



# PHARMAHORIZON

A PANORAMA IN THE WORLD OF HEALTH SCIENCES

A NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH



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## CARTOON



"This medication can actually improve your memory.  
Each capsule contains a tiny hard drive."

## ASSOCIATE EDITOR'S VIEW



It is a great pleasure for me to write an Associate Editor's view for "Pharmahorizon" – A Newsletter series published by Dept. of Pharmacy, SV.

The current issue of "Pharmahorizon" encompasses the breakthrough discovery related to cell cycle regulation which is presently being used in diagnosis of cancer and also, it serves as a new target for drug development. Furthermore, it includes information about Bevacizumab – a drug used in treatment of Metastatic Colorectal Cancer.

From the desk of WHO, we would like to share a latest recommendation on Weekly Iron-Folic Acid Supplementation in women of reproductive age and its impact on Child development. Moreover, a concise review on a new molecular entity, Brexpiprazole, and a new combination (Sacubitir + Valsartan) approved by US FDA in the treatment of CHF, is also incorporated. For the patient's safety, we also provide updated news about Adverse Drug Reactions published by US FDA.

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We have also incorporated two important molecules, Semaglutide and Tiraseptiv for the treatment of Type 2 DM and ALS respectively, which are on clinical trials, it's a great deal for the pharma giant Lupin as it acquires Gavis – a US based Pharma Company. Additionally, MedGenome receives a funding to establish a diagnostic-research infrastructure in India and US.

Regarding the activity of SV, there was a EBES workshop for PG students and a visit of various faculties of SV to CHARUSAT and Anand Agriculture University. Department of Pharmacy welcomes the new students of Pharm.D program by organizing an orientation program.

Mr. Girish Sailor, M.Pharm

Asst. Prof., DoP, SV

**Breakthrough Discoveries:  
Controlling the Cell Cycle  
Nobel Prize (2001) (Physiology or  
Medicine)  
Paul Nurse (25 January 1949, age  
66)**



Beginning in 1976, Nurse identified the gene *cdc2* in fission yeast (*Schizosaccharomyces pombe*). This gene controls the progression of the cell cycle from G1 phase to S phase and the transition from G2 phase to mitosis. In 1987, Nurse identified the homologous gene in human, *Cdk1*, which codes for a cyclin dependent kinase.

When cells with nuclei divide, they divide in phases called G1 (growth), S (synthesis), G2 (growth), and M (mitosis). Nurse, Hartwell and Hunt together discovered two proteins, cyclin and cyclin dependent kinase (CDK), that control the transition from one stage to another. These proteins are called checkpoints, because they check whether the cell has divided properly. If the cell doesn't divide correctly, other proteins will attempt to repair it, and if unsuccessful, they will destroy the cell. If a cell divides incorrectly and survives, it can cause cancer and other serious diseases.

In 1989, he was elected as Fellow of the Royal Society (FRS) and in 1995 he received a Royal Medal and became a foreign associate of the U.S. National Academy of Sciences. He was also awarded the Copley Medal in 2005. He was elected as Foreign Honorary Member of the American Academy of Arts and Sciences – one of the top honours – in April 2006.

He was awarded the 2001 Nobel Prize in Physiology or Medicine along with Leland Hartwell and Tim Hunt for their discoveries of protein molecules that control the division (duplication) of cells in the cell cycle.

(Source: [https://en.wikipedia.org/wiki/Paul\\_Nurse](https://en.wikipedia.org/wiki/Paul_Nurse)  
18 July 2015, at 01:55)

## MOLECULE OF THE MILLENNIUM

**Avastin (Bevacizumab)** is a vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treatment of: Metastatic colorectal cancer, Non-squamous non-small cell lung cancer, Glioblastoma – as a single agent for adult patients with progressive disease following prior therapy. It is also can be used in Metastatic renal cell carcinoma with interferon  $\alpha$ , Cervical cancer, Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan.

**Dosage:** Metastatic colorectal cancer – 5 mg/kg IV every 2 weeks with bolus-IFL, 10 mg/kg IV every 2 weeks with FOLFOX4, 5 mg/kg IV every 2 weeks or 7.5 mg/kg IV every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first-line Avastin containing regimen. Non – squamous non – small cell lung cancer – 15 mg/kg IV every 3 weeks with carboplatin/paclitaxel. Glioblastoma – 10 mg/kg IV every 2 weeks. Metastatic renal cell carcinoma (mRCC) – 10 mg/kg IV every 2 weeks with interferon  $\alpha$ . Persistent, recurrent, or metastatic carcinoma of the cervix – 15 mg/kg IV every 3 weeks with paclitaxel/cisplatin or paclitaxel/topotecan. Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer – 10 mg/kg IV every 2 weeks with paclitaxel, pegylated liposomal doxorubicin or weekly topotecan, 15 mg/kg IV every 3 weeks with topotecan given every 3 weeks.

**WARNINGS:** Perforation or Fistula, Arterial Thromboembolic Events, Venous Thromboembolic Events, Hypertension, Posterior Reversible Encephalopathy Syndrome, Proteinuria, Infusion Reactions, Embryo-fetal Toxicity, Ovarian Failure.

(Source: [http://www.gene.com/download/pdf/avastin\\_prescribing.pdf](http://www.gene.com/download/pdf/avastin_prescribing.pdf))

Perfection is not attainable, but if we chase perfection we can catch excellence.

- Vince Lombardi



Many of life's failures are people who did not realize how close they were to success when they gave up.

- Thomas A. Edison

### WEEKLY IRON-FOLIC ACID SUPPLEMENTATION (WIFS) IN WOMEN OF REPRODUCTIVE AGE: ITS ROLE IN PROMOTING OPTIMAL MATERNAL AND CHILD HEALTH

Anaemia is a multi-factorial disorder that requires a multi-pronged approach for its prevention and treatment. Iron deficiency and infections are the most prevalent etiological factors. However other conditions may have a contributory role. They include nutritional deficiencies of vitamin A, vitamin B12, folate and riboflavin as well as thalassemias and hemoglobinopathies. The global prevalence of anemia is estimated to be 30.2% in non-pregnant women rising to 47.4% during pregnancy. Improving iron and folate nutrition of women of reproductive age could improve pregnancy outcomes as well as enhance maternal and infant health. WIFS is an approach that can be effective for ensuring adequate iron status of women, particularly before pregnancy and during the first trimester in communities where food-based strategies are not yet fully implemented or effective. Short-and medium-term WIFS has been effective in reducing the prevalence of anaemia among women of reproductive age in several community settings. Although the proven method for decreasing the risk for neural tube defects (NTDs) is through daily dosing with folic acid before pregnancy through the first trimester of pregnancy, WIFS provides an additional opportunity for ensuring adequate folate status before pregnancy and in the very early stages of pregnancy particularly for those who may become pregnant or do not know that they are already pregnant and are not covered by other programs. Many pregnancies are not planned. Various studies have demonstrated that WIFS can improve iron status in women of reproductive age when supplementation is continuous for periods from several months to two years. A review concluded that WIFS taken for at least 12 weeks improved iron status, as judged by increased hemoglobin and in some studies serum ferritin levels. The impact of weekly supplementation with 60 mg of iron was similar to daily supplementation except in severely anaemic women.

For more information:

[http://apps.who.int/iris/bitstream/10665/89743/1/WHO\\_NMH\\_NH\\_D\\_MNM\\_09\\_2\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/89743/1/WHO_NMH_NH_D_MNM_09_2_eng.pdf?ua=1)



### NEW DRUG APPROVAL

**Entresto (Sacubitril and Valsartan) Novartis; For the treatment of chronic heart failure, Approved July 2015**

Entresto is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker.

Entresto is specifically indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. The recommended starting dose of Entresto is 49/51 mg (sacubitril/valsartan) twice-daily. Double the dose of Entresto after 2 to 4 weeks to the target maintenance dose of 97/103 mg (sacubitril/valsartan) twice-daily, as tolerated by the patient.

Reduce the starting dose to 24/26 mg (sacubitril/valsartan) twice-daily for:

- Patients not currently taking an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) or previously taking a low dose of these agents
- Patients with severe renal impairment
- Patients with moderate hepatic impairment.

Double the dose of Entresto every 2 to 4 weeks to the target maintenance dose of 97/103 mg (sacubitril/valsartan) twice-daily, as tolerated by the patient.

### Side Effects:

Adverse effects associated with the use of Entresto may include, but are not limited to, the following:

Hypotension, hyperkalemia, cough, dizziness, and renal failure.

For more information:

<http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100083/entresto-sacubitril-and-valsartan>

### DRUG SAFETY COMMUNICATION

#### FDA reporting mental health drug Ziprasidone (Geodon) associated with rare but potentially fatal skin reactions

FDA is warning that the antipsychotic drug ziprasidone is associated with a rare but serious skin reaction that can progress to affect other parts of the body. A new warning has been added to the Geodon drug label to describe the serious condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Patients who have a fever with a rash and/or swollen lymph glands should seek urgent medical care. Health care professionals should immediately stop treatment with ziprasidone if DRESS is suspected.

Ziprasidone is an antipsychotic drug used to treat the serious mental health disorders schizophrenia and bipolar-I disorder.

DRESS may start as a rash that can spread to all parts of the body. It can include fever, swollen lymph nodes, and inflammation of organs such as the liver, kidney, lungs, heart, or pancreas. DRESS also causes a higher-than-normal number of a particular type of white blood cell called eosinophils in the blood. DRESS can lead to death.

FDA reviewed information from six patients in whom the signs and symptoms of DRESS appeared between 11 and 30 days after ziprasidone treatment was started. None of these patients died.

Source: <http://www.fda.gov/Drugs/DrugSafety/ucm426391.htm>

#### FDA Drug Safety Communication: FDA approves label changes for asthma drug Xolair (Omalizumab), including describing slightly higher risk of heart and brain adverse events

A review of 5-year safety study found a slightly higher rate of heart and brain blood vessel problems occurred in patients being treated with Xolair compared to those patients not treated with Xolair. The heart and brain blood vessel problems included transient ischemic attacks or TIAs; heart attacks; sudden, unexpected chest pain; high blood pressure in the arteries of the lungs called pulmonary hypertension; and blood clots in the lungs and veins. Although the data are suggestive of a serious safety signal, due to weaknesses in how the safety study was designed and carried out, unable to definitively confirm or determine the exact increased level of these risks with Xolair.

To further evaluate the heart and brain risks noted in the 5-year safety study, reviewed a combined analysis of 25 randomized double-blind clinical trials comparing Xolair to a placebo. An increased risk of heart- and brain-related problems in patients treated with Xolair was not noted in this combined analysis, but the low number of these events, the young patient population, and the short duration of follow-up prevented from making any definite conclusions about the absence of a risk.

Source: <http://www.fda.gov/Drugs/DrugSafety/ucm414911.htm>



Health is the greatest gift,  
contentment the greatest wealth,  
faithfulness the best relationship.

- Buddha



#### DRUGS IN CLINICAL TRIALS:

##### **Novo Nordisk successfully completes first phase 3a trial with Semaglutide in people with type 2 diabetes**

July 10, 2015 - Novo Nordisk today announced the results from SUSTAIN1, the first phase 3a trial for semaglutide, a new GLP-1 analogue administered once-weekly. Trial investigated the efficacy and safety of 0.5 mg and 1.0 mg semaglutide as monotherapy during 30 weeks of treatment compared with placebo in 388 people with type 2 diabetes previously on diet and exercise. The trial achieved its primary objective by demonstrating that from a mean baseline HbA1c of 8.1%, people treated with doses of 0.5 mg and 1.0 mg semaglutide, achieved superior improvements in HbA1c of 1.5% and 1.6%, respectively, compared to no change in HbA1c in the placebo group.

Source: <http://globenewswire.com>

##### **Cytokinetics announces start of Phase 3 clinical trial of Tirasemtiv in Patients with Amyotrophic Lateral Sclerosis (ALS)**

July 14, 2015 - Cytokinetics, Inc., a leading muscle biology company, today announced the start of VITALITY-ALS (Ventilatory Investigation of Tirasemtiv and Assessment of Longitudinal Indices after Treatment for a Year in ALS), a Phase 3 clinical trial designed to assess the effects of tirasemtiv versus placebo on slow vital capacity (SVC) and other measures of respiratory function in patients with ALS. VITALITY-ALS is designed to confirm and extend results observed in Phase 2b trial.

Source: <http://www.cytokinetics.com>

#### **NEW MOLECULE ENTITY & NEW THERAPEUTIC BIOLOGICAL PRODUCT**

##### **Rexulti (Brexipiprazole)**

July 10, 2015 - The U.S. Food and Drug Administration approved Rexulti (brexpiprazole) tablets to treat adults with schizophrenia and as an add-on treatment to an antidepressant medication to treat adults with major depressive disorder (MDD). The effectiveness of Rexulti in treating schizophrenia was evaluated in 1,310 participants in two 6-week clinical trials. Rexulti was shown to reduce the occurrence of symptoms of schizophrenia compared to placebo. The effectiveness of Rexulti as an add-on treatment for MDD was evaluated in two 6-week trials that compared Rexulti plus an antidepressant to placebo plus an antidepressant in 1,046 participants for whom an antidepressant alone did not adequately treat their symptoms. The participants taking Rexulti reported fewer symptoms of depression than those taking the placebo.

Source: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm454647.htm>

##### **DIETARY RESEARCHUPBEAT: Diet plus exercise doesn't prevent Gestational Diabetes**

A behavioral intervention that combines diet and exercise did not prevent gestational diabetes (GDM) or large-for-gestational age (LGA) babies in obese pregnant women, according to results from one of the largest randomized controlled trials. Results from the UK Pregnancies Better Eating and Activity Trial (UPBEAT) were published online in the Lancet Diabetes and Endocrinology on July 10, 2015.

"The study found that obese women who take part in a health-trainer-led program will improve their diet and take more exercise, the benefits of these changes are unlikely to be adequate to reverse the insulin resistance that leads to gestational diabetes," lead author Lucilla Poston, from the division of women's health at King's College London, United Kingdom, told Medscape Medical News.

Source: <http://www.medscape.com/viewarticle/848223>

#### **CURRENT AFFAIRS IN PHARMACEUTICAL INDUSTRY**

##### **Lupin acquires Gavis Pharma for \$880 million**

Pharma major Lupin Limited has acquired a US-based privately held research-oriented generic company Gavis Pharmaceuticals LLC and Novel Laboratories Inc. for \$880 million. The acquisition enhances Lupin's scale in the US generic market and also broadens its pipeline in dermatology, controlled substance products and other high-value and niche generics. Gavis' New Jersey-based manufacturing facility will become Lupin's first manufacturing site in the US.

Source: <http://businesstoday.intoday.in>

##### **MedGenome gets Series B funding of \$20 mn from Sequoia Capital to build diagnostics-research infrastructure in India & US**

MedGenome, the market leader in genomics-based diagnostics in India and a leading provider of genomics research services globally, has received a Series B funding of \$20 million from Sequoia Capital. The investment will support MedGenome in accelerating the expansion of its portfolio of genetic tests, enhancement of sequencing facilities in India and the US, and expanding its collaborative network with specialty hospitals/clinics and genomic research institutions in India.

Source: <http://www.pharmabiz.com>



## SUMANDEEP VIDYAPEETH ACTIVITIES

### Evidence Based Education System Workshop organized by Sumandeep Vidyapeeth

EBES core committee of SV organized one day EBES workshop for various departments of Sumandeep Vidyapeeth on 14th, 17th, 23rd and 24th July as well as on 25th August 2015 at Biochemistry demo room, SBKS medical college. Main objective of the workshop was to familiarize the PG students of SV regarding the Evidence Based Education System and its utility for protocol development. Some of the topics which are covered during the workshop are: Quality Evidence Generation Research, Evidence Based Decision Making and concept of Critical Appraisal, Searching for Literature and use of Evidence Based Databases.

### Educational visit:

Faculty members of DoP and other departments, SV visited P. D. Patel Institute of Applied Sciences (PDPIAS), CHARUSAT University, Changa and College of Veterinary Science and Animal Husbandry, Anand on 27th Jul. 2015. At PDPIAS, faculty members explored the laboratories of Biochemistry, Microbiology and Biotechnology department. Furthermore, at College of Veterinary Science and Animal Husbandry, faculties visited Department of Animal Biotechnology where they acquired practical knowledge of genomic sequencing and its instruments (e.g. PCR/RT-PCR, Gene Sequencer, Ion Torrent) by visiting DNA and RNA laboratory.

### Department of Pharmacy

#### Orientation program for first year Pharm.D students:

Department of Pharmacy, Sumandeep Vidyapeeth organized an orientation program for the first year Pharm.D Students on Monday, 6th July 2015. Twenty eight students and their parents attended the program. Dr. (Col.) V.P.Singh (Director General) and Dr. M.M.Sattigeri, (I/c. Registrar), Sumandeep Vidyapeeth interacted with each and every parent and student. Furthermore, Dr. A.K.Seth (Principal & HOD, DoP) explained about the scope and opportunities of Pharm.D program. He also spoke about general rules and regulations of Sumandeep Vidyapeeth as well as Department of Pharmacy.

#### Research cell of SBKSMIRC sanctioned research grant for two research projects of DoP, SV:

1. Research cell, SBKSMIRC sanctioned research grant of Rs. 48 lakhs to principal investigator Dr. R. Balaraman, and co-investigators Dr. A K Seth, Mr. Ghanshyam Parmar and Dr. Rajesh Maheswari for major research project entitled "Biochemical & pharmacological investigations of some antidiabetic and antihyperlipidemic drugs in combination with antioxidants on the levels of adipocytokines in metabolic syndrome".
2. Research cell, SBKSMIRC sanctioned research grant of Rs. 42 lakhs to principal investigator Dr. R. Balaraman, and co-investigators Dr. A K Seth, Mr. Ghanshyam Parmar and Mr. Girish U Sailor for major research project entitled "Pharmacognostic profile and Pharmacological effects of different parts of Moringa oleifera plant".



### LAUGH & LIVE LONGER

A man goes to his doctor and says, "I don't think my wife's hearing isn't as good as it used to be. What should I do?" The doctor replies, "Try this test to find out for sure. When your wife is in the kitchen doing dishes, stand fifteen feet behind her and ask her a question, if she doesn't respond keep moving closer asking the question until she hears you." The man goes home and sees his wife preparing dinner. He stands fifteen feet behind her and says, "What's for dinner, honey?" He gets no response, so he moves to ten feet behind her and asks again. Still no response, so he moves to five feet. still no answer. Finally he stands directly behind her and says, "Honey, what's for dinner?" She replies, "For the fourth time, I SAID CHICKEN!"

**One laugh per day is better than eating one apple a day**

There are three kinds of men in this world.

- Some remain single and make wonders happen.
- Some have girlfriends and see wonders happen.
- The rest get married and wonder what happened.

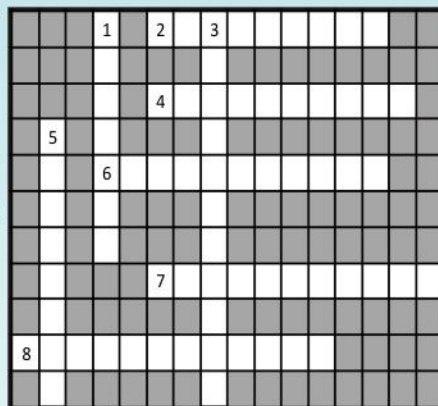
sick jokes@ballu.com

#### Across

2. Used for treatment of Diabetes
4. beta 2 adrenergic receptor antagonist
6. An H2 receptor antagonist
7. Crocin contains \_\_\_\_ as API
8. A proton pump inhibitor

#### Down

1. Disprin contains \_\_\_\_ as API
3. Used to treat high BP
5. A non steroidal anti inflammatory drug



To, \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

### Book-Post

Postal stamp

## Department of Pharmacy Sumandeep Vidyapeeth, Piparia, Vadodara (Gujarat)

Please email your suggestions, comments and contribution for next issue to [editorpharmahorizon@gmail.com](mailto:editorpharmahorizon@gmail.com)

Note: If you have any query regarding medication and disease please write us at: [svdruginfo@gmail.com](mailto:svdruginfo@gmail.com)