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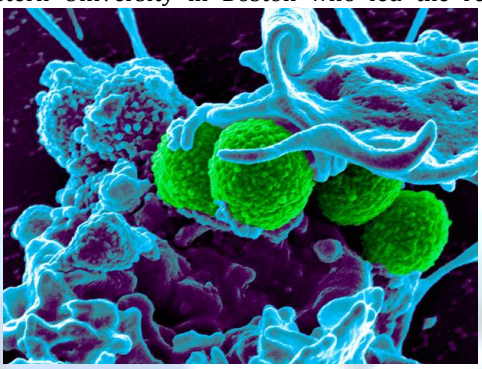
PHARMA HIGHLIGHTS

A New Antibiotic ... Finally!

A new antibiotic – the first in nearly 30 years – has been discovered by scientists who claim that it appears to be as good or, even, better than many existing drugs with the potential to work against a broad range of fatal infections such as pneumonia and tuberculosis. Laboratory tests have shown that the new antibiotic called teixobactin can kill some bacteria as quickly as established antibiotics as well as cure laboratory mice suffering from bacterial infections with no toxic side-effects. Studies have also revealed that the prototype drug works against harmful bacteria in a unique way that is highly unlikely to lead to drug resistance – one of the biggest stumbling blocks in developing new antibiotics. Such a development would represent a huge boost for medicine because of growing fears that the world is running out of effective antibiotics given the rapid rise of drug resistant strains of superbugs and the spread of these diseases around the globe.

Professor Kim Lewis of Northeastern University in Boston who led the research and is working with NovoBiotic Pharmaceuticals based in Cambridge, Massachusetts that owns the patents on teixobactin said that the first clinical trials on humans could begin in two years and, if successful, the drug could be in widespread use in 10 years. According to Professor Lewis, teixobactin is highly effective against tuberculosis and there is an opportunity to develop a single-drug treatment against tuberculosis based on teixobactin rather than a treatment regime based on administering three different antibiotics.



Professor Lewis said that the failure to detect any signs of resistance to teixobactin establishes a new paradigm in the development of antibiotics which had assumed resistance will eventually occur. "Bacteria develop resistance by mutations in their proteins. The targets of teixobactin are not proteins; they are polymer precursors of cell wall building blocks so there is really nothing to mutate," Professor Lewis said. "We've been operating under the dogma that the development of resistance is inevitable and we need to focus on introducing antibiotics faster than pathogens can acquire resistance," he said. "Teixobactin gives us an example of how we can develop an alternative strategy on developing compounds where resistance is not going to rapidly develop," he added.

About 25,000 people a year in Europe alone already die from infections that are resistant to antibiotics and the World Health Organisation has described the rise of antibiotic-resistance as one of the most significant global risks facing modern medicine. However, Dr Angelika Gründling, Reader in Molecular Microbiology at Imperial College London, said: "It's important to bear in mind that the new antibiotic only works against certain types of bacteria – such as MRSA and streptococcus, and not on other multi-drug resistant pathogens such as *E. coli*. And of course the new antibiotic described in the paper has yet to be tested in humans. It is possible that it might not be as effective as hoped and there could be unforeseen side-effects that might limit its use."

[Source: Health News @ www.independent.co.uk]

Trulicity: A New Once-Weekly Treatment For Type II Diabetes

Eli Lilly, the American pharmaceutical giant, has launched Trulicity (dulaglutide) in September 2014, a once-weekly glucagon-like peptide-1 (GLP-1) agonist which can be used in moderate renal impairment. Dulaglutide increases insulin release in the presence of increased blood glucose and suppresses glucagon secretion from the islets of Langerhans. Lilly has received the European approval in November 2014 to sell this new drug Trulicity for treating Type 2 diabetes, putting pressure on its Danish rival Novo Nordisk, the market leader in its category. Lilly's new drug will compete directly against the leader in the class, Victoza, made by Novo Nordisk.

About 387 million people worldwide are thought to have diabetes, a condition in which the body does not produce enough insulin or is not able to use it efficiently. Within the overall numbers, the incidence of the Type 2 variety, which is often associated with obesity, unhealthy diets or a lack of exercise, has been rising at epidemic rates. People with Type 1 diabetes must have daily insulin injections to survive. Many of those with Type 2 can control their condition with exercise and changes in diet but some need drugs to help manage their blood sugar.

Trulicity (dulaglutide) is indicated in adults with type II diabetes when diet and exercise provide inadequate glycaemic control. It can be used as monotherapy when metformin is inappropriate or in combination with other hypoglycaemics including insulin when these alone are inadequate since Dulaglutide is a long-acting GLP-1 receptor agonist. Trulicity belongs to a category of drugs called GLP-1 receptor agonists, also known as incretin mimetics. Such drugs act by mimicking the body's own glucagon-like peptide-1, a natural hormone, which increases insulin production and slows digestion. It improves glycaemic control by lowering fasting, pre-meal and postprandial glucose concentrations. The hypoglycaemic effect starts after the first dose and is sustained throughout the once-weekly dosing interval, as a result of the prolonged half-life of 4.7 days. Trulicity can be used as a stand-alone treatment or for use in

tandem with other treatments. It is injected with a proprietary pen, which contains a concealed needle. All doses are administered by subcutaneous injection into the abdomen, thigh or upper arm and can be given at any time of the day, independent of meals. The single-use prefilled pens are available in 750 microgram and 1.5mg strengths. The most common side effects reported include mild nausea and low blood sugar when Trulicity is used in combination with insulin. As a condition of authorization, the company must continue monitoring patients for complications.

[Source: MIMS; January 2015]

FDA Issues A "Final Rule" In Labelling Information For Pregnant And Lactating Mothers

On the 3rd of December 2014, the U.S. Food and Drug Administration published a "final rule" that sets the standards for presenting information about using medicines during pregnancy and breastfeeding in the labels of prescription drugs and biological products.

The "final rule" replaces the current product letter categories – A, B, C, D and X – used to classify the risks of using prescription drugs during pregnancy with three subsections titled "Pregnancy," "Lactation" and "Females and Males of Reproductive Potential" that provide details about use of the drug or biological product. The detailed subsections which would include a summary of the risks of using the drug during pregnancy and breastfeeding along with a discussion of the data supporting the summary and relevant information will help health care providers make prescribing and counseling decisions.

Furthermore, FDA has issued a "draft guidance for industry" which provides detailed description of how the labeling is to be formatted subsection-by-subsection to help the drug and biological product manufacturers comply with the new labeling content and format requirements.

FDA is confident that the new content along with the formatting requirements would provide a more consistent way to include the relevant information. The rule finalizes many of the provisions in the proposed rule that the FDA issued in May 2008, and will be in effect as of June 30, 2015.

By Zainab Syed Ahmed

[Source: http://www.fda.gov/default.htm]

Immunotherapy can be the Ray of Hope in Curing Alzheimer's disease

In the recent and modernized era of medical and healthcare sector, the treatment of Alzheimer's disease still remains a challenge. Alzheimer's disease is a common form of dementia occurring with age due to accumulation of beta amyloid protein in brain which forms plaques and leads to detrimental effects on many mental functions like memory, thinking and behaviour. Immunotherapy can be used to trigger the brain's natural defense mechanism to clear the plaques and to develop vaccines.

The immunotherapy consists of both active and passive vaccination. The active vaccine involves introducing peptides like CAD106, ACC001, and Affitope to cause release of antibodies. The passive vaccine involves direct introduction of antibodies like olanezumab, gantenerumab, and crenezumab that are manufactured in vitro. Reasearchers at the University of Cardiff have shown that the antibody 2B12 can prevent the production of beta amyloid in cultured cells grown in the laboratory. They are confident that 2B12 can offer a new approach in immunotherapy for the treatment of Alzheimer's disease. Currently all these vaccines are under different phases of clinical trials. However, immunotherapy has side-effects like inflammation of brain cells that must not be ignored. Advanced research on immunotherapy for the treatment and prophylaxis of Alzheimer's disease is in progress and success in it can be a huge break-through in the field of healthcare sector.

By Nausheen Syeara

[Source: http://www.alzheimers.org.uk/]

Hypertension and latest drugs prescribed

Hypertension, also referred to as high blood pressure, is a condition in which there is a persistent elevated blood pressure. It is a particularly risky condition, both because it often occurs without symptoms and because it is a leading risk-factor for other severe conditions and events including heart attack, stroke, kidney disease and heart failure. Researchers from UC Davis reported in the Journal of the American Academy of Neurology that high blood pressure in a middle aged individual may raise the risk of cognitive decline later in life. Patients with diabetes or kidney diseases are at very high risk to develop hypertension. Anybody can take a few drugs for a few months, but people suffering from hypertension have to be on drugs indefinitely. US Food and Drug Administration approved Caduet, a tablet containing Norvasc (amlodipine), for treating high blood pressure. Other agents include oral renin-inhibitors, a novel class of medications that target an enzyme released by the kidneys that can affect blood pressure. Of these, the first that is expected to be released is Aliskiren, a drug made by Novartis. Some commonly drugs prescribed to patients suffering from hypertension are Vasotec (generic name: enalapril), Maxzide (generic name: hydrochlorothiazide/triamterene), Benicar (generic name: olmesartan), Lasix (generic name: furosemide), Tenormin (generic name: atenolol). These drugs have very high ratings which indicate their work is successful to a greater extent compared to others.

By Raihanatul Anwar

[Source: http://www.webcrawler.com]

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