The Veeda Newsletter

SEP 2018
ISSUE 09

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CPHI WORLDWIDE
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Madrid , Spain.

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VEEDA COMPLETES 20th PATIENT BASED PHARMACOKINETIC STUDY SUCCESSFULLY.

We are happy to inform you that recently we have completed 20th patient based Pharmacokinetic study. This has been achieved by our dedicated team of experienced professionals and an elaborate network of experienced Clinical Trial sites across India.

The team has overseen the enrolment of 818 patients from 103 sites across India in therapeutic areas such as Oncology, Psychiatry, HIV, Rheumatology and Dermatology. In addition, the team is currently working on 11 patient PK studies which are in different stages of execution for targeted enrollment of 553 patients in Oncology, Psychiatry and Respiratory therapeutic areas.

Completed PK studies				
Therapeutic area	**Molecule**	**Indication**	**No. of studies**	**Total patient enrolled**
Oncology	Etoposide 50 mg Cap	Small cell lung cancer	1	24
	Imatinib 400 mg Tab	Chronic Myeloid Leukemia	7	232
	Capacitabine 500 mg Tab	Metastatic Breast Cancer and Colorectal cancer	1	54
	Doxorubicin Hcl (Pegylated liposomal)	Ovarian & Breast Cancer	2	79
	Paclitaxel 100 mg/vial	Metastatic Breast Cancer	1	76
	Everolimus 10 mg Tab	Renal Cell Carcinoma	1	30
Rheumatology and Dermatology	Methotrexate 2.5 mg Tab	Rheumatoid Arthritis and Psoriasis	1	42
Psychiatry	Quetiapine 400 mg and 600 mg ER tab	Schizophrenia	2	116
	Paliperidone PR 9 mg Tab	Schizophrenia	1	75
	Clozapine Tab 100 mg and 25 mg	Schizophrenia	2	42
HIV	Nevirapine Tab 400 mg	HIV-1 Infection	1	48

Read More: https://www.veedacr.com/2018/Flyers/Patient-Based-Study/Sep-Flyer-2018.htmll

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INDIAN PHARMA

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US proposal on drug pricing may shake up Indian pharma

In response to President Trump's complaints over escalating healthcare costs in the US, Pfizer announced it will defer its previously-planned price increases for later this year.
Read More: https://www.thehindubusinessline.com/specials/pulse/us-proposal-on-drug-pricing-may-shake-up-indian-pharma/article24595704.ece

State drug controllers get power to issue NOCs for drugs meant for export

State drug controllers have been given complete jurisdiction to issue no objection certificates (NOCs) for the manufacture of unapproved, banned or new drugs that are solely meant for exports.
Read More: https://www.business-standard.com/article/economy-policy/state-drug-controllers-get-power-to-issue-nocs-for-drugs-meant-for-export-118080301042_1.html

In a push to pharma exports, states get NOC booster shot

Drug Controller General of India Dr S Eswara Reddy on Thursday issued orders to the drug controllers of all states .
Read More: http://timesofindia.indiatimes.com/articleshow/65251855.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Trade war opens exports opportunity for Indian pharma companies

The trade disputes between the US and China have intensified lately, which can potentially escalate to a full-fledged trade war. While the rhetoric of verbal exchanges between the two countries were on for some time, the triggering action was the initiation of a Section 301 case by the United States Trade Representatives (USTR) against China's intellectual property right (IPR) policies.
Read More: http://www.dnaindia.com/business/report-trade-war-opens-exports-opportunity-for-indian-pharma-companies-2647434

Indian pharma market registers growth of 12.7% in July 2018

The Indian Pharmaceutical Market (IPM) has posted strong growth of 12.7 per cent during July 2018 and touched to Rs.10,616 crore. Last year, due to GST roll out, the market slumped to a de-growth of 2.4 per cent and sales worth Rs.9,280 crore.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=110610&sid=1

There's an explosion of data & digital opportunities in Indian healthcare: Vasant Narasimhan, CEO, Novartis

Earlier this year Vasant "Vas" Narasimhan(42) was named the CEO of NovartisNSE 0.00 %, the $50 billion Swiss pharmaceutical behemoth.
ReadMore: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/theres-an-explosion-of-data-digital-opportunities-in-indian-healthcare-vasant-narasimhan-ceo-novartis/articleshow/65481279.cms

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REGULATORY NEWS

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FDA issues worldwide recall of common blood pressure medication

"We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards.

Read More: http://www.fox5dc.com/news/fda-issues-worldwide-recall-of-blood-pressure-medication

DTAB gives green signal to uniform implementation of new labelling norms from April 1, 2019

The Drugs Technical Advisory Board (DTAB) of the Union health ministry has given its green signal to the DCGI's proposal to implement labelling change for drug packs uniformly from April 1, 2019 thus bringing the much needed respite to pharmaceutical industry from complying with changes in drug label twice within a couple of months.

Read More http://www.pharmabiz.com/NewsDetails.aspx?aid=110440&sid=1

FDA Drafts Guidance on Seamless Clinical Trials for Cancer Drug Developers

The US Food and Drug Administration (FDA) on Friday released draft guidance to help sponsors design and conduct first in human (FIH) clinical trials that speed the clinical development of cancer drugs through multiple expansion cohort study designs.

Read more: https://www.raps.org/news-and-articles/news-articles/2018/8/fda-drafts-guidance-on-seamless-clinical-trials-fo

USFDA issues draft guidance on risk valuation and mitigation strategy for multiple prescription drugs including biologicals

The USFDA has issued a draft guidance on the development of a shared system for risk valuation and mitigation strategy (REMS).This guidance provides recommendations to industry on the development of a shared system REMS for multiple prescription drugs including biologicals.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=110846&sid=2

CDSCO issues FAQs on new phytopharmaceuticals to help industry in manufacture, clinical trials & marketing

In an effort to ensure that the pharma and nutraceutical sectors are able to easily adhere to the new phytopharmaceutical drugs regulations, the Central Drugs Standard Control Organization (CDSCO) has issued Frequently Asked Questions (FAQs) on the approval of the latest products. The regulatory authority has addressed 17 set of queries and provided the responses to the possible doubts that could arise for the industry.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=110839&sid=1

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CLINICAL RESEARCH

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Mayo research team identifies genes that increase risk for triple-negative breast cancer

"Triple-negative breast cancer is an aggressive type of cancer that cannot be treated using targeted therapies," says Dr. Couch. "It accounts for 15 percent of breast cancer in the Caucasian population and 35 percent in the African-American population.

Read More: https://eurekalert.org/pub_releases/2018-08/mc-mrt073118.php

New guide to clinical trials and FDA's expanded access program

Clinical Research Pathways issues new guide for patients with critical or life-threatening illnesses.When someone is diagnosed with a serious or life-threatening illness and they have exhausted standard treatments, it's important to know that there are still options.

Read More https://newswise.com/articles/new-guide-to-clinical-trials-and-fda-s-expanded-access-program

How Small and Medium-Sized Businesses Can Capitalize on New ICH E6 Regulations

For the first time in over ten years, the publication of the ICH Guideline for Good Clinical Practice (E6 R2) in November 2016 put new regulations in the spotlight, making sponsors and CROs sit up and take note.

Read More: http://www.appliedclinicaltrialsonline.com/how-small-and-medium-sized-businesses-can-capitalize-new-ich-e6-regulations

Elephants rarely get cancer because their bodies have a rare 'zombie gene'

LIF6 is a gene that has gone dead in virtually every other animal except for elephants, but researchers have shown that LIF6 is responsible for fighting cancerous mutations in elephants, which rarely get the disease.

Read More: http://www.foxnews.com/science/2018/08/16/elephants-rarely-get-cancer-because-their-bodies-have-rare-zombie-gene.html

New chemical causes deadly brain cancer to self-destruct

Glioblastoma is a deadly form of brain cancer. Glioblastoma tumors emerge from the sticky, supportive tissue of the brain, which gets an ample supply of blood.

This makes the cancer particularly difficult to treat; the malignant cells multiply very fast.

Read More: https://www.medicalnewstoday.com/articles/322786.php

Researchers find hope in tears for new transplant rejection drug

A fatty compound found in animal tears could be used to develop new drugs to prevent the human body from rejecting transplanted organs, according to researchers.

Read More: http://www.asahi.com/ajw/articles/AJ201808200001.html

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FINANCIAL NEWS

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Divi's Labs earns a total income of Rs. 1044 crores for Q1 of FY19

Divi's Laboratories has earned a total income of Rs. 1044 crores for the 1st quarter of the year 2018-19 on a stand-a lone basis, as against an income of Rs. 851 crores for the corresponding quarter of last year.

Read More: http://equitybulls.com/admin/news2006/news_det.asp?id=233736

Hexavest Inc. Has $1.34 Million Holdings in Dr.Reddy's Laboratories Ltd

Hexavest Inc. reduced its stake in Dr.Reddy's Laboratories Ltd (NYSE:RDY) by 76.9% in the 2nd quarter, according to the company in its most recent disclosure with the Securities and Exchange Commission.

Read More: https://www.fairfieldcurrent.com/2018/08/03/hexavest-inc-trims-holdings-in-dr-reddys-laboratories-ltd-rdy.html

Beacon Financial Group Has $2.24 Million Stake in Novartis AG

Beacon Financial Group decreased its stake in shares of Novartis AG (NYSE:NVS) by 4.1% during the second quarter, according to its most recent filing with the SEC.

Read More: https://www.fairfieldcurrent.com/2018/08/03/beacon-financial-group-reduces-stake-in-novartis-ag-nvs.html

Pharmaceutical exports up 3% to $17.3 billion in 2017-18

India's pharmaceutical exports grew merely 3 percent to $17.3 billion in 2017-18 due to increasing regulatory concerns and pricing pressures in the global markets, including the US. The sector's exports in 2016-17 had declined to $16.7 billion as against $16.9 billion in the previous fiscal, according to commerce ministry data.

Read More: https://www.moneycontrol.com/news/business/pharmaceutical-exports-up-3-to-17-3-billion-in-2017-18-2826461.html

Aurobindo Pharma consolidated net dips by 12.1% to Rs.456 cr in Q1

Aurobindo Pharma, a second largest Indian phrma company with net sales of Rs.16,200 crore plus, has received setback during the first quarter ended June 2018. Its consolidated net profit declined by 12.1 per cent to Rs.456 crore from Rs.519 crore in the corresponding period of last year.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=110500&sid=2

Pfizer, Novartis jump into an $84M development round for UK cancer drug stars at Artios

Lynparza got the first-mover advantage in PARP — and a blockbuster commercialization pact with Merck — after AstraZeneca picked it up in the $210 million KuDOS buyout, where Artios CEO Niall Martin and CSO Graeme Smith had played an important part in working on DNA repair pathways.

Read more: https://endpts.com/pfizer-novartis-jump-into-an-84m-development-round-for-uk-cancer-drug-stars-at-artios/

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MERGER & AQUISITION

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Carlyle in talks to invest $100 million in BDR Pharma

Private equity firm Carlyle is in talks with promoters of Mumbai-based BDR Pharma to invest $100 million in the drug company, the funding for which is expected to be used in expanding the company's operations, according to people aware of the development.

Read more: http://economictimes.indiatimes.com/articleshow/65394648.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Pharmexcil to sign MoU with China trade body for faster drug approvals

In a bid to boost the India-China pharmaceutical trade, the Pharmaceuticals Export Promotion Council of India (Pharmexcil), under the Ministry of Commerce, will be signing a memorandum of understanding (MoU) with the China Chamber of Commerce for Import and Export of Medicines and Health Products on August 20 to speed up drug approval processes, thereby opening the Chinese market for Indian exporters.

Read More: https://www.financialexpress.com/industry/pharmexcil-to-sign-mou-with-china-trade-body-for-faster-drug-approvals/1279687/

Haplogen, Bayer enter into drug discovery and development collaboration

Based in Vienna, Austria, Haplogen is a biotechnology company focused on developing therapeutic substances for the treatment and prevention of infection by the common cold virus.

Read more: https://www.pharmaceutical-business-review.com/news/haplogen-bayer-enter-into-drug-discovery-and-development-collaboration/

Aurobindo drops plan to acquire Mallinckrodt's generic portfolio

As per media sources, Aurobindo Pharma has dropped the plans to acquire Mallinckrodt's speciality generics business in the US. The deal was rumoured in July2018 and deal price was estimated to be ~$800mn.

Read More: https://www.indiainfoline.com/article/news-top-story/aurobindo-exits-mallinckrodt%E2%80%99s-acquisition-118082700014_1.html

Domestic pharma players eye Bharat Serums acquisition

Domestic pharmaceutical companies CiplaNSE 0.21 %, Zydus Cadilla, Dr Reddy's Laboratories and private equity fund Baring Asia are among those evaluating the acquisition of Mumbai-based vaccine maker Bharat Serums and Vaccines Ltd. (BSV), according to two people familiar with the development. **ReadMore:** https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/domestic-pharma-players-eye-bharat-serums-acquisition/articleshow/65599453.cms\\

Olon Acquires Manufacturing Facility in India

Olon S.p.A., a world leading Active Pharmaceutical Ingredients (API) contract development and manufacturing organization (CDMO) and generics supplier, announced today the acquisition of a local generics chemical operations API manufacturing facility in Mahad, India, as part of a continuing expansion of its global footprint.

Read More: https://pilotonline.com/business/jobs/article_db27de16-fcef-539e-94e6-d7ce6513c20b.html

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UPCOMING CONFERENCE

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