CMR College of Pharmacy, Hyderabad

News Letter, January –June 2015

Advisory Board:

Dr. J. Venkateswara Reddy, Superintendent, Gandhi Hospital

Dr. P Shravan Kumar, HOD, Gastroenteroloy

Dr .Chellam, HOD, Gen Sur

Dr. H Anupama, HOD, Ob & G

Editorial Board:

Dr.V.UmamaheswaraRao

Dr. T Rama Mohan Reddy

Ms. R. Sharadha

Editor-in-chief:

Mr. Sushanta Kumar Das

Associate Editor:

Dr. G. Ramya

Editorial Team Members:

Ms. Neelam I

Ms. Preethi

Ms. Aruna

Ms. Chandhana K

FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie.

The U.S. Food and Drug Administration (FDA) is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, we are requiring the manufacturer to add new information about this safety risk to the drug labels.

Viekira Pak and Technivie are used to treat chronic hepatitis C, a viral infection that can last a lifetime and lead to serious liver and other health problems, including cirrhosis, liver cancer, and death. These medicines reduce the amount of hepatitis C virus in the body by preventing it from multiplying and may slow down the disease.

Our review of adverse events reported to the FDA Adverse Event Reporting System (FAERS) database and to the manufacturer of these medicines, AbbVie, identified cases of hepatic decompensation and liver failure in patients with underlying liver cirrhosis who were taking these medicines. Some of these events resulted in liver transplantation or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment with it.

Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to FAERS were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended (see Data Summary). FAERS includes only reports submitted to FDA, so there are likely additional cases about which we are unaware.

Submitted By**: Ms. S. Mounika, B. Pharm 4th year.**

What is Gene Therapy?

Human gene therapy is the administration of genetic material to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use.

Gene therapy is a technique that modifies a person's genes to treat or cure disease. Gene therapies can work by several mechanisms:

- Replacing a disease-causing gene with a healthy copy of the gene
- Inactivating a disease-causing gene that is not functioning properly
- Introducing a new or modified gene into the body to help treat a disease

Gene therapy products are being studied to treat diseases including cancer, genetic diseases, and infectious diseases.

There are a variety of types of gene therapy products, including:

- **Plasmid DNA:** Circular DNA molecules can be genetically engineered to carry therapeutic genes into human cells.
- **Viral vectors:** Viruses have a natural ability to deliver genetic material into cells, and therefore some gene therapy products are derived from viruses. Once viruses have been modified to remove their ability to cause infectious disease, these modified viruses can be used as vectors (vehicles) to carry therapeutic genes into human cells.
- **Bacterial vectors:** Bacteria can be modified to prevent them from causing infectious disease and then used as vectors (vehicles) to carry therapeutic genes into human tissues.
- **Human gene editing technology:** The goals of gene editing are to disrupt harmful genes or to repair mutated genes.
- **Patient-derived cellular gene therapy products:** Cells are removed from the patient, genetically modified (often using a viral vector) and then returned to the patient.

Submited By: **Ms. A. Preethi, Asst. Prof.**

FDA approves new orphan drug to treat pulmonary arterial hypertension

Recently the U.S. Food and Drug Administration approved Uptravi (selexipag) tablets to treat adults with pulmonary arterial hypertension (PAH), a chronic, progressive, and debilitating rare lung disease that can lead to death or the need for transplantation.

“Uptravi offers an additional treatment option for patients with pulmonary arterial hypertension,” said Ellis Unger, M.D., director of the Office of Drug Evaluation I in the FDA’s Center for Drug Evaluation and Research. “The FDA supports continued efforts to provide new treatment options for rare diseases.”

PAH is high blood pressure that occurs in the arteries that connect the heart to the lungs. It causes the right side of the heart to work harder than normal, which can lead to limitations on exercise ability and shortness of breath, among other more serious complications.

Uptravi belongs to a class of drugs called oral IP prostacyclin receptor agonists. The drug acts by relaxing muscles in the walls of blood vessels to dilate (open) blood vessels and decrease the elevated pressure in the vessels supplying blood to the lungs.

Uptravi’s safety and efficacy were established in a long-term clinical trial of 1,156 participants with PAH. Uptravi was shown to be effective in reducing hospitalization for PAH and reducing the risks of disease progression compared to placebo. Participants were exposed to Uptravi in this trial for a median duration of 1.4 years. Common side effects observed in those treated with Uptravi in the trial include headache, diarrhea, jaw pain, nausea, muscle pain (myalgia), vomiting, pain in an extremity, and flushing.

Uptravi was granted orphan drug designation. Orphan drug designation provides incentives such as tax credits, user fee waivers, and eligibility for exclusivity to assist and encourage the development of drugs for rare diseases.Uptravi is marketed by San Francisco-based Actelion Pharmaceuticals US, Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Submitted By: **Ms. K. Chandana, Asst. Prof.**

FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie.

The U.S. Food and Drug Administration (FDA) is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, we are requiring the manufacturer to add new information about this safety risk to the drug labels.

Patients taking these medicines should contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of liver injury. Patients should not stop taking these medicines without first talking to their health care professionals. Stopping treatment early could result in drug resistance to other hepatitis C medicines. Health care professionals should closely monitor for signs and symptoms of worsening liver disease, such as ascites, hepatic encephalopathy, varicealhemorrhage, and/or increases in direct bilirubin in the blood.

Our review of adverse events reported to the FDA Adverse Event Reporting System (FAERS) database and to the manufacturer of these medicines, AbbVie, identified cases of hepatic decompensation and liver failure in patients with underlying liver cirrhosis who were taking these medicines. Some of these events resulted in liver transplantation or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment with it.

Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to FAERS were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended (see Data Summary). FAERS includes only reports submitted to FDA, so there are likely additional cases about which we are unaware.We are requiring AbbVie to include information about serious liver injury adverse events to theContraindications, Warnings and Precautions, Postmarketing Experience, and Hepatic Impairment sections of the Viekira Pak and Technivie drug labels.We urge health care professionals and patients to report side effects involving Viekira Pak or Technivie to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Submitted By**Dr.RamyaNaidu,** Asst.Prof,Department of Pharm D

FDA Newly Approved Drugs: January- June 2015

Cardiology/Vascular Diseases

Ivabradine: chronic heart failure, Approved April 2015

cangrelor : reducing periprocedural thrombotic events, Approved June 2015

perindopril arginine and amlodipine besylate: hypertension, Approved January 2015

edoxaban; deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation, Approved January 2015

Family Medicine

Cosentyx (secukinumab); Novartis; For the treatment of plaque psoriasis, Approved January 2015

Cresemba (isavuconazoniumsulfate) ; Astellas; For the treatment of invasive aspergillosis and invasive mucormycosis, Approved March 2015

Kybella (deoxycholic acid); KytheraBiopharma; For the treatment of submental fat, Approved April 2015

Savaysa (edoxaban); Daiichi Sankyo; For the treatment of deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation, Approved January 2015

Viberzi (eluxadoline); Actavis; For the treatment of irritable bowel syndrome with diarrhea, Approved May 2015

Xifaxan (rifaximin); Salix Pharmaceuticals; For the treatment of irritable bowel syndrome with diarrhea , Approved May 2015

Gastroenterology

Avycaz (ceftazidime-avibactam); Actavis; For the treatment of complicated intra-abdominal and urinary tract infections, Approved February 2015

Cholbam (cholic acid); Asklepion Pharmaceuticals; For the treatment of bile acid synthesis and peroxisomal disorders, Approved March 2015

Viberzi (eluxadoline); Actavis; For the treatment of irritable bowel syndrome with diarrhea, Approved May 2015

Xifaxan (rifaximin); Salix Pharmaceuticals; For the treatment of irritable bowel syndrome with diarrhea , Approved May 2015

Immunology

Cosentyx (secukinumab); Novartis; For the treatment of plaque psoriasis, Approved January 2015

Evotaz (atazanavir and cobicistat) ; Bristol-Myers Squibb; For the treatment of HIV-1 infection, Approved January 2015

Prezcobix (darunavir and cobicistat); Janssen; For the treatment of HIV-1 infection, Approved January 2015

Infections and Infectious Diseases

Avycaz (ceftazidime-avibactam); Actavis; For the treatment of complicated intra-abdominal and urinary tract infections, Approved February 2015

Bexsero (Meningococcal Group B Vaccine); Novartis; For the treatment of invasive meningococcal disease caused by serogroup B, Approved January 2015

Cresemba (isavuconazoniumsulfate) ; Astellas; For the treatment of invasive aspergillosis and invasive mucormycosis, Approved March 2015

Evotaz (atazanavir and cobicistat) ; Bristol-Myers Squibb; For the treatment of HIV-1 infection, Approved January 2015

Prezcobix (darunavir and cobicistat); Janssen; For the treatment of HIV-1 infection, Approved January 2015

Oncology

Farydak (panobinostat); Novartis; For the treatment of multiple myeloma, Approved February 2015

Ibrance (palbociclib); Pfizer; For the treatment of ER-positive, HER2-negative breast cancer, Approved February 2015

Lenvima (lenvatinib); Eisai; For the treatment of thyroid cancer, Approved February 2015

Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of metastatic squamous non-small cell lung cancer, Approved March 2015

Unituxin (dinutuximab); United Therapeutics; For the treatment of pediatrics with high-risk neuroblastoma, Approved March 2015

Pediatrics/Neonatology

Bexsero (Meningococcal Group B Vaccine); Novartis; For the treatment of invasive meningococcal disease caused by serogroup B, Approved January 2015

Cholbam (cholic acid); Asklepion Pharmaceuticals; For the treatment of bile acid synthesis and peroxisomal disorders, Approved March 2015

Unituxin (dinutuximab); United Therapeutics; For the treatment of pediatrics with high-risk neuroblastoma, Approved March 2015

Submitted By: **Mr. Sushanta Kumar Das, Assoc. Prof.**

Various academic and o-curricular activities during the month of January to June 2015:

CMR College of Pharmacy Students and faculty was participated in Workshop held on "Anticoagulation – Coumadin Clinic" at St. Peter's Institute of Pharmaceutical Sciences, Warangal during 7th – 9th January 2015	
CMR College of Pharmacy Students and faculty was attended a National Conference on Emerging & Re-emerging Viral outbreaks in India – Clinical Challenges & Management at CSIR-IICT-CCMB, Hyderabad during 20th – 22th January 2015	
Guest Lecture on "Cardiovascular Diseases and their Management" was delivered by Dr. P. David Anand, M.D, Director, Hope Hospital at CMR College of Pharmacy on 31st January 2015.	
Guest Lecture on 'Antibiotics prophylaxis for surgical site infection' was delivered by Dr. V.P. Raman, MS(Gen Sur), MS (Ortho), Professor, Department of Orthopedics, Malla Reddy Institute of Medical Science at CMR College of Pharmacy on 12th March 2015.	
CMR College of Pharmacy conducted A workshop on "Pharmacist's role in First Aid & Emergency Services" was conducted in association with Apollo MedskillsPvt. Ltd at CMR College of Pharmacy on 20th March 2015.