



the medical Review

FDA Approves RestoreULTRA™

In February 2008, Medtronic received FDA approval to market the RestoreULTRA™ neurostimulation system for the treatment of chronic intractable pain of the back and/or legs. The device delivers electrical pulses to the epidural space in order to block pain signals traveling through the nervous system from reaching the brain. The neurostimulator is placed under the skin of the abdomen and connected to flexible leads that deliver the electrical pulses. In contrast to surgical treatments for chronic pain, neurostimulation therapy is adjustable and reversible.

The RestoreULTRA™ has a unique patient programmer. This feature allows patients to make appropriate and immediate adjustments in their stimulation in order to best address normal fluctuations in pain, including changing pain patterns. By

using the remote control programmer, patients can fine-tune their stimulation to specific sites up and down the spinal cord and increase/decrease the intensity of the electrical impulses. These adjustments allow the patient to customize their pain therapy in a way that was previously only possible with a physician programmer during an office visit.

The device is the size of a pocket watch and rechargeable. Its charge will last two weeks for patients on medium stimulation settings. Implantation of this device is similar to other spinal stimulators already on the US market and will carry the same risks. The device is currently available only in Europe but is expected to be sold in the US shortly. Estimated costs for the device will be similar to other stimulators which are approximately \$30,000-\$50,000.

NEWS IN BRIEF...

HLA-mismatched renal transplantation without maintenance immunosuppression

Five patients with end-stage renal disease received combined bone marrow and kidney transplants from HLA single-haplotype mismatched living related donors with the use of a nonmyeloablative preparative regimen.

It was possible to discontinue all immunosuppressive therapy 9 to 14 months after the transplantation, and renal function remained stable for 2.0 to 5.3 years since transplantation.

Evolving Treatment For Colon Cancer

In 2006, the FDA approved Vectibix (panitumumab) for treatment in metastatic colon cancer. Vectibix is a fully human anti-EGFR monoclonal antibody which inhibits the growth and survival of selected tumor cells expressing EGFR. It is indicated as a single agent for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine (5-FU)-, oxaliplatin (Eloxatin)-, and irinotecan (CPT-11)-containing chemotherapy regimens. It does not currently

have first line approval nor is indicated for use in combination with chemotherapy with or without bevacizumab (Avastin).

The effectiveness of Vectibix as a single agent is based on progression-free survival. Currently no data are available that demonstrate an improvement in disease related symptoms or increased survival with Vectibix. Vectibix is given as an intravenous infusion every two weeks. The recommended dose of Vectibix is 6 mg/kg administered over 60

minutes. Doses higher than 1000 mg should be administered over 90 minutes. Eighty-nine percent of patients who receive Vectibix had a dermatologic (skin) reaction. Some of these were severe skin infections that led to sepsis and septic death. The other most serious adverse event observed was pulmonary fibrosis.

The average wholesale price for 400 mg of Vectibix is \$3,840. An average patient weighing 75 kg would require 420mg each time the drug is given.

Hospital bills increased from \$462 billion in 1997 to \$873 billion in 2005 (approximately 90%)

THE BOTTOM LINE

Spring 2008
Volume 5, Number 1

The Medical Review
is a publication of
Advanced Medical Strategies

Written, designed and edited by
the AMS Public Relations Team



7 Kimball Lane
Building A
Lynnfield, MA 01940

Phone: 781.224.9711
Fax: 781.224.9713

E-mail: info@mdstrat.com

Find us on the web at:
www.mdstrat.com



5-year relative survival for
Non Hodgkin's Lymphoma patients
has increased from 50.4% to 66.8%

New Coronary Stent Undergoes First Human Clinical Trial

Fully degradable coronary stents have been explored for more than 20 years. No clinically useful products were developed due to the lack of polymers that could meet demanding performance requirements. A new biomaterial developed at Rutgers University may soon change that. Reva Medical Inc., has selected the biomaterial for use in its new coronary stent design.

Stents are tiny tubes inserted into diseased arteries to keep them open. The Reva stent being tested is intended to act as a temporary scaffold to support the blood vessel during the healing process and maintain blood flow. It subsequently dissolves, leaving the patient free of any permanent implant. Safety studies on the new stent are being conducted in Germany and Brazil on

approximately 30 patients.

The polymer is exceptionally strong and very suitable for stent applications. In addition, the material was designed to be radio-opaque so it is x-ray visible, a property critical to the proper placement of the stent in the artery. It is also biodegradable and biocompatible. The polymer was developed by creating a library of degradable polymers comprising 10,000 theoretically possible compositions and applying combinatorial methods to identify the best possible biomaterial. If initial studies are promising, more widespread clinical trials would be done and the degradable stent could make its way to the US market in the next few years. The patient selection criteria and costs associated with this novel stent are currently unknown.

Avastin (Bevacizumab) Update

In February 2008, the FDA approved Avastin for use in metastatic breast cancer. It is now indicated for first line treatment in combination with Paclitaxel (Taxol) in HER-2 negative tumors. The effectiveness of Avastin in metastatic breast cancer is based on an improvement in progression free survival. Avastin is not indicated for patients with breast cancer that has progressed following anthracycline and taxane chemotherapy administered for metastatic disease. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer.

Avastin is a monoclonal antibody approved by the FDA for first- or second-line treatment of patients with metastatic cancer of the colon or rectum. It is approved for use in combination with intravenous 5-fluorouracil (5-FU) based chemotherapy. It also has FDA approval for

first line treatment, in combination with Carboplatin and Paclitaxel, of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer.

Monoclonal antibody therapy is also known as targeted/directed therapy. Avastin is a particular type of targeted therapy called anti-angiogenic therapy that may interfere with the growth of new blood vessels, which provide nutrients to the tumor. Patients treated with Avastin were more likely to see disease regression as well as an increased disease free survival period.

Avastin is administered as an intravenous infusion (5 mg/kg or 10 mg/kg) every 14 days until the tumor stops responding to it. The drug comes in 4ml and 16 ml vials, both at 25mg/ml concentrations. Average wholesale price for each vial is \$687.50 and \$2,750, respectively.

