CHIPS REGIMEN

Drug Information News Letter
Jan-Mar 2017, Volume 2, Issue 3

PRIORITY PATHOGENS

The World Health Organization (WHO) published a list of antibiotic-resistant "Priority Pathogens" for which new antibiotics are now urgently needed. The WHO published the list in a bid to help, guide and promote Research and Development (R&D) of new antibiotics as this list is a new tool to ensure R&D responds to urgent public health needs.

The WHO list is divided into critical, high, and medium priority categories to convey the level of urgency for the antibiotics needed.

The "critical" group includes multidrug-resistant bacteria that pose a particular threat in hospitals, nursing homes, and among patients whose care requires devices such as ventilators and blood catheters. They include ***Acinetobacter, Pseudomonas, and various Enterobacteriaceae (including Klebsiella, E coli, Serratia, and Proteus)****, which can cause severe and often deadly infections, such as bloodstream infections and pneumonia. These bacteria have become resistant to a large number of antibiotics, including carbapenems and third-generation cephalosporins – the best available antibiotics for treating multidrug-resistant bacteria, the WHO notes.*

The second and third tiers in the list – the high- and medium-priority categories – contain other bacteria that are increasingly resistant to existing antibiotics and that cause more common diseases, such as gonorrhea and food poisoning.

Priority: Critical

1. Acinetobacter baumannii, carbapenem-resistance
2. Pseudomonas aeruginosa, carbapenem-resistant
3. Enterobacteriaceae, carbapenem-resistant, ESBL-producing

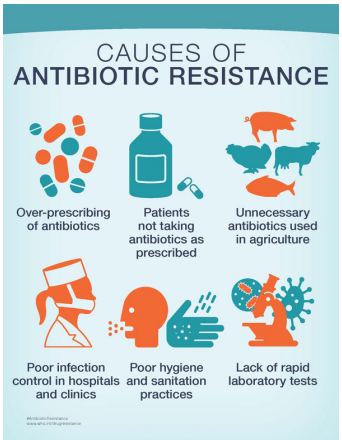
Priority: High

4. Enterococcus faecium, vancomycin-resistant
5. Staphylococcus aureas, methicillin-resistant, vancomycin-intermediate, and resistant
6. Helicobacter pylori, clarithromycin-resistant
7. Campylobacter spp, fluoroquinolone-resistant
8. Salmonellae, fluoroquinolone-resistant
9. Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant

Priority: Medium

10. Streptococcus pneumoniae, penicillin-nonsusceptible
11. Haemophilus influenzae, ampicillin-resistant
12. Shigella spp, fluoroquinolone-resistant

Reference : *http://www.who.int/mediacentre/news/releases/2017/bacteria-antibiotics-needed/en/*



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Dr.K. Basavapunnaiah, President
Dr.C.N. Srinivas, Secretary & Correspondent
Edited By
Dr.S.Vidyadhara, Principal
Editorial Team:
Dr. R. Hari Babu, Dr. R.L.C. Sasidhar, S. Vikas, Dr. M.Raghava Kalyan

TODAY'S MUST WATCH

The following are few important drugs approved by US FDA during the month Jan-Mar 2017.

BRAND	DRUG	INDICATION
Parsabiv	Etelcalcetide	Treatment of secondary hyperparathyroidism in adults with chronic kidney disease on hemodialysis
Qtern	Dapagliflozin and Saxagliptin	Treatment of inadequately controlled type II diabetes
Trulance	Plecanatide	Adults with chronic idiopathic constipation
Symproic	Naldemedine	Treatment of opioid-induced constipation
Xadago	Safinamide	Parkinson's disease
Emflaza	Deflazacort	Treatment of Duchenne muscular dystrophy
Xermelo	Telotristat	Treatment of carcinoid syndrome diarrhea

- Etelcalcetide is a calcimimetic agent that allosterically modulates the calcium-sensing receptor (CaSR). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases PTH secretion.
  Reference : *http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100184/parsabiv-etelcalcetide*
- Plecanatide is a guanylate cyclase-C agonist. Plecanatide binds to and activates guanylate cyclase C (GC-C) expressed on epithelial cells lining the GI mucosa, resulting in activation of the cystic fibrosis transmembrane conductance regulator (CFTR), and leading to augmented flow of chloride and water into the lumen of the gut, facilitating bowel movement.
  Reference : *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm537725.htm*
- Safinamide is a monoamine oxidase type B (MAO-B) inhibitor. Inhibition of MAO-B activity, by blocking the catabolism of dopamine, is thought to result in an increase in dopamine levels and a subsequent increase in dopaminergic activity in the brain.
  Reference : *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm547852.htm*
- Telotristat ethyl is a tryptophan hydroxylase inhibitor. Tryptophan hydroxylase mediates the rate limiting step in serotonin biosynthesis. Serotonin plays a role in mediating secretion, motility, inflammation, and sensation of the gastrointestinal tract, and is over-produced in patients with carcinoid syndrome. Through inhibition of tryptophan hydroxylase, telotristat and telotristat ethyl reduce the production of peripheral serotonin, and the frequency of carcinoid syndrome diarrhea.
  Reference : *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm544035.htm*

STUDENTS CORNER

The Free Style Libre Pro System: A Revolutionary Diabetes Sensing Technology

On September 28th 2016, The U. S Food and Drug Administration (F.D.A) has approved the free style libre pro system, developed by Abbott, for use by physicians for monitoring glucose in patients with diabetes.

The free style libre is the third "blinded" professional continuous glucose monitoring (C.G.M) system. Libre does not require finger-stick calibration, has no reusable components requiring disinfection, and provides a longer period of data capture (14 days).

The libre pro's small round sensor is applied to the back of the patients arm by a health care professional, where it is held in place with adhesive for up to 14 days, measuring and recording interstitial fluid glucose every 15min through a small filament that is inserted just under the skin. The patient does not interact with the device.

After two weeks, the patient returns and the doctor uses the device's practice-owned reader to scan the sensor, there by downloading the glucose data and generating a visual report. The physician can then show the patient the results and discuss them during the visit

Following are the key advantages of Free Style Libre Pro system compared to other professional C.G.M Systems,

- ✔ Convenient for both the doctor and the patient
- ✔ Provides reliable glucose data
- ✔ Reduce equipment cost, maintenance and time

India was the 1st country globally to launch the professional version of the flash glucose monitoring technology by Abbott on 16th June 2015.

Reference : *www.accessdata.fda.gov/cdrh-:docs/pdf15/p150021c.pdf*

CLINICAL CONNECTION

Drug safety communication: Tramadol and Codeine

- The US Food and Drug Administration (FDA) announced that children younger than 12 years should not take tramadol (multiple brands) or codeine, which pose the serious risk for slowed or difficult breathing and death, today.
- Tramadol is indicated for pain, while codeine is indicated for both pain and cough. The latter opioid is found in some prescription pain and cough medicines and in some over-the-counter cough medicines. The FDA has approved all tramadol-containing products and single-ingredient codeine only for adult use. However, some clinicians prescribe tramadol to children on an off-label basis.
- The two opioids are problematic, the FDA said, because some people metabolize the drugs much more quickly than usual, causing life-threatening, high levels of the active ingredients that can lead to respiratory depression. This trait stems from a variation in an enzyme — cytochrome P450 isoenzyme 2D6 (CYP2D6) — that converts codeine into morphine and tramadol into a metabolite called O-desmethyltramadol (M1). The prevalence of CYP2D6 ultrametabolizers varies by race and ethnic group.
- Labels for products containing codeine and tramadol will be revised as follows:
  - ✔ For children under 12 years of age, codeine is contraindicated for cough or pain, and tramadol for pain.
  - ✔ Tramadol is contraindicated for treating pain following tonsillectomy or adenoidectomy in children younger than 18 years of age.
  - ✔ Codeine and tramadol are not recommended in children 12 to 18 years of age who are obese, or have severe lung disease or obstructive sleep apnea. These conditions may increase the risk for breathing problems.

Reference: *https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm554029.htm*

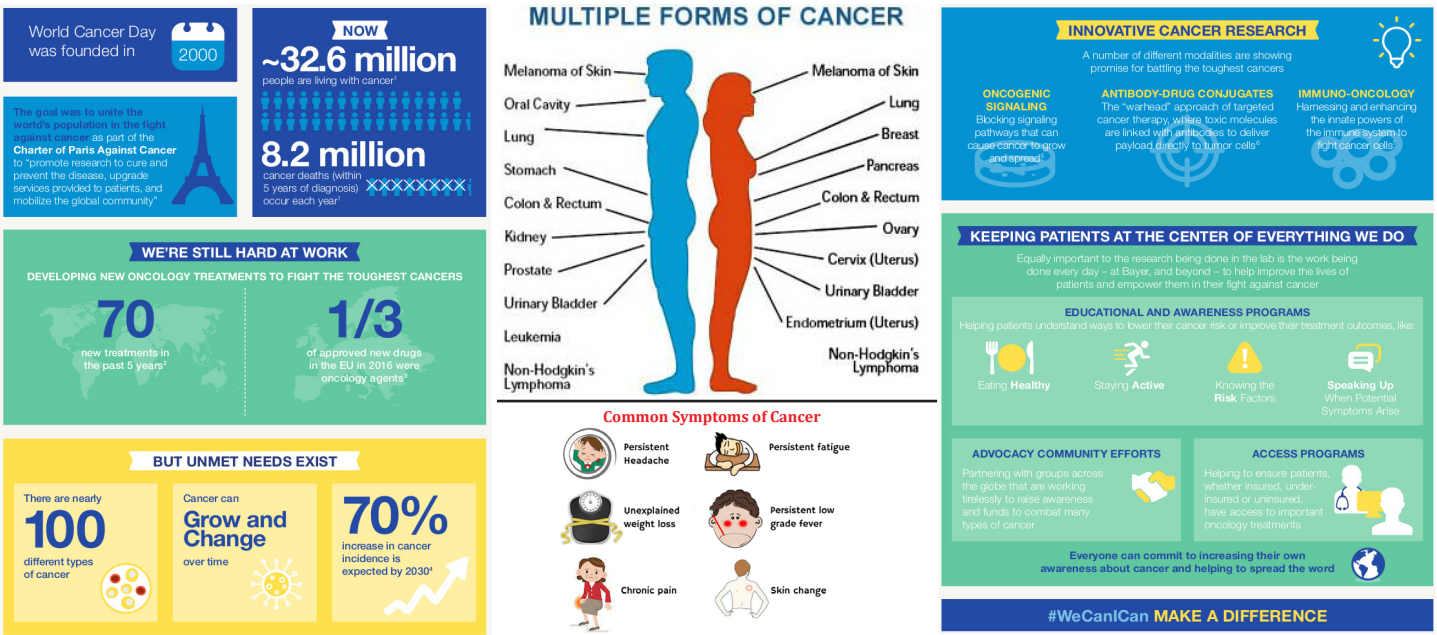
Empagliflozin Approved For A Newer Indication

- Empagliflozin is a selective inhibitor of sodium glucose cotransporter2 (SGLT2) 1st approved in the United States of America and in Europe in 2014 as a adjunctive diet and exercise to improve glycaemic control in adults with type II diabetes. Empagliflozin works by reducing the kidney's ability to reabsorb glucose into the blood stream, leading to urinary glucose excretion. Given as a monotherapy or as an add on therapy, Empagliflozin has been shown to reduce HbA1c in diabetic patients, including those with stage 2 or 3 chronic kidney disease. Plethora of evidence suggested an association between Empagliflozin and improved weight control, as well as blood pressure reduction without increase in heart rate.
- On 2nd December 2016, the U.S Food and Drug Administration (F.D.A) has approved Empagliflozin for the new indication 'Prevention of death due to Cardio Vascular Disease' (CVD) in adults with type II diabetes and established CVD, making it the first diabetes drug approved to reduce the risk of Cardio Vascular death in this population. Empagliflozin is also approved in Canada for the same indication.
- The approval of Empagliflozin for a new indication was based on findings from the landmark post marketing EMPAREG OUTCOME study. This study compared the effects of once daily Empagliflozin versus Placebo on Cardio Vascular morbidity and mortality in 7,020 adult patients with type II diabetes at high cardiovascular risk against a background of standard care (Statins, Angiotensin Converting Enzyme inhibitors and Aspirin). It showed that Empagliflozin reduced the primary composite outcome of Cardio Vascular death, non fatal Myocardial Infarction (M.I) and non fatal stroke by 14% in patients with type II diabetes and known CVD. However, the absolute risk reduction for the same was identified as only 1.6%. The beneficial effect was mainly driven by a 38% reduction in CV mortality with no significant decrease in non fatal MI or Stroke. When added to standard of care, Empagliflozin also prevented 1 in 3 deaths with a 32% reduction in risk of death from any cause. The study also identified an increased rate of genital infection (2.5 times) among patients received Empagliflozin compared to patients received placebo.

Reference: *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm531517.htm*

ADVICE

4th FEBRUARY : WORLD CANCER DAY



STAFF PUBLICATIONS

1. Vijetha Pendyala, Ramesh Babu Janga, Vidyadhara Suryadevara. Phytochemical and Pharmacological Evaluation of Commiphora Mukul for Antidepressant Activity in Albino Mice. Asian Journal of Pharmaceutical and Science Research. Vol 10, Issue 1 (2017)
2. T. Balakrishna, S. Vidyadhara, Rlc. Sasidhar, P. Satya Prasanna And T.E.G.K. Murthy. Formulation and Evalution of Lansoprazole Orodispersable Tablets. Int J Pharm Sci Res 2017; 8(2): 804-12.Doi: 10.13040/Ijpsr.0975-8232.8(2).804-12.
3. Vidyadhara Suryadevara, Vijetha Pendyala, B Sowjanyalakshmi. Role of Nutraceuticals in Cancer Treatment - An Overview. Inventi Impact: Nutraceuticals, 2017(1):1-5, 2017.
4. S. Vidyadhara, Rlc Sasidhar, B. Venkateswara Rao, P. Ratna Kumari. Simultaneous UV Spectrophotometric Method for the Determination of Tenofovir, Efavirenz and Lamivudine in Bulk and Combined Dosage Form. Asian J. Pharm. Ana.; 6(4): 253-258
5. G N S Jyothi, D Sandeep, S Vidyadhara T.N.V. Ganesh Kumar. Evaluation of Ex-Vivo Anti-Cholinergic Activity of Ethanolic Extract of Argemone mexicana. Inventi Impact: Ethnopharmacology, 2017(1):15-17, 2017.

Sankranti Sambaralu at CHIPS (08-01-2017)

Republic Day Celebrations at CHIPS (26-01-2017)

Health Awareness Walk Organized by CHIPS at Obulunaidu Palem Village (25-01-2017)

Free Medical Camp Organized by CHIPS at Obulunaidu Palem Village (26-01-2017)

SERB Sponsored National Seminar On "Recent Advances in Pharmaceutical Engineering, Pharmacogenomics And Pharmacokinetics" (28-01-2017)

IPA Sponsored Three Day Workshop On "Problem Based Teaching And Learning Of Organic Chemistry" (31-01-2017-02-02-2017)

We are Glad to Receive your Feedback to chipsregimen@gmail.com

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