FDA New Approvals

Abilify Maintena
Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announced the FDA has approved Abilify Maintena™ (aripiprazole) for extended-release injectable suspension, an intramuscular depot formulation indicated for the treatment of schizophrenia. Abilify Maintena is the first dopamine D2 partial agonist approved as a once-monthly injection. The companies expect the product will start becoming available in the U.S. on March 18, 2013. For more information, visit http://www.lundbeck.com/us/media/press-releases/2013/fda-approves-once-monthly-abilify-maintena-aripiprazole-for-extended-release-injectable-suspension-for-the-treatment-of-schizophrenia

Argus II Retinal Prosthesis System
The FDA has approved the Argus II Retinal Prosthesis System, the first implanted device to treat adult patients with advanced retinitis pigmentosa (RP). The device, which includes a small video camera, transmitter mounted on a pair of eyeglasses, video processing unit (VPU), and an implanted retinal prosthesis (artificial retina), replaces the function of degenerated cells in the retina and may improve a patient’s ability to perceive images and movement. The Argus II system is intended for use in adults age 25 years or older with severe to profound RP who have bare light perception or no light perception in both eyes, evidence of intact inner layer retina function, and a previous history of the ability to see forms. Patients must also be willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation. The VPU transforms images from the video camera into electronic data that is wirelessly transmitted to the array of electrodes that are implanted onto the patient’s retina. The electrodes transform the data into electrical impulses that stimulate the retina to produce images. While the Argus II Retinal Prosthesis System will not restore vision to patients, it may allow them to detect light and dark in the environment, aiding them in identifying the location or movement of objects or people. The FDA approved the Argus II Retinal Prosthesis System as a humanitarian use device, an approval pathway limited to those devices that treat or diagnose fewer than 4,000 people in the U.S. each year. For more information, visit http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm339824.htm?source=govdelivery

Delzicol
Warner Chilcott has announced that the FDA has approved its new 400mg mesalamine product indicated for the treatment of ulcerative colitis. The product will be marketed as Delzicol™ (mesalamine) 400mg delayed-release capsules. The company anticipates that it will commercially launch Delzicol in March 2013. For more information, visit http://ir.wcrx.com/releasedetail.cfm?ReleaseID=737871

Kadcyla
The FDA has approved Kadcyla (ado-trastuzumab emtansine), a new therapy for patients with HER2-positive, late-stage (metastatic) breast cancer. Kadcyla is intended for patients who were previously treated with trastuzumab and taxanes. Referred to as T-DM1 during clinical research, Kadcyla was reviewed under the FDA’s priority review program, which offers an expedited six-month review of drugs that either provide safe and effective therapy when no satisfactory alternative therapy exists, or that may offer significant improvement compared to marketed products. Kadcyla is being approved with a Boxed Warning alerting patients and healthcare professionals that the drug can cause liver toxicity, heart toxicity, and death. The drug can also cause severe life-threatening birth defects, and pregnancy status should be verified prior to starting Kadcyla treatment. The most common side effects reported in patients treated with Kadcyla were nausea, fatigue, pain in the muscles or joints, thrombocytopenia, increased levels of liver enzymes, headache, and constipation. Kadcyla is marketed by Genentech, a member of the Roche Group. For more information, visit http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm340704.htm?source=govdelivery

Osphena
The FDA has approved Osphena (ospemifene) to treat women experiencing moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy due to menopause. Osphena, a pill taken with food once daily, acts like estrogen on vaginal tissues to make them thicker and less fragile, resulting in a reduction in the amount of pain some women experience with sexual intercourse. Osphena is being approved with a Boxed Warning alerting women and healthcare professionals that the drug, which acts like estrogen on vaginal tissues, has shown it can stimulate the endometrium and cause it to thicken. The Boxed Warning also states the incidence rates of thrombotic and hemorrhagic strokes (0.72 and 1.45 per thousand women, respectively) and the incidence rate of deep vein thrombosis (1.45 per thousand women). These rates are considered to represent low risks in contrast to the increased risks of stroke and deep vein thrombosis seen with estrogen-alone therapy. Common side effects reported during clinical trials included hot flush/flashes, vaginal discharge, muscle spasms, genital discharge, and excessive sweating. Osphena is marketed by Shionogi, Inc. For more information, visit http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm341128.htm?source=govdelivery
**Pomalyst**
Celgene Corporation has announced that the FDA has approved Pomalyst® (pomalidomide) for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified. Pomalyst, an analogue of thalidomide, is contraindicated in pregnancy, and is only available through a restricted distribution program called Pomalyst REMSTM. Deep venous thrombosis and pulmonary embolism occur in patients with multiple myeloma treated with Pomalyst. For more information, visit [http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-newsArticle_print&id=1783482&highlight](http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-newsArticle_print&id=1783482&highlight)

**Ravicti**
The FDA has approved Ravicti (glycerol phenylbutyrate) for the chronic management of some urea cycle disorders (UCDs) in patients ages 2 years and older. Ravicti, a liquid taken three times a day with meals, helps dispose of ammonia in the body. It is intended for patients whose UCD cannot be managed by a protein-restricted diet or amino acid supplements alone. Ravicti must be used with a protein-restricted diet and, in some cases, dietary supplements. Ravicti was reviewed under the agency’s fast track program, designed to facilitate the development and expedite the review of drugs to treat serious diseases, fill unmet medical needs, and get important new drugs to patients earlier. Ravicti also was granted orphan product designation because it is intended to treat a rare disease. The most common side effects in patients treated with Ravicti include diarrhea, flatulence, and headache. Ravicti is marketed by Hyperion Therapeutics. For more information, visit [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm337639.htm?source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm337639.htm?source=govdelivery)

**Suprax Oral Suspension 500mg/5mL**
Lupin Ltd. has announced that its subsidiary, Lupin Pharmaceuticals Inc. (collectively, Lupin) has received approval for Suprax® (cefixime) for Oral Suspension, 500mg/5mL from the FDA for the treatment of otitis media, acute exacerbation of chronic bronchitis, uncomplicated urinary tract infections, uncomplicated gonorrhea (cervical/urethral) and pharyngitis/tonsillitis. Lupin expects to commence shipping the product in the near future. The approval will expand Lupin’s range of Suprax dosage forms available to treat approved indications in appropriate patients. Suprax is currently available as 100mg/5mL and 200mg/5mL suspensions, 400mg tablets, and 100mg and 200mg chewable tablets. For more information, visit [http://www.lupinworld.com/pdf/2013/New%20Drug%20Application%20for%20SUPRAX_%20Oral%20Suspension%20-%202012013.pdf](http://www.lupinworld.com/pdf/2013/New%20Drug%20Application%20for%20SUPRAX_%20Oral%20Suspension%20-%202012013.pdf)

**FDA New Indications**

**Stivarga**
The FDA has expanded the approved use of Stivarga (regorafenib) to treat patients with advanced gastrointestinal stromal tumors (GIST) that cannot be surgically removed and no longer respond to other FDA-approved treatments for this disease. Stivarga, a multi-kinase inhibitor, blocks several enzymes that promote cancer growth. With this new approval, Stivarga is intended to be used in patients whose GIST cancer cannot be removed by surgery or has spread to other parts of the body (metastatic) and is no longer responding to Gleevec (imatinib) and Sutent (sunitinib). Stivarga was reviewed under the FDA’s priority review program, which provides an expedited six-month review for drugs that may provide safe and effective therapy when no satisfactory alternative therapy exists, or may offer significant improvement compared to marketed products. The drug was also granted orphan product designation because it is intended to treat a rare disease. The most common side effects reported in patients treated with Stivarga were weakness and fatigue, hand-foot syndrome (also called palmar-plantar erythrodysesthesia), diarrhea, loss of appetite, high blood pressure, mouth sores, infection, changes in voice volume or quality, pain, weight loss, stomach pain, rash, fever, and nausea. Serious side effects, which occurred in less than one percent of patients, were liver damage, severe bleeding, blistering and peeling of skin, very high blood pressures requiring emergency treatment, heart attacks, and perforations in the intestines. Stivarga was approved in September 2012 to treat colorectal cancer. It is marketed by Bayer HealthCare Pharmaceuticals. For more information, visit [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm340958.htm?source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm340958.htm?source=govdelivery)

**Zortress**
Novartis announced that the FDA has approved Zortress® (everolimus) for the prophylaxis of organ rejection in adult patients receiving a liver transplant. Zortress is the first mammalian target of rapamycin (mTOR) inhibitor approved for use following liver transplantation. For more information, visit [http://www.novartis.com/newsroom/media-releases/en/2013/1678805.shtml](http://www.novartis.com/newsroom/media-releases/en/2013/1678805.shtml)
Ad-Tech Macro Micro Subdural Electrodes
The FDA and Ad-Tech have notified healthcare professionals of a Class 1 recall due to concern the microelectrodes are defective and may cause injury to the brain. These devices are intended for temporary (less than 30 days) use on patients with epilepsy for the recording, monitoring, and stimulation of electrical signals on the surface level of the brain. There is the potential for abrasion of brain tissue and for broken pieces to remain in the brain tissue when the physician removes the electrode. This may lead to hemorrhaging, seizure, or death. There has been one reported serious injury that may have been related to the use of the device. On January 2, 2013, Lumenis sent an Urgent Safety Advisory Notice letter to all affected customers. The letter identified the affected product, problem, and actions to be taken. The letter instructed customers to re-label the device with the two labels provided, remove and destroy the existing Operator’s Manual and replace it with the current revised Manual, complete the information requested on the confirmation card provided, and return the confirmation card using the enclosed, pre-paid UPS shipping label. The firm will send follow-up notices to customers who do not respond in 30, 60, and 90 days. For more information, visit

Lumenis VersaCut Tissue Morcellator
Lumenis Limited is recalling certain models of VersaCut Morcellator devices to correct its labeling. There is a potential for air embolism to occur if the aspiration tubing is hooked up backwards to the aspiration control box housing. This product may cause serious adverse health consequences, including death. Lumenis placed an immediate internal quarantine on all affected products within its possession. The firm will re-label these devices and replace the current Operator’s Manual with the revised Manual. On January 2, 2013, Lumenis sent an Urgent Safety Advisory Notice letter to all affected customers. The letter identified the affected product, problem, and actions to be taken. The letter instructed customers to re-label the device with the two labels provided, remove and destroy the existing Operator’s Manual and replace it with the current revised Manual, complete the information requested on the confirmation card provided, and return the confirmation card using the enclosed, pre-paid UPS shipping label. The firm will send follow-up notices to customers who do not respond in 30, 60, and 90 days. For more information, visit

Omontys
Affymax, Inc. and Takeda Pharmaceutical Company Limited along with the FDA are informing the public of a voluntary recall of all lots of Omontys® (peginesatide) Injection to the user level as a result of new postmarketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. Fatal reactions have been reported in approximately 0.02% of patients following the first dose of intravenous administration. The reported serious hypersensitivity reactions have occurred within 30 minutes after such administration of Omontys. There have been no reports of such reactions following subsequent dosing, or in patients who have completed their dialysis session. Since launch, more than 25,000 patients have received Omontys in the postmarketing setting. The rate of overall hypersensitivity reactions reported is approximately 0.2%, with approximately a third of these being serious in nature including anaphylaxis requiring prompt medical intervention, and in some cases, hospitalization. Dialysis organizations are instructed to discontinue use. For more information, visit

Reumofan Plus Tablets
Reumofan Plus USA, LLC and Reumofan USA, LLC are recalling "Reumofan Plus" Tablets, Lot# 99515, exp. 09/16, because the product contains undeclared active pharmaceutical ingredients: methocarbamol, dexamethasone, and diclofenac. Use of this product could result in serious and life-threatening injuries. Reumofan Plus is used as a treatment for muscle pain, arthritis, osteoporosis, bone cancer, and other conditions. The product comes in thirty-tablet containers and is packaged in a green and gold box. Reumofan Plus was distributed nationwide through internet sales. One illness has been reported in connection with this problem. The recall was initiated after it was discovered that the product was distributed in packaging that did not reveal the presence of the active pharmaceutical ingredients, making it an unapproved drug. Distribution of the product has been completely terminated by Reumofan Plus USA, LLC and Reumofan USA. For more information, visit
http://www.fda.gov/Safety/Recalls/ucm340161.htm?source=govdelivery

St. Jude Medical, Amplatzer TorqVue FX Delivery System
The FDA has notified healthcare professionals of a Class I recall of the St. Jude Medical, Amplatzer TorqVue FX Delivery System. In a small number of cases, the distal end of the core wire of the TorqVue FX Delivery System could potentially fracture when exposed to a combination of certain cardiac anatomies and usage conditions. This recall is for all batches and model numbers of the Amplatzer TorqVue FX Delivery System. The affected product was manufactured August 24, 2012 to September 24, 2012 and distributed October 1, 2012 to January 9, 2013. For more information, visit
**Triaminic Syrups and Theraflu Warming Relief Syrups**

Novartis Consumer Health, Inc. is voluntarily recalling certain lots of Triaminic® Syrups and Theraflu Warming Relief® Syrups that were manufactured in the U.S. before December 31, 2011. Novartis Consumer Health has decided to issue a voluntary recall to consumers, retail customers, and wholesalers in the U.S. because the child-resistant feature of the bottle cap may not function properly, enabling the cap to be removed with the tamper-evident seal still in place. For more information, visit http://www.novartisotc.com/recall_theraflu_triaminic.html

**Vistide**

Gilead Sciences, Inc. is voluntarily recalling lot B120217A of Vistide® (cidofovir injection) to the user level due to the presence of particulate matter found in some vials of this lot. Gilead is not currently aware of any complaint attributable to the particles. Gilead has notified its distributors and customers by e-mail and recall letter and is arranging for return of all recalled product. Before injecting Vistide, healthcare providers should inspect the product, and any product with lot number B120217A should not be injected. For more information, visit http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm340094.htm?source=govdelivery

**Vycor Medical Viewsite Brain Access System**

Vycor Medical recalled its Viewsite Brain Access System (VBAS) because an unidentified black fiber was found on the device. This product may cause serious adverse health consequences, including death. The Vycor Medical VBAS serves as a self-retaining retractor system for brain tissue and provides access to allow the surgeon to see the surgical site during brain and spinal procedures. Vycor Medical called their customers requesting that they place products of Model # TC171105, Lot # VM83450 into quarantine until further notice. Vycor Medical also asked customers holding the affected lot numbers to call the company immediately. For more information, visit http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm337475.htm?source=govdelivery

**Avastin**

The FDA is warning healthcare professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the U.S. The counterfeit version of Avastin does not contain the medicine’s active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy. The counterfeit version is labeled as Avastin, manufactured by Roche. Roche is the company that manufactures Avastin approved for marketing outside of the U.S. Roche conducted laboratory tests that confirmed the counterfeit version of Avastin. Packages or vials may be counterfeit if they are labeled with Roche as the manufacturer or display batch numbers that start with B6010, B6011, or B86017. The only FDA approved version of Avastin for use in the U.S. is marketed by Genentech (a member company of Roche). The FDA approved version does not include the Roche logo on the packaging or vials. In addition, Genentech’s FDA-approved version of Avastin vials and packaging have a 6-digit numeric batch number and expiration dates in a 3-letter month and 4-digit year format (eg, JAN 2014). For more information, visit http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm

**Codeine**

The FDA is updating the public about new actions being taken to address a known safety concern with codeine use in certain children after tonsillectomy and/or adenoidectomy. Deaths have occurred post-operatively in children with obstructive sleep apnea who received codeine for pain relief following these procedures. Codeine is converted to morphine by the liver. These children had evidence of being ultra-rapid metabolizers of codeine, which is an inherited (genetic) ability that causes the liver to convert codeine into life-threatening or fatal amounts of morphine in the body. A new Boxed Warning will be added to the drug label of codeine-containing products about the risk of codeine in post-operative pain management in children following tonsillectomy and/or adenoidectomy. A Contraindication will be added to restrict codeine from being used in this setting. The Warnings/Precautions, Pediatric Use, and Patient Counseling Information sections of the drug label will also be updated. Healthcare professionals should prescribe an alternate analgesic for post-operative pain control in children who are undergoing tonsillectomy and/or adenoidectomy. Codeine should not be used for pain in children following these procedures. For more information, visit http://www.fda.gov/Drugs/DrugSafety/ucm339112.htm

**Sensipar**

The FDA has stopped all pediatric clinical trials of Sensipar (cinacalcet HCl) after the recent death of a 14-year-old patient in a trial. The FDA continues to gather information on the circumstances surrounding the patient’s death. Sensipar is a medication used to decrease the release of parathyroid hormone (PTH) from the parathyroid gland. Sensipar lowers high PTH levels leading to lower calcium levels in the blood; when calcium levels are too low it can result in health problems. The FDA has approved Sensipar for use in adults but not in children (less than 18 years of age), and the clinical trials were underway to determine if the drug is effective and can be used safely in children. For more information, visit http://www.fda.gov/Drugs/DrugSafety/ucm340551.htm
**Clindamycin in 5% Dextrose**
Sandoz has announced the FDA approval and U.S. launch of clindamycin in 5% dextrose in minibag form, the first generic version of Cleocin Phosphate® in Dextrose 5%. Sandoz is marketing clindamycin in 5% dextrose in the same strengths as those of the originator brand. For more information, visit [http://www.us.sandoz.com/media_center/news/2012/2013_02_06_generic_version_cleocin_phosphate.shtml](http://www.us.sandoz.com/media_center/news/2012/2013_02_06_generic_version_cleocin_phosphate.shtml)

**Doxorubicin HCl Liposome Injection**
The FDA has approved the first generic version of the cancer drug Doxil (doxorubicin HCl liposome injection). Doxorubicin HCl liposome injection is currently on the FDA’s drug shortage list. For products on the shortage list, the FDA’s Office of Generic Drugs is using a priority review system to expedite the review of generic applications to help alleviate shortages. The generic is made by Sun Pharma Global FZE (Sun) and will be available in 20mg and 50mg vials. For more information, visit [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm337872.htm?source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm337872.htm?source=govdelivery)