer(s)	Description
<b>Xospata</b> <sup>®</sup> (gilteritinib) Astellas Pharma	A new <i>Boxed Warning</i> was added to the Xospata drug label regarding differentiation syndrome

## Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Amikacin and prochlorperazine</b> Heritage Pharmaceuticals	Amikacin sulfate injection, 1 g/4 mL Prochlorperazine edisylate injection, 10 mg/2 mL	Recall	Heritage Pharmaceuticals recalled two lots of amikacin injection and prochlorperazine injection due to microbial growth having been detected in a couple unreleased sublots, which may indicate a lack of sterility in the other sublots.  Amikacin injection is indicated in the short-term treatment of serious infections due to susceptible strains of certain types of Gram-negative bacteria.  Prochlorperazine injection is indicated to control severe nausea and vomiting and for the treatment of schizophrenia.
<b>Ketorolac tromethamine</b> Sagent Pharmaceuticals	60 mg/ 2 mL injection	Recall	Sagent recalled one lot of ketorolac injection due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products.  Ketorolac tromethamine injection is indicated for the short-term management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting.
<b>Losartan</b> Vivimed	25 mg, 50 mg and 100 mg tablets	Recall	Vivimed recalled several lots of losartan tablets due to N-Methylnitrosobutyric acid (NMBA) that is above the FDA's interim acceptable exposure limit. The finished product lots were made by Vivimed and distributed by Heritage Pharmaceuticals.  Losartan tablets are used for the treatment of hypertension (HTN) and

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			to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan tablets are also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of HTN.
<b>Promacta</b> <sup>®</sup> (eltrombopag) Novartis	12.5 mg oral suspension	Recall	Novartis recalled some lots of Promacta oral suspension because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site.  Promacta oral suspension is indicated for the treatment of chronic immune thrombocytopenia, hepatitis C-associated thrombocytopenia, and severe aplastic anemia

### Key guideline/literature updates

Topic	Reference
Enhancing the Value of PCSK9 Monoclonal Antibodies by Identifying Patients Most Likely to Benefit – National Lipid Association	<a href="#"><i>Journal of Clinical Lipidology</i></a> . May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</i></a> . May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 3.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i></a> . May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 3.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i></a> . May 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 5.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u></a> May 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management – Version 3.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u></a> May 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u></a> May 2019



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