HIV vaccine study approved

Scientists are able to begin the enrollment of HIV-positive individuals to a study that will investigate the therapeutic potential of a HIV vaccine.

The first trial of its kind has been designed to investigate a vaccine in individuals with HIV, and has now received approval to proceed. This permits the recruitment of participants for the trial.

The vaccine is a promising HIV vaccine candidate produced by GeoVax Inc. (Smyrna, GA, USA). Current studies are looking at the vaccine for HIV prevention, whereas this new study will investigate the vaccine for the treatment of individuals who already have infection with HIV.

The study, expected to last up to 77 weeks, will be run by the AIDS Research Consortium of Atlanta (ARCA), which is a not for profit clinical research, testing, outreach and educational organization founded in 1988. ARCA has also contributed key scientific information leading to the US FDA approval of more than 27 individual and combination drugs now available for people with HIV/AIDS worldwide.

"ARCA is pleased to be conducting this important clinical trial," said Melanie Thompson, Principal Investigator for ARCA. "New approaches to HIV treatment are critically needed, and an effective therapeutic vaccine would be an important tool in our ongoing efforts to treat people with HIV infection. A vaccine that enhanced the body's ability to control HIV and delayed or decreased the dependence on anti-HIV drugs would be a major breakthrough for HIV treatment."

ARCA worked together with GeoVax to design the protocol for the Phase I clinical trial. The trial is based on the achievement of excellent postvaccine viral control in animal studies conducted in recently infected nonhuman primates at the Yerkes National Primate Research Center (Atlanta, GA, USA).

The eligibility criteria for the study are strict, as the investigators are looking for persons with a negative HIV test followed by a positive test up to 6 months later. Furthermore, they should have started antiviral therapy for HIV within 6 months of diagnosis.

Source: www.geovax.com

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Recruitment halted in EMPHASIS-HF trial as primary end point reached earlier than expected

Pfizer Inc. has announced that the Executive Steering Committee of the EMPHASIS-HF trial into the use of eplerenone (Inspra®) have recommended recruitment be halted earlier than expected, based on primary efficacy end points already being reached.

Eplerenone, currently indicated for the treatment of cardiac failure and hypertension in various countries, was undergoing investigation comparing its use with standard heart failure therapy to placebo with standard heart failure therapy. The trial was primarily concerned with mortality and morbidity outcomes in patients with mild chronic systolic heart failure and left ventricular systolic dysfunction.

The EMPHASIS-HF study was originally planned to enroll 3100 patients and continue until October 2011. The primary end point was set to evaluate the possible reduction in risk of cardiovascular death or heart failure hospitalization compared with those on the placebo arm of the trial where patients received standard of care in addition to a matching placebo, and the trial was intended to continue until a total of 813 adjudicated primary end point events were reported. However, an interim analysis by the independent Data Safety Monitoring Committee confirmed the end points were already reached and that the trial had met the predefined stopping criteria.

future medicine part of fsg

Professor Faiez Zannad, Inserm and University of Nancy, France, co-Chair of the Executive Steering Committee, commented: "It is not common for clinical studies to conclude early for reasons of efficacy. The EMPHASIS-HF trial had an estimated end date around October 2011 so to have met the predefined efficacy end points early is certainly a positive outcome."

Pfizer have announced they are keen to work closely with the Executive Steering Committee, Data Safety Monitoring Committee, and ethical and regulatory agencies to ensure those involved in the trial are informed and that the trial protocol can be amended accordingly. There will also be an open label follow-up extension to the trial for consenting patients after completion of the double-blind phase.

Source: http://media.pfizer.com/files/news/press_releases/2010/inspra_emphasis_trial_052710.pdf

Antiobesity drug application accepted by US FDA

The US FDA has accepted a new application, the first of its kind, for the investigational drug, Qnexa®, for the treatment of obesity.

The US FDA has accepted the VIVUS, Inc. (CA, USA) drug application for Qnexa® for treatment of obesity. The FDA aim to complete its review of the new drug application (NDA) for Qnexa by 28 October 2010. In critical Phase III clinical trials (previously announced by the corporation) patients treated with all three doses of Qnexa achieved considerable weight loss compared with placebo, and significant dose-related improvements across a wide variety of secondary end points including reductions in cardiovascular and inflammatory risk factors.

"...Qnexa ... will play an important role in treating the millions of patients living with obesity and related diseases."

VIVUS Inc. have high hopes for Qnexa. This oral-taken formulation of low dose phentermine and topiramate, it is hoped, will address both appetite and satiety – the two main mechanisms that impact eating behavior. To date, in Phase II and III clinical data, Qnexa has induced significant weight loss in patients, as well as improved individuals' glycemic control, reduced sleep apnea events and improved cardiovascular risk.

"The FDA's acceptance of the Qnexa NDA marks an important milestone in the development of Qnexa as a treatment for patients who are obese or overweight with co-morbidities," stated Leland F Wilson, Chief Executive Officer for VIVUS. "We believe that Qnexa, if approved, will play an important role in treating the millions of patients living with obesity and related diseases, and who are in need of safe and effective options."

Source: VIVUS, Inc. http://ir.vivus.com/releasedetail.cfm?ReleaseID=469346

Specially trained dogs detect prostate cancer derived compounds in urine

According to data presented at the 105th Annual Meeting of the American Urological Association in San Francisco (CA, USA) on the 1st June 2010, dogs have been trained to recognize the olfactory signatures of certain volatile organic compounds (VOCs) that are produced by prostate cancer cells and excreted in the urine.

Using clicker training methods (whereby a behavior is reinforced by sounding a clicker and rewarding the dog with a treat until the association is learned), the researchers trained dogs to sniff out these VOC signatures in urine samples. The dogs were able to correctly classify 63 out of 66 urine samples, 33 of which came from patients with biopsy-confirmed prostate cancer and 33 from healthy controls. The sensitivity and specificity were 100 and 91%, respectively, while the negative predictive value was 100%.

"These data suggest that prostate cancer tumors may excrete certain VOCs that turn up in a patient's urine and that this 'scent' may be specific to prostate cancer," claimed Anthony Smith, Chair of the American Urologic Association Public Media Committee. "What we need to do now is figure out what those VOCs are and whether or not we can develop a specific test to identify them. But, don't be surprised in a few years if we have to 'call in the dogs' to make a diagnosis – if it holds up, the dogs are better than PSA!"

Source: AUA press release Dogs trained to effectively sniff out prostate cancer http://www.auanet.org/content/press/press_releases/article.cfm?articleNo=201

EMA and US FDA approve Prolia® (denosumab) for the treatment of postmenopausal osteoporosis

Amgen Inc.'s Prolia® (denosumab) has been granted marketing authorization by the European Medicines Agency (EMA) and the US FDA for the treatment of postmenopausal osteoporosis in women at increased risk of fractures. It has also been approved by the EMA for the treatment of bone loss due to hormone ablation in prostate cancer patients at increased risk of fractures. In addition to the US and 27 EU member states, denosumab has also been approved in Iceland, Lichtenstein and Norway.

The approvals were based on six Phase III trials and results from the two pivotal studies demonstrated that denosumab reduced the incidence of fractures when given as a 60 mg subcutaneous injection every 6 months. The Fracture Reduction Evaluation of Denosumab in Osteoporosis Every Six Months (FREEDOM) trial involved 7808 women with postmenopausal osteoporosis and showed a 68% decrease in the relative risk of suffering a new vertebral fracture, a 40% decrease in the relative risk of suffering a hip fracture and a 20% decrease in the relative risk of suffering a nonvertebral fracture at 36 months, compared with placebo. Bone mineral density was also seen to increase in all six Phase III studies, at all skeletal sites tested.

Socrates E Papapoulos, Leiden University Medical Center, The Netherlands, comments: "Osteoporosis is a serious, chronic disease that can significantly impact the lives of millions of affected women. Despite widely available treatments, new options are still needed to help protect against fractures. By targeting RANK Ligand, Prolia offers an innovative new approach that helps reduce fracture risk."

Approximately 30% of all postmenopausal women in Europe suffer from osteoporosis and of those, more than 40% will suffer osteoporotic fractures. The dual approval of denosumab is a significant breakthrough in the treatment of this silent epidemic.

Source: http://wwwext.amgen.com/media/media_pr_detail.jsp?year=2010&releaseID=1432232

Red Heart polypill to be tested in new international Trial

Researchers in the UK as well as in Ireland and The Netherlands, are currently recruiting volunteers to test the efficacy of a new one-a-day 'polypill', which is expected to reduce the risk of cardiovascular events such as heart attacks and strokes. The new 'red heart pill' is a low-cost pill that contains low-dose aspirin, a statin and two blood-pressure lowering medicines. The trial called the Use of a Multidrug Pill in Reducing Cardiovascular Events (UMPIRE) is recruiting 2000 individuals who are at high risk of a heart attack or stroke or who have already experienced such a cardiovascular event.

Related trials have already commenced in New Zealand and Australia and further trials are planning to be conducted in Canada, Brazil, China and South Africa. These trials are expected to collectively recruit 7000 participants and also assess the efficacy of the polypill in reducing blood pressure and cholesterol.

Researchers will also investigate whether the polypill increases patient compliance in comparison with taking multiple tablets. If the red heart pill does improve patient compliance and the treatment strategy is effective then plans to establish the polypill as a treatment in countries such as India would be looked in to. In countries such as India where 80% of health care is paid out of pocket this combined pill could be a more cost-effective method of treating cardiovascular events in comparison to prescribing separate medications.

Trials in the UK are being conducted to determine whether the red heart pill is a more convenient alternative to taking multiple medications thus increasing patient compliance. Currently, medications such as statins and antihypertensives are prescribed individually; however, many people who start on such medications fail to take them in the long term.

Professor Simon Thom, the coprincipal investigator on the study from the National Heart and Lung Institute at Imperial College London, said: "The polypill idea is really simple: make it easier for people to get the medication they need by giving them just one polypill to take each day, rather than lots of different pills that may need to be taken at different times. It's likely that combining medications in one polypill could enable people in low-income countries to have easy access to cheap preventive medication."

"Polypills are being used successfully to treat other diseases like tuberculosis and HIV, but we don't yet know whether they could be effective in those with cardiovascular problems. The UMPIRE trial aims to test whether the polypill does help people take their cardiovascular medicines in the long term and whether there are any unintended problems with this approach," he added.

The UMPIRE trial is expected to last 2 years and results are eagerly awaited.

Source: http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/newssummary/news_17–15–2010–2011–47–27

Drug Approvals April 2010- June 2010.

Trade name	Generic name	Indication	Region	Manufacturer	Date approved
Immunology					
Vimovo™	Naproxen/ esomeprazole magnesium delayed-release tablets	Relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.	USA	Pozen	April 2010
Zortress®	Everolimus	Prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.	USA	Novartis	April 2010
Neurology					
Sprix™	Ketorolac tromethamine nasal spray	For short term (up to 5 days) management of moderate to moderately severe pain.	USA	Roxro Pharma	May 2010
Oncology					
Prolia™	Denosumab	For the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures.	EU	Amgen	May 2010
Provenge®	Sipuleucel-T	For the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.	USA	Dendreon Corporation	April 2010
Tarceva®	Erlotinib	Monotherapy maintenance treatment in patients with advanced non-small cell lung cancer whose disease remains largely unchanged (stable disease) after platinum-based initial chemotherapy.	EU	Roche	April 2010
Rheumatology					
Prolia™	Denosumab	For the treatment of postmenopausal women with osteoporosis at high risk for fracture.	USA & EU	Amgen	June 2010
Other					
Lumizyme™	Alglucosidase α	For patients 8 years and older with late (non-infantile) onset Pompe disease (GAA deficiency) who do not have evidence of cardiac hypertrophy.	USA	Genzyme	May 2010
Natazia™	Estradiol valerate and estradiol valerate/ dienogest	For use by women to prevent pregnancy.	USA	Bayer HealthCare	May 2010