

APC's Drug News Corner and Quarterly Pipeline Forecast

Volume 1, January 2008



New Molecular Entity (NME) New Drug Application (NDA) Approvals through November 30, 2007

Brand and Generic Name	Manufacturer	Chemical Type/ Classification ¹	Approval Date (Launch Date)	Indication(s)
Omniscan (gadodiamide)	GE Healthcare	5, S	5-Sep-2007	New Manufacturer. For IV, a visualization aid for select MRI imaging studies.
Totec (dextrazoxane HCl)	Topotarget	5, P	6-Sep-2007	New Manufacture. Injectable treatment of extravasation resulting from IV anthracycline chemotherapy.
Evista (raloxifen HCl)	Lilly	6, S, O	13-Sep-2007	New Indication: reduce the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at increased risk for invasive breast cancer.
Fludarabine PO4	Ebewe Pharma	5,S	21-Sep-2007	New Manufacturer. Indicated for the treatment of adults with B-cell CLL who did not respond to, or who failed, at least 1 standard alkylating agent containing regimen.
Azor (amlodipine / olmesartan)	Daiichi Sankyo	4, S	26-Sep-2007 (2- Oct-07)	New fixed-dose combination of two antihypertensives, the calcium channel blocker amlodipine besylate and the angiotensin receptor blocker olmesartan medoxomil indicated for the treatment of hypertension alone on in conjunction with other agents.
Amlodipine mesylate	Synthon Pharms	3, S	27-Sep-2007	New Dosage Form: orally disintegrating tablet (2.5, 5 and 10mg)
Lamisil (terbinafine)	Novartis	3, S	28-Sep-2007	New Dosage Form: oral granules (125mg/base packet and 187.5mg/base packet)
Simvastatin	Synthon Pharms	3, S	9-Oct-2007	New Dosage Form: orally disintegrating tablet (10, 20, 40 and 80mg)
Hycamtin (topotecan)	SmithKline Beecham	3, S	Oct-12-2007	New Dosage Form: oral base capsule (0.25mg and 1mg)
Doribax (doripenem)	Johnson & Johnson	1, S	12-Oct-2007 (15-Oct-07)	NME: For the treatment (IV infusion) of complicated intra-abdominal and complicated urinary tract infections caused by susceptible isolates of the designated microorganisms.

¹ **NDA Chemical Type:** 1 -New molecular entity (NME); 2 -New ester, new salt, or other noncovalent derivative; 3 -New dosage form; 4 -New combination; 5 -New formulation or new manufacturer; 7 -Drug already marketed, but without an approved NDA; 8 -OTC switch

Review Classification: P -**Priority Review** - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease. S - **Standard Review** - Products that do not qualify for priority review O - **Orphan Designation** - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended)

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Ixempra Kit (ixabepilone)	Bristol-Myers Squibb	1, P	16-Oct-2007	NME: For use in combination with capecitabine (IV infusion) for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated. Monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.
Voltaren (diclofenac)	Novartis	3, S	17-Oct-2007	New Dosage Form: 1% topical gel
Renvela (selvelamer)	Genzyme	3, S	Oct-19-2007	New Dosage Form: 800mg tablet
Tasigna (nilotinib)	Novartis	1, S, O	29-Oct-2007 (5-Nov-2007)	NME: for the treatment (oral capsule) of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML) in adults resistant or intolerant to prior therapy that included Gleevec® (imatinib, Novartis).
Combigan (brimidone/timolol)	Allergan	4, S	30-Oct-2007 (Dec-2007)	New Combination: indicated for the reduction of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension in patients who require adjunctive or replacement therapy due to inadequate IOP control.
Isentress (raltegravir)	Merck	P	12-Oct-2007 (12-Oct-07)	This product is a first in class oral HIV-1 integrase-inhibitor, indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.
Protonix (pantoprazole)	Wyeth	3, S	14-Nov-2007	New Dosage Form: delayed release oral granules (40mg)
Mircera (methoxy polyethylene glycol-epoetin beta)	Hoffman-LaRoche	-	14-Nov-2007	Injection solution for the treatment of anemia associated with renal failure.
Seroquel XR (quetiapine)	AstraZeneca	6, S	15-Nov-2007	New Indication: for the maintenance treatment of Schizophrenia.
Children's Zyrtec Allergy (cetirizine)	Pfizer	8, S	16-Nov-2007	OTC-switch. The Zyrtec OTC launch is expected to occur on January 21, 2008.
Children's Zyrtec Hives (cetirizine)	Pfizer	8, S	16-Nov-2007	OTC switch. The Zyrtec OTC launch is expected to occur on January 21, 2008.
Omnaris (ciclesonide)	Nycomed US Inc	6, S	21-Nov-2007	New Indication: Nasal Spray for the treatment of seasonal allergic rhinitis in children 6 years to less than 12 years of age.

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Triesence (triamcinolone acetonide)	Alcon	3, P	29-Nov-2007	New Dosage Form: Indicated for intravitreal injection for the treatment of select ophthalmic diseases unresponsive to topical steroids and visualization during vitrectomy.
Triesence (triamcinolone acetonide)	Alcon Res	6, S	29-Nov-2007	New Indication: Intravitreal injection for the treatment of select ophthalmic diseases unresponsive to topical steroids and visualization during vitrectomy.
Omeprazole	Dexcel Ltd	5, S	4-Dec-2007	New Manufacturer. Indicated for the OTC treatment of frequent heartburn.
Kuvan (sapropterin dihydrochloride)	Biomarin	1, P	13-Dec-2007	NME: The first drug of its kind to treat the generic disorder phenylketonuria (PKU) that causes mental retardation, smaller brain size, delayed speech and other neurologic problems. This agent is indicated (in conjunction with a phenylalanine-restricted diet) for the reduction of blood phenylalanine levels in patients with hyperphenylalaninemia caused by tetrahydrobiopterin- (BH4-) responsive PKU.
Bystolic (Nebivolol)	Mylan Bertek	1, S	17-Dec-2007 (1-Jan-2008)	NME: A beta-1 selective antagonist indicated for the treatment of hypertension alone or in combination with other agents.
Luvox (fluvoxamine)	Mylan Bertek	3, S	20-Dec-2007	New Dosage Form: Tablets (25, 50, 100mg)
Valproic Acid	Banner Pharma	-	Tentative	125, 250, 500mg delayed release capsules
Biologic License Application (BLA) Approvals				
Brand and Generic Name	Manufacturer	Chemical Type/ Classification ¹	Approval Date (Launch Date)	Indication(s)
Mircera (methoxy polyethylene glycol-epoetin beta)	Hoffman-La Roche	P	14-Nov-2007	Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.

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Some Recent Supplemental New Drug Application (sNDA) Approvals

Drug Information & Manufacturer	Indication(s)	FDA Approval Date	Comments
Taxotere (docetaxel) by <i>Sanofi-Aventis</i>	Induction treatment in combination with cisplatin and fluorouracil for patients with locally advanced squamous cell carcinoma of the head and neck prior to chemotherapy and surgery.	10/1/2007	New indication for an already approved drug
Erbix (cetuximab) by <i>ImClone Systems Inc./BMS</i>	Use as single agent for the treatment of epidermal growth factor-receptor-expressing metastatic colorectal carcinoma after failure of both irinotecan- and oxaliplatin-based regimens or in patients who are intolerant to irinotecan-based regimens.	10/2/2007	New indication for an already approved drug
Menactra (meningococcal [Groups A, C, Y, and W-135] polysaccharide diphtheria toxoid conj. vaccine) by <i>Sanofi Pasteur Inc.</i>	Protection against meningococcal disease in children age 2 – 10 years.	10/18/2007	Expanded indication for this product
Abilify (aripiprazole) Tab, orally disintegrating tabs, oral solution and IM injection by <i>Otsuka America/BMS</i>	Treatment of schizophrenia in adolescents aged 13-17 years.	10/29/2007	New indication for an already approved drug
	Use as an adjunctive treatment to antidepressants for major depressive disorder in adults.	11/19/2007	
Crestor (rosuvastatin) Tablets by <i>AstraZeneca</i>	Slowing the progression of atherosclerosis as part of treatment strategy to lower total-C and LDL-C as an adjunct to diet.	11/8/2007	New indication for an already approved drug
Avalide (irbesartan/HCTZ) Tablets by <i>BMS/Sanofi-Synthelabo</i>	Use as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.	11/19/2007	New indication for an already approved drug
Cymbalta (duloxetine) Capsules by <i>Eli Lilly</i>	Maintenance therapy of major depressive disorder in adults.	11/28/2007	New indication for an already approved drug
Diovan (valsartan) by <i>Novartis</i>	Treatment of hypertension in pediatric patients 6-16 years of age.	11/29/2007	Expanded indication for this product
Thyrogen (thyrotropin alfa) for injection by <i>Genzyme</i>	Adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.	12/14/2007	New indication for an already approved drug
Effexor XR (venlafaxine) Capsules by <i>Wyeth</i>	Long-term treatment of social anxiety disorder.	12/14/2007	New indication of an already approved drug

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Recent Drug Withdrawals

- Voluntary withdrawal of Exubera from the US market: In October 2007, the drug company Pfizer announced that it will stop selling its inhaled insulin product (Exubera) for financial reasons based on low utilization of this product.
- Voluntary withdrawal of OTC oral infant cough and cold medicines: On October 11, the Consumer Healthcare Products Association (CHPA), on behalf of the leading makers of over-the-counter (OTC) cough and cold medicines, announced the voluntary withdrawal of oral infant cough and cold medications from store shelves.

Recent First Time Generics

Generic Name (Brand Name)	Manufacturer(s)	Dosage Form; Strength(s)	Approval Date	Comments
Carvedilol (Coreg)	Dr. Reddy, Mylan, Zydus, Lupin, Caraco, Ranbaxy, Glenmark, Teva	3.125, 6.25, 12.5, 25mg Tablet	9/5/2007	
Ciclopirox Topical Solution (PenLac Nail Lacquer)	G&W Labs, Taro, Watson, Actavis	8% Nail Lacquer	9/18/2007	
Nifedipine Extended Release (Procardia XL)	Osmotica	90mg Tablet	10/3/2007	
Risedronate (Actonel)	Teva	5, 30, 35mg Tablet	10/5/2007	
Oxcarbazepine (Trileptal)	Roxane, Glenmark, Sun	150, 300, 600mg Tablet	10/9/2007	
Hydrocodone/Ibuprofen (Vicoprofen)	Interpharm	2.5mg/200mg Tablet	10/19/2007	New strength
Rivastigmine tartrate (Exelon)	Sun	1.5, 4, 4.5, 6mg (base) Capsule	10/22/2007	
Norethindrone acetate and Ethinyl Estradiol (Estrostep Fe, Estrostep-21)	Barr	1mg/0.02mg, 1mg/0.03mg, 1mg/0.035mg Tablet	10/26/2007	21-day and 28-day
Indocyanine Green for Injection (IC Green for Injection)	Pulsion Medical Systems	25mg/vial for Injection	11/21/2007	
Oxycodone HCl/Ibuprofen (Combunox)	Watson	5mg/400mg Tablet	11/26/2007	

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Primary Patent Expirations for Selected High Revenue Drugs

Brand/Generic Name	Manufacturer	Indication/Use	Patent Exp. Date/TA
Clarinet (desloratadine)	Schering	Allergic rhinitis	10/01/07
Meridia (sibutramine)	Abbott	Obesity	12/11/07
Zyrtec (cetirizine)	Pfizer	Allergic rhinitis	12/25/07 (TA)
Risperdal (risperidone)	Janssen Pharma	Psychosis	12/29/07 (TA)
Depakote (divalproexen sodium)	Abbott	Epilepsy, Migraine prophylaxis, Bipolar disorder	01/29/08 (TA)
Fosamax (alendronate sodium)	Merck	Osteoporosis	02/06/08* (TA)
Advair (fluticasone/salmeterol)	GSK	Asthma/COPD	02/12/08
Serevent (salmeterol)	GSK	Asthma/COPD	02/12/08
Sonata (zaleplon)	Jones Pharma	Insomnia	06/06/08 (TA)
Effexor XR (venlafaxine HCl)	Wyeth	Depression	06/13/08*
Lamictal (lamotrigine)	GSK	Epilepsy, Bipolar disorder	07/22/08
Topamax (topiramate)	Ortho McNeil	Epilepsy, Migraine prophylaxis	09/26/08 (TA)
Keppra (levetiracetam)	UCB Inc	Epilepsy	07/14/08
Casodex (bicalutamide)	AstraZeneca	Prostate Cancer	10/01/008
Trusopt (dorzolamide HCl)	Merck	Glaucoma	10/28/08*
Zerit (stavudine)	BMS	HIV	12/24/08* (TA)

*Patent expiration date includes 6 months of pediatric exclusivity; TA = Generic product tentatively approved by FDA

The information contained herein is compiled from a variety of sources and is provided for informational purposes only. Due to circumstances beyond the control of APC, information related to prospective drug launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes.

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Clinical Guidelines

- October 2007: The National Asthma Education and Prevention Program (NAEPP) issued the first comprehensive update in a decade of clinical guidelines for the diagnosis and management of asthma. The full 2007 guidelines can be accessed at <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>.
- American Society of Hematology (ASH) and American Society of Clinical Oncology (ASCO) Release Updated Guideline on the Use of Chemotherapy-Related Anemia Treatment in Cancer Patients (press release). Washington, DC; American Society of Hematology, October 22, 2007. <http://www.hematology.org/media/10222007.cfm>.
- ASH-ASCO 2007 Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin Released (press release). Washington, DC; American Society of Hematology, October 22, 2007. <http://www.hematology.org/policy/news/10222007.cfm>.
- Diagnosis and Treatment of Low Back Pain from the American College of Physicians and the American Pain Society. Ann Intern Med 2007 Oct 2;147:478-505.
- Guidelines for Perioperative Cardiovascular Evaluation for Patients Considering Noncardiac Surgery. Fleisher LA et al. ACC/AHA 2007 Guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery. Executive Summary. Circulation 2007 Oct. 23; 116:1971.
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