

## New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Duaklir® Pressair®</b> (aclidinium/formoterol fumarate) AstraZeneca	Anticholinergic and long-acting beta2-adrenergic agonist	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	TBD
<b>Jatenzo®</b> (testosterone undecanoate) capsules Clarus Therapeutics	Androgen	Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired)	Before the end of 2019
<b>Mavenclad®</b> (cladribine) EMD Serono	Purine antimetabolite	Treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Mavenclad is not recommended for use in patients with clinically isolated syndrome because of its safety profile	TBD
<b>Mayzent®</b> (siponimod)* Novartis	Selective sphingosine-1 phosphate receptor modulator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	March 28, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Rocklatan</b> <sup>™</sup> (netarsudil/latanoprost) Aerie Pharmaceuticals	Rho kinase inhibitor/prostaglandin analogue	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	2Q2019
<b>Spravato</b> <sup>™</sup> (esketamine)* Janssen, J&J	NMDA receptor antagonist	In conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults	March 10, 2019
<b>Sunosi</b> <sup>™</sup> (solriamfetol) <sup>†*</sup> Jazz Pharmaceuticals	Dopamine and norepinephrine reuptake inhibitor	To improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea	June 20, 2019
<b>Trazimera</b> <sup>™</sup> (trastuzumab-qyyp) <sup>§*</sup> Pfizer	HER-2/neu receptor antagonist	Adjuvant breast cancer, metastatic breast cancer, and metastatic gastric or gastroesophageal junction adenocarcinoma	TBD
<b>Zulresso</b> <sup>™</sup> (brexanolone)* SAGE Therapeutics	Gamma-aminobutyric acid A receptor positive modulator	Treatment of postpartum depression in adults	June 2019
<b>Zykadia</b> <sup>®</sup> (ceritinib) tablets Novartis	Tyrosine kinase inhibitor	Treatment of adults with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test	TBD

\*New molecular entity †Orphan Drug 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>Amrix<sup>®</sup></b> (cyclobenzaprine) Teva	Twi <sup>†</sup> , Apotex <sup>†</sup>	15 mg and 30 mg extended release capsules	Muscle spasm	March 1, 2019
<b>Exjade<sup>®</sup></b> (deferasirox) Novartis	Teva <sup>†</sup>	125 mg, 250 mg, and 500 mg tablets for oral suspension	Iron toxicity, transfusional iron overload	March 22, 2019
<b>Flector<sup>®</sup></b> (diclofenac epolamine) Pfizer	Teva <sup>*</sup> , Greenstone <sup>*</sup>	1.3% topical system	Acute Pain	March 1, 2019
<b>Humalog<sup>®</sup></b> (insulin lispro) Eli Lilly	ImClone Systems <sup>*</sup>	100 units/mL injection	Diabetes mellitus	TBD
<b>Mestinon<sup>®</sup></b> (pyridostigmine) Bausch Health	Novitium Pharma <sup>†±</sup>	60 mg/ 5 mL oral syrup	Myasthenia gravis	March 11, 2019
<b>Sensipar<sup>®</sup></b> (cinacalcet) Amgen	Slate Run <sup>†</sup> , Aurobindo <sup>†</sup> , Cipla <sup>†</sup> , Strides <sup>†</sup> , Sun <sup>†</sup> , Mylan <sup>†</sup> , Teva <sup>†</sup>	30 mg, 60 mg and 90 mg tablets	Hyperparathyroidism associated with chronic kidney disease; hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism	March 12, 2019 <sup>Δ</sup>
<b>Tekturna<sup>®</sup></b> (aliskiren) Noden Pharma	Noden/Prasco <sup>*</sup> , Par <sup>†</sup>	150 mg and 300 mg tablets	Hypertension	March 4, 2019 <sup>¥</sup> , March 25, 2019 <sup>‡</sup>

†A-rated generic manufacturer ±180-days of marketing exclusivity \*Authorized generic  
Δ Slate Run Pharmaceuticals; other manufacturers pending ¥Noden/Prasco; ‡Par

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Avycaz</b> <sup>®</sup> (ceftazidime/avibactam) Allergan	Expanded indication	Treatment of complicated intra-abdominal infections and complicated urinary tract infections
<b>Cimzia</b> <sup>®</sup> (certolizumab pegol) UCB	New indication	Treatment of non-radiographic axial spondyloarthritis with objective signs of inflammation
<b>Dupixent</b> <sup>®</sup> (dupilumab) Regeneron Pharmaceuticals	Expanded indication	Treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis
<b>Flector</b> <sup>®</sup> (diclofenac epolamine) Teva	Expanded indication	Topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years and older
<b>Opdivo</b> <sup>®</sup> (nivolumab) Bristol-Myers Squibb	Updated indication	Treatment of patients with unresectable or metastatic melanoma as a single agent or in combination with Yervoy <sup>®</sup> (ipilimumab)
<b>Tecentriq</b> <sup>®</sup> (atezolizumab) Genentech	New indications	Treatment of adult patients with extensive-stage small cell lung cancer and unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1
<b>Turdoza</b> <sup>®</sup> <b>Pressair</b> <sup>®</sup> (aclidinium bromide) AstraZeneca	Updated indication	Maintenance treatment of patients with COPD
<b>Zelnorm</b> <sup>™</sup> (tegaserod) US WorldMeds	Updated indication	Treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C)

## Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Drospirenone and ethinyl estradiol</b> Apotex	3 mg/0.03 mg tablets	Recall	Apotex announced a voluntary, consumer-level recall of four lots of drospirenone and ethinyl estradiol tablets because some may possibly contain defective blisters with incorrect tablet arrangements and/or an empty blister pocket.  Drospirenone and ethinyl estradiol tablets are indicated for use by women to prevent pregnancy.
<b>Losartan-containing products</b> Torrent	Losartan: 25 mg, 50 mg and 100 mg tablets  Losartan/HCTZ 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg tablets	Recall	Torrent announced a voluntary, consumer-level recall of several lots of losartan and losartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of N-Methylnitrosobutyric acid (NMBA) found in an active pharmaceutical ingredient manufactured by Hetero Labs.  Losartan and losartan/HCTZ tablets are used for the treatment of HTN and 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>Losartan-containing products</b> AvKARE	Losartan: 50 mg tablets  Losartan/HCTZ: 50 mg/12.5 mg and 100 mg/12.5 mg tablets	Recall	AvKARE announced a voluntary, consumer-level recall of some lots of losartan and losartan/HCTZ tablets due to the detection of trace amounts of NMBA found in the active pharmaceutical ingredient manufactured by Hetero Labs.
<b>Losartan</b> Preferred Pharmaceuticals	50 mg tablets	Recall	Preferred Pharmaceuticals announced a voluntary, consumer-level recall of multiple lots of losartan tablets due to the presence NMBA found in finished product.
<b>Valsartan</b> American Health Packaging	160 mg tablets	Recall	American Health Packaging announced a voluntary, consumer-level recall of one lot of valsartan tablets due to the detection of N-Nitrosodiethylamine (NDEA).  Valsartan is used to control high blood pressure and for the treatment of heart failure.

## Key guideline/literature updates

Topic	Reference
American College of Cardiology and American Heart Association – Primary Prevention of Cardiovascular Disease	<a href="#"><i>Journal of the American College of Cardiology</i></a> . March 2019
American College of Gastroenterology – Ulcerative Colitis in Adults	<a href="#"><i>American Journal of Gastroenterology</i></a> . March 2019
American Diabetes Association – Standards of Medical Care in Diabetes	<a href="#"><i>Diabetes Care</i></a> . March 2019
American Society of Transplantation Infectious Diseases Community of Practice - BK Polyomavirus in Solid Organ Transplantation	<a href="#"><i>Clinical Transplantation</i></a> . March 2019
Endocrine Society – Diabetes in Older Adults	<a href="#"><i>Diabetes Care</i></a> . March 2019
Endocrine Society - Osteoporosis in Postmenopausal Women	<a href="#"><i>The Journal of Clinical Endocrinology &amp; Metabolism</i></a> . March 2019
Enhanced Recovery After Surgery Society - Perioperative Care in Gynecologic/Oncology	<a href="#"><i>International Journal of Gynecological Cancer</i></a> . March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i></a> . March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i></a> . March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i></a> . March 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 4.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 4.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers – Version 1.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u></a> March 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</i></a> March 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors – Version 2.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</i></a> March 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 1.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</i></a> March 2019



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