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NEW DRUGS APPROVED - 2013

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

| Generic/Trade/ Manufacturer | Category | Use | Route | *Preg Cat/ †Warnings |
|--|---|---|--------------|---------------------------------|
| fluticasone furoate and vilanterol inhalation powder Breo® Ellipta™ GlaxoSmithKline | Pulmonary (long-acting beta2-agonist / corticosteroid) | Chronic obstructive pulmonary disease | Inhalation | C BBW Med Guide |
| gadoterate meglumine Dotarem® Guerbet | Diagnostic agent (gadolinium-containing) | Magnetic resonance imaging | IV | C BBW |
| glycerol phenylbutyrate Ravicti® Hyperion Therapeut. | Urea cycle disorder (UCD) treatment | Urea cycle disorders | Oral | C Med Guide |
| ibrutinib Imbruvica™ Pharmacyclics | Antineoplastic (tyrosine kinase inhibitor) | Mantle cell lymphoma | Oral | D |
| levomilnacipran HCl Fetzima™ Forest Pharm. | Antidepressant (serotonin/norepinephrine reuptake inhibitor) (SNRI) | Depression | Oral | C BBW Med Guide |
| luliconazole Luzu® Medicis | Antifungal | Fungal infections | Topical | C |
| macitentan Opsumit® Actelion | Endothelin receptor antagonist | Pulmonary arterial hypertension | Oral | X BBW REMS Med Guide |
| mipomersen sodium Kynamro® Genzyme | Anti-hyperlipidemic | Homozygous familial hyper- cholesterolemia | Sub Q | B BBW REMS Med Guide |
| obinutuzumab Gazyva™ Genentech | Antineoplastic (monoclonal antibody) | Chronic lymphocytic leukemia | IV | C BBW |
| ospemifene Osphena® Shionogi | Selective estrogen receptor modulator (SERM) | Dyspareunia (moderate-to- severe) | Oral | X BBW |
| pomalidomide Pomalyst® Celgene | Antineoplastic Immuno-modulator | Multiple myeloma (relapsed/refractory) | Oral | X BBW REMS Med Guide |
| radium Ra 223 dichloride Xofigo® 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 Olysio™ Janssen | Antihepaciviral (protease inhibitor) | Chronic hepatitis C | Oral | C [X with ribavirin] |

| Generic/Trade/ Manufacturer | Category | Use | Route | *Preg Cat/ †Warnings |
|--|--|--|--------------------|---------------------------------|
| sofosbuvir Sovaldi™ 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 | B |
| technetium Tc 99m tilmanocept Lymphoseek® Navida/Biopharm | Radio-pharmaceutical | Breast cancer lymphatic mapping Melanoma lymphatic mapping | Intraderm Sub Q | C |
| trametinib Mekinist™ GlaxoSmithKline | Antineoplastic (MEK inhibitor) | Melanoma (metastatic or unresectable with BRAF V600E or V600K mutations) | Oral | D |
| vortioxetine HBr Brintellix™ Takeda | Selective serotonin reuptake inhibitor (SSRI) | Major depressive disorder | Oral | C BBW Med Guide |

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

†Warnings: BBW=Black Box Warning; REMS=Risk Evaluation and Mitigation Strategy; Med Guide=Medication Guide

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 (Olysio™) and sofosbuvir (Sovaldi™). 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 led to the development of thirteen new drugs that were the first in their class.

References:

1. FDA: Drug Innovation [Internet]. Maryland: U.S. Food and Drug Administration; c2013. CDER's New Molecular Entities and New Therapeutic Biological Products of 2013; 5 Dec 2013 [cited 2013 Dec 9]. [About 2 screens]. Available from: <http://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/default.htm>
2. PL: New Drugs [Internet]. California: Pharmacist Letter; c1995-2013. New Drug approved by the FDA in 2013; c2013 [cited 2013 Dec 9]. [About 3 screens]. Available from: <http://pharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?cs=student&s=PL&pt=20>
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>



The last "dose" ...

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

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



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