

PHARMA HIGHLIGHTS

Novel Recombinant Adenovirus type-5 Ebola Vaccine Passes Phase-1 of Clinical Trial

Earlier this month, *Lancet* published a paper on a double-blind, placebo-controlled study conducted in China, where 120 healthy adults ranging from 18-60 years of age were randomly enrolled and assigned to receive placebo, low dose vaccine, or high-dose adenovirus type-5 vector-based Ebola vaccine.

Antibody levels specific to the glycoprotein were elevated by day 14 and continued to rise by day 28 in both low- and high-dose groups. There were no serious adverse events. Although, mild pain at the site of injection was experienced by all the 3 groups on day 7 and mild fever observed in 18% of all the patients, the adverse effects are not specific to the

high-dose group. This implies that a high-dose vaccine can be safely administered to the Ebola patients to produce a high immunogenic response in the patients without causing major adverse effects.

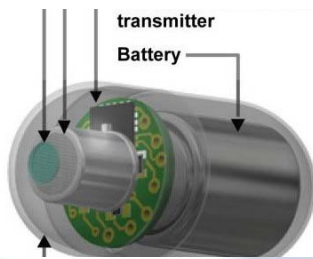
The team now waits for the next phase 2 of the clinical trial which will be conducted in the affected area of Ebola outbreak.

Zainab Syed Ahmed [Source: <http://click.jwatch.org>]



Wireless Diagnosis of Stomach Diseases Possible with Swallowable Gas Capsules.

The way technology advances and becomes integrated part of human life is known to all but when technology sets its foot in the field of healthcare, it can result in outcomes that is beyond imagination. Such an example is the development of a high-tech capsule which can be swallowed to determine the reason of various gastrointestinal diseases. The researchers elaborated that there are microbes present in intestine that release various gases while carrying out metabolism, for example, sulfate reducing bacteria release the acidic and unpleasant smelling hydrogen sulfide gas, while some release methane. These



gases are found to play important role in developing gastrointestinal diseases, like irritable bowel syndrome, bowel inflammatory conditions and even colon cancer and thus can be used as biomarkers for diagnosis of such diseases. The researchers of RMIT University used this concept to make swallowable capsule that can determine the composition of these intestinal gases and hence can diagnose the occurrence of gastrointestinal diseases. The capsule consists of protective plastic shell, a gas-permeable membrane window, a gas sensor, a microprocessor and wireless transmitter to process and transfer the data, and a miniature battery. So it can detect the amount and mixture of gases before passing out of the body, unlike breath analysis. The technique is non-invasive, rapid and cost effective; further research is being carried out regarding on its implementation and to make use of it to design diet or drug therapy for gastrointestinal diseases.

Nausheen Sayeera [Source: <http://health-innovations.org>]

Drinking Six Cups of Raw Tea per Day Leads to a Healthier Heart

All four types of tea known as true teas—white, green, oolong, and black—offer a myriad of health benefits. Most studies show that black and green teas are the heart-health leaders. Each tea type is made from the leaves of the evergreen shrub *Camellia sinensis*, but the differences between them are due to the ways in which they are processed into individual varieties. According to *Food and Function*, data published in 2012, black and green tea may reduce the risk of coronary heart disease and stroke by 10% to 20%. One of the largest studies on the impact of tea drinking on cardiac health was published in *Arteriosclerosis, Thrombosis and Vascular Biology*.

The study followed more than 37,000 people in the Netherlands for 13 years and found that people who drink plenty of tea are less likely to die of heart disease than people who don't drink tea. Study participants who drank three to six cups of tea per day were 45% less likely to die from heart disease than those who drank less than one cup, and drinking more than six cups of tea per day was associated with a 36% lower risk of developing heart disease than drinking less than one cup. The July 2012 issue of *Pharmacological Reports* showed that the powerful antioxidants in green tea, particularly EGCG (epigallocatechin-3-gallate) may help prevent atherosclerosis, specifically coronary artery disease, because of their anti-inflammatory effects on plaque buildup in the bloodstream and arterial walls which can lead to heart disease and stroke. A 2012 study published in *Preventive Medicine* found that drinking three cups of black tea per day for 12 weeks led to significant reductions in blood sugar levels and triglycerides, an increase in HDL cholesterol levels, and increased blood levels of antioxidants which can protect against oxidative stress and inflammation. Rooibos or red tea made from the South African plant *Aspalathus linearis*, has been shown to have heart benefits, exemplified in a 2011 study where volunteers drank six cups of rooibos tea per day for six weeks and experienced reduced LDL cholesterol and significantly increased HDL cholesterol, both



associated with a lower risk of developing cardiovascular disease.

- Pritesh Ranjan Dash [Source: <http://pubs.rsc.org/en/content/articlelanding/2012/fo/c2fo30075c#!divAbstract>]

What Is the Biological Basis for Statin-Induced Type 2 Diabetes?

Increased production of LDL cholesterol receptor is probably the answer. Chronic statin use increases risk for developing type 2 diabetes mellitus by about 9%. A Dutch team wondered why and reasoned that the answer might involve differential production of the LDL cholesterol receptor:

- Statins therapy results in increased production of the LDL cholesterol receptor.
- Patients with familial hypercholesterolemia have *low* incidence of type 2 diabetes mellitus.
- The central lesion in familial hypercholesterolemia is genetically determined *low* production of the LDL cholesterol receptor.
- The investigators reasoned that if *low* production of the LDL cholesterol receptor in familial hypercholesterolemia is what confers *low* risk for diabetes, and statins *increase* production of the LDL cholesterol receptor, then perhaps this increase is what explains excess risk for diabetes in people who take statins.

To test this hypothesis, the investigators first had to establish that underproduction of the LDL cholesterol

receptor in familial hypercholesterolemia was linked to low risk for type 2 diabetes. The team performed DNA testing in >25,000 people with familial hypercholesterolemia and in >38,000 relatives who did not have this condition. After adjusting for many diabetes risk factors, the team confirmed that patients with familial hypercholesterolemia had considerably lowered risk for developing diabetes (odds ratio, 0.45). Moreover, mutations that most powerfully attenuated production of the LDL cholesterol receptor were associated with lowest risk for diabetes. The strength of this study are its huge size and the comparison of risk among two genetically related groups (patients with, and relatives without, mutations that caused familial hypercholesterolemia) — a random “genetic lottery” of cholesterol mutations that limit the chances for unidentified confounding factors. The authors speculate, based on a few laboratory studies, that augmented uptake of cholesterol (caused by statins) in pancreatic β cells lowers insulin production. This interesting result should not discourage use of statins. Many studies demonstrate that benefits of statins exceed risks when prescribed appropriately.

[Source: JAMA. March 2015]

New Drugs That Could Reduce Cardiac Complications in Half

Repatha, made by Amgen and Praluent, under development by Sanofi and Regeneron, both cut cholesterol levels by more than 60 percent in studies published in the New England Journal of Medicine. The trials also showed patients getting the injected drugs were half as likely to die or suffer a major cardiac complication, such as a heart attack, stroke or chest pain, after just a year to 18 months of treatment. While the findings aren't definitive, the positive results will make it easier for regulators to approve the drugs based on their cholesterol-lowering ability alone, said Steve Nissen, chief of cardiology at the Cleveland Clinic in Ohio, who wasn't involved in the research. The results will also pressure insurance companies to pay for the treatments, which analysts expect to generate more than \$2 billion a year in sales at their peak. The Praluent study, funded by Sanofi and



Regeneron, found the drug slashed bad cholesterol (LDL) by 62 percent and lowered heart risks, including stroke and death from cardiovascular disease, by 48 percent. The patients were already on the maximum tolerated dose of statins and started the trial with LDL cholesterol of 70 milligrams per deciliter or more. While Praluent is delivered as an injection, which makes it less convenient than oral pills like Lipitor, Sanofi and Regeneron, patients can use the injections at home. The medications are the first of a new class called PCSK9 inhibitors that can lower cholesterol levels when treatment with statins such as Pfizer Inc.'s Lipitor aren't enough to get patients into a healthy range. Analysts expect the drug by Regeneron and Sanofi to reach the market first this year, with an FDA decision by July, followed by Amgen's treatment in August. Pfizer also has a drug in early stages of development. [Source: www.bloomberg.com]

A New Drug Glyxambi (Empagliflozin and Linagliptin) for Type 2 Diabetes!

Approximately 29 million Americans and an estimated 387 million people worldwide have type 1 or type 2 diabetes, and nearly 28 percent of Americans with diabetes—totaling 8 million people—are undiagnosed. In order to treat this disastrous disease recently the U.S. Food and Drug Administration (FDA) has approved another new drug Glyxambi (empagliflozin/ linagliptin) tablets, from Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) when both empagliflozin and linagliptin are appropriate treatments.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies, headquartered in Ingelheim, Germany and Lilly has been a global leader in

diabetes care since 1923. In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. This alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs.

Glyxambi is a prescription medicine that contains 2 diabetes medicines, empagliflozin and linagliptin. Glyxambi can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes when treatment with both empagliflozin and linagliptin is appropriate. Although not approved for lowering weight.

-Fabiha Tasnim

[Source: <http://www.drugs.com>]