New Drugs Approvals

Envarsus XR

FDA Approves Envarsus XR (tacrolimus) for Prevention of Organ Rejection in Kidney Transplant Patients

July 10, 2015

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced U.S. Food and Drug Administration (FDA) approval of Envarsus XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus XR.

Rexulti

FDA Approves Rexulti (brexpiprazole) for Schizophrenia and Adjunctive Treatment for Major Depressive Disorder

July 11, 2015

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announced today that the U.S. Food and Drug Administration (FDA) approved Rexulti (brexpiprazole) as an adjunctive therapy for the treatment of adults with major depressive disorder (MDD) and as a treatment for adults with schizophrenia. Rexulti was discovered by Otsuka and co-developed with Lundbeck. It will be co-marketed by the two companies and is expected to become available to patients in the U.S. in early August 2015.

Entresto

FDA Approves Entresto (sacubitril/valsartan) for Heart Failure

July 7, 2015

The U.S. Food and Drug Administration today approved Entresto (sacubitril/valsartan) tablets for the treatment of heart failure. The drug has been shown to reduce the rate of cardiovascular death and hospitalization related to heart failure.

Orkambi

FDA Approves Orkambi (lumacaftor/ivacaftor) for Cystic Fibrosis

July 2, 2015

The U.S. Food and Drug Administration today approved the first drug for cystic fibrosis directed at treating the cause of the disease in people who have two copies of a specific mutation. Orkambi (lumacaftor 200 mg/ivacaftor 125 mg) is now approved to treat cystic fibrosis (CF) in patients 12 years and older, who have the mutation, which causes the production of an abnormal protein that disrupts how water and chloride are transported in the body. Having two copies of this mutation (one inherited from each parent) is the leading cause of CF.

Tuxarin ER

Spriaso Announces FDA Approval of Long Acting Tuxarin ER (codeine and chlorpheniramine)

July 1, 2015

Spriaso LLC announced FDA approval of a New Drug Application (NDA) for Tuxarin ER, a unique high strength long acting Rx cough/cold combination product containing codeine and chlorpheniramine. Tuxarin ER, co-developed with Nexgen Pharma, will be the first product to offer long lasting cough suppression with a safer opiate that is less prone to respiratory distress while minimizing serious risk of dosing errors in patients 18 years and older. As a convenient solid unit dose form, Tuxarin ER is easy to dispense and overcomes disadvantages associated with acting liquids that are prone to spills and dosing errors.

Rociletinib

Treatment for Non-Small Cell Lung Cancer

Clovis Oncology Initiates Rolling NDA Submission for Rociletinib in Advanced EGFR-Mutant Non-Small Cell Lung Cancer.

July 1, 2015

Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that it has commenced the submission of a New

Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rociletinib for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test. Rociletinib is the Company's novel, oral targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M.

Obeticholic acid

Treatment for Biliary Cirrhosis

Intercept Pharmaceuticals Submits NDA for Obeticholic Acid for the Treatment of Primary Biliary Cirrhosis

June 29, 2015

Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic underserved liver diseases, today announced the achievement of two important regulatory milestones for obeticholic acid (OCA) in primary biliary cirrhosis (PBC): submission of a New Drug Application (NDA) for accelerated approval to the U.S. Food and Drug Administration (FDA) and acceptance of the Marketing Authorization Application (MAA) by the European Medicines Agency (EMA). Intercept is seeking approval of OCA for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

Reference: www.drugs.com

Common hormone could help treat breast cancer

Wednesday, 08 July 2015

Around half of all breast cancer patients could one day benefit from having the cheap and widely-available female hormone progesterone added to their treatment, according to Cancer Research UK funded research published in Nature today. Tumoursfuelled by the female hormone oestrogen are treated with drugs like tamoxifen to block oestrogen receptors, which cause cancer cells to grow.

Vitamin C related to reduced risk of cardiovascular disease and early death

Tuesday, 07 July 2015

New research from the University of Copenhagen and Herlev and Gentofte Hospital shows that high vitamin C concentrations in the blood from the intake of fruit and vegetables are associated with a reduced risk of cardiovascular disease and early death. Fruit and vegetables are healthy. We all know that. And now there is yet another good reason for eating lots of it.

Discovery points to a new path toward a universal flu vaccine

Monday, 06 July 2015

Flu vaccines can be something of a shot in the dark. Not only must they be given yearly, there's no guarantee the strains against which they protect will be the ones circulating once the season arrives. New research by Rockefeller University scientists and their colleagues suggests it may be possible to harness a previously unknown mechanism within the immune system to create more effective and efficient vaccines against this ever-mutating virus.

FDA takes action to protect consumers from potentially dangerous counterfeit medicines and devices sold online

Friday, 03 July 2015

The U.S. Food and Drug Administration, in partnership with international regulatory and law enforcement agencies, took action this week against more than 1,050 websites that illegally sell potentially dangerous, unapproved prescription medicines and medical devices to consumers.

The BMJ's data sharing policy now applies to all clinical trials

Thursday, 02 July 2015

From 1st July 2015 The BMJ requires sharing of individual patient data for all clinical trials. This means

that trials will be considered for publication only if the authors agree to make the relevant anonymised patient level data available on reasonable request. The BMJ is the first general medical journal to require data sharing for all trials,

Citrus fruit consumption may be associated with increased melanoma risk

Wednesday, 01 July 2015

A new analysis of dietary patterns among more than 100,000 Americans suggests that frequent consumption of citrus - namely whole grapefruit and orange juice - may be associated with an increased risk of melanoma. Melanoma risk was 36% higher in people who consumed citrus fruit or juice at least 1.6 times daily compared to those who consumed them less than twice per week.

Reference: www.worldpharmanews.com

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