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Industry News

US FDA Advises Caution on Baxter's Multiple-dose Vial Heparin

Baxter Healthcare Corporation has temporarily stopped manufacturing multiple-dose vials of the injectable blood-thinning drug heparin due to reports of serious allergic reactions and hypotension in patients who receive high bolus doses of the drug.

Adverse events have not been seen in other uses of heparin involving lower doses or administration over a longer period of time. Healthcare providers are advised to use an alternate source of heparin or other bloodthinning drug when possible.

When only Baxter product is available:

• Administer the heparin as an infusion rather than a bolus;

• Use the lowest dose necessary at the slowest infusion rate acceptable to obtain the desired clinical effect;

• Closely monitor the patient for adverse events, particularly hypotension and signs and symptoms of hypersensitivity and ensure that resuscitation equipment is available, and

• Consider pre-treatment with corticosteroids though it is unclear if this is effective.

Avista Capital Gains FDA Exclusivity Extension for Cardiolite

The FDA has granted paediatric exclusivity for studies conducted on Cardiolite (kit for the preparation of technetium Tc99m sestamibi for injection). This grant extends the marketing exclusivity of Cardiolite for an additional six months beyond patent expiration, the company said.

St Jude Medical Announces Renewal of Purchase Agreements

St. Jude Medical has renewed its product agreements with HealthTrust Purchasing Group. The renewal will extend through December 2010 and covers all existing purchasing agreements, including St. Jude Medical's complete line of cardiac rhythm management, atrial fibrillation, cardiac surgery and cardiology products.

Pfizer to Cancel 'Misleading' US Ad Campaign

Pfizer has announced the cancellation of its widely-known US ad campaign which features artificial heart pioneer Robert Jarvik as a spokesman for its cholesterol drug Lipitor. The campaign had come under scrutiny from a Congressional committee examining consumer drug advertising that asked if the ads misrepresented Dr. Jarvik and his credentials. Although he has a medical degree, Dr. Jarvik is not a cardiologist and is not licensed to practice medicine.

Pfizer's Sutent Under Scrutiny

US researchers at the Stanford University School of Medicine in California have found that 15% of patients who took Sutent, a pill used to treat kidney and stomach cancers, developed heart failure.

Sutent, made under the generic name 'sunitinib' by Pfizer, has also been shown to damage heart cells. While heart failure is serious, it can be treated with a variety of drugs. When caused by drugs, stopping the medication usually clears up the problem. Sutent works by starving tumours - it stops them from growing blood vessels to feed themselves. It is being widely tested for the treatment of several other cancers.

BR-102 Plus Validated by British Hypertension Society

The SCHILLER BR-102 plus noninvasive ambulatory blood pressure monitor was validated according to the International Protocol for validation of blood pressure measuring devices in adults introduced by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension.

The conclusion of the protocol states that the obtained results presented in tables and graphics satisfy the requirements of the international protocol. The accurate readings of systolic and diastolic blood pressure when operating either in auscultatory or in oscillometric modes during the evaluation procedure enable SCHILLER BR-102 plus to be recommended for ambulatory blood pressure measurement in clinical practice.

Cardiovascular Systems, Inc. Files Registration Statement for IPO

Cardiovascular Systems, Inc. Has filed a registration statement for a proposed initial public offering (IPO) of its common stock. The number of shares to be offered and the price range for the offering have not been determined. The offering will be made only by means of a prospectus.

EVICEL™ Fibrin Sealant Approved For General Haemostasis In Surgery

ETHICON has announced that the US FDA has granted an expanded indication for EVICEL ™ Fibrin Sealant (Human). The product is the first fibrin sealant to be indicated as an adjunct to haemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or impractical.

EVICEL™ is the only all-human plasma-derived fibrin sealant commercially available in the US.

Medtronic Foundation Funds US School Programmes

The Medtronic Foundation announced new grant guidelines for its HeartRescue programme, allocating funding priority to school programmes that educate students about sudden cardiac arrest and prepare them to act in an emergency.

To increase the number of bystanders trained in CPR and AED use, the 2008 HeartRescue programme will focus US grants on schools, school districts, government agencies, and non-profit organisations that develop comprehensive school-based programmes to prepare people to recognise SCA and take action.

Guidelines for Canada and Europe will also include schoolbased initiatives, as well as funding first responder and public access defibrillation efforts, to meet the different needs of each country.

CeloNova BioSciences Introduces New Coronary Stent

CeloNova BioSciences has announced results from the ATLANTA study of the CATANIA(TM) Coronary Stent System with NanoThin Polyzene(R)-F at the 20th Annual International Symposium on Endovascular Therapy (ISET). Dr. Corrado Tamburino, principal investigator for the ATLANTA study, stated, "I perform many angioplasties each day, and I am impressed by the performance of this stent in a very complex patient population. No thrombosis. Low binary restenosis. No MIs." The CATANIA(TM) Stent System withNanoThin Polyzene(R)-F has completed CE marking and is available for sale anywhere the CE mark is accepted.

Boston Scientific Announces Approval of New Cardiac Devices

Boston Scientific Corporation announced CE Mark approval for its COGNIS(TM) cardiac resynchronisation therapy defibrillator (CRT-D) and TELIGEN(TM) implantable cardioverter defibrillator (ICD). These devices treat heart failure and sudden cardiac death. The COGNIS CRT-D and the TELIGEN ICD are among the world's smallest and thinnest high-energy devices at 32.5cc and 31.5cc respectively, while less than 10mm thick. Both offer features including extended battery longevity, self-correcting software and improved programming technology. Both devices also offer SafetyCore(TM), a feature that in the event of a system error provides lifesaving shock therapy and basic pacing functionality.

eCardio Diagnostics Launches Cardiac Event Monitoring Features

eCardio Diagnostics will release several new product features and services to enhance its cardiac diagnostic product line. Among eCardio's new product releases is the eTimer™ Automatic Data Capture feature to its cardiac event monitor, the eTrigger™ AF 920. This allows for the capture and monitoring of ECG data at pre-defined and programmable intervals throughout the patient's cardiac monitoring protocol. The function expands the flexibility of eTrigger for its use in various patient therapy or clinical study applications such as treatment or device monitoring, post-ablation follow-up, drug titration, safety and efficacy assessments, and the documentation of normal cardiac function.

FDA Approves Medtronic's Drug- Eluting Stent

Medtronic, Inc. has announced that it has received approval from the US Food and Drug Administration (FDA) for the Endeavor® Zotarolimus-Eluting Coronary Stent System to be used in the treatment of coronary artery disease.

The Endeavor data encompasses the largest, most wide-ranging patient population submitted to the FDA in support of a drugeluting stent,

including more than 4,100 patients, followed up for as long as four years. This extensive clinical research has shown that Endeavor provides a consistent and sustained reduction in the need for repeat procedures compared to a bare-metal stent, while also maintaining an excellent safety profile. The Endeavor stent is the first new drug-eluting stent approved by the FDA since 2004.

Published on : Sun, 11 May 2008