



### Dear PharmSolians!

While writing this editorial, and precisely we being in to “Services” sector, it shall be apt to begin it with those quotes which impressed me...

### In this issue:

Science/News Corner	- 2
Recall	- 4
Drug Approvals	- 5
Warning Letters	- 6
Guidelines	- 6
Granny Therapy	- 7

**"None of us, including me, ever do great things.  
 But we can do small things, with great love,  
 And together, we can do something wonderful."  
 – Mother Teresa**

**"If you want to lift yourself up, lift up someone else."  
 – Booker T. Washington**

It is true that there is a difference between a Services / advisory industry of our kind (Domain PharmSol is into) and other segments of Pharmaceutical industry. We being into Services always need to bring up the best so that our clients get what they look up from us. Keeping up the tempo all these years, is an incredible work and nothing is possible without a **TEAM** around.

We, as an Organization lay emphasis to such great efforts always and build a Proactive and Positive culture within PharmSol. This is a standout quality in our Organization that sees and ensures a “Team” which believes and carries the same belief at every level.

In this edition, I am also excited to introduce an editorial board to carry forward the beginning of the mission “**Pharm Breeze**”. The members of the editorial committee and the team PharmSol shall ensure, creative and informative articles that entices our grey cells every time.

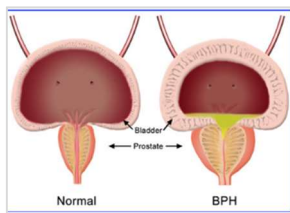
Happy Reading!

Thanks & Best Regards



S Lakshminarasimhan  
 Director – Operations, PharmSol Group

### Drug Like compounds that reverse chemotherapy failure in three aggressive cancer cells.



Researchers at Southern Methodist University have discovered three drug-like compounds that successfully reverse chemotherapy failure in three of the most commonly aggressive cancers - ovarian, prostate and breast. The molecules were first discovered computationally via high-performance supercomputing. Now their effectiveness against specific cancers has been confirmed via wet-lab experiments, said biochemistry professors Pia Vogel and John G. Wise, who led the study.

<http://www.worldpharmanews.com/research/4268-cells-of-3-advanced-cancers-die-with-drug-like-compounds-that-reverse-chemo-failure>

## SCIENCE & NEWS CORNER

**Cancer** – The state of body when cells in the body begin to grow out of control. Cells in nearly any part of the body can become cancer cells, and can spread to other areas of the body.

**Prostate Cancer:** Prostate cancer affects the prostate gland, the gland that produces some of the fluid in semen and plays a role in urine control in men.

### Cancer blood tests detects 8 tumor types



The Cancer SEEK test measures circulating tumor DNA (ctDNA) from 16 genes and eight protein biomarkers, then uses machine-based learning to analyse the data.



The researchers applied the test to 1,005 patients with non-metastatic, clinically detected cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast. Cancer SEEK tests were positive in a median of 70% of the eight cancer types.

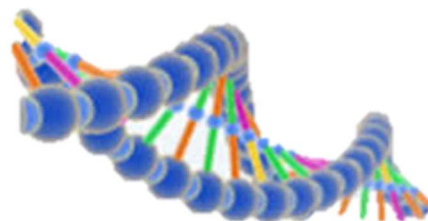
[http://www.pharmatimes.com/news/cancer\\_blood\\_tests\\_detects\\_8\\_tumour\\_types\\_1217899](http://www.pharmatimes.com/news/cancer_blood_tests_detects_8_tumour_types_1217899)

A **gene** is the basic physical and functional unit of heredity.

**Genes**, which are made up of DNA, act as instructions to make molecules called proteins.

Biomarkers are biological characteristics that are objectively measured and evaluated as indicators of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention.

Abnormal growth of tissue which, if it forms a mass, is commonly referred to as a **tumor**.



## Dwelling microbe produces potential anti-melanoma weapon

A type of soil-dwelling bacterium produces molecules that induce death of melanoma cells, by a research at Oregon State University. The molecule is a secondary metabolite, also known as a natural product, of *Streptomyces bottropensis*, and its properties are important because there are not many therapies that effectively manage melanoma, the most dangerous form of skin cancer.

<http://www.worldpharmanews.com/research/4251-dirt-dwelling-microbe-produces-potential-anti-melanoma-weapon>

A biosimilar (also known as follow-on biologic or subsequent entry biologic) is a biologic medical product which is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original "innovator" products, and can be manufactured when the original product's patent expires.

## SCIENCE & NEWS CORNER

### New research paper shows that AstraZeneca has achieved greater than four-fold improvement in R&D productivity

AstraZeneca's IMED Biotech Unit documents a more than four-fold improvement in R&D productivity following significant revision of its approach and adoption of a '5R framework' - right target, right patient, right tissue, right safety, right commercial potential.

The publication explains how adoption of the research unit's 5R framework has guided successful, efficient drug discovery and development whilst financial investment in R&D has remained unchanged. It shows that the research unit's success rate in discovering new compounds, which then progress through the pipeline to completion of Phase III clinical trials, has increased from 4% in the period 2005-2010 to 19% in the period 2012-2016 based on the 5R framework.

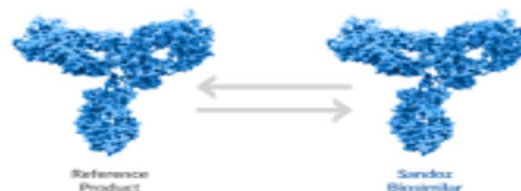
The improvement positions R&D productivity above the pharmaceutical industry average of 6% for small molecules in the 2013-2015-time frame. The transformation accompanied a strategic re-focusing on three main therapy areas: Oncology, Cardiovascular & Metabolic Diseases and Respiratory.

<http://www.worldpharmanews.com/astrazeneca/4265-new-research-paper-shows-that-astrazeneca-has-achieved-greater-than-four-fold-improvement-in-r-d-productivity>

### Sandoz announces exclusive global collaboration with Biocon on next-generation biosimilars

Sandoz, a Novartis division and the global leader in biosimilars, today announced a global partnership with Asia's premier biopharmaceuticals company, Biocon, to develop, manufacture and commercialize multiple biosimilars in immunology and oncology for patients worldwide.

<http://www.worldpharmanews.com/novartis/4264-sandoz-announces-exclusive-global-collaboration-with-biocon-on-next-generation-biosimilars>



## SCIENCE & NEWS CORNER

A more complete Mediterranean diet may protect against aggressive prostate cancer



Researchers determined that men who followed a Mediterranean diet, rich in fish, boiled potatoes, whole fruits, vegetables, legumes, and olive oil, and low consumption of juices had lower risk of aggressive prostate cancer (PC) than those who followed other dietary patterns like Prudent or Western diets

<http://www.worldpharmanews.com/research/4255-a-more-complete-mediterranean-diet-may-protect-against-aggressive-prostate-cancer>

Hospitals, sick of drug shortages, take matters into their own hands

A consortium representing more than 450 hospitals is teaming up to form a nonprofit generic drug maker (*Pixabay.com*).

<https://www.fiercepharma.com/pharma/hospital-groups-plan-new-drugmaker-to-combat-generic-shortages-and-price-hikes>

## RECALL

BRAND NAME	COMPANY NAME	PRODUCT DESCRIPTION	REASON FOR RECALL
GERICARE	Kareway Products Inc.	Sterile Eye Irrigation Solution	Potential microbial contamination.
LIMBREL	Primus Pharmaceuticals, In	Limbrel, Limbrel 250, Limbrel 500	Due to potential serious side effects.
BASIC DRUGS	Magno-Humphries Laboratories, Inc.	Senna Laxative	Mislabeled
NEXTERONE	Baxter International Inc.	Nexterone 150 mg/100 ml injection	Presence of particulate matter
AUROMEDICS	AuroMedics Pharma LLC	Levofloxacin in 5% Dextrose Injection 250 mg/50 mL	Presence of particulate matter
PHARMEDIUM	PharMEDium Services LLC	Various compounded drug products intended to be sterile	Lack of sterility assurance
INTERNATIONAL LABORATORIES	International Laboratories, LLC	Clopidogrel Tablets USP, 75 mg	Due to Mislabeled
AUROMEDICS	AuroMedics Pharma LLC	Ampicillin and Sulbactam for Injection USP	Presence of glass particles

<https://www.fda.gov/Drugs/DrugSafety/DrugRecalls/default.htm>

## DRUG APPROVALS EUROPE IN JAN 2018

DRUG NAME	ACTIVE INGREDIENT	COMPANY
JORVEZA	BUDESONIDE	DR. FALK PHARMA GMBH
OCREVUS	OCRELIZUMAB	ROCHE REGISTRATION LIMITED

## USFDA

DRUG NAME	ACTIVE INGREDIENTS	COMPANY
EXCEDRIN (MIGRAINE)	ACETAMINOPHEN; ASPIRIN; CAFFEINE	GLAXOSMITHKLINE CONS
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	ACTAVIS LABS FL INC
INVOKAMET XR	CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE	JANSSEN PHARMS
TROKENDI XR	TOPIRAMATE	SUPERNUS PHARMS
PARNATE	TRANLYCYPROMINE SULFATE	CONCORDIA PHARMS INC
NOXAFIL	POSACONAZOLE	SCHERING
PROLIA	DENOSUMAB	AMGEN
KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP DOHME
DOCETAXEL	DOCETAXEL	DR REDDYS LABS LTD
ERAXIS	ANIDULAFUNGIN	VICURON
COARTEM	ARTEMETHER; LUMEFANTRINE	NOVARTIS
RIFADIN	RIFAMPIN	SANOFI AVENTIS US
RIFATER	ISONIAZID; PYRAZINAMIDE; RIFAMPIN	SANOFI AVENTIS US
TETRABENAZINE	TETRABENAZINE	DR REDDYS LABS LTD
UVADEX	METHOXSALEN	MALLINCKRODT HOSP
ACIPHEX	RABEPRAZOLE SODIUM	EISAI INC
OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB
JEVTANA KIT	CABAZITAXEL	SANOFI AVENTIS US
OSELTAMIVIR PHOSPHATE	OSELTAMIVIR PHOSPHATE	LUPIN ATLANTIS
LEVONORGESTREL; ETHINYL ESTRADIOL; FERROUS CHG SCRUB	LEVONORGESTREL; ETHINYL ESTRADIOL; FERROUS	NEUVOSYN LABORATORIES LLC
AZACITIDINE	CHLORHEXIDINE GLUCONATE	ECOLAB
DUPIXENT	AZACITIDINE	ACTAVIS LLC
RAXIBACUMAB	DUPILUMAB	REGENERON PHARMACEUTICALS
ADEMPAS	RAXIBACUMAB	HUMAN GENOME SCIENCES INC.
CLARITIN	RIOCIGUAT	BAYER HLTHCARE
RAPAMUNE	LORATADINE	BAYER HEALTHCARE LLC
TRISENOX	SIROLIMUS	PF PRISM CV
ZORTRESS	ARSENIC TRIOXIDE	CEPHALON
GILOTRIF	EVEROLIMUS	NOVARTIS
COMETRIQ	AFATINIB DIMALEATE	BOEHRINGER INGELHEIM
LYNPARZA	CABOZANTINIB S-MALATE	EXELIXIS
SINUVA	OLAPARIB	ASTRAZENECA PHARMS
REMIFENTANIL HYDROCHLORIDE	MOMETASONE FUROATE	INTERSECT ENT INC
	REMIFENTANIL HYDROCHLORIDE	FRESED33:D37NIUS KABI USA

## NOVEL DRUG APPROVALS BY USFDA

**Novel Drug Delivery System (NDDS)** refers to the approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effects. NDDS is a system for delivery of **drug** other than conventional **drug** delivery system.

**Neuroendocrine tumors (NETs)** are neoplasms that arise from cells of the endocrine (hormonal) and nervous systems. Many are benign, while some are malignant. They most commonly occur in the intestine, where they are often called carcinoid **tumors**, but they are also found in the pancreas, lung and the rest of the body.

FDA approved Lutathera drug of Advanced Accelerator Applications USA Inc.

Lutathera drug (lutetium Lu 177 dotatate) for the treatment of a type of cancer that affects the pancreas or gastrointestinal tract called gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

<https://www.novartis.com/news/media-releases/advanced-accelerator-applications-receives-fda-approval-lutathera-treatment-gastroenteropancreatic-neuroendocrine-tumors>

### WARNING LETTER

Company Name	Manufacturing	Product	Warning letter received for
<b>Becton Dickinson &amp; Company</b>	Medical Devices	BD Vacutainer Blood Collection tube.	Medical Device/Adulterated/Misbranded/Lacks PMA and/or 510(k)
<b>American CryoStem Corporation</b>	(HCT/P)	ATCELL™.	PHS Act/Violation/Adulterated
<b>Yicheng Chemical Corp.</b>	API	-	CGMP/Active Pharmaceutical Ingredient (API)/Adulterated

### UPDATED GUIDANCE DOCUMENTS BY FDA

S.NO.	TITLE	SUBJECT	VERSION
01	180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day	Generics	Final
02	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff	Labeling, Safety	Final
03	Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs	Food Safety Modernization Act, CGMP	Final
04	Good ANDA Submission Practices Guidance for Industry	Generic Drugs	Draft
05	Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders Guidance for Industry	Clinical - Medical	Draft

## GRANNY THERAPY



No side effects are observed but care must be taken to completely flushout the paste and no soap to be applied. The effect depends on the tenure of usage.

### Fenu greekseeds fights dandruff

One can use leaves or seeds as an effective cure for dry scalp and dermatitis.

This Indian ayurvedic medicine prescribes the application of paste of fenugreek leaves or seeds of a size of two tablespoons before bathing (at least 30 minutes before bathing) to treat dandruff and dermatitis.

## EDITORIAL BOARD

**Inspiration & Facilitation** S. Lakshminarasimhan, PharmSol GmbH, Germany

**Editor-in-Chief** S. Saravananaraja, PharmSol Europe Limited, Malta

**Sub-Editor** A. Majorette, Pharmaceutical Solutions FZCO, Dubai, UAE

**Innovation Initiatives** Dr. Abhay Asthana, PharmSol India Private Ltd., India

**Ideas & Insights** Jyothsna Reddy, PharmSol India Private Ltd., India  
S. Mamata, Pharmaceutical Solutions FZCO, Dubai, UAE  
O. Anait, Pharmaceutical Solutions FZCO, Dubai, UAE  
F. Silvia, Pharmaceutical Solutions FZCO, Dubai, UAE

**Collation & Compilation** Divya Madireddy, PharmSol India Private Ltd., India

**Design & Layouts** Ketan & Nakul, PharmSol, Australia

**Printed by** PharmSol Group

## DISCLAIMER

The information in this magazine is for information purposes only. No liability or responsibility for any inaccurate, or incomplete information is accepted by PharmSol nor for any actions taken in reliance of the information. Wherever, a general information is produced, due source of the information is also provided for further reading.