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PSG NEWS DIGEST

A news letter from PSG College of Pharmacy, Department of Pharmacy Practice,

FROM THE PHARMACIST'S DESK

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CGRP RECEPTOR ANTAGONIST & ANTIBODIES - AN EMERGING THERAPY FOR MIGRAINE

Migraine is a chronic, complex neurological disorder that manifests as recurrent attacks of moderate to severe headache lasting for 4–72h. In migraine with aura, the headache phase is preceded by reversible focal neurological symptoms, often visual or sensory, that usually develop gradually over 5–20min prior to headache and last for 15 migraine days per month. The success of older and current drugs for migraine prevention and abortion has been limited by inadequate efficacy, tolerability and patient adherence . Drugs that are currently taken for prophylaxis are not specific for migraine but include antiepileptic drugs, β-blockers and antidepressants. These new therapies use a unique strategy to treat migraine, and work by interfering with the signalling of a potent neuropeptide expressed in sensory nerves: calcitonin gene-related peptide (CGRP). All CGRP-targeted therapies tested for the treatment of migraine till date have consistently produced positive results. Thus, identification of CGRP as a specific therapeutic target for migraine has resulted in a major breakthrough in providing pain relief for this common disorder

CONCEPT OF CGRP

CGRP is a 37 aminoacid neuropeptide ,which is widely distributed in sensory neurons(Trigeminal ganglion,nerve endings,dorsal ganglia ,cerebelllum etc) .Discovery of CGRP in 1985 suggested that this peptide could be an important factor in migraine pathophysiology. Vasodilatory effect of CGRP in cerebral arteries gave support to the concept. In 1990,Goadsby et.al made a seminal observation that neuropeptides released at the time of migraine attack were CGRP and Pitutary adenylate cyclase activating peptide(PACAP) . In chronic migraineurs,CGRP remains elevated constantly. Elevated level of CGRP is also observed in blood samples collected from jugular vein,plasma,saliva and CSF during migraine attack. Research suggest that CGRP infusion can produce migraine like symptoms.Thus,it is confirmed that CGRP have a potent role in migraine pathophysiology

CGRP RECEPTOR TARGETED THERAPY

Cgrp Receptor Antagonist-The Gepants - for the acute treatment of migraine.

DRUG NAME	DOSAGE	STATUS IN PHARMACOLOOGICAL TRIALS
OLCEGEPANT	2.5mg	Discontinued –poor oral bioavailability
TELCAPEGANT	300mg	Discontinued-hepatic concerns
BI44370	400mg	Phase IIa completed
RIMEGEPANT	150mg	Phase IIa completed
URBOGEPANT		Ongoing PhaseIII trials

Anti CGRP antibodies -Prophylactic treatment of migraine

DRUG	AVAILABLE DOSAGES	ROUTE AND FREQUENCY	CURRENT STAGE
ERENUMAB	7mg/21mg/70mg	SC & Once in a month for 12 wk	FDA approved and marketed
FREMANEZUMAB	225mg/675mg/900mg	SC & Once in a month for 12 wk	Under review of FDA
GALCANEZUMAB	150mg	SC &twice a month for 12 wk	Phase 3
EPTINEZUMAB	1000mg	Iv&once only-8wk	

The main advantage of CGRP receptor antagonist is its long half life .As they it does not have a vasoconstrictive effect it can be safely used in cardiac patients.

CDSCO APPROVED DRUGS FROM AUGUST TO DECEMBER 2018

S.NO	NAME OF THE DRUG	INDICATION	DATE OF ISSUE
1	FDC of Ceftolozane (1.0 gm) and Tazobactum (0.5 gm) Injection	Indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms: -Complicated intra-abdominal infections (cIAI)caused by the following Gram negative and Gram- positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis and Streptococcus salivarius. its used in combination with metronidazole in ICU setting only. -Complicated UTI including pyelonephritis caused by the Gram negative microorganisms: Escherichia coli, Klebsiella pneumoniae and Pseudomonas aeruginosa in ICU setting only.	06.08.2018
2	Evogliptin Tartrate Bulk and Tablets 5 mg	For treatment of type-2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control, when used as a monotherapy or in combination with Metformin.	22.10.2018

3	Lorcaserin hydrochloride Bulk and 10 mg tablets	As an adjunct to reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (overweight) in the presence of atleast one weight related comorbid condition (e.g.Hypertension,Dyslipidaemia, type 2 DM)	22.10.2018
4	Fimasartan potassium trihydrate bulk drug and Fimasartan film coated tablets 30 mg/60 mg/ 120 mg	For the treatment of mild hypertension	22.11.2018
5	Sacubitril/Valsartan and FDC of Sacubitril + Valsartan 50 (24 + 26)/100 (49+51)200 (97 + 103) mg film coated tablets.	To reduce the risk of cardiovascular death and hospitalisation for heart failure in patients with chronic heart failure and reduced ejection fraction.	24.12.2018

Ref : http://www.cdsco.nic.in/forms/list.aspx?lid=2034&Id=11

2018 Biological License Application Approvals by FDA

S.No	BIOLOGICALS	INDICATION FOR USE
1	**JIVI** Antihemophilic Factor (Recombinant),PEGylated-aucl	Indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: (1) On-demand treatment and control of bleeding episodes; (2) Perioperative management of bleeding; (3) Routine prophylaxis to reduce the frequency of bleeding episodes.
2	**PANZYGA** Immune Globulin Intravenous (Human)-ifas	Indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older and chronic immune thrombocytopenic purpura (ITP) in adult
3	Hematopoietic Progenitor Cells, Cord (HPC-C)	It is indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment
4	ALBUMINEX Human Albumin Solution (HAS) 5% and 25%	Albumin, human-kjda 5% and albumin, human-kjda 25% are indicated for hypovolemia, ascites, hypoalbuminemia including from burns, acute nephrosis, acute respiratory distress syndrome and cardiopulmonary bypass

5	**ANDEXXA** Coagulation Factor Xa (Recombinant), Inactivated	Indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-theratening or uncontrolled bleeding

Ref : https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicalApprovalsbyYear/ucm596371.htm

Ms.G.K.SOUMYA Pharm D Intern.

NEWS ROOM

Poor sleep increases risk for cardiovascular disease

Sleep is an essential physiological process that protects our physical and mental health. Epidemiological studies suggest that not only short but also long sleep duration (LSD) is related to an increased cardiovascular risk. Heart attack , coronary heart disease ,stroke , and diabetes were among the adverse cardiometabolic risks for short sleep duration. The groups were categorized as very short sleep duration(VSSD) <6h , short sleep duration (SSD) 6 to 7h , reference sleep duration (RSD) 7 to 8h , long sleep duration >8h.LSD was related to higher atherosclerotic burden specifically in women.VSSD ,SSD, more fragmented sleep were overweight and LSD, non-fragmented sleep had lower BMI values. caffeine intake related to unhealthier sleep patterns with more cardiovascular risk factors.Overall findings support the potential role of healthy sleeping in protecting against atherosclerosis and for healthy sleep duration it should be restricted to 7 to 8 hours.Thus , recommending a good sleep hygiene should be part of the lifestyle modifications provided in our daily clinical practice.

Ref : Domínguez, et al (2019). Association of Sleep Duration and Quality With Subclinical Atherosclerosis. Journal of the American College of Cardiology, 73(2), 134-144 **Ms.D.Sharmilaa V Pharm D**

KETAMINE , PARTY POPPER TO AN ANTIDEPRESSANT

Ketamine , widely used as a party drug in the 1990's is known for its psychedelic properties and is sought after for the feeling of "mind-body separation" that the users experience at low doses. However, recent studies show that Ketamine and Esketamine , an S- enantiomer of Ketamine have anti-depressant properties that may be life saving for people suffering from treatment resistant depression (TRD). Esketamine has been granted break through therapy status by the FDA for TRD and for major depressive disorder.Esketamine was administered as an intransasal spray in five phase 3 studies and data from from these studies show that treatment with esketamine nasal spray and a newly initiated anti-depressant drug was associated with rapid reduction of depressive symptoms.While, recent studies explore the enantiomeric counterpart of ketamine, earlier studies have also showed that serial infusions of low dose ketamine are highly tolerated and effective for treating depression. Ketamine and Esketamine block the NMDA glutamate receptors.This modulation is thought to restore connections between brain cells in patients suffering from depression.The drug also appear to modulate dopamine transmission but the effect of this modulation as the anti-depressant properties of the drugs is yet to be clearly established. Thus, if approved, Esketamine nasal spray would be one of the first novel approaches to treating Major Depressive Disorder in the past decades

Ref : https://www.ncbi.nim.nih.gov//pmc/articles/PMC4243034/

Ms.Sruthi Krishnamoorthy Pharm D V year, PSG College of Pharmacy.

DEPARTMENT ACTIVITIES

Department of Pharmacy Practice conducted a two day Health screening camp at Kalinganaicken palayam, Coimbatore on a 7th & 18th November 2018 to asses Medication Awarness among the Resident villages. A of Total 56 members were screened for diabetis, HTN, Anemia and 103 Homes were surveyes by this camp. A complete survey of that village was taken by the 2018 Pharm D Interns on the day before. Also the Department of Pharmacy Practice conducted CPE (Continuing Pharmacy Education) on 18th December 2018 at PSG Hospitals ,Coimbatore. Dr.Alan Kurian Pharm D,Clinical Pharmacist presented a topic on . Drugs dosing in renal impairment. 13 research and review papers are published in the year 2018 by the Faculties of the Department of Pharmacy Practise.

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