TrendsRx®Drug Pipeline & News

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Pipeline Highlights: March 26, 2010 – April 29, 2010 and Recent Selected Health Care News Highlights

Recent Product Launches[1,2*]

Menveo® (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine) **Novartis Vaccines and Diagnostics, Inc.**	**Dosage Form; Strength** **Indication** **Launch Date‡**	Injection, intramuscular; 0.5 mL dose For active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135 in persons 11 to 55 years of age March 23, 2010
Qutenza™ (capsaicin) **NeurogesX, Inc.**	**Dosage Form; Strength** **Indication** **Launch Date‡**	Transdermal patch, topical; 8% For the management of neuropathic pain associated with postherpetic neuralgia April 6, 2010
Differin® (adapalene) **Galderma Research**	**Dosage Form; Strength** **Indication** **Launch Date‡**	Lotion, topical; 0.1% For the treatment of acne vulgaris in patients 12 years and older April 12, 2010
Exalgo™ (hydromorphone) **ALZA Corporation**	**Dosage Form; Strengths** **Indication** **Launch Date‡** **Comments**	Tablet, oral, extended-release; 8 mg, 12 mg and 16 mg For the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. Exalgo is not intended for use as an as-needed analgesic. March 31, 2010 New formulation
Hizentra™, Immune Globulin Subcutaneous (Human), 20% Liquid **CSL Behring AG**	**Dosage Form; Strength** **Indication** **Launch Date‡** **Comments**	Injection, subcutaneous; 0.2 g/mL (20%) protein solution For the treatment of primary immunodeficiency April 15, 2010 New formulation
Zirgan™ (ganciclovir) **Sirion Therapeutics, Inc.**	**Dosage Form; Strength** **Indication** **Launch Date‡** **Comments**	Ophthalmic gel, topical; 0.15% For the treatment of acute herpetic keratitis (dendritic ulcers) April 26, 2010 New formulation

Recent Biologic License Application (BLA) Approvals[1,2*]

Provenge® (sipuleucel-T) **Dendreon Corporation**	**Dosage Form; Strength** **Indication** **Approval Date** **Anticipated Launch Date‡**	Infusion, intravenous; Each dose contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, suspended in 250 mL of Lactated Ringer's Injection, USP in a sealed, patient-specific infusion bag Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. April 29, 2010 May 2010

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Selected Generic Product Approvals/Launches[1,2*]

dactinomycin (Cosmegen®)	**Dosage Form; Strength** **Approval Date†** **Anticipated Launch Date‡** **Comments**	Injection, intravenous; 0.5 mg/vial March 16, 2010 TBD The reference brand is indicated: • As part of a combination chemotherapy and/or multi-modality treatment regimen: for the treatment of Wilms' tumor, childhood rhabdomyosarcoma, Ewing's sarcoma and metastatic, nonseminomatous testicular cancer • As a single agent or as part of a combination chemotherapy regimen: for the treatment of gestational trophoblastic neoplasia • As a component of regional perfusion: for the palliative and/or adjunctive treatment of locally recurrent or locoregional solid malignancies. This product is AP-rated and will be available from a single source generics manufacturer.
fexofenadine/ pseudoephedrine (Allegra-D® 24 hour)	**Dosage Form; Strength** **Approval Date†** **Anticipated Launch Date‡** **Comments**	Tablet, extended-release, oral; 180 mg/240 mg March 17, 2010 Mid-May 2010 The reference brand is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 12 years of age and older. Symptoms treated include sneezing; rhinorrhea; itchy nose, palate and/or throat; itchy, watery red eyes; and nasal congestion. This product is AB-rated and will be available from a single generics manufacturer.
tretinoin	**Dosage Form; Strength** **Approval Date†** **Anticipated Launch Date‡**	Cream, topical; 0.0375% March 22, 2010 Q3 2010
clindamycin (Evoclin®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Aerosol, foam, topical; 1% March 31, 2010 March 31, 2010 The reference brand is indicated for the treatment of acne vulgaris. This product is AT-rated and will be available from a single generics manufacturer.
metaxalone (Skelaxin®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Tablet, oral; 800 mg March 31, 2010 March 31, 2010 The reference brand is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions. This product is AB-rated and will be available from a single generics manufacturer.
losartan (Cozaar®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Tablet, oral; 25 mg, 50 mg and 100 mg April 6, 2010 April 7, 2010 The reference brand is indicated: • For the treatment of hypertension, alone or in combination with other antihypertensive agents, including diuretics • To reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy • For the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension This product is AB-rated and will be available from multiple generics manufacturers.
losartan/ hydrochlorothiazide (Hyzaar®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Tablet, oral; 12.5 mg/50 mg, 25 mg/100 mg and 12.5 mg/100 mg April 6, 2010 April 7, 2010 The reference brand is indicated: • For the treatment of hypertension • To reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy This product is AB-rated and will be available from multiple generics manufacturers.
memantine (Namenda™)	**Dosage Form; Strengths** **Approval Date†** **Anticipated Launch Date‡** **Comments**	Tablet, oral; 5 mg and 10 mg April 2010 2011 The reference brand is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.
imipramine (Tofranil-PM®)	**Dosage Form; Strengths** **Approval Date†** **Launch Date‡** **Comments**	Capsule, oral; 75 mg, 100 mg, 125 mg and 150 mg April 16, 2010 April 16, 2010 The reference brand is indicated for the relief of symptoms of depression. This product is AB-rated and will be available from multiple generics manufacturers.
methamphetamine (Desoxyn®)	**Dosage Form; Strength** **Approval Date†** **Launch Date‡** **Comments**	Tablet, oral; 5 mg April 21, 2010 April 21, 2010 The reference brand is indicated for: • Attention Deficit Disorder with Hyperactivity • Exogenous Obesity This product is AA-rated and will be available from a single generics manufacturer.

Recent New Drug Application (NDA) Approvals[1,2*]

Zyclara™ (imiquimod)	**Dosage Form; Strength**	Cream, topical; 3.75%
	Indication	For actinic keratosis of the face and/or scalp
	Approval Date	March 25, 2010
Graceway Pharmaceuticals	**Launch Date‡**	May 1, 2010
Asclera™ (polidocanol)	**Dosage Form; Strengths**	Injection, intravenous; 0.5% and 1%
	Indication	For treatment of uncomplicated spider veins (varicose veins ≤1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity
Chemische Fabrik Kreussler & Co. GmbH	**Approval date**	March 30, 2010
	Anticipated Launch Date‡	TBD
OxyContin® (oxycodone controlled release)	**Dosage Form; Strengths**	Tablet, extended-release, oral; 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg
	Indication	For the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. It is not for use on an as-needed basis or on the immediate postoperative period.
	Approval Date	April 5, 2010
Purdue Pharmaceuticals L.P.	**Anticipated Launch Date‡**	Third quarter 2010
	Comments	This is a new formulation. Schedule C-II controlled substance
Pancreaze™ (pancrelipase)	**Dosage Form; Strengths**	Capsules, delayed-release, oral; • 4,200 USP units of lipase, 10,000 USP units of protease, 17,500 USP units of amylase • 10,500 USP units of lipase, 25,000 USP units of protease, 43,750 USP units of amylase
Nordmark Arzneimittel GmbH & Co. KG	**Indication**	For the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
	Approval Date	April 12, 2010
	Anticipated Launch Date‡	TBD
Oravig™ (miconazole)	**Dosage Form; Strength**	Tablet, buccal; 50 mg
	Indication	For the treatment of oropharyngeal candidiasis in adults and children age 16 and older
	Approval Date	April 16, 2010
	Launch Date‡	Third quarter 2010
BioAlliance Pharma	**Comments**	Known as Loramyc® in Europe
Zortress® (everolimus)	**Dosage Form; Strengths**	Tablet, oral; 0.25 mg, 0.5 mg and 0.75 mg
	Indication	For prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant
	Approval Date	April 20, 2010
	Launch Date‡	TBD
Novartis Pharmaceuticals	**Comments**	Known as Certican® outside the United States

Recent Supplemental New Drug Application (sNDA) Approvals[1,2*]

Tarceva® (erlotinib)	**Dosage Form**	Tablets, oral
	Indication	For maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
	Approval Date	April 16, 2010
	Comments	This is a new indication for an already approved product.
Genentech USA Inc.		Refer to full Prescribing Information for a complete list of indications.

* Adapted from RxPipeline Services Week In Review. For more information, contact: pipeline@caremark.com<mailto:pipeline@caremark.com>

† The Approval Date is established by the FDA but does not necessarily mean a generic product is available as of that date or that such product is available.

‡ A launch date/anticipated launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes.

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News

Medication Safety

Information regarding selected medication safety issues can be found on the CVS Caremark Web site at www.caremark.com > Health Professional Services > Drug Safety Alerts.

Boxed Warning for Propylthiouracil-Induced Liver Failure[3,4]

On April 21, 2010, the FDA changed prescribing information for propylthiouracil to include a Boxed Warning about severe liver injury. Propylthiouracil is one of several options for treating hyperthyroidism, or overactivity of the thyroid gland, due to Graves' disease. The warning is based on a review of 34 postmarketing reports (23 adult and 11 pediatric) of serious liver injury associated with propylthiouracil use. Of those, 15 resulted in death, while 12 required liver transplants. The new warning includes information about these reports and also states that propylthiouracil should be reserved for patients who cannot tolerate or are not candidates for alternative treatments, such as methimazole, radioactive iodine or surgery, for the management of hyperthyroidism. In addition, due to the risk of fetal abnormalities associated with methimazole, propylthiouracil may be the treatment of choice during or just prior to the first trimester of pregnancy. These changes were recommended based on the FDA's review of postmarketing safety reports, as well as meetings held with the American Thyroid Association, the National Institute of Child Health and Human Development, and the pediatric endocrine clinical community.

CVS Caremark has reviewed this medication safety issue. In response to the Boxed Warning, CVS Caremark Mail Service Pharmacy will be sending notification letters to health care providers whose patients filled prescriptions for propylthiouracil via mail service in the last six months.

Health Care News

FDA's Infusion Pump Improvement Initiative[5]

In April 2010, the FDA announced the launch of its *Infusion Pump Improvement Initiative* that addresses reports of adverse events associated with the use of external infusion pumps. Infusion pumps are medical devices that deliver fluids, nutrients and medications into a patient's body. They are used in both health care facilities and home settings. Infusion pumps allow health care providers and patients better control, accuracy and precision in drug delivery. There are many types of infusion pumps designed to administer general and specialty medications such as insulin, antibiotics, pain relievers and chemotherapy agents.

From 2005 through 2009, significant safety concerns associated with the use of infusion pumps have come to the FDA's attention. Infusion pump problems have been observed across multiple manufacturers and pump types, some of them causing serious injuries and deaths, and resulting in 87 recalls. The agency has concluded that many of these problems are related to deficiencies in device design, software defects or user errors.

In response, the FDA is taking a proactive and comprehensive approach to prevent safety problems by fostering the development of safer, more effective infusion pumps across the industry. The *Infusion Pump Improvement Initiative* is being designed to

- establish additional requirements for infusion pump manufacturers;
- proactively facilitate device improvements; and
- increase user awareness.

The agency will work with manufacturers, health care providers and end users to retain the benefits of infusion pumps while reducing associated risks. For more information on this initiative, please visit http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm.

References:

1. CVS Caremark. RxPipeline. Available at: www.caremark.com/wps/portal/client. Accessed April 2, 2010; April 9, 2010; April 16, 2010; April 23, 2010; and April 30, 2010.
2. Drugs@FDA. Rockville, MD: Food and Drug Administration, Center for Drug Evaluation and Research. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed April 2010.
3. FDA Drug Safety Communication: New Boxed Warning on severe liver injury with propylthiouracil. Food and Drug Administration Web site. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209023.htm. Accessed April 25, 2010.
4. CVS Caremark. Clinical Quality DSA: 2010 Professional Practice Alerts. Accessed April 26, 2010.
5. FDA Medical Devices. White Paper: Infusion Pump Improvement Initiative. Food and Drug Administration Web site. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm. Accessed April 26, 2010.