New Drugs Approval

FDA approves Imatinib for children with acute lymphoblastic leukemia

Monday, 28 January 2013 - The U.S. Food and Drug Administration has approved a new use of imatinib to treat children newly diagnosed with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL). ALL is the most common type of pediatric cancer, affecting approximately 2,900 children annually, and progresses quickly if untreated. Children with Ph+ ALL have a genetic abnormality that causes proteins called tyrosine kinases to stimulate the bone marrow to make too many immature white blood cells. This leaves less room for healthy white blood cells needed to fight infection.

FDA approves new seasonal influenza vaccine made using novel technology

Thursday, 17 January 2013 - The U.S. Food and Drug Administration has approved Flublok, the first trivalent influenza vaccine made using an insect virus (baculovirus) expression system and recombinant DNA technology. Flublok is approved for the prevention of seasonal influenza in people 18 through 49 years of age.

FDA approves Eliquis to reduce the risk of stroke, blood clots in patients with non-valvular atrial fibrillation

Wednesday, 02 January 2013 - The U.S. Food and Drug Administration approved the anti-clotting drug Eliquis (apixaban), an oral tablet used to reduce the risk of stroke and dangerous blood clots (systemic embolism) in patients with atrial fibrillation that is not caused by a heart valve problem.

Atrial fibrillation, one of the most common types of abnormal heart rhythm, is an abnormal, irregular, and rapid beating of the heart in which the heart's two upper chambers (atria) do not contract properly, allowing blood clots to form in them. These clots can break off and travel to the brain or other parts of the body.

FDA Approves Pomalyst for Advanced Multiple Myeloma

February 8, 2013 - The U.S. Food and Drug Administration today approved Pomalyst (pomalidomide) to treat patients with multiple myeloma whose disease progressed after being treated with other cancer drugs. Multiple myeloma is a form of blood cancer that primarily affects older adults and arises from plasma cells in the bone marrow.

Warner Chilcott Announces FDA Approval of New Ulcerative Colitis Product Delzicol

DUBLIN, Ireland, Feb. 5, 2013 - Warner Chilcott plc today announced that the United States Food and Drug Administration (FDA) has approved its new 400 mg mesalamine product indicated for the treatment of ulcerative colitis. The product will be marketed as Delzicol (mesalamine) 400 mg delayed-release capsules. The Company anticipates that it will commercially launch Delzicol in March 2013.

Hemispherx Biopharma Receives Complete Response Letter from FDA on Ampligen New Drug Application for Chronic Fatigue Syndrome

PHILADELPHIA, Feb. 4, 2013 (GLOBE NEWSWIRE) -- Hemispherx Biopharma, Inc. announced that it received a Complete Response Letter from the US Food and Drug Administration ("FDA") declining to approve its new drug application ("NDA") for Ampligen(R) for Chronic Fatigue Syndrome ("CFS"). The FDA said Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses.

FDA Approves Ravicti for the Chronic Management of Some Urea Cycle Disorders

February 1, 2013 - The U.S. Food and Drug Administration today approved Ravicti (glycerol phenylbutyrate) for the chronic management of some urea

cycle disorders (UCDs) in patients ages 2 years and older. UCDs are genetic disorders that involve deficiencies of specific enzymes involved in the urea cycle, a series of biochemical steps normally required to remove ammonia from the blood.

FDA Approves New Orphan Drug Kynamro to Treat Inherited Cholesterol Disorder

January 29, 2013 - The U.S. Food and Drug Administration today approved Kynamro (mipomersen sodium) injection as an addition to lipid-lowering medications and diet to treat patients with a rare type of high cholesterol called homozygous familial hypercholesterolemia (HoFH). The addition of Kynamro helps to reduce low-density lipoprotein-cholesterol (LDL-C), apolipoprotein B, total cholesterol, and non-high density lipoprotein-cholesterol (non HDL-C).

FDA Advisory Committee Recommends Approval for Boehringer Ingelheim's Olodaterol for Maintenance Treatment of COPD

RIDGEFIELD, Conn., Jan. 29, 2013 /PRNewswire/ Boehringer Ingelheim announced today that the U.S. Food and Drug Administration (FDA) Pulmonary-Allergy Drugs Advisory Committee (PADAC) recommended that clinical data included in a new drug application (NDA) provide substantial and convincing evidence to support the approval of olodaterol as a once-daily maintenance bronchodilator treatment for airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. If approved by the FDA, it is anticipated that olodaterol will be marketed under the brand name Striverdi Respimat in the United States.

Genzyme's Lemtrada (alemtuzumab) Application for MS Accepted for Review by the FDA

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan 28, 2013 Genzyme, a Sanofi Company, announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's supplemental Biologics License Application (sBLA) file seeking approval of Lemtrada (alemtuzumab) for the treatment of relapsing multiple sclerosis (RMS). The company also reported key highlights from the U.S. launch of once-daily.

Takeda Receives FDA Approval for Kazano (alogliptin and metformin) for Type 2 Diabetes

DEERFIELD, Ill. and OSAKA, Japan, Jan. 25, 2013 /PRNewswire/ -Takeda Pharmaceutical Company Limited (Takeda) and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved Kazano (alogliptin and metformin HCl) for the treatment of type 2 diabetes in adults as adjuncts to diet and exercise.

FDA Issues Complete Response Letter for Rytary (Carbidopa and Levodopa) Extended-Release Capsules (IPX066) New Drug Application

HAYWARD, Calif.--(BUSINESS WIRE)--Jan 21, 2013 - Impax Pharmaceuticals, a division of Impax Laboratories, Inc., announced today that the U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) for Rytary (IPX066), an extended-release capsule formulation of carbidopa-levodopa, a potential treatment for the symptomatic treatment of Parkinson's disease currently under review in the United States.

Genzyme Announces Positive New Data from Two Phase 3 Studies for Oral Eliglustat Tartrate for Gaucher Disease

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb 15, 2013 - Genzyme, a Sanofi company (EURONEXT: SAN and NYSE: SNY), today announced positive new data from the Phase 3 ENGAGE and ENCORE studies of eliglustat tartrate, its investigational oral therapy for Gaucher disease type 1. The results from the ENGAGE study were presented today at the 9th Annual Lysosomal Disease Network WORLD Symposium in Orlando, Fla. In conjunction In conjunction with this meeting, Genzyme also released topline data from its second Phase 3 study,

ENCORE. Both studies met their primary efficacy endpoints and together will form the basis of Genzyme's registration package for eliglustat tartrate.

Scripps Research Institute Scientists Find Promising New Approach to Preventing Progression of Breast Cancer

LA JOLLA, Calif. , Feb. 15, 2013 /PRNewswire-USNewswire/ -- Doctors currently struggle to determine whether a breast tumor is likely to shift into an aggressive, life-threatening mode—an issue with profound implications for treatment. Now a group from The Scripps Research Institute (TSRI) has identified a mechanism through which mitochondria, the powerhouses of a cell, control tumor aggressiveness. Based on their findings, the team developed a simple treatment that inhibits cancer progression and prolongs life when tested in mice.

AbbVie Announces First Long-term, Patient-Reported Health Outcomes Data for Use of HUMIRA® (Adalimumab) in Patients with Pediatric Crohn's Disease

In the Phase 3 IMAgINE-1 trial, pediatric patients taking HUMIRA experienced a significant improvement in select measures of health-related quality of life at 12 weeks -- Analysis of data showed that pediatric patients taking HUMIRA continued to experience quality of life improvement through 52 weeks VIENNA, Feb. 15, 2013 /PRNewswire/ -- AbbVie (NYSE:ABBV) today announced the first long-term, patient-reported health outcomes data from analyses of the Phase 3 IMAgINE-1 trial. The analyses assessed improvements in health-related quality of life (HRQOL) measures for pediatric patients aged 6 to 17 years with severe active Crohn's disease, taking HUMIRA, who had an inadequate response, were intolerant or had contraindications to conventional therapy, as well as the work productivity of their caregivers throughout the 52-week study. The results of these analyses are being presented this week at the European Crohn's and Colitis Organisation (ECCO) 8th Annual Congress.

ATryn Antithrombin (Recombinant) Prevents Venous Thromboembolic Events in Pregnant Patients with Hereditary Antithrombin Deficiency

FRAMINGHAM, Mass.--(BUSINESS WIRE)--Feb 15, 2013 - rEVO Biologics announced today the results of a major retrospective study analysis of its pivotal phase 3 studies which demonstrate that pregnant patients with hereditary antithrombin deficiency (HD) benefit from ATryn Antithrombin (Recombinant) therapy to prevent venous thromboembolic events (VTE).

New Findings on Morning Sickness Treatment Presented at Society for Maternal-Fetal Medicine Annual Pregnancy Meeting

BLAINVILLE, Canada, February 14, 2013 /PRNewswire/ -- Early use of Diclectin ® reduces the severity of nausea and vomiting of pregnancy (NVP) symptoms in pregnant women who had severe NVP in a previous pregnancy Duchesnay Inc. announced results from a new study concluding that pre-emptive use of Diclectin® (a delayed-release combination of 10 mg doxylamine and 10 mg pyridoxine) is effective in reducing symptoms of severe nausea and vomiting of pregnancy (NVP) in patients at high risk for recurrence of severe NVP.

Source: Drugs.com & worldpharmanews.com

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