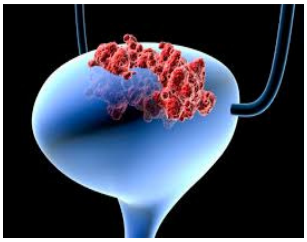
PHARMAPEDIA

PSGCP *E-News Letter*

VOL 3 / ISSUE 9 / FEB 2019 – MAY 2019

FDA Approves First Targeted Therapy for Metastatic Bladder Cancer



The U.S. Food and Drug Administration granted accelerated approval to Balversa (erdafitinib), a treatment for adult patients with locally advanced or metastatic bladder cancer that has a type of susceptible genetic alteration known as FGFR3 or FGFR2, and that has progressed during or following prior platinum-containing chemotherapy. Patients should be selected for therapy with Balversa using an FDA-approved companion diagnostic device.

The efficacy of Balversa was studied in a clinical trial that included 87 patients with locally advanced or metastatic bladder cancer, with FGFR3 or FGFR2 genetic alterations, that had progressed following treatment with chemotherapy. The overall response rate in these patients was 32.2%, with 2.3% having a complete response and almost 30% having a partial response. The response lasted for an average of approximately five-and-a-half months. About a quarter of patients in the study were previously treated with anti PD-L1 / PD-1therpy, which is a standard treatment for patients with locally advanced or metastatic bladder cancer.

Ref : https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-metastatic-bladder-cancer

One-Off Gene Therapy Treatment for Rare Infant Disease

A new gene therapy treatment for paediatric patients with spinal muscular atrophy (SMA) has been approved by the U.S. Food and Drug Administration. The single dose treatment, designed to correct a gene mutation causing the rare disease, has been priced at US$2.1 million by pharmaceutical company Novartis, making it the most expensive drug in the world to date. Zolgensma was developed to target a rare inherited genetic mutation in the SMN1 gene. Children born with this mutation are unable to produce effective volumes of SMN protein, which is vital for functional motor neurons in the brain and spinal cord. In its most extreme cases this rare disease is a death sentence for a majority of children. The new therapy works by delivering a healthy copy of the SMN gene directly into motor neuron cells. If effective the therapy can correct the genetic mutation and result in motor neuron cells properly producing vital SMN proteins.

Ref:https://www.livemint.com/companies/news/novartis-gets-us-approval-for-2-1-million-gene-therapy-1558759580308.html

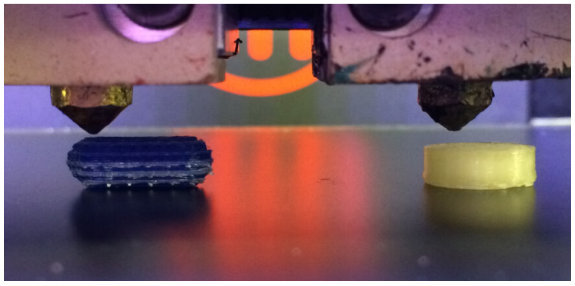
Innovative Paediatric Formulations: Ibuprofen in Chocolate-Coated Honey Core

In particular study, a new taste masking processing wherein the drug's disagreeable taste and the associated unpleasant throat burning sensation are covered with honey and chocolate. Ibuprofen was used as the active pharmaceutical ingredient dispersed in formula after being suitably pre-treated. Honey and agar are the two main excipients of the formulation while the new pharmaceutical preparation is further coated with milk chocolate to mask its bitter taste. Vitamins A and E were also added in a separate formula as an alternative choice which, apart from the curative action of ibuprofen, display additional benefits.

Ref : https://link.springer.com/article/10.1007/s12247-019-09389-1

Novel 3D Printed Tablet for Rapid Drug Release

Millions of people around the world are regular users of medicinal pills and capsules. The conventional drug manufacturing process uses standard drug formulations that are more suitable for mass manufacturing. Nowadays, scientists and pharmaceutical researchers believe that 3D printing may be an answer to most of the problems associated with drug intake. The main idea behind 3D printing drugs is to design and develop medicines that are suited to an individual's needs. In this way, we can easily adjust the size, appearance, shape, and rate of delivery of a wide array of medicines.



Ref:

1. Nayan G. Solanki Md Tahsin, Ankita V. Shah, Abu T.M. Serajuddin*,Formulation of 3D Printed Tablet for Rapid Drug Release by Fused Deposition Modeling: Screening Polymers for Drug Release, Drug-Polymer Miscibility.Journal of Pharmaceutical Sciences, Volume 107, Issue 1, 390 – 401.

2. https://all3dp.com/2/3d-printing-drugs-the-latest-advancements-around-the-world/

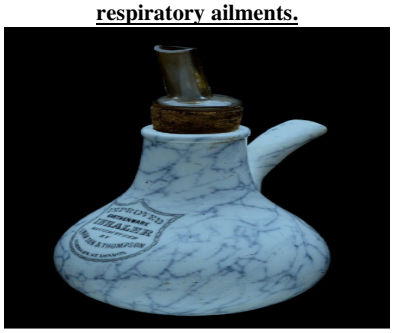
PHARMA TEASER!!!!!

1. Which Avengers hero worked at a pharmacy before he became famous?
2. Name the other class of amphiphilic copolymers which are similar to poloxamers in function and has a ability to self assembly in response to pH and temperature ?.
3. Which is the first prescription drug developed using 3D technology to get USFDA approval?
4. What is the essential rheological property for rectal ointment?
5. Name the British painter who invented and patented the first tablet Compression machine in 1842?

Send your correct answers to psgcp.ceutics@gmail.com .

The first three participants with correct answers will be acknowledged in the next issue.

Dr Nelson's Improved Inhaler' was the first marketed inhaler in 1865 for the treatment of respiratory ailments.



Futuristic Formulation Technologies:

FLEXITAB : Tedor pharma developed extended release tablets that can be taken intact or broken cleanly and precisely resulting in two to four, dose proportional, extended release segments. https://www.prnewswire.com/news-releases/tedor-pharma-licenses-flexitab-breakable-extended-release-tablet-technology-300861182.html

Patented DehydraTECh : Lexaria Bioscience able to deliver 8X more cannabidiol into blood and over 19X more cannabidiol into brain tissue than standard formulations https://www.proactiveinvestors.com/companies/news/221475/lexaria-bioscience-crafts-new-dehydratech-innovation-files-patents-221475.html

Waterless formulation: Waterless cosmetics represent a new generation of cosmetics aimed to provide cost effective semi solid dosage forms. http://www.packagingtoday.co.uk/features/featureli ke-oil-and-water-7215325/

Interesting Facts

- Depressants, opioids and antidepressants are responsible for more overdose deaths (45%) than cocaine, heroin, methamphetamine and amphetamines (39%) combined.
- India is among the leading global producers of cost-effective generic medicines and vaccines, supplying 20 percent of the total global demand by volume. At present, Indian companies supply over 80 percent of the anti-retro-viral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome).
- In the last few years, Indian pharmaceutical companies have agreed to pay over $13 billion to resolve U.S. Department of Justice allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the Food and Drug Administration.

PUBLISHER:
Department of Pharmaceutics
PSG College of Pharmacy
Peelamedu, Coimbatore – 641004
Phone: 0422- 2570170 Extn: 5841
Website: www.psgpharma.ac.in
E-mail:psgcp.ceutics@gmail.com