Recent Pharma News

FDA Okays Horizon Pharma's Time-Release Painkiller

FRIDAY, 27 July 2012

The Food and Drug Administration on Thursday gave the suburban biotech company Horizon Pharma Inc. the thumbs up on a new anti-inflammatory drug, the second the company will bring to market. Deerfield-based Horizon won approval to sell Rayos, a delayed-release version of the corticosteroid drug prednisone, which is sold in Europe under the brand name Lodotra by Horizon's Swiss-based partner Mundipharma.

Doctors Petition FDA to Change Labeling of Painkillers

THURSDAY, 26 July 2012

Nearly 40 doctors, researchers and public health officials Wednesday asked the Food and Drug Administration to change the labeling used on narcotic painkillers, a move that, if approved, would make it more difficult for drug companies to market the medications for chronic, non-cancer pain.

FDA: More Than 150 Antiretroviral Drugs Available Through PEPFAR for Worldwide HIV/AIDS Relief

MONDAY, 23 July 2012

Today, U.S. Food and Drug Administration (FDA) Commissioner Margaret A. Hamburg announced the agency has approved or tentatively approved a total of 152 antiretroviral drugs in association with the President's Emergency Plan for AIDS Relief (PEPFAR) to treat those infected with HIV/AIDS in countries that lack the tools needed to fight the AIDS epidemic.

The most recent FDA actions in association with PEPFAR were tentative approvals of the following generic drugs:
- abacavir oral solution (Hetero Labs Ltd. Unit III, July 2, 2012)
- lopinavir and ritonavir oral solution (Cipla Ltd., June 29, 2012)
- efavirenz tablets (Edict Pharmaceuticals Private Ltd., June 25, 2012 and Micro Labs Ltd., June 20, 2012)

Tentative approval means that although FDA has found that a drug product has met all required manufacturing quality, clinical safety, and efficacy requirements, it cannot be approved for marketing in the U.S. at this time because of existing patents and/or marketing exclusivity. However, the product is eligible for purchase outside the U.S. through the PEPFAR program. All FDA reviews of drug applications received in association with PEPFAR are expedited, as are any inspections of the overseas manufacturing facilities.

FDA Approves Weight-Management Drug Qsymia

WEDNESSDAY, 18 July 2012

The U.S. Food and Drug Administration has approved the weight loss drug Qsymia, but officials say certain patients, including pregnant women, should not use it. Dr. Janet Woodcock, director of the FDA Center for Drug Evaluation and Research, said Qsymia contains phentermine and topiramate in an extended-release formula, which should be used in addition to a reduced-calorie diet and exercise. The drug is approved for use by adults only.

FDA Schedules Advisory Committee Meeting for Insulin Degludec and Insulin Degludec/Insulin Aspart

MONDAY, 23 July 2012

Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA) has informed the company that an FDA Advisory Committee meeting is tentatively scheduled to be held on November 8, 2012, to discuss the New Drug Applications (NDA) for the ultra-long-acting insulin degludec and insulin degludec/insulin aspart.

FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

Novo Nordisk submitted the NDAs to the FDA on 29 September 2011, and on 8 June this year, the FDA informed Novo Nordisk that the updated action date is 29 October 2012. In its communication about the advisory committee meeting the agency has not informed Novo Nordisk of a new action date.

UCB Launches Neupro in the U.S. to Treat Parkinson's Disease and Restless Legs Syndrome

MONDAY, 16 July 2012

UCB announced today that Neupro(R) (Rotigotine Transdermal System) is now available in U.S. pharmacies. Neupro(R) was approved by the U.S. Food and Drug Administration in April to treat the signs and symptoms of early and advanced stage idiopathic Parkinson's disease and moderate-to-severe primary Restless Legs Syndrome.

Neupro(R) improves motor function and activities of daily living in patients with PD and provides effective symptom relief for patients with Restless Legs Syndrome (RLS). Neupro(R) is a once-daily patch that provides continuous delivery of the dopamine agonist rotigotine for 24 hours.

Over 100,000 patients have been treated with Neupro(R) worldwide, and seven clinical trials for the approved indications have demonstrated efficacy, safety and tolerability.

Watson's Generic Version of Plan B One-Step Receives FDA Approval

FRIDAY, 13 July 2012

Watson Pharmaceuticals, Inc. (NYSE: WPI) today announced that its subsidiary Watson Laboratories, Inc., has received approval from the United States Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Next Choice™ ONE DOSE (Levonorgestrel Tablet, 1.5 mg), the generic equivalent to Teva Women's Health's Plan B One-Step®. Watson plans to launch the product immediately.

For the twelve months ending May 31, 2012, Plan B One-Step® had total U.S. sales of approximately $88 million according to IMS Health data. Plan B One-Step® is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

Abbott Announces New Test for the Management of Patients with Diabetes

TUESDAY, 10 July 2012

More than 346 million people worldwide are living with diabetes, and the World Diabetes Foundation estimates that number will increase by nearly 27 percent by 2030. In order to help physicians appropriately monitor

treatment efficacy for these patients, Abbott announced today CE Marking (Conformité Européenne) for the Abbott ARCHITECT HbA1c (IA) Assay. Glycated hemoglobin, also known as HbA1c, is a form of hemoglobin used primarily to monitor long-term diabetes control. This helps physicians understand how well the patient's diabetes is being managed from a treatment or dosing perspective. The HbA1c test differs from a patient-administered blood glucose test, which takes a snapshot of a patient's blood sugar level at a moment in time. The HbA1c test must be performed on a laboratory instrument.

FDA Introduces New Safety Measures for extended-release and Long-acting Opioid Medications

MONDAY, 09 July 2012

The U.S. Food and Drug Administration today approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids, highly potent drugs approved for moderate to severe, persistent pain that requires treatment for an extended period. The REMS is part of a federal initiative to address the prescription drug abuse, misuse, and overdose epidemic. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain. The new ER/LA opioid REMS will affect more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies will be required to make education programs available to prescribers based on an FDA Blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education (CE) providers, who will develop and deliver the training. The REMS also will require companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

Lupin Receives FDA Approval for Generic Lyrica

THURSDAY, 05 July 2012

Pharma major, Lupin Ltd., announced today that its subsidiary, Lupin Pharmaceuticals Inc. (collectively, Lupin) has received final approval for its Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg from the United States Food and Drugs Administration (FDA) to market a generic version of C.P. Pharmaceuticals C.V., LYRICA® (Pregabalin) capsules. Lupin’s Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg are the AB-rated generic equivalent of LYRICA® capsules, which is indicated for neuropathic pain associated with diabetic peripheral neuropathy, post herpetic neuralgia, adjunctive therapy for adult patients with partial onset seizures and fibromyalgia.

FDA Approves Genetic Test to Help Some Colon Cancer Patients, Physicians Considering Erbitux Therapy

FRIDAY, 06 July 2012

The U.S. Food and Drug Administration today approved the first genetic test that can help some colorectal cancer (CRC) patients and their doctors determine if the drug Erbitux (cetuximab) would be an effective treatment based on the absence of a gene mutation.

The *therascreen* KRAS RGQ PCR Kit can provide information about the KRAS gene mutation in patients whose CRC has spread to other parts of their body (metastasized). Studies have found that Eribitux is not effective in those who have the mutation.

CRC is the third leading cause of cancer death in the United States. According to the American Cancer Society, there were more than 141,000 new CRC cases in 2011, and nearly 50,000 deaths resulted from CRC.

Erbitux targets the epidermal growth factor receptor (EGFR) on the surface of CRC cells. When certain chemicals in the body bind to EGFR, the receptor starts a complex chain of biochemical reactions inside the cell that signals the cancer cell to reproduce. Erbitux blocks EGFR, interrupting a signal to reproduce which can stop the growth of CRC cells. However, when CRC cells have a mutation in the KRAS gene, they continue to reproduce even when Erbitux blocks EGFR.

The FDA first approved Erbitux in 2004 to treat EGFR-expressing late-stage colorectal cancer after patients stopped responding to chemotherapy. In 2009, the FDA approved updated recommendations for Erbitux, based on studies that found the drug is not effective in patients whose tumors have a mutated KRAS gene.

Source: Drugs.com & worldpharmanews.com

Information collected by: **Md. Akbar Hossain**
Assistant Professor, Department of Pharmacy
Dhaka International University

New Drugs Approved

The following drugs have recently been approved by the FDA. These include newly approved drugs and new indications for drugs already approved:

Rayos (prednisone) Delayed-Release Tablets - formerly Lodotra

Company: Horizon Pharma, Inc.

Date of Approval: July 26, 2012

Treatment for: Rheumatoid Arthritis, Polymyalgia Rheumatica, Psoriatic Arthritis, Ankylosing Spondylitis, Asthma, Chronic Obstructive Pulmonary Disease

Rayos (prednisone) is a delayed release corticosteroid indicated as an anti-inflammatory or immunosuppressive agent to treat a broad range of diseases including rheumatoid arthritis, polymyalgia rheumatica, psoriatic arthritis, ankylosing spondylitis, asthma and chronic obstructive pulmonary disease (COPD).

Vascepa (icosapent ethyl) Capsules

Company: Amarin Corporation plc

Date of Approval: July 26, 2012

Treatment for: Hypertriglyceridemia

Vascepa (icosapent ethyl) is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia.

Tudorza (aclidinium bromide) Pressair

Company: Forest Laboratories, Inc. and Almirall, S.A.

Date of Approval: July 23, 2012

Treatment for: Chronic Obstructive Pulmonary Disease

Tudorza Pressair (aclidinium bromide inhalation powder) is an anticholinergic indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Kyprolis (carfilzomib) Injection

Company: Onyx Pharmaceuticals, Inc.

Date of Approval: July 20, 2012

Treatment for: Multiple Myeloma

Kyprolis (carfilzomib) is a proteasome inhibitor indicated for the treatment of patients with multiple myeloma.

Qsymia (phentermine and topiramate) Extended-Release Capsules - formerly Qnexa

Company: Vivus, Inc.

Date of Approval: July 17, 2012

Treatment for: Obesity

Qsymia (phentermine and topiramate) is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate extended-release, an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults.

Prepopik (sodium picosulfate, magnesium oxide and citric acid) for Oral Solution

Company: Ferring Pharmaceuticals

Date of Approval: July 16, 2012

Treatment for: Bowel Preparation

Prepopik (sodium picosulfate, magnesium oxide and citric acid) is a stimulant laxative and osmotic laxative combination indicated for cleansing of the colon as a preparation for colonoscopy in adults.

Myrbetriq (mirabegron) Extended Release Tablets

Company: Astellas Pharma Inc.

Date of Approval: June 28, 2012

Treatment for: Overactive Bladder

Myrbetriq (mirabegron) is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Belviq (lorcaserin) Tablets - formerly Lorqess

Company: Arena Pharmaceuticals, Inc.

Date of Approval: June 27, 2012

Treatment for: Obesity

Belviq (lorcaserin) is a serotonin 2C receptor agonist indicated for chronic weight management in adults who are obese, or overweight and who have at least one weight-related condition such as high blood pressure, type 2 diabetes, or high cholesterol.

MenHibrix (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine)

Company: GlaxoSmithKline

Date of Approval: June 14, 2012

Treatment for: Haemophilus influenzae Prophylaxis, Meningococcal Meningitis Prophylaxis

Source: Drugs.com & worldpharmanews.com
Information collected by: **Md. Akbar Hossain**
Assistant Professor, Department of Pharmacy
Dhaka International University

MenHibrix (Hib-MenCY-TT) is a combination vaccine for the active immunization of infants and young children 6 weeks through 18 months of age for the prevention of invasive diseases caused by *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b (Hib).

Perjeta (pertuzumab) Injection

Company: Genentech

Date of Approval: June 8, 2012

Treatment for: Breast Cancer

Perjeta (pertuzumab) is a humanized monoclonal antibody indicated in combination with Herceptin (trastuzumab) and docetaxel chemotherapy for the treatment of HER2-positive metastatic breast cancer.

Recent Health Issue

Egg Yolk Consumption Almost as Bad as Smoking When It Comes to Atherosclerosis
University of Western Ontario [www.sciencedaily.com/releases/2012/08/120813155640.htm]

Newly published research led by Dr. David Spence of Western University, Canada, shows that eating egg yolks accelerates atherosclerosis in a manner similar to smoking cigarettes. Surveying more than 1200 patients, Dr. Spence found regular consumption of egg yolks is about two-thirds as bad as smoking when it comes to increased build-up of carotid plaque, a risk factor for stroke and heart attack. The research is published online in the journal *Atherosclerosis*.

Atherosclerosis, also called coronary artery disease, is a disorder of the arteries where plaques, aggravated by cholesterol, form on the inner arterial wall. Plaque rupture is the usual cause of most heart attacks and many strokes. The study looked at data from 1231 men and women, with a mean age of 61.5, who were patients attending vascular prevention clinics at London Health Sciences Centre's University Hospital. Ultrasound was used to establish a measurement of total plaque area and questionnaires were filled out regarding their lifestyle and medications including pack-years of smoking (number of packs per day of cigarettes times the number of years), and the number of egg yolks consumed per week times the number of years consumed (egg yolk-years).

The researchers found carotid plaque area increased linearly with age after age 40, but increased exponentially with pack-years of smoking and egg yolk-years. In other words, compared to age, both tobacco smoking and egg yolk consumption accelerate atherosclerosis. The study also found those eating three or more yolks a week had significantly more plaque area than those who ate two or fewer yolks per week.

"The mantra 'eggs can be part of a healthy diet for healthy people' has confused the issue. It has been known for a long time that a high cholesterol intake increases the risk of cardiovascular events, and egg yolks have very high cholesterol content. In diabetics, an egg a day increases coronary risk by two to five-fold," says Dr. Spence, a Professor of Neurology at Western's Schulich School of Medicine & Dentistry and the Director of its Stroke Prevention and Atherosclerosis Research Centre (SPARC) at the Robarts Research Institute. "What we have shown is that with aging, plaque builds up gradually in the arteries of Canadians, and egg yolks make it build up faster - about two-thirds as much as smoking. In the long haul, egg yolks are not okay for most Canadians."

The issue is with the yolk, not the egg, says Dr. Spence "One jumbo chicken egg yolk has about 237 milligrams of cholesterol." Keeping a diet low in cholesterol is key, he adds. Even if you are young and healthy, eating egg yolks can increase the risk of cardiovascular diseases later. "Just because you are 20 doesn't mean egg yolks aren't going to cause any trouble down the line," he says.

Dr. Spence adds the effect of egg yolk consumption over time on increasing the amount of plaque in the arteries was independent of sex, cholesterol, blood pressure, smoking, body mass index and diabetes. And while he says more research should be done to take in possible confounders such as exercise and waist circumference, he stresses that regular consumption of egg yolk should be avoided by persons at risk of cardiovascular disease.