

New Drugs and Biological Agents Approved by the FDA in 2007

Kendra Bryant, Pharm.D. and Cathy H. Turner, Pharm.D.

The following is a summary of the new drugs and biological approved by the Food and Drug Administration in 2007. For further information on these agents, please call the Drug Information Center at 460-6531.

Generic	Brand	Manufacturer	Form	Class/Indication	Usual Dose(s)
Aliskiren	Tekturna®	Novartis	Tablet	Direct renin inhibitor for treatment of hypertension	150 - 300 mg daily
Ambrisentan	Letairis™	Gilead	Tablet	Endothelin receptor antagonist for pulmonary arterial hypertension (PAH)	5 -10 mg daily
Doripenem	Doribax™	Ortho-McNeil	Intravenous infusion	Carbapenem antibiotic for intra-abdominal & urinary tract infection, including pyelonephritis	500 mg IV every 8 hrs
Eculizumab	Soliris®	Alexion	Intravenous infusion	Treatment of paroxysmal nocturnal hemoglobinuria to reduce hemolysis	Initiation: 600 mg q 7 days x 4 wks; then 900 mg on 5 th week; Maintenance: 900 mg q 14 days
Ixabepilone	Ixempra™	Bristol-Myers Squibb	Intravenous Infusion	Microtubule inhibitor for metastatic or advanced breast cancer	40 mg/m ² IV over 3 hours every 3 weeks
Lanreotide	Somatuline® Depot	Tercica	Subcutaneous injection	Depot injection for treatment of acromegaly; synthetic analog of somatostatin	60 - 120 mg every 4 weeks for 3 months; dose and frequency adjusted based on growth hormone levels thereafter
Lapatinib	Tykerb®	GlaxoSmithKline	Tablets	Kinase inhibitor used with capecitabine (Xeloda®) for advanced HER2+ breast cancer	1250 mg daily for 21-day cycle
Lisdexamfetamine	Vyvanse™	Shire	Capsule	Prodrug of dextroamphetamine for ADHD on patient 6-12 years old	Initial dose: 30 mg daily; Range: 20 - 70 mg daily

Generic	Brand	Manufacturer	Form	Class/Indication	Usual Dose(s)
Maraviroc	Selzentry™	Pfizer	Tablets	CCR5 antagonist, antiretroviral for treatment of HIV-1	150 mg – 600 mg twice daily
Methoxy polyethylene glycolepoetin beta	Mircera®	Roche	Injection	Erythropoiesis-stimulating agent for anemia associated with chronic renal failure	0.6 mcg/kg IV or SC injection every 2 weeks
Nebivolol	Bystolic™	Forest	Tablets	Beta1-blocker for treatment of hypertension	5 mg - 40 mg daily
Nilotinib	Tasigna®	Novartis	Capsules	Kinase inhibitor for Philadelphia chromosome positive chronic myelogenous leukemia	200 mg every 12 hours
Protein C concentrate (human)	Ceprotrin	Baxter	Intravenous Injection	Protein C replacement to prevent/ and or treat blood clots in congenital deficiency	100 - 120 IU/kg IV, then 60-80 IU/kg q6h x3 doses; then 45-60 IU/kg q6 or q12 h; dosing based on protein C activity levels
Raltegravir	Isentress™	Merck	Tablet	Integrase inhibitor for use in combination with other antiretrovirals for treatment of HIV-1	400mg twice daily
Retapamulin	Altabax™	GlaxoSmithKline	Topical Ointment	Pleuromullin antibiotic ointment for topical treatment of impetigo caused by <i>Streptococcus pyogenes</i> or methicillin sensitive <i>Staphylococcus aureus</i> in patients at 9 months old or older	Apply in a thin layer twice-daily
Rotigotine	Neupro®	UCB	Transdermal Patch	Treatment for symptoms of early Parkinson's disease	Initial dose: 2mg/24hrs patch; Maximum dose: 6 mg/24 h
Sapropterin	Kuvan™	BioMarin	Tablets	Co-enzyme for treatment of phenylketonuria (PKU)	Initial dose: 10mg/kg/day; Range: 5 - 20 mg/kg/day
Temsirolimus	Torisel™	Wyeth	Intravenous Injection	Kinase inhibitor for advanced renal cell carcinoma	25mg IV over 30-60 minutes once per weekly

Accreditation Site Visit for the School of Pharmacy Scheduled for April 16-18th

The accreditation team from the American Council on Pharmaceutical Education (ACPE) will arrive on April 16th to evaluate the preparedness of our school of pharmacy to admit students for the fall semester of 2008. We are very excited about this opportunity to showcase Belmont University and the College of Health Sciences and Nursing. Thanks to all of you for your support of the pharmacy program.