BRAC UNIVERSITY
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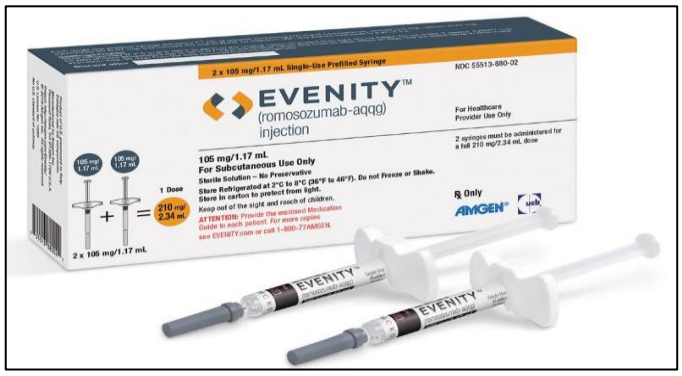
Department of Pharmacy

PHARMA HIGHLIGHTS

ISSUE 67 | APRIL 2020

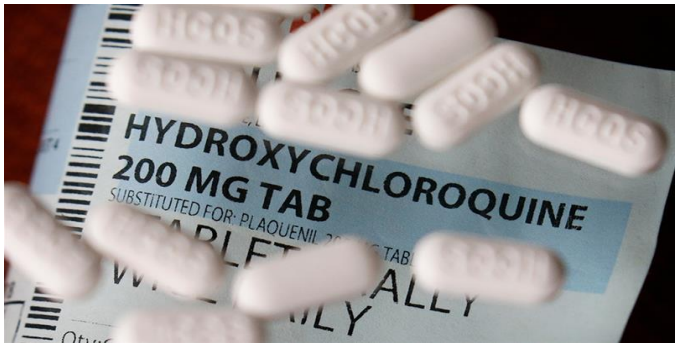
Dual-Acting Osteoporosis Therapy Development



Romosozumab, a new osteoporosis therapy with brand name Evenity which was approved by the FDA in April 2019. Romosozumab drug is an anti-sclerostin monoclonal antibody for the treatment of osteoporosis for example in the case of postmenopausal women who are at increased risk of fracture, its called dual-acting osteoporosis drug as it decreases bone resorption and increases bone formation. Researchers predict that by 2025 osteoporosis will be responsible for approximately three million fractures, a disease defined by low bone mass and reduction of bone tissue, which can lead to increased risk of fracture. Sometimes known as the "silent thief", as it can progress over many years without presenting any symptoms until the first devastating fracture. Since 1995 drug therapy for this condition was only limited to antiresorptive agents to slow down born loss but in 2002 anabolic medication become popular for acting to increase bone formation by stimulating the cell that builds the bone. However, these anabolic medications did not solve the problem completely that prompted the scientist to find an alternative hence forthcoming up with Romosozumab drugs as a new therapy. Romosozumab has shown very promising results in stimulating bone formation by binding and inhibiting the activity of the protein sclerostin and, hence, has a dual effect of both increasing bone formation and decreasing bone resorption. Romosozumab drug went in two clinical trials involving a total of more than 11,000 women with postmenopausal osteoporosis to test its efficacy and safety and the following results were got, In the first trial, one year of treatment with Romosozumab lowered the risk for new vertebral fracture by 73% compared with placebo. This benefit was maintained over the second year of the trial when Romosozumab was followed by one year of Denosumab compared with placebo followed by Denosumab. In the second trial, one year of treatment with Romosozumab followed by one year of alendronate reduced the risk for a new vertebral fracture by 50% compared to the second year of alendronate alone.

Written by: Namanda Fred (4th Year 1st Semester)

Hydroxychloroquine: The Controversial Use



COVID-19 was officially declared a public health threat on January 30th. Approved FDA treatments are still non-existent. But, the anti-malarial drug, hydroxychloroquine grew as a potential therapeutic for pneumonia caused by COVID-19. However, a brief report published in JAMA Cardiology warns of the use of hydroxychloroquine as recent evidence suggest it places COVID-19 patients at risk for increased risk of electrical changes to the heart and cardiac arrhythmias. In fact, combining hydroxychloroquine use with another antibiotic called azithromycin elevates the risk even more.

"While hydroxychloroquine and azithromycin are generally well-tolerated medications, increased usage in the context of COVID-19 will likely increase the frequency of adverse drug events (ADEs)," said co-first author Nicholas J. Mercuro, PharmD, a pharmacy specialist in infectious diseases at BIDMC.

The use of hydroxychloroquine and azithromycin can disrupt the electrical environment of the heart leading to cardiac arrhythmias and that results into the likelihood of cardiac arrest, stroke or death. In a study, patients who were hospitalized and receiving hydroxychloroquine for COVID-19 frequently experienced QTc prolongation and adverse drug events. One participant taking the drug combination experienced a potentially lethal tachycardia called torsades de pointes, which to our knowledge has yet to be reported elsewhere in the peer-reviewed COVID-19 literature.

The Food and Drug Administration has also cautioned against prescribing hydroxychloroquine to COVID-19 patients outside of hospital settings or clinical trials.

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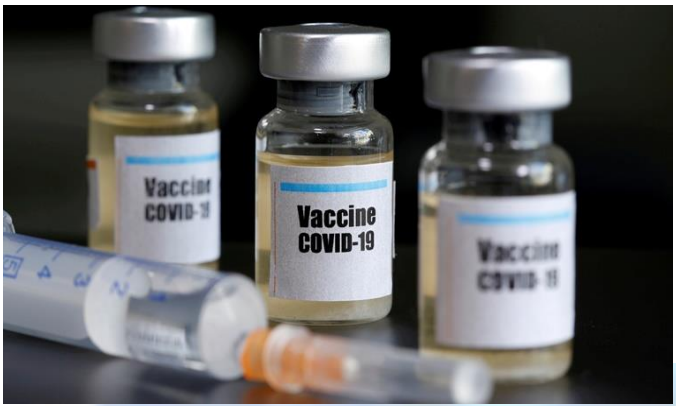
New COVID-19 Vaccine Defends Monkeys Against Infection



Researchers from Beijing-based Sinovac Biotech have reported their preliminary findings from a study on the development of a vaccine against COVID-19. This is some of the first evidence of a vaccine showing efficacy in a primate experimental model and provides hope for a global community anxiously awaiting countermeasures against the escalating pandemic. Experts estimate that a clinically-available vaccine against SARS-CoV-2 could take 18 months or longer to develop, even at the current accelerated pace. A new vaccine needs to be thoroughly tested for safety and efficacy in animals and humans prior to any commercialization.

In Sinovac's study, the vaccine testing protocol involved two doses of inactivated SARS-CoV-2, administered to a cohort of eight rhesus monkeys. The animals were allowed to develop a natural immune response to the inactivated virus over the course of three weeks. They were then exposed to live, unadulterated SARS-CoV-2 to test the protective capabilities of the vaccine treatment.

Encouragingly, none of the monkeys experienced the symptoms of severe infection, nor had any unwanted side-effects as a result of the shot. Meanwhile, the control animals developed pneumonia and high levels of circulating virus as a result of exposure to the coronavirus.

While promising, experts warn that preclinical validation of a new vaccine will involve much more work including larger testing cohorts to provide statistical significance and testing protection against viral strains that specifically infect humans and escape variant strains.

Sinovac has already launched phase I human trials of its vaccine in China to evaluate the safety and degree of protection in over 100 volunteers. If these clinical trials go as planned, phase II studies will kick off in mid-May in a larger group of over 1,000 individuals.

Written by: Rakhi Chowdhury (TA)

Even Minimal Exercise Can Reduce Breast Cancer Recurrence

New research urges individuals at high-risk of breast cancer to get moving, and start exercising. According to a study published recently in the Journal of the National Cancer Institute, even minimal exercise can have a significant impact on helping patients stay cancer-free after treatment. The comprehensive analysis is a result of a clinical trial run by SWOG Cancer Research Network, a cancer clinical trials network funded by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH).

"Aiming for as little as two and half hours a week of exercise which is the minimum under federal guidelines, can have a big impact for women with high-risk breast cancer," said study lead Rikki Cannioto, Ph.D., EdD.

Not only does physical activity extend lives, but the study revealed that patients who met the minimum federal exercise guidelines before and after treatment, showed a 55% decrease in risk of cancer relapse. Exercising also reduced the risk of death by 68%. The study also showed that you don't have to have been exercising before treatment to get these beneficial outcomes. Even patients who started exercising only after treatment still showed a 46% decreased chance of recurrence and a 43% decreased chance of mortality. Based on their findings, the researchers recommend that cancer-treatment protocols involve guidelines about getting sufficient physical activity, stating that these associations suggest that even minimal exercise is associated with statistically significantly reduced hazards of recurrence and mortality among breast cancer patients, to help women with high-risk breast cancer live longer and healthier lives.

Written by: Syeda Fahria Hoque Mimmi (TA)