



# pharmahorizon

A panorama in the world of health sciences



NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH

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## MANAGING EDITOR'S VIEW:

It is an honour to serve as managing editor of Pharmahorizon. Its been two years now since we have started publishing Pharmahorizon.



With this first issue of 2017, we bring you recent updates of latest recommendations, news about newly approved drugs and status of clinical trials.

With this issue, we are paying the tribute to one of the Nobel laureates of 2013 Dr. Randy Wayne Schekman, who has discovered the very essential element of cellular biology; Cell membrane vesicle trafficking. In this issue, we have included the newly invented drug Canakinumab, a monoclonal antibody, in our "Molecule of Millennium" section, which has recently shown the potential preventive effect against lung cancer in the patient with pre-existing atherosclerosis.

Currently, swine flu is again in full swing in Gujarat region like the previous year. Hence we have made effort to help spreading the awareness amongst the people by including some common but very important DO's and DONT's about swine flu in this issue. Further, we have included one of the important recently approved drugs, Ibrutinib, which is used for the treatment of B cell cancer.

The last section of our newsletter summarize the activities carried out by DoP, SV. This time we had organized an expert talk on "Financial Planning" by inviting an expert of the same field, Mr Rinkal D. Patel. In Feb 2017, DoP celebrated annual sports and cultural week, Pharmashine'17, by organizing various sports and cultural events.

Dr. Ankur R Javia, M. Pharm, Ph. D

Asst. Prof., DoP, SV

## A tribute to Discoverer of Cell membrane Vesicle trafficking Nobel Prize: 2013



### Randy Wayne Schekman

Randy Wayne Schekman (born December 30, 1948) is a Nobel Prize-winning American cell biologist at the University of California. He shared the 2013 Nobel Prize for Physiology or Medicine with James Rothman and Thomas C. Südhof for their "discoveries of machinery regulating vesicle traffic, a major transport system in our cells".

In 1996, he discovered that the trafficking of proteins within eukaryotic cells is achieved by the capture of cargo and targeting molecules into vesicles that bud from a donor membrane and deliver their contents to a receiving compartment. This process is bidirectional and may involve multiple organelles within a cell. Distinct coat proteins mediate each budding event, serving both to shape the transport vesicle and to select by direct or indirect interaction of desired set of cargo molecules. Secretion, which has been viewed as a default pathway, may require sorting and packaging signals on transported molecules to ensure their rapid delivery to the cell surface.

He received a PhD in 1975 from Stanford University for research on DNA replication. Since 1991, Schekman has been an Investigator at Department of Molecular and Cell Biology, University of California, Berkeley. The Schekman Lab at that university carries out research into molecular descriptions of the process of membrane assembly and vesicular traffic in eukaryotic cells including yeast.

Source: Schekman, R.; Orci, L. (1996). "Coat Proteins and Vesicle Budding". *Science*. 271 (5255): 1526–1533

Source:<http://science.sciencemag.org/content/271/5255/1526>, [https://en.wikipedia.org/wiki/Randy\\_Schekman](https://en.wikipedia.org/wiki/Randy_Schekman)

## CARTOON



## MOLECULE OF THE MILLENNIUM

### Canakinumab

In a recent study, Canakinumab, a monoclonal antibody, is found to be very effective in preventing the lung cancer in patients with atherosclerosis. Canakinumab is working by inhibiting the interleukin 1 $\beta$ , which mediates inflammatory signals in the tumor microenvironment, is hypothesised to have a major role in cancer invasiveness, progression, and metastases. Research was done, to explore the role of interleukin-1 $\beta$  inhibition by canakinumab in atherosclerosis condition, which might alter lung cancer incidence.

Randomised, double-blind, placebo-controlled trial of canakinumab was done in 10061 patients with atherosclerosis who have had a myocardial infarction, free of previously diagnosed cancer, and had concentrations of high-sensitivity C-reactive protein (hsCRP) of 2 mg/L or greater. The different dose of canakinumab (50 mg, 150 mg, and 300 mg, subcutaneously every 3 months) or placebo was randomly given to the patients.

Concentrations of hsCRP (median 6.0 mg/L vs 4.2 mg/L) and interleukin 6 (3.2 vs 2.6 ng/L) were significantly higher among participants subsequently diagnosed with lung cancer than among those not diagnosed with cancer. During follow-up of 3.7 years, compared with placebo, canakinumab was found to be associated with dose-dependent reductions in concentrations of hsCRP of 26–41% and of interleukin 6 of 25–43%. Total lung cancer mortality (n=196) was also found to be significantly lower in the pooled canakinumab group than in the placebo group, but was significantly lower than placebo, only in the 300 mg group individually. Incidence of lung cancer (n=129) was significantly less frequent in the 150 mg and 300 mg groups. All-cause mortality did not differ significantly between the canakinumab and placebo groups.

These results might be a suggestive of the possibility that anti-inflammatory therapy with canakinumab targeting the interleukin-1 $\beta$  innate immunity pathway could significantly reduce lung cancer incidence and lung cancer mortality.

Source:

Paul M Ridker, Jean G MacFadyen, Tom Thuren, Brendan M Everett, Peter Libby\*, Robert J Glynn. *The Lancet* Published online August 27, 2017 [http://dx.doi.org/10.1016/S0140-6736\(17\)32247-X](http://dx.doi.org/10.1016/S0140-6736(17)32247-X)



### SWINE FLU: A RECENT OUTBREAK

Swine flu is one of several strains of flu that are now considered to be seasonal flu. The official name for swine flu is Influenza A virus subtype H1N1. Swine flu was a pandemic in 2009. This strain of flu, like other strains, can be serious for some people in at-risk groups. Swine flu got its name because the first outbreaks mainly affected people who had direct contact with pigs.

**Risk Factors:** Transmission of H1N1 virus usually occurs from person to person, not animal to person. You can't catch swine flu from eating properly cooked pork products. Swine flu is very contagious. The disease is spread through saliva and mucus particles. People may spread it by: Sneezing, Coughing, touching a germ-covered surface and then touching their eyes or nose. Some people are at higher risk for becoming seriously ill if they're infected with swine flu. These groups include: adults over age 65 and children under 5 years old, young adults and children under age 19 who are receiving long-term aspirin (Bufferin) therapy, people with compromised immune systems (due to a disease such as AIDS), pregnant women, people with chronic illnesses such as asthma, heart disease, diabetes mellitus, or neuromuscular disease

**Symptoms:** The symptoms of swine flu are similar to those of other strains of seasonal flu: Fever, Unusual tiredness, Headache. Runny nose, Sore throat, Shortness of breath or cough, Loss of appetite, Aching muscles, Diarrhea, Vomiting.

**Prevention:** The best way to prevent swine flu is to get a yearly flu vaccination. Other easy ways to prevent swine flu include: Frequently washing hands with soap or hand sanitizer. Not touching your nose, mouth, or eyes (The virus can survive on surfaces like telephones and tabletops.) Staying home from work or school if you're ill. Avoiding large gatherings when swine flu is in season

**Treatment:** Two antiviral drugs are recommended for treating swine flu: the oral drugs oseltamivir (Tamiflu) and zanamivir (Relenza). Because flu viruses can develop resistance to these drugs, they're often reserved for people who are at high risk for complications from the flu. People who are otherwise generally healthy and get swine flu will be able to fight the infection on their own.

Source: <http://www.healthline.com/health/swine-flu?tre=true>

### NEW DRUG APPROVAL

#### IBRUTINIB

Ibrutinib (Imbruvica) is a small molecule drug that binds permanently to a protein, Bruton's tyrosine kinase (BTK), that is important in B cells; the drug is used to treat B cell cancers like mantle cell lymphoma, chronic lymphocytic leukemia, and Waldenström's macroglobulinemia, a form of non-Hodgkin's lymphoma.

Ibrutinib was created by scientists at Celera Genomics as a tool compound for studying BTK function; it covalently binds its target which is ideal for a reagent but generally not considered ideal for drugs.

It was approved by the US FDA on November 13, 2013 for the treatment of mantle cell lymphoma. [On Feb. 12, 2014, the FDA expanded the approved use of ibrutinib to chronic lymphocytic leukemia (CLL). It was approved for Waldenström's macroglobulinemia in 2015. In January 2017 the FDA approved ibrutinib as a second line treatment for graft vs host disease. It was the first drug approved by the FDA for this condition.

Ibrutinib has been reported to reduce CLL cell chemotaxis towards the chemokines CXCL12 and CXCL13, and inhibit cellular adhesion following stimulation at the B cell receptor (BCR). Additionally, ibrutinib down-modulates the expression of CD20 (target of rituximab/ofatumumab) by targeting the CXCR4/SDF1 axis. Together, these data are consistent with a mechanistic model whereby ibrutinib blocks BCR signaling, which drives cells into apoptosis and/or disrupts cell migration and adherence to protective tumour microenvironments.

Source:

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205552>

<https://en.wikipedia.org/wiki/Ibrutinib>

## OUTBREAK OF HEPATITIS A ILLNESSES LINKED TO FROZEN STRAWBERRIES

The U.S. Food and Drug Administration and the Centers for Disease Control and Prevention, state and local officials investigated an outbreak of hepatitis A illnesses linked to frozen Egyptian strawberries in smoothies served at Tropical Smoothie Café locations.

The FDA's investigation in connection with this outbreak identified five samples of ICAPP's frozen strawberries that tested positive for hepatitis A. ICAPP recalled all frozen strawberries and frozen strawberry products that it imported into the United States since January 1, 2016. ICAPP's recalled frozen strawberries were distributed to food service establishments nationwide. The products were not offered for retail sale to consumers. Frozen strawberry products subject to recall include whole, sliced and sugared, and diced strawberries.

As of October 20, 2016, CDC reports 134 people with hepatitis A linked to this outbreak have been reported from 9 states. Among people with available information, 52 people have been hospitalized.

The FDA's traceback investigation indicates that the strawberries served in Tropical Smoothie Café locations where ill people reported drinking smoothies were from ICAPP, imported from Egypt. Tropical Smoothie Café reported that they stopped using Egyptian frozen strawberries in their locations in Virginia and neighboring states by August 8, 2016. Additionally, on August 19, 2016, the firm reported that they removed Egyptian frozen strawberries from all cafes nationwide.

The agency discussed the investigation with the Egyptian International Health Regulations National Focal Point, and placed frozen strawberries from ICAPP on Import Alert 99-35 after multiple positive samples confirmed hepatitis A in the product.

The FDA recommended that institutions and food service operations supplied by any of the five companies identified immediately reach out to their suppliers and determine if they received frozen strawberry product recalled by ICAPP. Then, if needed, institutions and food service operations that find they served any recalled product within the last two weeks should contact their local health department and communicate to their customers regarding possible exposure to hepatitis A virus and the potential benefit of post exposure prophylaxis. The FDA and CDC are not currently aware of any illnesses related to any recalled products other than whole frozen strawberries. However, because hepatitis A can have serious health consequences, CDC advises post exposure prophylaxis (PEP) for unvaccinated persons who have consumed any of the recalled frozen strawberry products in the last 2 weeks. PEP offers no preventive benefit to persons whose exposure occurred more than 2 weeks ago.

Source: <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm518775.htm>

## DRUGS IN CLINICAL TRIALS:

**Allergan and Gedeon Richter announce positive Phase III results for Ulipristal Acetate 5 and 10 mg in the treatment of Uterine Fibroids** – Allergan and Gedeon Richter announced positive results from Venus II, the second of two pivotal phase III clinical trials evaluating the efficacy and safety of Ulipristal acetate in women with abnormal bleeding due to uterine fibroids. The study included 432 U.S. patients with 162 and 157 patients randomized to Ulipristal acetate 5 and 10 mg respectively, and 113 to placebo. The study met all the co-primary and secondary endpoints with both Ulipristal treatment arms achieving statistically significant results over placebo ( $p < 0.0001$ ). Source: [https://www.drugs.com/clinical\\_trials/allergan-gedeon-richter-announce-positive-phase-iii-results-ulipristal-acetate-5-10-mg-uterine-17319.html](https://www.drugs.com/clinical_trials/allergan-gedeon-richter-announce-positive-phase-iii-results-ulipristal-acetate-5-10-mg-uterine-17319.html)

**Lilly Announces Phase 3 MONARCH 2 Breast Cancer study of Abemaciclib met primary endpoint of progression-free survival** – Eli Lilly and Company announced that its MONARCH 2 trial of Abemaciclib met the primary endpoint of progression-free survival (PFS). The Phase 3 study evaluated Abemaciclib, in combination with Fulvestrant in women with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), advanced breast cancer who have relapsed or progressed after endocrine therapy. The results demonstrated that the addition of Abemaciclib to Fulvestrant shows statistically significant improvement in PFS, when compared to the control arm of placebo plus Fulvestrant. Source: [https://www.drugs.com/clinical\\_trials/lilly-announces-phase-3-monarch-2-breast-cancer-study-abemaciclib-met-primary-endpoint-progression-17372.html](https://www.drugs.com/clinical_trials/lilly-announces-phase-3-monarch-2-breast-cancer-study-abemaciclib-met-primary-endpoint-progression-17372.html)

## DIETARY RESEARCH:

### Browned toast, potatoes may raise cancer risk

Toast and potatoes should be cooked to a golden colour, not browned, to reduce our intake of a chemical that may increase the chance of having cancer. Acrylamide is not deliberately added to food. It is a natural by product of the cooking process. Acrylamide is a natural chemical which is formed by heating (above 120°) certain food, such as starchy foods like potatoes and root vegetables. Studies in rats have linked Acrylamide exposure to cancer, according to the National Cancer Institute. Evidence from human studies is incomplete, but the National Toxicology Program and the International Agency for Research on Cancer consider Acrylamide to be a "probably human carcinogen."

Source: <http://www.medscape.com/viewarticle/874874>

## NEW MOLECULE ENTITY & NEW THERAPEUTIC BIOLOGICAL PRODUCT

### Alectinib Hydrochloride

January 23, 2017 – The New Drugs Devison of CDSCO, India approved Alectinib 150mg Capsules for the treatment of patients with anaplastic lymphoma kinase (ALK)-Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.

Source: <http://www.cdsc.nic.in/forms/list.aspx?lid=2034&ld=11>

### Brodalumab

February 15, 2017 - The U.S. Food and Drug Administration approved Siliq (Brodalumab) to treat adults with moderate-to-severe plaque psoriasis. Administered as an injection, it is intended for patients who are candidates for systemic therapy or phototherapy (ultraviolet light treatment) and have failed to respond, or have stopped responding to other systemic therapies. Active ingredient, Brodalumab binds to a protein that causes inflammation, inhibiting the inflammatory response that plays a role in the development of plaque psoriasis.

Source: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm541981.htm>

## DEPARTMENT OF PHARMACY ACTIVITIES:

### A two day national seminar & workshop on "Optimization and Screening of Variables by DOE" on 17-18<sup>th</sup> March 2017

This program was organized by Department of Pharmacy, Sumandeep Vidyapeeth for the purpose of sharing the scope of DoE in research field for Pharma researchers. Total 350 delegates from various institutions participated in this program. First day consisted of four plenary lectures and second day comprised of workshop, for hands on training of some important DoE softwares. Dr. D. M. Patel, Dr. Remeth J. Dias, Dr. Mukesh. C. Gohel and Dr. Tejal Gandhi delivered the lectures on basics of fundamental of DOE. Mr. Lalji H. Baldaniya and Dr. Vaishali T. Thakkar showed the application of the experimental designs and analyzing its effect to the audience with hands on training of the software "Design expert version 7.0.0" and "minitab version 17.3.1.0". At the end, winners of poster session, in each sub-category, were awarded. This two day national seminar & workshop was a grand success and the positive feedback from participants encouraged us to organise such events in the future.

### A seminar on Micromedex use on 18<sup>th</sup> Feb. 2017

Ms. Mili Toase, Business Development Manager, Vans Scientific Information was invited as a speaker to deliver lecture on Systematic use of Micromedex Drug Database.

### A lecture on "Eco Friendly Pharmaceutical Applications of Hydrotropic Solubilization and Novel Concept of Solubilization" on 21<sup>st</sup> Jan. 2017

Dr. Rajesh Maheshwari, Professor, Department of Pharmacy, Shri G. S. Institute of Technology and Science, Indore delivered a talk on "Eco Friendly Pharmaceutical Applications of Hydrotropic Solubilization and Novel Concept of Solubilization".





## DEPARTMENT OF PHARMACY ACTIVITIES (CONT.):

### Guest Lecture on Financial Literacy at DoP, SV

Mr Rinkal D. Patel from Shubh Financial Planning was invited to deliver a talk on "Financial Literacy" for all staff members of DoP, Sumandeep Vidyapeeth University on 4<sup>th</sup> Jan 2017. He discussed about insurance planning, child's future planning, retirement planning, tax planning, investment planning etc. All the staff were benefitted with the updated information regarding financial planning.

### Faculty of DoP, SV at Conferences:

Dr. Kushal H. Gohel, Assistant Professor attended a two week QIP program at Poona College of Pharmacy, Bharati Vidyapeeth University from 1<sup>st</sup> to 13<sup>th</sup> Feb 2017.

Dr. Vikas R Chandrakar, Assistant Professor presented e-poster in the IPHACON 2017 held at AIIMS, Jodhpur from 24<sup>th</sup> to 26<sup>th</sup> Feb 2017.



## Pharmashine' 17 - Sports & Cultural week:

Department of Pharmacy successfully celebrated sports and cultural week "Pharmashine'17" from 6<sup>th</sup> to 14<sup>th</sup> Feb'17. Sport events were organized like cricket, football, volleyball, badminton, table-tennis, chess, carom, and many others. As a part of cultural events, mehndi, rangoli, nail art, face painting and cooking without fire competition were organised. All the students and staff members participated enthusiastically in various events, making 'Pharmashine-2017' a grand success, like every other year. Besides that, duties of different games were distributed amongst staff members and students to conduct the program smoothly. The winners were awarded certificates.



Pharmashine' 17 - Sports & Cultural week

## LAUGH & LIVE LONGER

The real meaning of "An Apple A Day" . . .

A phlebotomist at the hospital, entered a patient's room to draw blood. Noticing an apple on his nightstand, she remarked, "An apple a day keeps the doctor away, right?" "That's true," he agreed. "I haven't seen a doctor in last three days."

A Risk For All Seasons

A Mother was rushed to the hospital following a serious tumble. There the staff placed a band around her wrist with large letters warning: Fall Risk. Unimpressed, Mom said to her son, "I'll have them to know, I have a winter, spring, and summer risk too."

## Book-Post

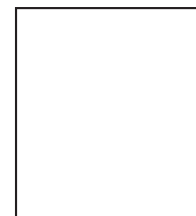
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