Recent Pharma News

New 'smart' nanotherapeutics can deliver drugs directly to the pancreas

FRIDAY, 13 JANUARY 2012

A research collaboration between the Wyss Institute for Biologically Inspired Engineering at Harvard University and Children's Hospital Boston has developed "smart" injectable nanotherapeutics that can be programmed to selectively deliver drugs to the cells of the pancreas. Although this nanotechnology will need significant additional testing and development before being ready for clinical use, it could potentially improve treatment for Type I diabetes by increasing therapeutic efficacy and reducing side effects.

The approach was found to increase drug efficacy by 200-fold in *in vitro* studies based on the ability of these nanomaterials to both protect the drug from degradation and concentrate it at key target sites, such as regions of the pancreas that contain the insulin-producing cells. The dramatic increase in efficacy also means that much smaller amounts of drugs would be needed for treatment, opening the possibility of significantly reduced toxic side effects, as well as lower treatment costs.

Using nanoparticles that can be programmed to deliver drug or stem cell therapies to specific disease sites is an excellent alternative to systemic treatments because improved responses can be obtained with significantly lower therapeutic doses and hence, fewer side effects. To date, such nanotherapeutics have been developed primarily to treat cancer, since they can home in on the tumor via its leaky blood vessels.

Chemotherapy may influence leukemia relapse

THURSDAY, 12 JANUARY 2012

The chemotherapy drugs required to push a common form of adult leukemia into remission may contribute to DNA damage that can lead to a relapse of the disease in some patients, findings of a new study suggest. The research, by a team of physicians and scientists at Washington University School of Medicine in St. Louis, is published Jan. 11 in the advance online edition of Nature. Results of the new research provide evidence for a theory that scientists have long held: Chemotherapy contributes to relapse in cancer patients by damaging DNA and generating new mutations that allow tumor cells to evolve and become resistant to treatment.

Chemotherapy is known to damage the DNA of both cancer cells and healthy cells. But until now, scientists have had little direct evidence to suggest that chemotherapy itself helps shape the evolution of cancer cells and may contribute to disease recurrence. The researchers suspect this phenomenon is not unique to AML and may occur in other cancers as well.

The researchers found that the relapsed cancer cells did not contain a large number of new mutations, as some had predicted. In fact, while the relapsed cells in all the patients had gained some mutations, the percentage was relatively small compared to the number of mutations in the primary tumor.

The scientists also discovered a type of mutation in the relapsed cells that is associated with DNA damage. The frequency of these alterations, known as transversions, was significantly higher for relapse-specific mutations (46 percent) than for primary-tumor mutations (31 percent), suggesting that the chemotherapy may have contributed to some of these mutations, the researchers report. Transversions are also more commonly found in the tumor cells of lung cancer patients who smoke.

FDA alerts pharmacists and health care professionals to potential for injury when dispensing the similar-sounding drugs Durezol and Durasal

WEDNESDAY, 28 DECEMBER 2011

FDA is alerting pharmacists and other health care professionals of potential injury due to confusion between the FDA-approved eye medicine Durezol (difluprednate ophthalmic emulsion) 0.05% and the unapproved prescription topical wart remover *Durasal* (salicylic acid) 26%.

There has been one report of serious injury when a pharmacist mistakenly gave an eye surgery patient *Durasal*, the salicylic acid–containing wart remover, instead of the prescribed Durezol eye drops. Durezol is approved for treatment of inflammation and pain association with ocular surgery.

Several other cases were reported arising from confusion between Durezol and *Durasal*. In some cases, the error was discovered prior to the medication reaching the patient. There were also complaints received from health care practitioners concerning the similarity between the names Durezol and *Durasal*.

Due to the potential for confusion between these two products, pharmacists should be vigilant when filling prescriptions for the ophthalmic solution Durezol.

The FDA, as part of the drug approval process, screens proprietary names for similarities to the names of other products currently on the market; however, *Durasal* (salicylic acid) is an unapproved product that did not undergo FDA's drug approval process. The agency, therefore, was not able to evaluate *Durasal* for potential name confusion prior to the product being marketed. Additionally, *Durasal* (salicylic acid) entered the market shortly after FDA approved Durezol.

Elorac, Inc., the distributor of the unapproved product *Durasal*, has to date not responded to FDA's inquiry into removing the product from the market place. To date, Elorac has also not recalled the product in response to FDA's inquiry regarding the risk to patients.

Health care professionals and patients are encouraged to scrutinize packaging and labeling information carefully and to report any potential for confusion arising from similar drug names to the FDA's MedWatch Safety Information and Adverse Event Reporting program. In this context, any side effects associated with the use of Durezol or *Durasal* should be especially noted and reported.

Benefits of statin therapy may extend beyond lowering lipids

WEDNESDAY, 4 JANUARY 2012

People with high cholesterol are at risk of heart attack and stroke because atherosclerotic plaques within their arteries can rupture triggering the formation of a blood clot called an occlusive thrombus that cuts off the blood supply to their heart or brain.

For years, scientists have studied the cause of this abnormal clotting. Now, a study led by researchers from the University of North Carolina at Chapel Hill School of Medicine has identified a molecular pathway that leads to this abnormal blood clotting. The researchers then turned off the pathway by using a popular class of cholesterol-lowering drugs, statins.

The research was performed using humans, monkeys and mice with highly elevated blood lipid levels. It indicated that elevated levels of oxidized low density lipoprotein (LDL) induces a molecule called "tissue factor" that triggers clotting. The study appears online in the January 3, 2012 issue of the *Journal of Clinical Investigation.*

"Statins have been shown to have antithrombotic activity in several previous studies. However, I believe our study is the first to elucidate how statins reduce the activation of the blood clotting process independently of their lipid lowering activity, said senior study author Nigel Mackman, PhD, FAHA. Mackman is the John C. Parker Distinguished Professor of Hematology in the Department of Medicine and Director of the UNC McAllister Heart Institute.

Pfizer receives FDA approval to extend use of Prevnar 13® for prevention of pneumococcal pneumonia and invasive disease in adults 50 years and older

FRIDAY, 30 DECEMBER 2011

Pfizer announced that the U.S. Food and Drug Administration (FDA) has granted approval of the Company's pneumococcal conjugate vaccine Prevnar 13®* (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) as a single dose for use in adults. Prevnar 13 is indicated for adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes contained in the vaccine.

"As adults grow older they become more susceptible to infectious diseases, such as pneumococcal pneumonia, due to their aging immune systems"

"Pneumococcal disease, including pneumonia, in adults 50 years and older represents a significant personal and societal health burden in the United States. The FDA approval of Prevnar 13 for these adults offers the potential to contribute to the health of millions of aging Americans," said Ian Read, chairman and chief executive officer, Pfizer Inc. "This approval is representative of Pfizer's dedication to discovering and bringing to market life-changing medicines and vaccines."

New Drugs Approved

The following drugs have recently been approved by the FDA. Includes newly approved drugs and new indications for drugs already approved

Subsys (fentanyl) Sublingual Spray - formerly Fentanyl SL Spray

Company: INSYS Therapeutics, Inc.

Date of Approval: January 4, 2012

Treatment for: Pain

Subsys (fentanyl) is an opioid analgesic sublingual spray formulation indicated for the treatment of breakthrough cancer pain.

Edarbyclor (azilsartan medoxomil and chlorthalidone) Tablets

Company: Takeda Pharmaceutical Company Limited

Date of Approval: December 20, 2011

Treatment for: **Hypertension**

Edarbyclor (azilsartan medoxomil and chlorthalidone) is a fixed-dose combination of an angiotensin II receptor blocker (ARB) and a diuretic, indicated for the treatment of hypertension.

Source: Drugs.com & worldpharmanews.com

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Anturol (oxybutynin) Gel

Company: Antares Pharma, Inc.

Date of Approval: December 7, 2011

Treatment for: **Overactive Bladder**

Anturol (oxybutynin) is an anticholinergic transdermal gel formulation indicated for the management of overactive bladder.

Intermezzo (zolpidem tartrate) Sublingual Tablets

Company: Transcept Pharmaceuticals, Inc.

Date of Approval: November 23, 2011

Treatment for: **Insomnia**

Intermezzo is a low dose, fast acting, sublingual formulation of the hypnotic agent zolpidem, indicated for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.