CMR College of Pharmacy, Hyderabad

News Letter. July –December 2016

Vission

To be the most preferred Institution for education in Pharmacy in this state.

Mission

- To foster professional graduates with consistent quality education, training &reserach to serve the needs of industry, environment and society.
- To inculcate leadership qualities, teamwork and professional ethics.
- To make the students globally competitive.

FDA Approved drug

Lixisenatide

The U.S. Food and Drug Administration approved Adlyxin (lixisenatide), a once-daily injection to improve glycemic control (blood sugar levels), along with diet and exercise, in adults with type 2 diabetes. Adlyxin is a glucagon-like peptide-1 (GLP-1) receptor agonist, a hormone that helps normalize blood sugar levels.

Lifitegrast ophthalmic solution

The U.S. Food and Drug Administration approved Xiidra (lifitegrast ophthalmic solution) for the treatment of signs and symptoms of dry eye disease. Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease.

Xiidra

The U.S. Food and Drug Administration approved Xiidra (lifitegrast ophthalmic solution) for the treatment of signs and symptoms of dry eye disease. Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease.

Eteplirsen

The U.S. Food and Drug Administration approved Exondys 51 (eteplirsen) injection, the first drug approved to treat patients with Duchenne muscular dystrophy (DMD). Exondys 51 is specifically indicated for patients who have a confirmed mutation of the dystrophin gene amenable to exon 51 skipping, which affects about 13 percent of the population with DMD.

Olaratumab

The U.S. Food and Drug Administration today granted accelerated approval to Lartruvo (olaratumab) with doxorubicin to treat adults with certain types of soft tissue sarcoma (STS), which are cancers that develop in muscles, fat, tendons or other soft tissues. Lartruvo is approved for use with the FDA-approved chemotherapy drug doxorubicin for the treatment of patients with STS who cannot be cured with radiation or surgery and who have a type of STS for which an anthracycline (chemotherapy) is an appropriate treatment.

Submitedby.**Preethi.A,Asst.Prof,**Department of Pharm D

FDA approves first drug for spinal muscular atrophy

The U.S. Food and Drug Administration today approved Spinraza (nusinersen), the first drug approved to treat children and adults with spinal muscular atrophy (SMA), a rare and often fatal genetic disease affecting muscle strength and movement. Spinraza is an injection administered into the fluid surrounding the spinal cord.

“There has been a long-standing need for a treatment for spinal muscular atrophy, the most common genetic cause of death in infants, and a disease that can affect people at any stage of life,” said Billy Dunn, M.D., director of the Division of Neurology Products in the FDA’s Center for Drug Evaluation and Research. “As shown by our suggestion to the sponsor to analyze the results of the study earlier than planned, the FDA is committed to assisting with the development and approval of safe and effective drugs for rare diseases and we worked hard to review this application quickly; we could not be more pleased to have the first approved treatment for this debilitating disease.”

SMA is a hereditary disease that causes weakness and muscle wasting because of the loss of lower motor neurons controlling movement. There is wide variability in age of onset, symptoms and rate of progression. Spinraza is approved for use across the range of spinal muscular atrophy patients.

The FDA worked closely with the sponsor during development to help design and implement the analysis upon which this approval was based. The efficacy of Spinraza was demonstrated in a clinical trial in 121 patients with infantile-onset SMA who were diagnosed before 6 months of age and who were less than 7 months old at the time of their first dose. Patients were randomized to receive an injection of Spinraza, into the fluid surrounding the spinal cord, or undergo a mock procedure without drug injection (a skin prick). Twice the number of patients received Spinraza compared to those who underwent the mock procedure. The trial assessed the percentage of patients with improvement in motor milestones, such as head control, sitting, ability to kick in supine position, rolling, crawling, standing and walking.

The FDA asked the sponsor to conduct an interim analysis as a way to evaluate the study results as early as possible; 82 of 121 patients were eligible for this analysis. Forty percent of patients treated with Spinraza achieved improvement in motor milestones as defined in the study, whereas none of the control patients did.

Additional open-label uncontrolled clinical studies were conducted in symptomatic patients who ranged in age from 30 days to 15 years at the time of the first dose, and in presymptomatic patients who ranged in age from 8 days to 42 days at the time of first dose. These studies lacked control groups and therefore were more difficult to interpret than the controlled study, but the findings appeared generally supportive of the clinical efficacy demonstrated in the controlled clinical trial in infantile-onset patients.

The most common side effects found in participants in the clinical trials on Spinraza were upper respiratory infection, lower respiratory infection and constipation. Warnings and precautions include low blood platelet count and toxicity to the kidneys (renal toxicity). Toxicity in the nervous system (neurotoxicity) was observed in animal studies.Spinraza is marketed by Biogen of Cambridge, Massachusetts and was developed by Ionis Pharmaceuticals of Carlsbad, California.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by 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**. Neelam I,**Asst.Prof,Department of Pharm D

2016 FDA Approved Drugs

Cardiology/Vascular Diseases

Byvalson (nebivolol and valsartan); Allergan; For the treatment of hypertension, Approved June 2016

Yosprala (aspirin and omeprazole); Aralez Pharmaceuticals; For the prevention of cardiovascular and cerebrovascular events, Approved September 2016

Dermatology

Ameluz (aminolevulinic acid hydrochloride); BiofronteraPharma; For the treatment of actinic keratoses, Approved May 2016

Eucrisa (crisaborole) ointment; Pfizer; For the treatment of atopic dermatitis, Approved December 2016

Taltz (ixekizumab); Eli Lilly; For the treatment of plaque psoriasis and active psoriatic arthritis, Approved March 2016

Endocrinology

Adlyxin (lixisenatide); Sanofi Aventis; For the treatment of type II diabetes, Approved July 2016

Soliqua 100/33 (insulin glargine and lixisenatide injection); Sanofi Aventis; For the treatment of inadequately controlled type II diabetes, Approved November 2016

Xultophy 100/3.6 (insulin degludec and liraglutide injection); Novo Nordisk; For the treatment of inadequately controlled type II diabetes, Approved November 2016

Family Medicine

Byvalson (nebivolol and valsartan); Allergan; For the treatment of hypertension, Approved June 2016

OnzetraXsail (sumatriptan nasal powder) ; Avanir; For the treatment of migraine, Approved January 2016

Soliqua 100/33 (insulin glargine and lixisenatide injection); Sanofi Aventis; For the treatment of inadequately controlled type II diabetes, Approved November 2016

Xultophy 100/3.6 (insulin degludec and liraglutide injection); Novo Nordisk; For the treatment of inadequately controlled type II diabetes, Approved November 2016

Gastroenterology

Zinplava (bezlotoxumab); Merck; For the treatment of recurrent Clostridium difficile infection in patients receiving antibacterial treatment, Approved October 2016

Genetic Disease

Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy, Approved December 2016

Hematology

Afstyla (Antihemophilic Factor (Recombinant), Single Chain); CSL Behring; For the treatment of hemophillia A, Approved May 2016

Idelvion (Coagulation Factor IX (Recombinant), Albumin Fusion Protein); CSL Behring; For the treatment of hemophilia B, Approved March 2016

Kovaltry [Antihemophilic Factor (Recombinant)]; Bayer ; For the treatment of hemophillia A, Approved March 2016

Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of classical Hodgkin lymphoma, Approved May 2016

Venclexta (venetoclax); AbbVie; For the treatment of chronic lymphocytic leukemia with 17p deletion, Approved April 2016

Hepatology (Liver, Pancreatic, Gall Bladder)

Defitelio (defibrotide sodium); Jazz Pharmaceuticals; For the treatment of hepatic veno-occlusive disease with renal or pulmonary dysfunction following HSCT, Approved March 2016

Ocaliva (obeticholic acid); Intercept Pharmaceuticals; For the treatment of primary biliary cholangitis, Approved May 2016

Vemlidy (tenofoviralafenamide); Gilead Sciences; For the treatment of chronic hepatitis B , Approved November 2016

Zepatier (elbasvir and grazoprevir); Merck; For the treatment of chronic HCV genotypes 1 or 4 , Approved January 2016

Immunology

Afstyla (Antihemophilic Factor (Recombinant), Single Chain); CSL Behring; For the treatment of hemophillia A, Approved May 2016

Descovy (emtricitabine and tenofoviralafenamide); Gilead; For the treatment of HIV-1 infection, Approved April 2016

Epclusa (sofosbuvir and velpatasvir) ; Gilead Sciences; For the treatment of hepatitis C, Approved June 2016

Odefsey (emtricitabine, rilpivirine, and tenofoviralafenamide); Gilead Sciences; For the treatment of HIV-1 as initial therapy, Approved March 2016

Taltz (ixekizumab); Eli Lilly; For the treatment of plaque psoriasis and active psoriatic arthritis, Approved March 2016

Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera, Approved June 2016

Infections and Infectious Diseases

Anthim (obiltoxaximab); Elusys Therapeutics; For the treatment of inhalational anthrax , Approved March 2016

Descovy (emtricitabine and tenofoviralafenamide); Gilead; For the treatment of HIV-1 infection, Approved April 2016

Epclusa (sofosbuvir and velpatasvir) ; Gilead Sciences; For the treatment of hepatitis C, Approved June 2016

Odefsey (emtricitabine, rilpivirine, and tenofoviralafenamide); Gilead Sciences; For the treatment of HIV-1 as initial therapy, Approved March 2016

Syndros (dronabinol oral solution); Insys Therapeutics; For the treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy, Approved July 2016

Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera, Approved June 2016

Vemlidy (tenofoviralafenamide); Gilead Sciences; For the treatment of chronic hepatitis B , Approved November 2016

Zepatier (elbasvir and grazoprevir); Merck; For the treatment of chronic HCV genotypes 1 or 4 , Approved January 2016

Zinplava (bezlotoxumab); Merck; For the treatment of recurrent Clostridium difficile infection in patients receiving antibacterial treatment, Approved October 2016

Musculoskeletal

Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping, Approved September 2016

Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy, Approved December 2016

Zinbryta (daclizumab) ; Biogen; For the treatment of relapsing multiple sclerosis, Approved May 2016

Nephrology

Cabometyx (cabozantinib); Exelixis; For the treatment of advanced renal cell carcinoma, Approved April 2016

Lenvima (lenvatinib); Eisai; For the treatment of advanced renal cell carcinoma, Approved May 2016

Rayaldee (calcifediol) ; Opko Health; For the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease, Approved June 2016

Neurology

Briviact (brivaracetam); UCB; For the treatment of partial onset seizures related to epilepsy, Approved February 2016

Carnexiv (carbamazepine); Lundbeck; replacement therapy when oral administration is not feasible, in adults with seizures, Approved October 2016

Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping, Approved September 2016

Nuplazid (pimavanserin); Acadia Pharmaceuticals; For the treatment of hallucinations and delusions associated with Parkinson’s disease, Approved April 2016

Nuplazid (pimavanserin); Acadia Pharmaceuticals; For the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis, Approved May 2016

OnzetraXsail (sumatriptan nasal powder) ; Avanir; For the treatment of migraine, Approved January 2016

Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy, Approved December 2016

Troxyca ER (oxycodone + naltrexone); Pfizer; For the management of severe pain, Approved August 2016

Zinbryta (daclizumab) ; Biogen; For the treatment of relapsing multiple sclerosis, Approved May 2016

Obstetrics/Gynecology (Women's Health)

Intrarosa (prasterone vaginal inser t); Endoceutics; For the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause, Approved November 2016

Rubraca (rucaparib); Clovis Oncology; For the treatment of advanced ovarian cancer in women with deleterious germline or somatic BRCA mutation, Approved December 2016

Oncology

Cabometyx (cabozantinib); Exelixis; For the treatment of advanced renal cell carcinoma, Approved April 2016

Keytruda (pembrolizumab); Merck; For the treatment of head and neck squamous cell cancer , Approved August 2016

Lartruvo (olaratumab) ; Eli Lilly; For the treatment of soft tissue sarcoma, Approved October 2016

Lenvima (lenvatinib); Eisai; For the treatment of advanced renal cell carcinoma, Approved May 2016

Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of classical Hodgkin lymphoma, Approved May 2016

Opdivo (nivolumab); Bristol-Myers Squibb; For the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck, Approved November 2016

Rubraca (rucaparib); Clovis Oncology; For the treatment of advanced ovarian cancer in women with deleterious germline or somatic BRCA mutation, Approved December 2016

Sustol (granisetron); Heron Therapeutics; For the prevention of chemotherapy-induced nausea and vomiting, Approved August 2016

Syndros (dronabinol oral solution); Insys Therapeutics; For the treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy, Approved July 2016

Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer, Approved May 2016

Venclexta (venetoclax); AbbVie; For the treatment of chronic lymphocytic leukemia with 17p deletion, Approved April 2016

Ophthalmology

Humira (adalimumab); Abbvie; For the treatment of uveitis, Approved July 2016

Xiidra (lifitegrast); Shire; For the treatment of dry eye disease, Approved July 2016

Pediatrics/Neonatology

Exondys 51 (eteplirsen); Sarepta Therapeutics; For the treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping, Approved September 2016

Kovaltry [Antihemophilic Factor (Recombinant)]; Bayer ; For the treatment of hemophillia A, Approved March 2016

Spinraza (nusinersen); Biogen; For the treatment of spinal muscular atrophy, Approved December 2016

Pharmacology/Toxicology

Sustol (granisetron); Heron Therapeutics; For the prevention of chemotherapy-induced nausea and vomiting, Approved August 2016

Psychiatry/Psychology

Nuplazid (pimavanserin); Acadia Pharmaceuticals; For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, Approved May 2016

Pulmonary/Respiratory Diseases

Bevespi Aerosphere (glycopyrrolate and formoterolfumarate); AstraZeneca; For the treatment of chronic obstructive pulmonary disease, Approved April 2016

Cinqair (reslizumab); Teva Pharmaceuticals; For the treatment of severe asthma, Approved March 2016

Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer, Approved May 2016

Rheumatology

Taltz (ixekizumab); Eli Lilly; For the treatment of plaque psoriasis and active psoriatic arthritis, Approved March 2016

Urology

Tecentriq (atezolizumab); Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer, Approved May 2016

Vaccines

Vaxchora (Cholera Vaccine, Live, Oral); PaxVax; For active immunization against Cholera, Approved June 2016

Submitted ByMr.**Sushanta Kumar Das,**Asst.Prof,Department of Pharm D

Various academic and clinical activities during the month of January to June 2015:

International Day of Disability, 3rd December 2016:

Faculty and students of CMR College of Pharmacy conducted an awareness rally on International Day of Disability In association with Kandlakoya Village Panchyat. This rally was conducted to create awareness about bringing the disable persons in the main stream of the society

World Diabetes Day, 14th November 2016:

CMR College of Pharmacy conducted an awareness camp & health screening on World Diabetes Day. More than 50 participants includes faculty, students and other staffs participates in this program. This program was aimed to create awareness about rapid progressive nature of type 2 diabetes mellitus and its management

World Heart Day, 29th September 2016:

CMR College of Pharmacy conducted an awareness camp & health screening on World Heart Day. More than 200 participants includes faculty, students and other staffs of CMR Group of Institutes were present in this program. With overwhelm participation the program was even extended on 30th September also. The aim of the program was to create awareness about various heart diseases and provide screened health report of individual participant.