pharmahorizon

A panorama in the world of health sciences

NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH DEEMED UNIVERSITY

NAAC 'A' Grade
UGC Category I Deemed University

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CARTOON

"Do you carry over-the-counter placebos?"

EDITOR'S VIEW:

Welcome to Pharmahorizon, a new twice-yearly newsletter about the latest news in the pharma field as well as glimpses and research profile of Department of Pharmacy. It gives me immense joy and satisfaction to write the editorial for this issue. This issue includes articles from Industry person, clinician, students, alumni etc. Besides we have other issues like molecule of the millennium, India's vaccine "God Mother", WHO guidelines for care and treatment of Hepatitis C virus infection, New drug recommendation, Newly approved drugs, dietary research and new molecule entity and therapeutic biological product.

Dr. Girish U. Sailor

We have also incorporated, laurels brought by our staff as well as students in various academic and cocurricular activities.

We hope you enjoy reading this issue as much as we have enjoyed making it. Any suggestions or criticism on the magazine would be most welcome.

DRUG RESEARCH IN INDUSTRY :

The Pharmaceutical industries have been successful for big bets on a few molecules, promoting them heavily and turning them into blockbusters worked well for many years, but its R&D productivity has now plummeted and the environment's changing as instances of chronic disease are increasing, placing even greater pressure on already stretched healthcare budgets and Regulators are becoming more cautious about approving truly innovative medicines. Hence, there are lot many challenges Pharmaceutical industries already faces, but they'll also provide some major opportunities.

The Zydus Research Centre (ZRC) is the dedicated research arm of the Zydus Group. With its team of over 400 research professionals, ZRC spearheads the group's quest of creating healthier and happier communities globally. Spread over an area of over 4,75,000 sq ft, ZRC is working on cutting edge technologies in different scientific disciplines to discover novel therapeutic agents. The centre has capabilities to conduct drug discovery & development from concept to IND enabling preclinical and clinical studies.

In 2013, the group was the first to identify, develop and launch LipaglynTM (Saroglitazar) the novel drug to treat diabetic dyslipidemia – a global, unmet healthcare need. Lipaglyn is the first NCE from an Indian research pipeline to move from the lab to the market. It offers dual benefits of lipid and glycemic control in one single molecule. It is an innovation that has helped over 700000 people suffering from diabetic dyslipidemia in India lead healthier lives.

Lipaglyn™ (Saroglitazar Mg) currently approved in India is a prescription medicine for the treatment of Hypertriglyceridemia and Diabetic Dyslipidemia in Patients with Type 2 Diabetes not controlled by statins. The recommended dose of Lipaglyn™ is 4 mg once-a-day. Saroglitazar Mg is an investigational new drug in the United States and is currently being evaluated in Phase II clinical trials for the treatment of Severe Hypertriglyceridemia (TG > 500) and Non-Alcoholic SteatoHepatitis (NASH).

Desidustat- oral HIF PH inhibitor to treat anemia is currently in Phase 3. Anemia is a condition of having lower red blood cells or lower hemoglobin levels than is normal. Anemia is a serious medical condition linked to increased morbidity and mortality, and is commonly observed in patients with chronic kidney disease (CKD). Currently available agents for the treatment of anemia include injectable EPO stimulating agents (ESA's) and intravenous iron supplements. The estimated global market for treatments for anemia related to CKD is $ 10 billion.

The Vaccine Technology Centre (VTC) is the vaccine research centre of the Zydus Group. VTC has two state-of-the-art R & D Centers, one located in Catania, Italy and the other in Ahmedabad, in the western part of India. The Vaccine Technology Centre (VTC) has been developing vaccines for the basic vaccine programmes such as Diphtheria, Pertussis, Tetanus, Haemophilus Influenzae type B, Hepatitis B, Measles, Mumps, Rubella, Varicella, Influenza and Typhoid fever. In addition, VTC is developing new vaccines such as Human Papilloma Virus, Leishmaniasis, Malaria, Haemorrhagic Congo Fever, Ebola and Japanese Encephalitis.

Zydus has indigenously developed, manufactured and launched India's first Tetravalent Inactivated Influenza vaccine, VaxiFlu – 4. The vaccine provides protection from the four influenza viruses- H1N1, H3N2, Type B (Brisbane) and Type B (Phuket). Zydus' rabies vaccine manufacturing facility has received WHO pre-qualification, and is one of the largest rabies manufacturing facilities in India.

At Zydus Research Centre, We have been working with Department of Pharmacology and Toxicology at Zydus Research Centre, Cadila Healthcare Ltd., Ahmedabad, Gujarat in the field of Diabetes, Obesity, Dyslipidemia, Inflammation and cardiovascular research. During my journey at Zydus, I have been involved in In vivo experiments for developement of NCEs in diabetic and dyslipidemic animal models of mice, rats, hamsters, guinea pigs. Further, being in the group of Lipaglyn discovery we are in constant mind storming process for developing Saroglitazar for other indications like NASH.

Contributed By:

Dr Chitrang Trivadi

Zydus Research Centre, Ahmedabad

Clinician's Stance:

Pharm.D Students involvement in ADR Research:
We have conducted a Research on ADR with Pharm.D students and faculty which is as follows.

Study of cutaneous adverse drug reaction patterns with causality and severity assessment at a tertiary care centre
Dhaval B Joshi[1], Rashmi Mahajan[2],*, Kishan Ninama[3], Foram Shukla[4], Charansakhi Panchal[5]

Introduction: Prescribed medications are intended to relieve sufferings during the course of illness. Occasionally due to the unpredictable pharmacological nature of the drug, the unique physiological condition of the patients and/or due to any other factors, drugs cause Adverse Drug Reactions (ADRs). Few of the ADRs are quite severe and if not adequately and promptly managed, may lead to serious complications and even death. Apart from this, the high frequency of obnoxious ADRs may also drive the patients to question the reliability of the given pharmacotherapy and that may further lead to medication nonadherance. Cutaneous ADRs are quite common and few of them are very severe which lead to significant comorbidities. Early identification of the condition as well as the culprit drug and omitting it at earliest holds the keystone in management and prevention of a more serious reaction. Thus, it is necessary to have a sound monitoring and reporting of cutaneous ADRs and also an adequate analysis and interpretation of their entire pattern of the occurrence.
Aim: To study the patterns of cutaneous adverse drug reactions with causality and severity assessment in tertiary care hospital.
Objective: To Identify, analyse and report cutaneous ADRs and drug classes responsible for the same.
Materials and Methods: A Prospective study was carried out over a period of 5 months among the out-patients and in-patients in Department of Skin and Venereal Diseases. A total of 35 patients were enrolled as per selection criteria. Chi-square test was applied in order to investigate whether the distribution of categorical variables differ from one another.
Result: Out of 35 patients enrolled in the study, 12 patients had maculopapular drug rash and the commonest causative drug was phenytoin. 9 patients in the study had fixed drug reaction, the commonest cause was nimesulide. 4 patients were of erythema multiforme, the commonest cause was NSAIDS. 3 patients each of Toxic Epidermal Necrolysis and Steven Johnson syndrome. There was 1 case of idiosyncratic drug toxicity due to methotrexate, 1 case of Drug Reaction with Eosinophilia and Systemic Symptoms due to phenytoin, 1 case of drug induced urticaria due to metronidazole and 1 case of bullous drug reaction.
Conclusion: After the cutaneous drug eruption was diagnosed and treated, Patients were counselled and provided with the ADR alert card provided for emergency condition.

References :

- Verma R, Vasudevan B, Pragasam V. Severe cutaneous adverse drug reactions. Medical Journal Armed Forces India. 2013;69(4):375-83
- Nayak S, Acharjya B. Adverse cutaneous drug reaction. Indian Journal of dermatology. 2008;53(1):2
- Das N, Hazra A, Gharami R, Chowdhury S, Datta P, Saha A. Cutaneous ADRs profile in a tertiary care outpatient setting in Eastern India. Indian Journal of Pharmacology. 2012;44(6):792
- Tejas. K. Patel. Cutaneous ADRs in Indian population: A systematic review: Indian Dermatology Journal. 2017;21(2).
- Acharya, L., Rao, P. and Ghosh, S. (2006). Study and evaluation of the various cutaneous adverse drug reactions in Kasturba hospital, Manipal. Indian Journal of Pharmaceutical Sciences. 2010;68(2):212.

Dr. Rashmi Mahjan, M.D.
Professor,
Department of Skin & Vd
SBKS Medical Institute and Research Institute, Pipalia.

Student's Outlook:

Clinical Internship experience by Pharm. D student

I have completed my one year internship at Dhiraj General Hospital and 15 days clinical exposure at Bangalore BAPTIST hospital as a part of Student Exchange Program. It was a great leaning experience during which we got the exposure of working pattern of clinical pharmacist. Being an intern, it was good to attend and participate in the ward round to update knowledge in clinical and therapeutic area. While attending ward rounds at different departments, I came across many new clinical cases and identified many important therapeutically significant interventions. As a part of clinical pharmacy services, I provided patient counselling to improve medication adherence and to reduce Drug Related Problems.
Various drug queries from consultant and residents physicians were answered with adequate evidences like details of newer cephalosporins, immunization schedule, updated information regarding SSSRI and Benzodiazepines, Poison informations etc. I found around 34 ADRS and many rare cases during internship. Some of the rare cases are:

- Erdheim Chester Disease with Hydrocephalus.
- Adverse Event Following Immunization.
- Alleged h/o Unknown Substance (Rare Humic Acid Poisoninig).
- RCVS (Thunderclap Headache).
- Corrosive Acid Poisoning.
- Progressive Supranuclear Palsy.

In OPD of psychiatry department, it was quite challenging to counsel the psychiatry patients and their relatives. By putting enough efforts, I learnt to deal with these type of patients and approach of counselling for thesis patients.

The most satisfactory thing I felt was the spending of quality time with needy patients to listen them carefully, providing them all necessary information, resolving their doubts thoroughly and most importantly to give them sympathy.

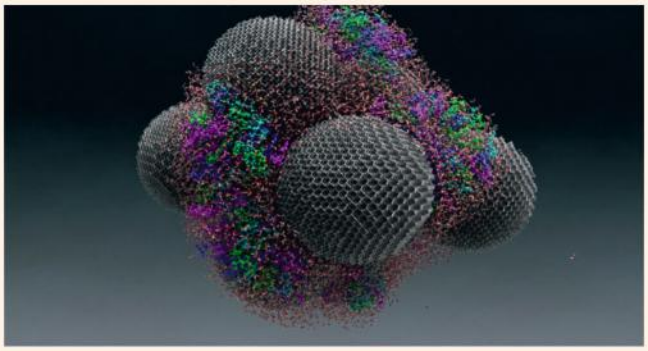
Mahek Mistry
Pharm. D Intern

Production, surface modification and biomedical applications of nanodiamonds: A sparkling tool for theranostics

Nanotechnology has evolved incredibly in the last few decades and revolutionized the several applications in multiple areas. Nanomaterials are widely explored in the pharmaceutical science in the hope to develop delivery systems, which can overcome the issues of conventional drug delivery such as incompatibility, unpredictability etc. Similarly, nanomaterials have also been studied extensively as a tool for diagnostic purpose.

In the nanomaterials domain, diamond nano particles or nanodiamonds (NDs) have recently been included in the nanocarbon family. They are allotropes of carbon like a jewellery diamond; the only difference is seen in their size that happens to be in nanometre range. NDs have grabbed a special attention because of their distinguished biocompatibility and safety, imparted due to their distinct structural and optical properties. NDs exist in nature since billions of years, few such ND particles have been reported to exist in the earth sediment layers prior to 13,000 calendar years. Also, presence of such diamond nanoparticle were found in meteorites and their clear finger prints were described in IR region in two Star Systems (Elias 1 and HD97048). In addition, they have been reported to be present in petroleum and natural gas in the form of diamonoids, molecules having diamond cages terminated by hydrogen atoms, in minute quantities. In comparison with other carbon nanomaterials like fullerenes and carbon nanotubes, NDs have lower toxicity and adequate biocompatibility to employ them as a potential vehicle for drug delivery.

Diamond nano-particles or nanodiamonds (NDs) are nano-scale carbon allotropes and exhibit characteristic mechanical and optical properties. Unlike other nanocarbon materials NDs are highly bio-compatible and comparatively safe which makes them the material of future interest in the field of medicine. Various methods for synthesis of NDs were developed including the detonation technique, micro-plasma-assisted ND formation, laser ablation, chemical vapour deposition (CVD), high energy ball milling of microdiamonds produced using high pressure high temperature (HPHT), chlorination of carbides, ultra sound cavitation, irradiation of graphite by ion beam, carbon onions irradiated by electron etc. Commonly, NDs synthesized using detonation technique are called as detonation NDs (DND). DNDs can be synthesized via three techniques which are classified based upon the starting material used for the detonation..



The first method involves conversion of graphite, a carbon precursor, into NDs in a closed chamber by applying pressure above 5 GPa presence of metal catalyst.

The second method involves detonation of carbon precursor and explosives in a closed chamber which can create pressure as high as (20–200 GPa) and temperature (> 1727 °C) that is sufficient for conversion of graphite into ND(~20 nm).

The third method involves synthesis of NDs using carbon-containing explosives without any carbon precursor. In this technique, the temperature and pressure of the detonation chamber rises sharply due to explosion to a point (also called jouget point) where liquified clusters of carbon (1–2 nm) are formed. As the temperature and pressure decreases in the chamber these liquid clusters are converted into larger droplet size and eventually ND crystals are formed.

It is important to characterize NDs with modified surface due to its potential applications in the field of biology, medicine and bio-medical science. The important properties like particle size of ND cluster and its size distribution, ratio of sp3 and/or sp2 hybridized carbon, nature and content of impurities are characterized using various techniques. Electron spin resonance (ESR), Raman spectroscopy, HRTEM, SEM, NMR, X-Ray diffraction and many other techniques have been successfully utilized for structural characterisation of NDs. FTIR is employed to detect functional groups on the ND surface and can also give insights regarding surface chemistry of modified NDs.

NDs have carved a niche in the field of nanomedicines with potential biomedical applications in diagnostics as well as in therapeutics and emerged as a novel theranostic agent. Several studies have been conducted to improve synthesis, purification and surface modification of NDs.

Fluorescence and versatility of ND surface were proven to be beneficial for enhancing its applicability, however, certain surface modifications have been reported to increase its toxicity. Thus, a rationale selection of functional groups for surface modification is required of safe use of NDs. Although NDs have been proposed to possess better biocompatibility and safety profile as compared to other nano-carbon materials, its metabolism and fate in the human body is not fully established even after substantial attempts. Hence, these aspects seem to be major limitations of NDs for translation into clinical usage. Nanodiamonds for bone regeneration and dental applications are under investigation and innovative developments may be accomplished in future. Similarly, nanodiamonds trials are ongoing for their use in cosmetic applications and prosthetic devices. Thus, breakthrough role of multifaceted nanodiamonds can be foreseen not only in early diagnosis of ailments but also to overcome the limitations of conventional therapy in upcoming years.

Mr. Hussain Tinwala
(Alumni, Department of Pharmacy, SVDU)

Prominent Scientist:

Scientist **Dr Gagandeep Kang** has become the first Indian woman to be inducted as a Fellow of the Royal Society (FRS) in London. Called India's vaccine "God Mother", Dr Gagandeep Kang has joined the likes of Isaac Newton and Charles Darwin to be elected to the almost 360-year-old scientific body. Dr Kang has studied MBBS at Christian Medical College in Vellore. She is currently Executive Director, Translational Health Science and Technology Institute in Haryana's Faridabad.

Union Minister for Science and Technology Dr Harsh Vardhan described Dr Kang's election to the Royal Society as a "proud moment for India".

Dr Kang developed an oral vaccine against the Rota virus that causes diarrhoea, a disease that kills almost 100,000 children in India.

The vaccine was first identified by researchers at the All Indian Institute of Medical Sciences (AIIMS) in New Delhi way back in 1985. Since then, with over $100 million in funding-- including that from the Indian government and the Bill and Melinda Gates Foundation-- it is now part of India-approved vaccines.

Speaking to NDTV earlier, Dr Roger I Glass, a noted researcher on Rota virus and Director of the Fogarty International Center, US National Institutes of Health, Bethesda, had said, "We cannot feel content until this Rota Virus vaccine reaches all Indian children. "On her part, Dr Kang said, "I would like to make vaccines better in Indian children."

Reference : https://www.ndtv.com/science/gagandeep-kang-is-first-indian-woman-to-be-elected-royal-society-fellow-2025717

MOLECULE OF THE MILLENNIUM

Zolgensma is used for the treatment of paediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.

ZOLGENSMA is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. SMA is caused by a bi-allelic mutation in the SMN1 gene, which results in insufficient SMN protein expression. Intravenous administration of ZOLGENSMA that results in cell transduction and expression of the SMN protein has been observed in two human case studies. The efficacy of ZOLGENSMA in paediatric patients less than 2 years of age with SMA with bi-allelic mutations in the SMN1 gene was evaluated in an open-label, single-arm clinical trial (ongoing) and an open-label, single-arm, ascending-dose clinical trial (completed). Patients experienced onset of clinical symptoms consistent with SMA before 6 months of age. All patients had genetically confirmed bi-allelic SMN1 gene deletions, 2 copies of the SMN2 gene, and absence of the c.859G>C modification in exon 7 of SMN2 gene (which predicts a milder phenotype). All patients had baseline anti-AAV9 antibody titers of ≤ 1:50, measured by ELISA. Among the 12 infants who received the high dose of Zolgensma, 11 were able to achieve head control. Nine were able to roll at least 180 degrees from the back to both the left and the right. The results showed 11 of the children were able to sit unaided for at least five seconds, 10 for at least 10 seconds, and nine for at least 30 seconds, something normally never seen in babies with SMA type 1.

In both trials, ZOLGENSMA was delivered as a single-dose intravenous infusion. Efficacy was established on the basis of survival, and achievement of developmental motor milestones such as sitting without support. Survival was defined as time from birth to either death or permanent ventilation.

PATIENT COUNSELING INFORMATION

Acute Serious Liver Injury and Elevated Aminotransferases Inform caregivers that ZOLGENSMA could increase liver enzyme levels and cause acute serious liver injury. Inform caregivers that patients will receive an oral corticosteroid medication before and after infusion with ZOLGENSMA, and will undergo regular blood tests to monitor liver function. Advise caregivers to contact their healthcare provider immediately if the patient's skin and/or whites of the eyes appear yellowish, or if the patient misses a dose of corticosteroid or vomits it up

Thrombocytopenia Inform caregivers that ZOLGENSMA could decrease blood platelet count and increase the risk of bruising or bleeding. Advise caregivers to seek medical attention if the patient experiences unexpected bruising or bleeding.

Reference: https://smanewstoday.com/avxs-101-avexis

NEW DRUG APPROVAL

Fingolimod Capsules 0.5mg and Fingolimod hydrochloridebulk"

Indicated For the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Drug dosing Indicated for relapsing forms of multiple sclerosis (MS): 0.5 mg PO qDay (Note: Doses >0.5 mg are associated with a greater incidence of adverse reactions without additional benefit).

Side effects: Headache, increased ALT & AST, nausea, Diarrhea, Influenza viral infection, Cough, Sinusitis, Abdominal pain, Back pain etc.

Contraindications: History within past 6 months of MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure.

History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker.

Baseline QTc interval ≥500 ms.

Coadministration with Class Ia or Class III antiarrhythmic drugs.

Source: 1. New drugs approval may 2019 to till date. (release date: 2019-Apr-29)

< https://https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM0OQ==>

2. https://reference.medscape.com/drug/gilenya-fingolimod-999602

3. https://www.nejm.org/doi/full/10.1056/NEJMoa052643

WHO recommendation on calcium supplementation during pregnancy for the prevention of pre-eclampsia and its complications

Hypertensive disorders of pregnancy are a significant cause of severe morbidity, long-term disability and death among both mothers and their babies. Worldwide, they account for approximately 14% of all maternal deaths. Among the hypertensive disorders that complicate pregnancy, pre-eclampsia and eclampsia stand out as major causes of maternal and perinatal mortality and morbidity. The majority of deaths due to pre-eclampsia and eclampsia are avoidable through the provision of timely and effective care to the women presenting with these complications.

It is recommended that Dietary counselling of pregnant women should promote adequate calcium intake through locally available, calcium-rich foods. Dividing the dose of calcium may improve acceptability. The suggested scheme for calcium supplementation is 1.5–2.0g daily, with the total dose divided into three doses, preferably taken at mealtimes. Negative interactions between iron and calcium supplements may occur. Therefore, the two micronutrients should preferably be administered several hours apart rather than concomitantly. As there is no clear evidence on the timing of initiation of calcium supplementation, stakeholders may wish to commence supplementation at the first antenatal care contact, in order to improve compliance to the regimen. To reach the most vulnerable populations and ensure a timely and continuous supply of supplements, stakeholders may wish to consider task shifting the provision of calcium supplementation in community settings with poor access to healthcare professionals. The implementation and impact of this recommendation should be monitored at the health service, regional and country levels based on clearly defined criteria and indicators associated with locally agreed targets. Barriers, enablers and pathways should be evaluated to inform integration of this recommendation into the antenatal care package.

Source: https://apps.who.int/iris/bitstream/handle/10665/277235/9789241550451-eng.pdf?ua=1

GUIDELINES FOR THE CARE AND TREATMENT OF PERSONS DIAGNOSED WITH CHRONIC HEPATITIS C VIRUS INFECTION

The objective of these guidelines is to provide updated evidence-based recommendations on the care and treatment of persons with chronic hepatitis C virus (HCV) infection in terms of when to treat and what treatment to use in children, adolescents and adults. Following are the new recommendation provided by WHO.

- When to start treatment in adults and adolescents: WHO recommends offering treatment to all individuals diagnosed with HCV infection who are 12 years of age or older, irrespective of disease stage.
- What treatment to use for adults and adolescents: WHO recommends the use of pangenotypic DAA regimens for the treatment of persons with chronic HCV infection aged 18 years and above.
- **In adolescents aged 12–17 years or weighing at least 35 kg with chronic HCV infection, WHO recommends:**
  - ❖ sofosbuvir/ledipasvir for 12 weeks in genotypes 1, 4, 5 and 6
  - ❖ sofosbuvir/ribavirin for 12 weeks in genotype 2
  - ❖ sofosbuvir/ribavirin for 24 weeks in genotype 3.
- **Pangenotypic regimens currently available for use in adults 18 years of age or older.**

For adults without cirrhosis	For adults with compensated cirrhosis
Sofosbuvir/velpatasvir12 weeks	Sofosbuvir/velpatasvir12 weeks
Sofosbuvir/daclatasvir12 weeks	Glecaprevir/pibrentasvir 12 weeks
Glecaprevir/pibrentasvir 8 weeks	Sofosbuvir/daclatasvir24 weeks
	Sofosbuvir/daclatasvir12 weeks

Source: https://apps.who.int/iris/bitstream/handle/10665/273174/9789241550345-eng.pdf?ua=1

DRUGS IN CLINICAL TRIALS:

Takeda phase 3 TIDES trial of tetravalent dengue vaccine meets primary endpoint – January, 2019, Takeda Pharmaceutical Company Limited announced that the pivotal phase 3 trial of its dengue vaccine candidate met the primary efficacy endpoint. This first analysis of the Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial showed that the company's investigational live-attenuated tetravalent dengue vaccine (TAK-003) was efficacious in preventing dengue fever caused by any of the four serotypes of the virus. The TIDES trial, Takeda's largest interventional clinical trial to date, enrolled over 20,000 healthy children and adolescents ages four to 16 years living in dengue-endemic areas. The study was designed to evaluate the efficacy, safety and immunogenicity of two doses of TAK-003, in both dengue exposed and naïve individuals. TAK-003 is not currently licensed anywhere in the world. In addition to dengue, Takeda is developing vaccines to address other high-priority infectious diseases, including Zika, norovirus and polio.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=113788&sid=2

Zydus announces phase 3 trial of Desidustat in NDD-CKD patients with anaemia – April, 2019, Zydus Cadila, an innovation-driven, global pharmaceutical company, announced the phase III trials of Desidustat, an investigational new drug targeted at treating anaemia in non-dialysis dependent chronic kidney disease (NDD-CKD) patients. Desidustat is a novel, oral, HIF-PH inhibitor being developed for treating anaemia in chronic kidney disease patients. Phase III study will be a multicenter (50- 60 sites), randomized, active-controlled clinical trial to evaluate the efficacy and safety of Desidustat versus Darbepoetin for the treatment of anaemia in patients with chronic kidney disease (CKD) who are not on dialysis. Earlier, Desidustat had met its primary endpoints in the phase II clinical study of NDD-CKD patients suffering from anaemia. Desidustat demonstrated superiority in efficacy versus placebo in terms of haemoglobin (Hb) response rate at all doses tested when compared to placebo over six weeks.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=115264&sid=2

NIH to fund US$ 42 mn over five years for clinical trials using genomics to treat chronic diseases – June, 2019, The National Institutes of Health (NIH) will fund clinical trials to assess the benefits, applicability and efficacy of applying genomic medicine interventions to improve management of diseases such as high blood pressure, depression and chronic pain. The trials are part of the second phase of the Implementing Genomics in Practice (IGNITE) Network with a total investment of US$ 42 million over five years. The first trial will examine whether early access to patients' genomic data can help with treatment of high blood pressure, hypertension and chronic kidney disease. Both hypertension and high blood pressure exacerbate end-stage kidney diseases, and all three conditions are more common among people of African ancestry than European and Asian descent. The second trial will focus on pain and depression – two conditions where finding safe and effective drug treatments have been difficult. Because there are few clinically useful predictors for whether a depression treatment will be successful, patients often struggle to find effective therapies.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=116244&sid=2

DIETARY RESEARCH:

New evidence links ultra-processed foods with a range of health risks

Two large European studies find positive associations between consumption of highly processed ("ultra-processed") foods and risk of cardiovascular disease and death. The researchers say further work is needed to better understand these effects, and a direct (causal) link remains to be established, but they call for policies that promote consumption of fresh or minimally processed foods over highly processed foods. Ultra-processed foods include packaged baked goods and snacks, fizzy drinks, sugary cereals, ready meals containing food additives, dehydrated vegetable soups, and reconstituted meat and fish products - often containing high levels of added sugar, fat, and/or salt, but lacking in vitamins and fibre. They are thought to account for around 25-60% of daily energy intake in many countries. Studies have linked ultra-processed foods to higher risks of obesity, high blood pressure, high cholesterol, and some cancers, but firm evidence is still scarce.

Source: https://www.sciencedaily.com/releases/2019/05/190529221040.htm

NEW MOLECULE ENTITY & NEW THERAPEUTIC BIOLOGICAL PRODUCT

Siponimod

March, 2019 – The U.S. Food and Drug Administration today approved Mayzent (Siponimod) tablets to treat adults with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communications between the brain and other parts of the body. Most people experience their first symptoms of MS between the ages of 20 and 40. The efficacy of Siponimod was shown in a clinical trial of 1,651 patients that compared Siponimod to placebo in patients with secondary progressive multiple sclerosis (SPMS) who had evidence of disability progression in the prior two years and no relapses in the three months prior to enrollment. The primary endpoint of the study was the time to three-month confirmed progression in disability. The fraction of patients with confirmed progression of disability was statistically significantly lower in the Siponimod group than in the placebo group.

Source: https://www.fda.gov/news-events/press-announcements/fda-approves-new-oral-drug-treat-multiple-sclerosis

Risankizumab

April, 2019 – The US Food and Drug Administration (FDA) has approved risankizumab-rzaa (Skyrizi) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. The recommended treatment with risankizumab begins with 2 initial doses totaling 150 mg given at week 0 and again at week 4, followed by 150 mg via 2 injections every 12 weeks thereafter. In ultIMMa-1 and ultIMMa-2, 75% of patients treated with risankizumab reached 90% skin clearance (PASI 90) at week 16, compared to 5% and 2% of patients receiving placebo, respectively ($P < .001$). Additionally, PASI 100 was reached by 36% and 51% of patients treated with risankizumab compared to 0% and 2% of those receiving placebo.

Source: https://www.mdmag.com/medical-news/fda-approves-risankizumab-for-plaque-psoriasis

DEPARTMENT OF PHARMACY ACTIVITIES

One day national seminar cum case presentation on "Clinical Pharmacy Services: An urgent need for India"

Department of Pharmacy, SVDU organized one day national seminar cum case presentation on **"Clinical pharmacy Services : An urgent need for India"**. Total 250 delegates from different parts of India participated in the event. In the morning session, Dr. Prashant Mathur delivered lecture on the topic "National and International perspective of Clinical Pharmacy Services". Second lecture of the session was "Major Challenges and Potential Benefits of Clinical Pharmacy Services in India" by Dr. Barun Ranjan Sarkar. Case presentation competition was conducted in the afternoon session. A total of 33 students participated in the competition. First prize was secured by Mahek Mistry, 6th pharm D, Sumandeep Vidyapeeth.

Work shop on "Building Consent Culture: Preventing Sexual Harassment"

The Antisexual Harassment and Women Welfare committee of Department of Pharmacy, SV in coordination with PLD, New Delhi and Sahiyar Stree Sangathan, Vadodara organized a workshop on **"Building Consent Culture: Preventing Sexual Harassment"** on 13th February 2019 . The venue of workshop was lecture hall 103, Department of Pharmacy, SV. Fifty students of Department of Pharmacy, SVDU attended the workshop. Various video were played to make audience understand about sexual consent. They also explained Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act.

Guest lecture on "Transition from Indian Pharmacist to Canadian Pharmacist: Hurdles and Solutions'

Department of Pharmacy, Sumandeep Vidyapeeth organized a guest lecture on **Transition from Indian Pharmacist to Canadian Pharmacist: Hurdles and Solutions** on 15th March 2019. Dr. Nilesh Kanzariya, Ex. Assistant Professor, Dept. of Pharmacology, SKPCPER, Ganpat University delivered the lecture. The lecture covered several aspects related to how to prepare for Visa, courses which can be selected and also gave information about various Universities of Canada, fees structure and information related to work permit.

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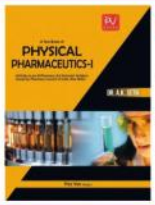
- Shukla D, Maheshwari RA, Patel K, Balaraman R, Sen AK. Effect of Vaccinium macrocarpon on MK-801-induced psychosis in mice. Indian journal of pharmacology. 2018 Sep;50(5):227.
- Zanwar Aarti S, Sen Dhanya B, Sen Ashim Kumar, Seth AK. Simultaneous estimation of Mometasone Furoate and Formoterol Fumarate by HPLC method in rotacaps. International Journal of Pharmacy and Pharmaceutical Sciences. 2019;11(2):12-16.
- Parmar G, Pundarikakshudu K, Balaraman R. Anti-anaphylactic and antiasthmatic activity of Euphorbia thymifolia L. on experimental animals. Journal of traditional and complementary medicine. 2019 Jan 1;9(1):60-5.
- Shah NV, Gohil DY, Seth AK, Aundhia CJ, Patel SS. Development of Risedronate Sodium-loaded Nanosponges by Experimental Design: Optimization and in vitro Characterization. Indian Journal of Pharmaceutical Sciences. 2019 Mar 27;81(2):309-16.
- Piyushkumar K Sadhu, S Saisivam, Sujit Kumar Debnath. Design and characterization of niosomes of ethionamide for multi drug resistance tuberculosis. World Journal of Pharmaceutical Research. 2019;8(6):921-933.
- Chandrakar Vikas R, Maheshwari Rajesh, R. Balaraman. Medication Adherence in Asthma Patients: A Randomized Control Study. International Journal of Research & Analytical Reviews. 2019;6(1):60-66.
- Chandrakar Vikas R, Maheshwari Rajesh, R. Balaraman. Assessment of Medication Compliance in Diabetic Patients: A Randomized Control Study. International Journal of Research & Analytical Reviews.2019;6(2):615-621.
- Mundra A, Jain D, Chandrakar VR, Lakhani JD, Erraboina M, Gopagoni K, Manthen A, Vurumadla S, Bandari S, Ramesh G, Sowjanya G. Insulin Therapy in Type-II Diabetes Mellitus–Is it Feasible and Acceptable?. Indian Journal of Pharmacy Practice. 2019 Apr;12(2):77.
- Shah AP, Parmar BM, Ghodawala MA, Seth A. In silico drug discovery of novel small lead compounds targeting nipah virus attachment glycoprotein. Journal of Integrated Health Sciences. 2018 Jul 1;6(2):60.
- Vaghani KN, Dave DH, Sailor GN. Comparative evaluation of ginger extract and chlorhexidine on periodontal pathogens: An invitro study. JIDA: Journal of Indian Dental Association. 2019 Apr 1;13(4).

Ongoing SVRFS Funded Project

- Design nd development of leflunomide novel carriers for the topical treatment of Rhematoid Arthritis
  PI: Dr. Nirmal Shah
  Co PI(S): Dr. AK Seth. Dr. Dipti Gohil, Mr. Joseph Vinod, Dr. Chintan Aundhia, Dr. Ghanshyam Parmar
- A study on the effect of Vit D alone and its combination with statin or insulin sensitizer on metabolic syndrome
  PI: Dr. Rajesh Maheshwari
  Co PI(S): Dr. AK Seth, Dr. Ashim Sen, Dr. Dhanya Sen, Dr. Ankur Javia, Mr. Joseph Vinod
- Bisphosphonate Conjugated Hydroxyapatite Bone Targeting Nanoparticles for the Therapy of Osteoporosis
  PI: Dr. Chintan J Aundhia
  Co PI(S): Dr. AK Seth, Dr. Nirmal Shah, Dr. Rajesh A. Maheshwari, Dr. Ashim Kumar Sen, Dr. Ghanshyam Parmar, Dr. Dipti Gohil
- Biochemical and Pharmacological investigation of some antidiabetic and antihyperlipidemic drugs in combination with antioxidants on the levels of adipocytokines in metabolic syndrome
  PI: Dr. R. Balaraman
  Co PI(S): Dr. A K Seth, Dr. Rajesh Maheswari, Dr. Ghanshyam Parmar
- Pharmacognostic profile and pharmacological effects of different parts of Moringa oleifera plants
  PI: Dr. R. Balaraman
  Co PI(S): Dr. A K Seth, Dr. Ghanshyam Parmar, Dr. Girish Sailor
- Preclinical investigation of a bioactive spray dressings and immune modulators for the management of diabetic foot ulcers
  PI: Dr. Maneesh Jaiswal
  Co PI(S): Dr. R V Devkar, Dr. Mahesh Pukar
- Stability indicating assay method for the simultaneous estimation of saxogliptin & dapaliflozin in bulk and pharmaceutical dosage form by HPTLC applying design of experiment
  PI: Dr. Ashim Sen
  Co PI(S): Dr. A K Seth, Dr. Rajesh Maheshwari, Dr. Dhanya Sen, Dr. Aarti Zanwar, Dr. Vikas Chandrakar, Mr. Vinod Ramani
- Design and synthesis of new hybrid cox-2 inhibitors as potential anticancer agents
  PI: Mr. Ashish Shah
  Co PI(S): Dr. A K Seth, Dr. Ghanshyam Parmar
- In vitro study of anticancer properties of phyla nodiflora on MCF -7, HEPG2 and HELA cell lines and characterization of bioactive compound
  PI: Dr. A K Seth
  Co PI(S): Dr. Velmurugan, Dr. Ghanshyam Parmar, Mrs Nimisha Patel

Ongoing SVRFS Funded Project

The Department of Pharmacy has initiated two Consultancy projects of Vital Care Pvt. Ltd, Vadodara worth Rs. 1,43,000/- under the supervision of Dr. Girish U. Sailor for the Platelet Augmentation and Atherosclerosis Activity.



Book Published

A Text Book of Physical Pharmaceuitcs -1 was published by Dr. A. K. Seth as per B Pharmacy 3rd Sem Syllabus issued by Pharmacy Council of India, New Delhi

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