



September 2016

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## New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Amjevita™</b> (adalimumab-atto) <sup>*,§</sup> Amgen	Tumor necrosis factor inhibitor	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis	TBD
<b>Cuvitru™</b> (immune globulin subcutaneous [human], 20% solution) Baxalta	Immune globulin	Replacement therapy for primary humoral immunodeficiency in adult and pediatric patients ≥ 2 years of age	September 26, 2016
<b>Epaned®</b> (enalapril) oral solution Silvergate	Angiotensin-converting enzyme-inhibitor	Treatment of hypertension in adults and children aged over one month, to lower blood pressure; treatment of symptomatic heart failure (HF), usually in combination with diuretics and digitalis; and for use in clinically stable asymptomatic patients with left ventricular dysfunction (ejection fraction ≤ 35%), Epaned decreases the rate of development of overt HF and decreases the incidence of hospitalization for HF	TBD
<b>Exondys 51™</b> (eteplirsen) <sup>*</sup> Sarepta Therapeutics	Antisense oligonucleotide	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping	September 19, 2016
<b>Invokamet® XR</b> (canagliflozin/metformin extended-release) Janssen	Sodium-glucose co-transporter 2 inhibitor/biguanide	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate	September 20, 2016

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Kyleena</b> ™ (levonorgestrel-releasing intrauterine system) Bayer	Progestin	Prevention of pregnancy for up to 5 years	October 2016
<b>Yosprala</b> ™ (aspirin/omeprazole) Aralez	Anti-platelet/proton pump inhibitor	Patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers	September 19, 2016

\*New molecular entity §Biosimilar TBD: To be determined (launch dependent on patent litigation and court decisions)

**New generics**

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Cordran</b> ® (flurandrenolide) Aqua Pharmaceuticals	Taro*, Perrigo†	0.05% lotion	Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	September 21, 2016
<b>Cubicin</b> ® (daptomycin) Merck	Teva†, Hospira†, Crane†	500 mg vial per injection	Treatment of complicated skin and skin structure infections and <i>Staphylococcus aureus</i> bloodstream infections, including those with right-sided infective endocarditis	September 1 - 14, 2016
<b>Epzicom</b> ® (abacavir/lamivudine) ViiV Healthcare	Teva†±, Prasco*	600 mg/300 mg tablet	Treatment of HIV-1 infection	September 29, 2016

\*Authorized generic † A-rated generic manufacturer ± Granted 180 days of marketing exclusivity

**Indications/label updates**

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Drug name Manufacturer(s)	Type	Description
<b>Blincyto</b> ® (blinatumomab)	Expanded dosing,	The label was updated with new data supporting the treatment of pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic

Drug name Manufacturer(s)	Type	Description
Amgen	New warnings	leukemia. The updated label also includes new warnings regarding pancreatitis and immunization.
<b>Ilaris</b> <sup>®</sup> (canakinumab) Novartis	New indications	Treatment of tumor necrosis factor (TNF) receptor associated periodic syndrome; hyperimmunoglobulin D syndrome/mevalonate kinase deficiency; and familial mediterranean fever
<b>Orkambi</b> <sup>®</sup> (lumacaftor/ivacaftor) Vertex	Expanded indication, New dosage form	Treatment of cystic fibrosis in patients age 6 years and older who are homozygous for the F508del mutation in the CFTR gene. To support the expanded indication, Orkambi 100 mg/125 mg tablets were FDA approved.
<b>Stelara</b> <sup>™</sup> (ustekinumab) Janssen	New indication	Treatment of adult patients with moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a TNF blocker or failed or were intolerant to treatment with one or more TNF blockers

## Drug safety news

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Drug name Manufacturer(s)	Description
<b>Cortef</b> <sup>®</sup> (hydrocortisone) tablets, <b>Solu-Cortef</b> <sup>®</sup> (hydrocortisone sodium succinate) injection, <b>Solu-Medrol</b> <sup>®</sup> (methylprednisolone sodium succinate) injection Pfizer	The <i>Warnings and Precautions</i> sections of the Solu-Cortef and Cortef drug labels were updated regarding central serous chorioretinopathy, epidural lipomatosis and pheochromocytoma. Additionally, a new update was added to the <i>Warnings and Precautions</i> section of the Solu-Medrol drug label regarding the risk of hepatotoxicity with high dose administration.
<b>Jevtana</b> <sup>®</sup> (cabazitaxel) Sanofi Aventis	The <i>Warnings and Precautions</i> section of the label was updated with information regarding the risk of interstitial pneumonia/pneumonitis, interstitial lung disease and acute respiratory distress syndrome.

<b>Zydelig®</b> (idelalisib) Gilead	The FDA approved new updates to the <i>Warnings and Precautions</i> and <i>Limitations of Use</i> sections of the Zydelig drug label. Information regarding fatal and/or serious infections was added to the <i>Warnings and Precautions</i> section. A new limitation of use was added to each indication stating that Zydelig is not indicated and not recommended for first line treatment of patients with relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma or relapsed small lymphocytic lymphoma.
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### Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Eye wash/eye irrigation solutions</b> Family Care, Major and Rugby	4 oz (118 mL) bottle	Recall	Some lots of Family Care eye wash, Rugby eye irrigating solution and Major eye wash were recalled due to microbial contamination.
<b>GlucaGen® HypoKit®</b> (glucagon [rDNA origin] for injection) Novo Nordisk	One kit contains 1 vial of 1 mg glucagon for injection and 1 disposable syringe of 1 mL sterile water for injection	Recall	Novo Nordisk announced a recall of some batches of GlucaGen HypoKit due to two customer complaints involving detached needles on the syringe with sterile water for injection. A syringe with a detached needle cannot be used as prescribed.
<b>Granulex™</b> (castor oil / balsam peru / trypsin) Mylan	Aerosol spray	Discontinuation	The FDA announced the discontinuation of the Granulex 2 oz. can due to business reasons. The discontinuation was not due to safety or efficacy issues. The 4 oz. can was discontinued December 2015.
<b>Hyoscyamine sulfate</b> Virtus	0.125 mg sublingual tablets, 0.125 mg orally disintegrating tablets, and 0.125 tablets	Recall	Virtus announced a voluntary, consumer-level recall of certain lots of hyoscyamine sulfate products, due to both superpotent and subpotent test results.
<b>Reserpine</b> Sandoz	0.1 mg and 0.25 mg tablets	Discontinuation	Sandoz has discontinued all strengths of Reserpine tablets for business reasons. The discontinuation is not related to product safety or efficacy.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Aristospan®</b> (triamcinolone hexacetonide) Sandoz	5 mg/mL and 20 mg/mL suspension for injection	Discontinuation	Sandoz has discontinued all strengths of Aristospan injection for business reasons. The discontinuation is not related to product safety or efficacy.

### Key guideline/literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 1.2017	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms – Version 1.2017	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary – Version 1.2017	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 2.2017	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian – Version 1.2017	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal – Version 2.2016	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal.</i></a> September 2016
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation – Version 1.2016	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</i></a> September 2016

Topic	Reference
American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2016	<a href="#"><i>Endocrine Practice</i></a> . September 2016
2016 Infectious Diseases Society of America Clinical Practice Guideline for the Treatment of Coccidioidomycosis	<a href="#"><i>Clinical Infectious Diseases</i></a> . September 2016



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