

March 2020

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## New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Durysta™</b> (bimatoprost implant) Allergan	Prostaglandin agonist	Reduction of intraocular pressure in patients with open angle glaucoma or ocular hypertension	TBD
<b>Hyperrab®</b> [rabies immune globulin (human)] 900 IU/mL solution for injection Grifols	Vaccine	For postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies, except persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer, who should receive only vaccine	March 3, 2020
<b>Isturisa®</b> (osilodrostat) <sup>†*</sup> Recordati	Cortisol synthesis inhibitor	Treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative	2 <sup>nd</sup> or 3 <sup>rd</sup> quarter 2020
<b>Romidepsin</b> 27.5 mg/5.5 mL single dose vial Teva	Histone deacetylase inhibitor	Treatment of cutaneous T-cell lymphoma in adult patients who have received at least one prior systemic therapy; treatment of peripheral T-cell lymphoma in adult patients who have received at least one prior therapy	TBD
<b>Sarclisa®</b> (isatuximab-irfc) <sup>†*</sup> Sanofi	CD38 antagonist	In combination with Pomalyst® (pomalidomide) and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide) and a proteasome inhibitor	March 3, 2020

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Triferic AVNU<sup>®</sup></b> (ferric pyrophosphate citrate) Rockwell Medical	Iron replacement	Replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease	TBD
<b>Zeposia<sup>®</sup></b> (ozanimod)* Bristol-Myers Squibb	Sphingosine 1-phosphate 1 and 5 receptor modulator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	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>Daraprim<sup>®</sup></b> (pyrimethamine) Vyera	Dr. Reddy†	25 mg tablets	Toxoplasmosis	March 20, 2020
<b>Dymista<sup>®</sup></b> (azelastine/fluticasone propionate) Meda Pharmaceuticals	Apotex†	137 mcg/50 mcg nasal spray suspension	Seasonal allergic rhinitis	March 2, 2020
<b>Geodon<sup>®</sup></b> (ziprasidone) Pfizer	Dr. Reddy†	20 mg/mL powder for reconstitution (solution) injection	Acute treatment of agitation in patients with schizophrenia	March 17, 2020
<b>Nexium<sup>®</sup></b> (esomeprazole) AstraZeneca	Cipla†	10 mg, 20 mg, and 40 mg delayed-release packets for oral suspension <sup>Δ</sup>	Gastroesophageal reflux disease, NSAID-associated gastric ulcer, <i>H. pylori</i> eradication, and pathological hypersecretory conditions	March 27, 2020
<b>Proglycem<sup>®</sup></b> (diazoxide) Teva	E5 Pharma†*	50 mg/mL oral suspension	Hypoglycemia due to hyperinsulinism	March 20, 2020

<b>Zortress</b> <sup>®</sup> (everolimus) Novartis	Hikmat <sup>†</sup>	0.25 mg, 0.5 mg and 0.75 mg tablets <sup>#</sup>	Prophylaxis of organ rejection in kidney and liver transplantation	March 10, 2020
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<sup>†</sup>A-rated generic manufacturer \* Granted 180-days of exclusivity  
<sup>Δ</sup>2.5 mg and 5 mg delayed-release packets for oral suspension are not available as generics  
<sup>#</sup>1 mg tablets are not available as generics

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Epclusa</b> <sup>®</sup> (sofosbuvir/velpatasvir) Gilead	Expanded indication, New strength	Treatment of adults and pediatric patients ≥ 6 years of age or weighing ≥ 17 kg with chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin.  A 200 mg/50 mg tablet strength of Epclusa was also approved to accommodate dosing for patients weighing 17 to < 30 kg.
<b>Eucrisa</b> <sup>®</sup> (crisaborole) Pfizer	Expanded indication	For topical treatment of mild to moderate atopic dermatitis in patients 3 ≥ months of age
<b>Imfinzi</b> <sup>®</sup> (durvalumab) AstraZeneca	New indication	In combination with etoposide and either carboplatin or cisplatin, for the first-line treatment of adults with extensive-stage small cell lung cancer
<b>Ofev</b> <sup>®</sup> (nintedanib) Boehringer Ingelheim <sup>†</sup>	Expanded indication	Treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype
<b>Opdivo</b> <sup>®</sup> (nivolumab) Bristol-Myers Squibb	Expanded indication	As a single agent or in combination with Yervoy <sup>®</sup> (ipilimumab), for the treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar <sup>®</sup> (sorafenib)
<b>Symtuza</b> <sup>®</sup> (darunavir/cobicistat/emtricitabine/tenofovir) Janssen	Expanded indication	Treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing ≥ 40 kg: who have no prior antiretroviral treatment history or who are virologically suppressed on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir

<p><b>Taltz<sup>®</sup></b> (ixekizumab) Eli Lilly</p>	<p>Expanded indication</p>	<p>Treatment of patients ≥ 6 years of age with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy</p>
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**Drug safety news**

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<p><b>Drug name Manufacturer(s)</b></p>	<p><b>Description</b></p>
<p><b>EpiPen<sup>®</sup></b> (epinephrine) and <b>EpiPen Jr<sup>®</sup></b> (epinephrine) Pfizer and Mylan</p>	<p>Pfizer and Mylan announced that administration of EpiPen and EpiPen Jr auto-injectors and their authorized brand alternatives may be delayed or prevented during an emergency due to device failure from spontaneous activation caused by using a sideways force to remove the blue safety release; device failure from inadvertent or spontaneous activation due to a raised blue safety release; difficulty removing the device from the carrier tube; or user errors.</p>
<p><b>Montelukast</b></p>	<p><i>Boxed Warnings</i> will be added to the drug labels for all brand and generic Singulair<sup>®</sup> (montelukast) products regarding serious behavior and mood-related changes.  Montelukast should only be reserved to treat allergic rhinitis in patients who are not treated effectively with or cannot tolerate other allergy medicines.</p>
<p><b>Sodium glucose co-transporter-2 inhibitors</b></p>	<p>The <i>Warnings and Precautions</i> section of the drug labels for the SGLT2 inhibitors canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin regarding the temporary discontinuation of these medications before scheduled surgery due to a potential risk for developing ketoacidosis.</p>

**Drug recalls/withdrawals/shortages/discontinuations**

<p><b>Drug name Manufacturer(s)</b></p>	<p><b>Dosage form(s)</b></p>	<p><b>Type</b></p>	<p><b>Description</b></p>
<p><b>Albuterol inhalers</b></p>	<p>--</p>	<p>Shortage</p>	<p>The American College of Allergy, Asthma and Immunology announced that certain areas of the country are experiencing shortages of albuterol inhalers. The shortage will probably spread throughout the U.S., although it is not a production problem. The shortage is occurring because of the increased use of albuterol inhalers in hospitals for COVID-19 and suspected COVID-19 patients to help with respiratory issues.</p>

<p><b>Arcapta® Neohaler®</b> (indacaterol maleate),  <b>Utibron® Neohaler®</b> (indacaterol maleate/glycopyrrolate) and  <b>Seebri® Neohaler®</b> (glycopyrrolate)                  Sunovion</p>	<p>All product strengths</p>	<p>Discontinuation</p>	<p>Sunovion discontinued Arcapta Neohaler, Utibron Neohaler and Seebri Neohaler due to business reasons. The discontinuation was not due to product quality, safety or efficacy issues. These products are no longer available as of March 31, 2020.</p> <p>Arcapta Neohaler, Utibron Neohaler and Seebri Neohaler are indicated for maintenance treatment of chronic obstructive pulmonary disease.</p>
<p><b>Eprosartan</b>                  Mylan</p>	<p>600 mg tablets</p>	<p>Discontinuation</p>	<p>Mylan discontinued eprosartan tablets due to business reasons. The discontinuation was not due to product quality, safety or efficacy issues.</p> <p>Eprosartan is indicated for the treatment of hypertension.</p>
<p><b>Neoral®</b> (cyclosporine) and  <b>Sandimmune®</b> (cyclosporine)                  Novartis</p>	<p>100 mg soft gelatin capsules</p>	<p>Recall</p>	<p>Novartis recalled some lots of Sandimmune and Neoral 100 mg capsule prescription drug blister packages because the drug packaging is not child resistant as required by the Poison Prevention Packaging Act, posing a risk of poisoning if the contents are swallowed by young children.</p> <p>Sandimmune is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.</p> <p>Neoral is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. It is also indicated for the treatment of rheumatoid arthritis and plaque psoriasis.</p>

**Key guideline/literature updates**

<p><b>Topic</b></p>	<p><b>Reference</b></p>
<p>Treatment of Latent Tuberculosis Infection – National Tuberculosis Controllers Association and the Centers for Disease Control and Prevention</p>	<p><a href="#">Morbidity and Mortality Weekly Report</a>. February 2020</p>

Topic	Reference
Management of Chronic Insomnia Disorder and Obstructive Sleep Apnea – Department of Veterans Affairs and U.S. Department of Defense	<a href="#"><i>Annals of Internal Medicine</i></a> . March 2020
Vaccinations in Adults – Advisory Committee on Immunization Practices	<a href="#"><i>Centers for Disease Control and Prevention</i></a> . February 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 3.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i></a> . March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</i></a> . March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 2.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</i></a> . March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i></a> . March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</i></a> . March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers</i></a> . March 2020

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 3.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u></a> March 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u></a> March 2020



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