

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Braftovi™ (encorafenib)* Array BioPharma	BRAF kinase inhibitor	In combination with Mektovi® (binimetinib) for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	June 27, 2018
Epidiolex® (cannabidiol)* GW, Greenwich Biosciences	Cannabinoid	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients ≥ 2 years of age	September 2018
Fulphila™ (pegfilgrastim-jmdb) [§] Mylan, Biocon	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	TBD
LymePak™ (doxycycline hyclate) Chartwell	Tetracycline	Treatment of early Lyme disease (as evidenced by erythema migrans) due to <i>Borrelia burgdorferi</i> in adults and pediatric patients ≥ 8 years of age weighing ≥ 45 kg	TBD
Mektovi® (binimetinib)* Array BioPharma	MEK inhibitor	In combination with Braftovi for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	June 27, 2018
Moxidectin† Medicines Development for Global Health	Chloride channel agonist	Treatment of onchocerciasis due to <i>Onchocerca volvulus</i> in patients ≥ aged 12 years of age	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Nocdurna [®] (desmopressin acetate) sublingual tablets Ferring	Vasopressin analog	Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void	Second half of 2018
Nuplazid [®] (pimavanserin) 34 mg capsules Acadia	5-HT-2A receptor agonist	Treatment of hallucinations and delusions associated with Parkinson's disease psychosis	August 2018
Olumiant [®] (baricitinib) [*] Eli Lilly, Incyte	Janus associated kinase 1/2 inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies	June 5, 2018
Qbrexza [™] (glycopyrronium) Dermira	Anticholinergic	Topical treatment of primary axillary hyperhidrosis in adult and pediatric patients ≥ 9 years of age	October 2018
Zemdri [™] (plazomicin) [*] Achaogen	Aminoglycoside	Treatment of patients ≥ 18 years of age with complicated urinary tract infections, including pyelonephritis caused by the following susceptible microorganism(s): <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , and <i>Enterobacter cloacae</i>	Late July 2018

*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
Invanz [®] (ertapenem) Merck	Aurobindo [†]	1 g injection	Treatment of infections	July 2018

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Loestrin® 1.5/30 (ethinyl estradiol/ norethindrone acetate) Teva	Glenmark ^{†‡}	0.03 mg/1.5 mg tablets	Prevention of pregnancy	TBD
Loestrin® FE 1.5/30 (ethinyl estradiol/ norethindrone acetate and ferrous fumarate) Teva	Glenmark ^{†‡}	0.03 mg/1.5 mg and 75 mg tablets	Prevention of pregnancy	TBD
Makena® (hydroxyprogesterone caproate) AMAG	American Regent [†] , Prasco	250 mg/mL preservative-free injection	Reduce the risk of preterm birth	June 25, 2018
Onexton® (benzoyl peroxide/clindamycin) Valeant	Taro [†]	1.2%/3.75% topical gel	Acne vulgaris	TBD
Sabril® (vigabatrin) Lundbeck	Upsher-Smith ^{†§}	500 mg packet for oral solution	Refractory complex partial seizures and infantile spasms	TBD
Suboxone® (buprenorphine/naloxone) Indivior	Dr. Reddy's [†] , Mylan [†]	2 mg [‡] , 4 mg [‡] , 8 mg ^{‡§} , and 12 mg ^{‡§} sublingual films	Opioid dependence	June 17, 2018 ^Δ

†A-rated generic manufacturer ‡ Branded generic marketed as Hailey and Hailey FE §Branded generic marketed as Vigadrone *Authorized generic †Dr. Reddy's product §Mylan product
^ΔLaunch date for Dr. Reddy's products; Mylan launch date is TBD
TBD: To be determined

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Indications/label updates

Drug name Manufacturer(s)	Type	Description
Alimta [®] (pemetrexed) Eli Lilly	Expanded indication	Initial treatment of patients with metastatic, non-squamous non-small cell lung cancer in combination with carboplatin and Keytruda [®] (pembrolizumab)
Avastin [®] (bevacizumab) Genentech	Expanded indication	Treatment of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection in combination with carboplatin and paclitaxel, followed by Avastin as a single agent
Cinryze [®] (C1 esterase inhibitor [human]) Shire	Expanded indication	Routine prophylaxis against angioedema attacks in patients (≥ 6 years old) with hereditary angioedema
Keytruda [®] (pembrolizumab) Merck	New indications, Expanded indication	Treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1; Treatment of refractory primary mediastinal large B-cell lymphoma, or who have relapsed after ≥ 2 prior lines of therapy; Treatment of locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status
Mircera [®] (methoxy polyethylene glycol- epoetin beta) Vifor	New indication	Treatment of anemia associated with chronic kidney disease in pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoietin stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA
Rituxan [®] (rituximab) Genentech	New orphan indication	Treatment of moderate to severe pemphigus vulgaris in adults
Tecentriq [®] (atezolizumab) Genentech	Expanded indication	Treatment of locally advanced or metastatic urothelial carcinoma in patients who: are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1, or are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression
Venclexta [®] (venetoclax) Genentech	Expanded indication	Treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, who have received at least one prior therapy

Drug safety news

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Drug name Manufacturer(s)	Description
Lenvima [®] (lenvatinib) Eisai	The <i>Warnings and Precautions</i> section of the Lenvima drug label was updated with information regarding wound healing complications.
Neupogen [®] (filgrastim), Neulasta [®] (pegfilgrastim) Amgen	The <i>Warnings and Precautions</i> section of the Neupogen and Neulasta drug labels were updated with information regarding aortitis.
Proton pump inhibitors	The <i>Warnings and Precautions</i> section of the proton pump inhibitors' drug labels was updated with information regarding fundic gland polyps.
Remodulin [®] (treprostinil) United Therapeutics	The <i>Warnings and Precautions</i> section of the Remodulin drug label was updated with information regarding risk of symptomatic hypotension and risk of bleeding.
Stelara [®] (ustekinumab) Janssen	The <i>Warnings and Precautions</i> section of the Stelara drug label was updated with information regarding noninfectious pneumonia.
Xgeva [®] (denosumab) Amgen	The <i>Warnings and Precautions</i> section of the Xgeva drug label was updated with information regarding hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
0.45% sodium chloride, 0.9% sodium chloride and 5% dextrose ICU Medical	Injection products	Recall	ICU Medical announced a user-level recall of some lots of sodium chloride and dextrose intravenous solutions due to the potential for flexible container leaks. ICU Medical identified these leaks, potentially related to a manufacturing issue, in returned complaint samples and in ICU Medical reserve samples.
Depen [®] (penicillamine) Mylan	250 mg tablets	Shortage	The shortage of Depen is ongoing. Depen is estimated to be available February 2019. Depen is indicated in the treatment of Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.
Profilnine [®] , Factor IX Complex Grifols	1000 units single-dose vial	Recall	Grifols announced a patient-level recall of one lot of Profilnine, Factor IX Complex because the incorrect volume of sterile water for injection was packaged with Profilnine.

Key guideline/literature updates

Topic	Reference
Infectious Diarrhea: IDSA Updates Guidelines for Diagnosis and Management	<i>American Family Physician</i> . May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . June 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis – Version 3.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening – Version 1.2019	<i><u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 5.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology – Version 1.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 3.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u></i> June 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></i> June 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> June 2018



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