Information for the Media

Medtronic and Genzyme Create Joint Venture

The following provides more information about MG Biotherapeutics, a joint venture created by Medtronic and Genzyme Corporation.

Objective: The objective of MG Biotherapeutics is to become the leader in the development of therapeutic solutions for unmet medical needs in cardiovascular disease through the combination of biologics and therapy delivery devices.

The initial focus will be the development and local delivery of cellular therapies for cardiac repair. These cellular therapies have the potential to repair damaged heart tissue (“myogenesis”) and stimulate new blood vessel growth (“angiogenesis”).

Supporting the Medtronic Mission: This collaboration represents the most advanced program designed to develop cellular therapies for cardiovascular disease. This is consistent with Medtronic’s strategic emphasis on the convergence of medical technology and biotechnology. It also is closely aligned with Medtronic’s Mission to alleviate pain, restore health and extend life – with particular relevance to restoring health.

Strength of Collaboration: This collaboration brings together two leaders with complementary strengths working toward the goal of creating a world leader in applied biotechnology therapy. Genzyme brings leadership in biologics, cell therapy clinical and commercial expertise, and biologics manufacturing. It has more than a decade of clinical, commercial and manufacturing experience with cell therapy products. Medtronic brings leadership in therapy delivery technologies, imaging and navigational technologies and biomaterials, as well as clinical and commercial expertise in the treatment of heart disease, and a global sales force and distribution channel.

Together, Medtronic and Genzyme will develop new cell therapies more effectively than either company could achieve independently – accelerating the pace of therapy development and commercialization for patients. This joint venture also will work to become a magnet that attracts leading academic, research and biotech innovators in this field to advance developments in cell therapy to treat heart disease.

Cell Therapy: Cell therapy is the transplantation of human or animal cells to replace or repair damaged tissue and / or cells. In the applications being pursued through this collaboration, cells involved in muscle formation (skeletal myoblasts) are obtained from a patient prior to his / her coronary artery bypass graft procedure. They are then grafted into a scarred region of the heart, with the goal of stimulating heart muscle repair and preventing the muscle from weakening and progressing to heart failure.
MG Biotherapeutics is focusing on autologous (see definition below) cells first because they are likely to be safer, further along in clinical studies, and closer in makeup to the actual cells of patients — therefore, more likely to be successful. Also, use of autologous cells are closer to market approval than the use of allogeneic cells being researched by some competitors.

[Note: Autologous refers to a graft or tissue from the same source — that is, taken from the patient and then returned to the patient. Allogeneic refers to a graft or tissue from someone other than the patient, from a donor or other third-party source; allogeneic cells offer the promise of mass producibility / production.]

**The Therapies:** MG Biotherapeutics will develop cellular therapies to provide physicians with the mechanism for local delivery of cellular therapies to safely reverse the damage done to cardiac muscle following a heart attack, or safely halt a patient’s further progression to heart failure, an incurable condition affecting more than 20 million individuals worldwide.

Genzyme will provide most of the biologic technology (skeletal myoblasts, genes, biomaterials, adult human stem cells). Medtronic will provide biomaterials, as well as transvascular, endocardial and epicardial delivery tools, plus imaging and navigational technologies to deliver the cell therapies. These technologies provide a portfolio of solutions for physicians and patients.

**Addressing An Unmet Need:** These therapies will address a significant unmet medical need — providing new and better treatment for the millions of people suffering from heart disease.

Heart failure affects an estimated 5 million Americans and 22 million people worldwide. People with heart failure are 6-9 times more likely to experience sudden cardiac arrest, which kills 450,000 Americans per year — making it the leading cause of death in America, more than stroke, AIDS, and breast and lung cancer combined. (Source: AHA Heart Disease and Stroke Statistics – 2004 Update)

**More Specifics:** MG Biotherapeutics will focus on the use of cellular therapies in the treatment of heart disease. This involves advancing Genzyme’s ongoing Phase 2 clinical trial (the MAGIC trial — Myoblast Autologous Graft in Ischemic Cardiomyopathy) that is examining whether injecting autologous skeletal myoblasts into the scarred portion of a patient’s heart during a bypass operation will help improve cardiac function. The joint-venture will also pursue next-generation applications, including (a) catheter-based delivery of these cells; (b) the potential use of genetically modified cells that may also be capable of spurring blood vessel formation; (c) the use of allogeneic cells to provide an off-the-shelf solution; and (d) and the use of sophisticated biomaterials that may improve cellular survival and engraftment.

**MAGIC Trial:** The MAGIC trial is a global, multi-center, Phase 2 clinical trial examining the safety and effectiveness of autologous cell therapy to restore function in areas of the heart damaged by a heart attack. The trial will involve up to 300 patients at multiple sites in Europe and North America. It builds on the successful completion of a nine-patient Phase 1 safety trial led by Principal Investigator Philippe Menasché, M.D., Ph.D., of Hôpital Bichat in Paris.
MAGIC is important because it is by far the largest trial of its kind ever undertaken. It is the first trial of its kind powered in a way that will allow investigators to gather meaningful information about safety and efficacy.

**Timeline:** The companies intend to complete enrollment in the MAGIC Phase 2 trial by the end of calendar year 2006. If this trial is successful, the companies anticipate conducting a Phase 3 clinical trial, which will involve the use of catheter delivery. This trial would begin in early 2008.

**Major Milestones for the JV:** Completion of enrollment in the MAGIC Phase 2 trial (late 2006); assessment of a catheter delivery system; launch of a Phase 3 trial using a catheter system.

**Financial Terms:** As part of the agreement, Medtronic and Genzyme have agreed not to discuss specific financial terms of the joint venture. However, we can say that investments will include a large initial cash outlay by both companies, significant staff resources dedicated to the joint venture, and future R&D funding by Medtronic.

**Biotechnology Strategy:** Therapies that combine medical technology (i.e., devices), biotechnology and information technology represent the state-of-the-art in healthcare and will become increasingly important in treating disease. With respect to biotechnology, Medtronic believes that delivery of drugs and biologics – in the right amount, at the right time, and in the right place – is critical to advancing care and to success in a world of converging technologies. For this reason, Medtronic intends to build on its position as the leader in local delivery of therapeutic agents.

**Experience in Biologics:** Medtronic has a long and successful history of combining chemical or biologic compounds with medical devices to achieve improved therapeutic results. Notable examples are steroid-eluting leads for pacemakers and defibrillators, bioactive coatings for heart valves, heparin-coated components used in open heart surgery, our upcoming drug-coated coronary stent, drug infusion systems and, most recently, the INFUSE™ Bone Graft, a morphogenic protein used in conjunction with spinal instrumentation. (Note: LT CAGE® + INFUSE®, INTERFIX™ and INTERFIX™ RP + INFUSE®, and BRYAN® TCD Instruments incorporate technology developed by Gary K. Michelson, M.D.)

In choosing to collaborate with Genzyme, we have aligned ourselves with a company that, to date, is pursuing the most advanced program in cell therapy for the treatment of heart disease.

**Potential Customers:** MG Biotherapeutics’ potential customers include cardiac surgeons and cardiologists (including heart failure specialists and interventional cardiologists).

**Fit With Medtronic Portfolio:** Medtronic offers a range of cardiovascular therapies and possesses the leading franchise of medical technologies for the treatment of heart failure. The local delivery of cells to treat heart disease is complementary to therapies Medtronic offers today, as it will provide physicians with a new, adjunctive option for improving the health of patients that suffer from the disease. Specifically, the initial therapy offered by the joint venture will be administered in conjunction with bypass
surgery. This therapy may restore the health of hearts with tissue damage caused by ischemic cardiomyopathy. If the MAGIC trial shows improved cardiac function with the injection of skeletal myoblast cells, minimally invasive delivery techniques will be employed, using delivery devices such as transvascular or endocardial catheters, as a discrete, stand-alone procedure.

[Note: Skeletal myoblasts are cells involved in muscle formation that are obtained from a patient prior to his / her coronary artery bypass graft procedure. Ischemic cardiomyopathy is heart muscle disease caused by a deficiency of blood flow; sometimes referred to as heart failure, in which the heart muscle becomes weak, enlarged and cannot pump blood effectively.]

**Distribution:** The Medtronic sales force in the Cardiac Surgery (epicardial), Cardiac Rhythm Management (endocardial), and Vascular (transvascular) businesses will promote these therapies if and when they achieve commercial release.

**Collaboration Track Record:** Medtronic works collaboratively with a wide range of companies, academic institutions and other organizations in developing new products and therapies. One recent collaboration is between Medtronic's Spinal business and Wyeth [and Yamanouchi Pharmaceutical Co.] to promote INFUSE® Bone Graft, a morphogenic protein used in conjunction with spinal instrumentation. (Note: LT CAGE®, INFUSE®, INTERFIX™ and INTERFIX™ RP + INFUSE®, and BRYAN® TCD Instruments incorporate technology developed by Gary K. Michelson, M.D.)

**Staff:** Approximately 50 employees of Medtronic and Genzyme will be engaged in the work of MG Biotherapeutics under consulting agreements. The staff will continue to be employees of their respective parent companies. This is a compelling advantage, in that we can benefit from the talent, expertise and resources of the parent companies immediately – rather than building a new work force.

**Governance:** The JV will be managed initially by a six-member Board of Directors consisting of three representatives from each company. Decisions about research funding and priorities will be made collectively by the Board of Directors.