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NEW DRUGS APPROVED - 2013

Generic/Trade/ Manufacturer	Category	Use	Route	*Preg Cat/ †Warnings
ado-trastuzumab emtansine <i>Kadcyla</i> TM	Antineoplastic (anti-HER2/ monoclonal antibody)	HER2-positive, late stage breast cancer (metastatic)	IV	D
Takeda				BBW
alogliptin Nesina TM	Dipeptidyl peptidase IV (DPP-IV) inhibitor and	Type 2 diabetes	Oral	B, C BBW
Takeda afatinib dimaleate Gilotrif TM Boehringer/Ingelheim	Thiazolidinedione Antineoplastic (tyrosine kinase inhibitor/EGFR inhibitor)	Late stage metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor	Oral	Med Guide D
canagliflozin <i>Invokana</i> ® Janssen	Sodium-glucose cotransporter 2 (SGLT2) inhibitor	receptor (EGFR) gene mutation Type 2 diabetes	Oral	Med Guide C
coagulation factor IX Rixubis TM Baxter	Antihemophilic agent	Hemophilia B or Christmas disease	IV	С
conjugated estrogens/ bazedoxifene Duavee®	Selective estrogen receptor modulator (SERM) Tissue-selective estrogen	Menopause Prevention of postmenopausal	Oral	X
Pfizer	complex (TSEC)	osteoporosis		BBW
dabrafenib mesylate Tafinlar® GlaxoSmithKline	Antineoplastic (BRAF kinase inhibitor)	Melanoma with BRAF mutation (metastatic or unresectable)	Oral	D Med Guide
dimethyl fumarate Tecfidera® Biogen Idec	Immuno-modulator	Multiple sclerosis	Oral	C
dolutegravir sodium <i>Tivicay</i> ®	Integrase inhibitor	HIV treatment	Oral	B Mod Guida
ViiV Healthcare eslicarbazepine acetate Aptiom® Sunovion	Anticonvulsant Miscellaneous	Epilepsy	Oral	Med Guide C
flutemetamol F-18 injection Vizamyl TM GE Healthcare	Radio-pharmaceutical	Brain imaging	IV	С

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fluticasone furoate and vilanterol inhalation powder	Pulmonary (long-acting beta2-agonsit / corticosteroid)	Chronic obstructive pulmonary disease	Inhalation	С
Breo® Ellipta TM GlaxoSmithKline	,			BBW Med Guide
gadoterate meglumine Dotarem ®	Diagnostic agent (gadolinium-containing)	Magnetic resonance imaging	IV	С
Guerbet glycerol phenylbutyrate Ravicti®	Urea cycle disorder (UCD) treatment	Urea cycle disorders	Oral	BBW C
Hyperion Therapeut. ibrutinib Imbruvica TM	Antineoplastic (tyrosine kinase inhibitor)	Mantle cell lymphoma	Oral	Med Guide D
Pharmacyclics levomilnacipran HCl	Antidepressant	Depression	Oral	С
Fetzima TM Forest Pharm.	(serotonin/norepinephrine reuptake inhibitor) (SNRI)			BBW Med Guide
luliconazole Luzu® Medicis	Antifungal	Fungal infections	Topical	С
macitentan <i>Opsumit</i> ® Actelion	Endothelin receptor antagonist	Pulmonary arterial hypertension	Oral	X BBW REMS Med Guide
mipomersen sodium <i>Kynamro</i> ® Genzyme	Anti-hyperlipidemic	Homozygous familial hyper- cholesterolemia	Sub Q	B BBW REMS Med Guide
obinutuzumab <i>Gazyva</i> TM Genentech	Antineoplastic (monoclonal antibody)	Chronic lymphocytic leukemia	IV	C BBW
ospemifene Osphena® Shionogi	Selective estrogen receptor modulator (SERM)	Dyspareunia (moderate-to- severe)	Oral	X
pomalidomide Pomalyst® Celgene	Antineoplastic Immuno-modulator	Multiple myeloma (relapsed/refractory)	Oral	X BBW REMS Med Guide
radium Ra 223 dichloride <i>Xofigo</i> ® Bayer Health Care	Radio-pharmaceutical	Prostate cancer, castration- resistant with symptomatic bone metastases	IV	X
riociguat Adempas® Bayer Health Care	Antihypertensive (soluble guanylate cyclase stimulator)	Chronic thromboembolic pulmonary hypertension Pulmonary arterial hypertension	Oral	X BBW REMS Med Guide
simeprevir <i>Olysio</i> TM Janssen	Antihepaciviral (protease inhibitor)	Chronic hepatitis C	Oral	C [X with ribavirin]

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sofosbuvir Sovaldi TM Gilead Sciences	Antihepaciviral (polymerase inhibitor)	Chronic hepatitis C	Oral	B [X with ribavirin]
sucroferric oxyhydroxide Velphoro® Vifor Fresenius Medical Care Renal Pharma	Phosphate binder	Hyperphosphatemia	Oral	В
technetium Tc 99m tilmanocept <i>Lymphoseek</i> ® Navida/Biopharm	Radio-pharmaceutical	Breast cancer lymphatic mapping Melanoma lymphatic mapping	Intraderm Sub Q	С
trametinib Mekinist TM GlaxoSmithKline	Antineoplastic (MEK inhibitor)	Melanoma (metastatic or unresectable with BRAF V600E or V600K mutations)	Oral	D
vortioxetine HBr <i>Brintellix</i> TM Takeda	Selective serotonin reuptake inhibitor (SSRI)	Major depressive disorder	Oral	C BBW Med Guide

^{*}Preg. Cat.: Pregnancy Category, A, B, C, D, X.

The year 2013 saw 30 new drug (new chemical entities [NME]) approvals by the U.S. Food and Drug Administration (FDA). There were 39 new drugs approved in 2012 and 30 new drugs approved in 2011. Over the last 20 years, the number of new drug approvals has averaged about 28 per year with a range of 17 to 53 per year.

The most common class of drugs to be approved this year are the antineoplastic agents, eight in 2013 which continues a trend of recent years, such as 11 in 2012. Two new type 2 diabetes mellitus drugs were approved in 2013 and one represents a new class, canagliflozin (Invokana®), a sodium-glucose co-transporter (SGLT2) inhibitor. Two new drugs for pulmonary arterial hypertension are macitentan (Opsumit®) and riociguat (Adempas®) with a cost of \$8000 to \$9000 per month. Perhaps the most impactful are two new drugs for chronic hepatitis C, simeprevir (OlysioTM) and sofosbuvir (SovaldiTM). Together with two other relatively recent approvals, telaprevir (Incevik®) and boceprevir (Victrelis®), real progress is being made for an emerging threat. The bad news is that for the two new drugs, depending on the length of therapy, a course of treatment could exceed \$100,000.

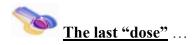
The breakdown of pregnancy categories was approximately the same as recent years: 15 of the new approved drugs this year were pregnancy category C, five drugs were category B, five were category D, and eight drugs were category X. In addition, 12 drugs rated a Black Box Warning and four were required to have a Risk Evaluation and Mitigation Strategy (REMS).

Overall, 2013 lead to the development of thirteen new drugs that were the first in their class.

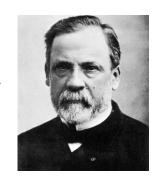
^{*}Warnings: BBW=Black Box Warning; REMS=Risk Evaluation and Mitigation Strategy; Med Guide=Medication Guide

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- 3. Lexi-comp Online [AUHSOP Intranet]. Hudson, OH: Wolters Kluwer Health, 2013 [cited 2013 Dec 9]. Available from: http://online.lexi.com/lco/action/home



"... chance only favours the mind which is prepared."



Louis Pasteur (1822-1895, French chemist and microbiologist)



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