BRAC UNIVERSITY
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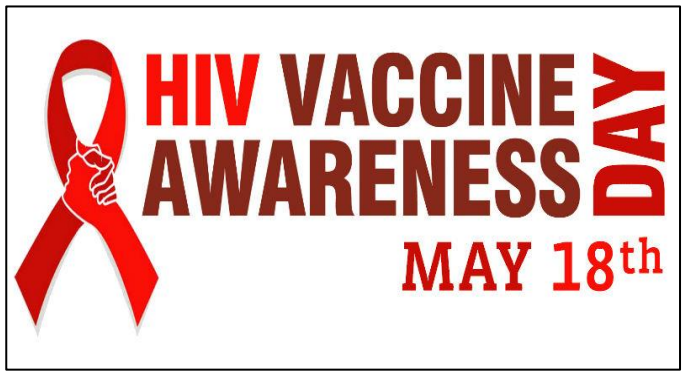
Department of Pharmacy

PHARMA HIGHLIGHTS

ISSUE 68 | MAY 2020

World AIDS Vaccine Day



Since 1998, 18th May has been celebrated as World AIDS Vaccine Day to commemorate the anniversary of Bill Clinton's speech in which he set new goals of developing an AIDS vaccine within the next decade. However, a matter of great regret is that about 35 million people worldwide are now infected with HIV and a vaccine is still not available. World-wide, AIDS is the the sixth leading cause of death overall and till date there is no human example of naturally curing an HIV infection. Fortunately, treatment known as antiretroviral therapy now exists. But in low and middle-income countries, only 10 million people living with HIV have access to this treatment.

While there is no licensed vaccine against HIV or AIDS, scientists are getting closer than ever before to developing an effective vaccine against HIV. Development of a safe, effective and preventive HIV vaccine remains key to realizing a durable end to the HIV/AIDS pandemic. Numerous investigative vaccines are at different stages of development. The challenge is that HIV mutates rapidly and has unique way to invade the immune system.

Results from the landmark RV144 clinical trial in Thailand, reported in 2009, provided the first signal of HIV vaccine efficacy, a 31% reduction in HIV infection among vaccine. RV144 evaluated the safety and efficacy of a prime boost combination of two vaccine components given in sequence; one using a harmless virus as a vector or carrier to deliver HIV genes and a second containing a protein found on the HIV surface. Broadly neutralizing antibodies or bNAbs, can stop many HIV strains from infecting human cells in the laboratory. A minority people living with HIV naturally produces bNAbs, but usually too late to overcome the virus. Researchers have isolated bNAbs from the blood of people living with HIV and are studying them in detail in an effort to design novel vaccine candidates.

With the contributions of the researchers, volunteers and pharmacists we can be hopeful that in near future we could be getting a budget-friendly effective HIV vaccine.

Written by: Nusrat Jahan (2nd Year 1st Semester)

Beximco Pharmaceticals Ltd. Introduces World's First Generic Remdesivir

Beximco Pharmaceuticals Ltd. recently announced the launch of Bemsivir (Remdesivir), an antiviral drug which has recently been given Emergency Use Authorisation by the US FDA for the treatment of COVID-19 patients. It is the first drug to be found effective in stopping the replication of the SARS-CoV-2, the virus which has caused a worldwide pandemic and for which there is currently no vaccine. Following thorough evaluation, Beximco Pharma's Remdesivir IV Injection (under the brand name Bemsivir) was granted Emergency Use Authorization by the Directorate General of Drug Administration (DGDA) on 21 May 2020.

It was announced that Beximco Pharma will supply Bemsivir to Government designated hospitals free of cost to treat the severely ill COVID-19 patients. The drug will not to be available through retail pharmacies, in compliance with the directives from Bangladesh drug regulatory authorities. On the very first day of receiving regulatory approval, Beximco Pharma already donated large quantities of Remdesivir (Bemsivir) to Bangladesh Government to help patients suffering from the disease. Originally developed by Gilead Sciences, Remdesivir is a direct acting antiviral drug that inhibits viral RNA synthesis. Remdesivir is administered intravenously and is authorized for the treatment of hospitalized patients with severe COVID-19 disease. Recent clinical trials have shown evidence that Remdesivir helps severe COVID-19 patients recover faster. The emergency approvals will help broaden use of Remdesivir in hospitalized patients, especially in developing and least developed countries where access to breakthrough, advanced drugs remains a major challenge, aid Nazmul Hassan MP, Managing Director of Beximco Pharma.

Written by: Nashrah Mustafa (TA)

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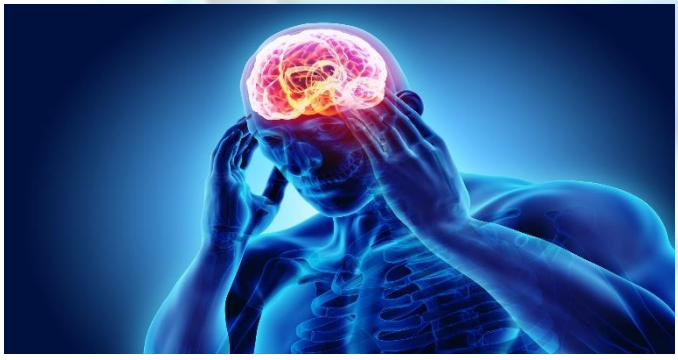
FDA Approves the First Treatment for Neurofibromatosis 1

In a major breakthrough, the Food and Drug Administration (FDA) has approved a treatment for a genetic disorder called neurofibromatosis type one (NF1). The disease impacts more than 2.5 million people and can cause a type of tumor growth on nerves called plexiform neurofibromas, which can be incapacitating and painful. The drug, Koselugo (selumetinib) is the first treatment for NF1, and is intended for use in patients who have been tested for the disease at the National Cancer Institute (NCI), a part of the National Institutes of Health (NIH). The FDA granted approval of Koselugo to AstraZeneca Pharmaceuticals LP. Clinical trials that assessed the efficacy of the drug showed that in more than 70 percent of patients with inoperable plexiform neurofibromas, Koselugo reduced tumor size by 20 to 60 percent. There was a visual reduction in tumor size, and pain was lessened in patients, who also reported greater mobility, better physical function, and improved quality of life.

The drug is an MEK inhibitor; it targets a biochemical signaling pathway in cells called Ras/Raf/MEK/ERK, which is involved in the survival and growth of cells. MEK inhibitors have been studied as potential cancer therapeutics, and it was found that they could dramatically affect the size of NF1 tumors. Kosulego can cause common side effects like nausea, vomiting and diarrhoea, but can also cause more serious side effects including heart failure and ocular toxicity. Therefore, it is advised that patients in need of this drug have cardiac and ophthalmic assessments performed before and during treatment. Based on findings from animal studies, Koselugo may cause harm to a newborn baby when administered to a pregnant woman, and therefore does have an FDA warning to healthcare professionals to be cautious when administering the drug to females of reproductive age. There are other MEK inhibitors in clinical trials now so patients might have more treatment options in the near future.

Written by: Sabiha Akhter (TA)

Scientists Find Brain Center That 'Profoundly' Shuts Down Pain



Researchers at Duke University have found that a small group of cells in the brain may be able to regulate our sense of pain. Using mouse models, the cells were located in the amygdala. Somewhat unexpectedly, this brain center turns pain off, not on. The findings are a follow-up to earlier research investigating how neurons are activated by general anesthetics. In 2019, the same researchers found that general anesthesia promotes slow-wave sleep as it activates a specific subset of neurons in the central amygdala, known as CeAga neurons.

Using various technologies, the researchers tracked the pathways of neurons activated in mice after giving them a mild pain stimulus. In total, they found that at least 16 areas of the brain known to process sensory and emotional aspects of pain received inhibitory signals from the CeAga. Next, the researchers used a technology known as optogenetics, to activate the CeAga neurons. In doing so, they found they could turn off self-caring behaviours in mice when they feel uncomfortable, such as licking their paws. Reducing the activity of these neurons caused the mice to immediately revert to comfort-seeking behaviours. Furthermore, they found that low doses of anaesthetic drug ketamine, known to allow sensation but block pain, also activated the CeAga cells, and could not function without them. Now, the researchers intend to identify the gene responsible for this process, and thus a drug target, so may then develop treatments to relieve pain using this mechanism.

Written by: Nuzhat Zahin (TA)