

# AU InforMed

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## NEW DRUGS APPROVED IN 2014

Generic/Trade/ Manufacturer	Category	Use	Route	Pregnancy Cat*/Warnings°
<b>albiglutide</b> Tanzeum™ GlaxoSmithKline (GSK)	Glucagon-like peptide-1 (GLP-1) agonist	Type 2 diabetes	Subcutaneous (SC)	C  BBW
<b>apremilast</b> Otezla® Celgene Corp	Phosphodiesterase-4 enzyme inhibitor	Active psoriatic arthritis	Oral	C
<b>belinostat</b> Beleodaq™ Spectrum Pharm	Antineoplastic agent (histone deacetylase inhibitor)	Peripheral T-cell lymphoma	Intravenous (IV)	D
<b>blinatumomab</b> Blincyto™ Amgen	Antineoplastic agent (monoclonal antibody)	Philadelphia chromosome-negative precursor B-cell acute lymphoblast leukemia	IV	C BBW REMS Medication Guide
<b>ceftolozane/tazobactam</b> Zerbaxa™ Cubist Pharms Inc	Beta-lactam (cephalosporin/penicillin) antibiotic	Complicated intra- abdominal infections (cIAI) and complicated urinary tract infections (cUTI)	IV	B
<b>ceritinib</b> Zykadia™ Novartis Pharms Corp	Antineoplastic agent (tyrosine kinase inhibitor)	Late-stage (metastatic) non-small cell lung cancer (NSCLC)	Oral	D
<b>dalbavancin</b> Dalvance™ Durata Therapeutics	Glycopeptide antibiotic	Skin infections	IV	C
<b>dapagliflozin</b> Farxiga™ AstraZeneca	Sodium-glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	Oral	C
<b>droxidopa</b> Northera™ Lundbeck	Alpha/Beta agonist	Neurogenic orthostatic hypotension	Oral	C  BBW
<b>dulaglutide</b> Trulicity™ Eli Lilly and Co.	GLP-1 agonist	Type 2 diabetes	SC	C BBW REMS Medication Guide

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<b>efinaconazole</b> Jublia® <b>Dow Pharm</b>	Antifungal	Mild to moderate onychomycosis (fungal infection)	Topical	C
<b>eliglustat</b> Cerdelga™ <b>Genzyme</b>	Glucosylceramide synthase inhibitor	Type 1 form of Gaucher disease	Oral	C
<b>Elosulfase alfa</b> Vimizim® <b>Biomarin Pharm</b>	Enzyme	Mucopolysaccharidosis Type IVA (Morquio A syndrome)	IV	C BBW
<b>empagliflozin</b> Jardiance® <b>Boehringer Ingelheim</b>	Sodium-glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	Oral	C
<b>finafloxacin</b> Xtoro™ <b>Alcon Res</b>	Antibiotic (fluoroquinolone)	Acute otitis externa	Otic	C
<b>florbetaben F-18</b> Neuraceq™ <b>Piramal Imaging</b>	Radiopharmaceutical	Positron Emission Tomography (PET) imaging of the brain	IV	C
<b>idelalisib</b> Zydelig® <b>Gilead Sciences Inc</b>	Antineoplastic agent	Blood cancer	Oral	D BBW REMS
<b>ledipasvir/sofosbuvir</b> Harvoni™ <b>Gilead Sciences Inc</b>	Antihepaciviral	Chronic hepatitis C virus (HCV) genotype 1 infection	Oral	B
<b>miltefosine</b> Impavido™ <b>Paladin Theraps Inc</b>	Antiparasitic agent	Leishmaniasis	Oral	D BBW Medication Guide
<b>metreleptin</b> Myalept™ <b>Amylin Pharms</b>	Leptin analog	Leptin deficiency	SC	C BBW REMS Medication guide
<b>naloxegol</b> Movantik™ <b>AstraZeneca</b>	Gastrointestinal agent (opioid peripheral antagonist)	Opioid-induced constipation in adults with chronic non-cancer pain	Oral	C
<b>netupitant/palonosetron</b> Akynzeo® <b>Eisai</b>	Antiemetic (5-HT <sub>3</sub> antagonist/neurokinin antagonist)	Nausea and vomiting in chemotherapy patients	Oral	C
<b>nintedanib</b> Ofev® <b>Boehringer Ingelheim</b>	Tyrosine kinase inhibitor	Idiopathic pulmonary fibrosis (IPF)	Oral	D

Generic/Trade/Manufacturer	Category	Use	Route	Pregnancy Cat*/Warnings
<b>nivolumab</b> Opdivo® <b>Bristol-Myers Squibb</b>	Antineoplastic agent (monoclonal antibody)	Unresectable or metastatic melanoma	IV	Risk Summary♦
<b>olaparib</b> Lynparza™ <b>AstraZeneca</b>	Antineoplastic agent	Advanced ovarian cancer	Oral	D
<b>olodaterol</b> Striverdi Respimat® <b>Boehringer Ingelheim</b>	Long acting beta-2 agonist	COPD	Inhalation	C  BBW Medication guide
<b>ombitasvir, paritaprevir and ritonavir tablet co-packaged with dasabuvir</b> Viekira Pak™ <b>AbbVie Inc</b>	Antiretroviral	Chronic hepatitis C virus (HCV) genotype 1 infection	Oral	B
<b>oritavancin</b> Orbactiv™ <b>Medicines Co.</b>	Glycopeptide antibiotic	Skin infections	IV	C
<b>peginterferon beta-1a</b> Plegridy™ <b>Biogen Idec</b>	Immunomodulator	Multiple Sclerosis	SC	C  Medication guide
<b>pembrolizumab</b> Keytruda® <b>Merck</b>	Antineoplastic agent (monoclonal antibody)	Advanced or unresectable melanoma	IV	D  Medication guide
<b>peramivir</b> Rapivab™ <b>BioCryst Pharms Inc</b>	Antiviral agent (neuraminidase inhibitor)	Influenza	IV	C
<b>pirfenidone</b> Esbriet® <b>InterMune</b>	Anti-inflammatory agent	Idiopathic pulmonary fibrosis (IPF)	Oral	C
<b>ramucirumab</b> Cyramza® <b>Eli Lilly and Co.</b>	Antineoplastic agent (monoclonal antibody)	Stomach cancer or gastroesophageal junction adenocarcinoma	IV	C  BBW
<b>siltuximab</b> Sylvant™ <b>Janssen Biotech</b>	Antineoplastic agent (monoclonal antibody)	Multicentric Castleman's disease (MCD)	IV	C
<b>sulfur hexafluoride lipid-type A microspheres</b> Lumason™ <b>Bracco</b>	Diagnostic agent	Cardiovascular imaging	IV	B  BBW
<b>suvorexant</b> Belsomra® <b>Merck Sharp &amp; Dohme</b>	Hypnotic (orexin receptor antagonist)	Insomnia	Oral	C

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<b>tasimelteon</b> Hetlioz® Vanda Pharms Inc	Melatonin receptor agonist (MT1, MT2)	Non-24 hours sleep-wake disorder	Oral	C
<b>tavaborole</b> Kerydin™ Ancor Pharms	Antifungal agent	Onychomycosis	Topical	C
<b>tedizolid</b> Sivextro® Cubist Pharms	Antibiotic (oxazolidinone)	Skin infections	Oral, IV	C
<b>vedolizumab</b> Entyvio® Takeda Pharms	Gastrointestinal agent (monoclonal antibody)	Ulcerative colitis and moderate to severe Crohn's disease	IV	B Medication guide
<b>vorapaxar</b> Zontivity™ Merck Sharp & Dohme	Antiplatelet agent (protease-activated receptor-1)	Cardiovascular prevention	Oral	B BBW

\*Pregnancy Categories (A, B, C, D, X)

°BBW (Black Box Warning), REMS (Risk Evaluation and Mitigation Strategy)

◆ This drug follows the updated Pregnancy and Lactation Labeling Rule (PLLR) that removes pregnancy categories. This rule will go into effect for all drugs by June 30, 2015. The risk summary for **Opdivo**® indicates that it can cause fetal harm when administered to pregnant females based on animal studies. The effects are likely to be greater during the 2<sup>nd</sup> and 3<sup>rd</sup> trimester of pregnancy.

In 2014, the U.S. Federal Drug Administration (FDA) approved 41 drugs (new chemical entities). In comparison, the FDA approved 27 new drugs in 2013, but 39 in 2012. From 2005 to 2013, the FDA's Center for Drug Evaluation and Research (CDER) approved 25 novel new drugs on average. While 2014 has had more than the average number approved annually, the number of applications submitted by sponsors has remained stable overtime.

17 of the 41 new drugs were designated as Fast Track if the medication had the potential to address unmet medical needs and showed an advantage over current drug therapy. Fast Track indicates that these medications received quick review which enabled the new drugs to be available to patients earlier. Medications designated as Fast Track includes Beleodaq™ (belinostat), Cyramza® (ramucirumab), Entyvio® (vedolizumab), Ofev® (nintedanib), and Northera™ (droxidopa). Beleodaq™ is indicated for peripheral T-cell lymphoma, Cyramza® is indicated for stomach cancer or gastroesophageal junction adenocarcinoma, Entyvio® is indicated for ulcerative colitis and moderate to severe Crohn's disease, Ofev® is indicated for pulmonary fibrosis, and Northera™ is indicated for neurogenic orthostatic hypotension.

17 of the 41 new drugs have been identified as First-In-Class (indicator of the innovative nature of a drug) including Harvoni™ (ledipasvir/sofosbuvir), Keytruda® (pembrolizumab), and Zontivity™ (vorapaxar). Harvoni™ is indicated to treat certain patients with Hepatitis C, Keytruda® is indicated for patients with unrespectable or metastatic melanoma, and Zontivity™ is used to reduce the risk of thrombotic cardiovascular events in certain patients with heart conditions.

17 of the novel new drugs were approved to treat rare (orphan) diseases that affect 200,000 or fewer Americans. Examples of 2014 approved orphan drugs include Vimizim<sup>®</sup> (elosulfase alfa) used to treat mucopolysaccharidosis type IVA (rare genetic disorder), Impavido<sup>™</sup> (miltefosine) used to treat leishmaniasis (rare tropical disease), and Sylvant<sup>™</sup> (siltuximab) which is used to treat Castleman's disease.

The drugs approved in 2014 include four type 2 diabetic medications (Farxiga<sup>™</sup>, Jardiance<sup>®</sup>, Tanzeum<sup>™</sup>, Trulicity<sup>™</sup>), five antibiotics (Dalavance<sup>™</sup>, Sivextro<sup>™</sup>, Orbactiv<sup>™</sup>, Zerbaxa<sup>™</sup>, Xtoro<sup>™</sup>), and two new hepatitis C drugs (Harvoni<sup>™</sup>, Viekira Pak<sup>™</sup>). Dalavance<sup>™</sup> (dalbavancin), Sivextro<sup>™</sup> (tedizolid), and Orbactiv<sup>™</sup> (oritavancin) are indicated for the treatment of skin and soft tissue infections. These antibiotics have activity against *Staphylococcus aureus* including methicillin resistance strains (MRSA).

Regarding the route of administration, the majority of the medications approved are administered orally or intravenously (18 and 15, respectively). Other routes of administration for the approved drugs include subcutaneous, topical, otic, and inhalation. The four medications administered subcutaneously are Tanzeum<sup>™</sup> (albiglutide), Trulicity<sup>™</sup> (dulaglutide), Myalept<sup>™</sup> (metreleptin), and Plegridy<sup>™</sup> (peginterferon beta-1a). The topical drugs approved are Jublia<sup>®</sup> (efinaconazole) and Kerydin<sup>™</sup> (tavaborole). Both are antifungal medications indicated for the treatment of onychomycosis. One otic drug, Xtoro<sup>™</sup> (flufenacin), was approved for the treatment of acute otitis externa. Lastly, Striverdi Respimat<sup>®</sup> (olodaterol) is an inhalant approved for chronic obstructive pulmonary disorder (COPD).

Concerning warnings and pregnancy categories, four medications required a Risk Evaluation and Mitigation Strategy (REMS) and 12 medications have a labeled black box warning (BBW). Twenty-seven drugs are classified as pregnancy category C, seven drugs as category D, and six drugs as category B. One medication (Opdivo<sup>®</sup>) follows the updated Pregnancy and Lactation Labeling Rule that removes pregnancy categories and lists a risk summary for pregnancy.

In two of the last three years, the FDA has approved 39 drugs in 2012 and 41 in 2014. It is unknown if this approval rate will be sustained, but the FDA has instituted several programs in the last few years to help accelerate new drug development/approval, particularly for innovative and breakthrough drugs. It appears there is a surge of orphan drug development as companies have explored aggressive revenue models and anti-infectives have enjoyed renewed attention, particularly for emerging antibiotic resistant microbes and for hepatitis C treatment. Specific targeted cancer therapies are also an area of growth.



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**The last “dose” ...**

*“Always laugh when you can, it is cheap medicine”*

*-Lord Byron [English poet, 1788 - 1824]*



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