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2014 Brings New Drugs

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With the year coming to a close, it has been a surprisingly slow quarter at the Food and Drug Administration (FDA) with only seven new entities approved. However, it was still a productive year because more new entities were approved by August 2014 than in all of 2013. Several drugs received new indications, including: Otezla® (apremilast; plaque psoriasis), Humira® (adalimumab; juvenile idiopathic arthritis and Crohn's disease in children >6 years), Eylea® (afibercept; all forms of macular edema after retinal vein occlusion), Lemtrada™ (alemtuzumab; relapsing forms of multiple sclerosis), Velcade® (bortezomib; mantle cell lymphoma), and Ozurdex® (dexamethasone intravitreal implant; diabetic macular edema). The imaging agents Lumason™ (echocardiography) and Lymphoseek® (solid tumors) also received approval.

Diabetes/Weight-Management: Trulicity™ (dulaglutide) is a once-weekly injectable GLP-1 agonist approved for type II diabetes mellitus. It was studied as monotherapy or combination therapy, but comes with a REMS strategy and carries a contraindication for patients with certain cancers. New diabetes product formulations include: Bydureon® (exenatide preassembled pen), Xigduo™ XR (dapagliflozin/metformin combination), and Iluvien® (fluocinolone 3-year intravitreal implant for diabetic macular edema). For chronic weight management the new combination Contrave® (naltrexone/bupropion) extended-release was approved for adults with BMI >30 kg/m2 and at least one weight-related comorbidity in conjunction with diet and exercise. Contrave® is contraindicated in patients with seizure disorders or uncontrolled hypertension.

Opioid-Related: Hysingla™ ER is a new high-dose hydrocodone product (20-120 mg/tablet) with an abuse-deterrent formulation, but unlike Zohydro™ ER, is taken every 24-hours. For complications of opioid therapy, Relistor® (methylnaltrexone) is newly indicated for opioid-induced constipation, and Movantik™ (naloxegol) was approved as the first once-daily peripherally-acting mu-opioid receptor antagonist to treat opioid-induced constipation. Movantik™ is classified as a Schedule II controlled-substance because of its similarity to noroxymorphone, but a petition has been submitted to the Drug Enforcement Agency (DEA) to deschedule the drug. Driven by demand and lack of competition, nasal naloxone doubled in price from $20 to $56 making it more costly for nonprofit organizations to distribute.

Pulmonary: Esbriet® (pirfenidone) and Ofev® (nintedanib) were approved for the treatment of idiopathic pulmonary fibrosis. The FDA granted both drugs a fast track, priority review with orphan product and breakthrough designations. Esbriet® carries warnings for patients with severe liver disease, end-stage kidney disease or those requiring dialysis, concomitant CYP1A2 inhibitors, and may cause patients to sunburn more easily. Ofev® is not recommended in patients with moderate-to-severe liver disease and carries the potential for embryofetal toxicity (e.g. birth defects, stillbirth). New pulmonary product formulations include an inhalation spray version of tiotropium (Spiriva® Respimat®) for COPD that delivers a metered-dose in a slow-moving mist in a way that does not depend on the how fast air is breathed in from the inhaler.

Brand Name	Indication	Formulation	Regimen	Average Cost
Chronic Care				
Trulicity™	Type II diabetes mellitus	Sub-Q	Once-Weekly	$586/month
Movantik™	Opioid-induced constipation	Oral	Once-Daily	-
Esbriet®	Pulmonary fibrosis	Oral	TID	$9,360/month
Ofev®	Pulmonary fibrosis	Oral	BID	$9,000/month
Infectious Disease				
Harvoni®	Chronic hepatitis C, genotype 1	Oral	Once-Daily	$1,350/tablet
Tybost®	HIV-1 infection	Oral	Once-Daily	$216/month
Trumenba®	Meningococcal B bivalent vaccine	IM	3-Dose Series	$400/course
Oncology				
Akynzeo®	Chemotherapy-induced nausea/vomiting	Oral	Pre-Treatment	$571/capsule
Blincyto™	Acute lymphoblastic leukemia	IV	Dosing Schedule	-

Infectious Diseases: Approval was granted to the third drug in a year to treat Hepatitis C. Harvoni® (ledipasvir/sofosbuvir) is the first drug combination approved and does not require administration with interferon or ribavirin. In clinical trials the hepatitis C virus was eradicated in >90% of participants within

12-weeks, and fatigue and headache were the most common adverse effects. Tybost® (cobicistat; integrase inhibitor) and Vitekta™ (elvitegravir; protease inhibitor) were approved as single-entities for HIV-1 infection. Both must be used as part of a cocktail and are not expected to have a major effect on clinical practice. Tybost® is a boosting agent used to increase blood levels of the protease inhibitors Reyataz® or Prezista®. Trumenba® was approved as the first vaccine against invasive meningococcal disease caused by Neisseria meningitides serogroup B, with 82% of trial participants seroconverting after a 3-dose series.

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Oncology: Blincyto™ (blinatumomab) was granted a priority review with orphan product and breakthrough designation to treat Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia. Blincyto™ carries a boxed warning for cytokine-release syndrome and neurological toxicities and requires a Medication Guide. Akynzeo® (netupitant/palonosetron) was approved to prevent acute and delayed chemotherapy-induced nausea/vomiting. Akynzeo® must be used cautiously with CYP3A4 substrates and avoided in severe hepatic and renal impairment. §

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