

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Inrebic [®] (fedratinib) [†] Celgene	Janus kinase 2 inhibitor	Treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis	August 19, 2019
Nourianz [™] (istradefylline)* Kyowa Kirin	A2A adenosine receptor antagonist	Adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes	TBD
Pretomanid ^{†*} TB Alliance	Nitroimidazole	Part of a combination regimen with Sirturo (bedaquiline) and linezolid for the treatment of adults with pulmonary extensively drug resistant or treatment-intolerant or nonresponsive multidrug-resistant tuberculosis	End of 2019
Rinvoq [™] (upadacitinib)* AbbVie	Janus kinase inhibitor	Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate	August 19, 2019
Riomet ER [™] (metformin) extended-release oral suspension Sun Pharma	Biguanide	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Rozlytrek™ (entrectinib) ^{†*} Roche and Genentech	Tyrosine kinase inhibitor	Treatment of adult patients with metastatic non-small cell lung cancer whose tumors are ROS1-positive; treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have either progressed following treatment or have no satisfactory alternative therapy	August 22, 2019
Turalio™ (pexidartinib) ^{†*} Daiichi Sankyo	Colony stimulating factor-1 receptor inhibitor	Treatment of adult patients with symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery	August 5, 2019
Wakix® (pitolisant) ^{†*} Harmony Biosciences	Inverse histamine H-3 receptor antagonist	Treatment of excessive daytime sleepiness in adult patients with narcolepsy	4Q2019
Xenleta™ (lefamulin)* Nabriva Therapeutics	Pleuromutilins	Treatment of adults with community-acquired bacterial pneumonia caused by the following susceptible microorganisms: <i>Streptococcus pneumoniae</i> , <i>Staphylococcus aureus</i> (methicillin-susceptible isolates), <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , <i>Mycoplasma pneumoniae</i> , and <i>Chlamydia pneumoniae</i>	August 22, 2019

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

New generics/authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Cloderm® (clocortolone) EPI Health	--	Prasco	0.1% cream	Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	August 21, 2019

Drug name Manufacturer(s)	Generic manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Dyrenium [®] (triamterene) Concordia	TruPharma [†]	--	50 mg and 100 mg capsules	Edema associated with congestive heart failure, cirrhosis of the liver and nephrotic syndrome; steroid-induced edema, idiopathic edema and edema due to secondary hyperaldosteronism	August 21, 2019
Halog [®] (halcinonide) Sun Pharma	Mylan [†]	--	0.1% cream	Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	August 16, 2019
Noxafil [®] (posaconazole) Merck	Lannett/ Sinotherapeutics [†]	Par	100 mg delayed- release tablet	Prophylaxis of invasive <i>Aspergillus</i> and <i>Candida</i> infections	August 30, 2019

[†]A-rated generic manufacturer

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Asmanex HFA [®] (mometasone furoate) Merck	Expanded indication, new strength	Maintenance treatment of asthma as prophylactic therapy in patients ≥ 5 years of age An Asmanex HFA 50 mcg strength (per actuation) for use in this patient population was also approved
Clenpiq [™] (sodium picosulfate/magnesium oxide/anhydrous citric acid) Ferring Pharmaceuticals	Expanded indication	For cleansing of the colon as a preparation for colonoscopy in patients ≥ 9 years of age

Dulera [®] (mometasone furoate/formoterol fumarate dihydrate) Merck	Expanded indication, new strength	Treatment of asthma in patients ≥ 5 years of age A Dulera 50 mcg/5 mcg strength (per actuation) for use in patients < 12 years of age was also approved
Harvoni [®] (ledipasvir/sofosbuvir) Gilead	Expanded orphan indication, new formulation, new strength	Treatment of patients ≥ 3 years of age with chronic hepatitis C virus (HCV): genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin 45 mg/200 mg and 33.75 mg/150 mg oral pellets and a 45 mg/200 mg oral tablet formulation of Harvoni were also approved for use in this patient population
Myobloc [®] (rimabotulinumtoxinB) US WorldMeds	New indication	Treatment of chronic sialorrhea in adults
Sirturo [®] (bedaquiline) Janssen	Expanded indication	As part of combination therapy in the treatment of pediatric patients with pulmonary multi-drug resistant tuberculosis
Sovaldi [®] (sofosbuvir) Gilead	Expanded orphan indication, new formulation, new strength	Treatment of chronic HCV genotype 2 or 3 infection in patients ≥ 3 years of age without cirrhosis or with compensated cirrhosis for use in combination with ribavirin 150 mg and 200 mg oral pellets and a 200 mg oral tablet formulation of Sovaldi were also approved use in this patient population
Taltz [®] (ixekizumab) Eli Lilly	New indication	For the treatment of adults with active ankylosing spondylitis
Tybost [®] (cobicistat) Gilead	Expanded indication	To increase systemic exposure of atazanavir in combination with other antiretroviral agents in the treatment of human immunodeficiency virus-1 infection in pediatric patients weighing at least 35 kg

Drug safety news

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Drug name Manufacturer(s)	Description
Entacapone-Containing Products	There is no increased risk of prostate cancer with the use of entacapone [ie, Comtan [®] (entacapone) and Stalevo [®] (carbidopa/levodopa/entacapone)] to treat Parkinson's disease and the recommendations for using these medicines will remain the same as labeled in the prescribing information.
Hepatitis C Medications	The use of Mavyret [™] (glecaprevir/pibrentasvir), Zepatier [®] (elbasvir/grazoprevir), or Vosevi [®] (sofosbuvir/velpatasvir/voxilaprevir) to treat chronic hepatitis C in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Relpax[®] (eletriptan) Pfizer	40 mg tablets	Recall	Pfizer announced a voluntary patient-level recall of two lots of Relpax 40 mg tablets because these product lots may not meet Pfizer's in-house microbiological specification for the potential presence of <i>Pseudomonas</i> and <i>Burkholderia</i> . Relpax is indicated for the acute treatment of migraine with or without aura in adults
Striant[®] (testosterone) Endo	30 mg buccal system	Discontinuation	Endo has made a business decision to permanently discontinue Striant. The discontinuation was not due to any safety, quality or efficacy issues. Striant is indicated for replacement therapy in adult males for certain conditions associated with a deficiency or absence of endogenous testosterone

Key guideline/literature updates

Topic	Reference
Advisory Committee for Immunization Practices - Updated recommendations for human papillomavirus vaccination in adults	<i>Morbidity and Mortality Weekly Report</i> . August 2019
United States and Canadian Hidradenitis Suppurativa Foundations – Clinical Management for Hidradenitis Suppurativa Part I and II	<i>Journal of the American Academy of Dermatology (Part I)</i> . July 2019 <i>Journal of the American Academy of Dermatology (Part II)</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer – Version 1.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer</i> . August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 1.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i> . August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 1.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia</i> . August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening</i> . August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal</i> . August 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia – Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes – Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 7.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 4.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> August 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> August 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> August 2019



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