



## **Philips and Celsion Advance Development of ThermoDox(R) and MR-Guided HIFU**

### ***Collaboration to Investigate Expansion of ThermoDox(R) Indications in Pancreatic Cancer and Bone Metastases***

ANDOVER, Mass. & COLUMBIA, Md., Sep 23, 2009 (BUSINESS WIRE) -- Royal Philips Electronics (NYSE: PHG; AEX: PHI) and Celsion Corporation (NASDAQ: CLSN) today announced that their joint research program to evaluate ThermoDox(R) in combination with MR-HIFU (Magnetic Resonance guided High Intensity Focused Ultrasound) as a combination therapy to non-invasively treat difficult cancers has successfully completed the feasibility stage. The program has now moved into pre-clinical development and will focus on the combined use of ThermoDox(R) (Celsion's heat-activated liposomal drug) and Philips' MR-HIFU system for the treatment of pancreatic cancer and cancer metastases in bone.

Philips' MR-HIFU system has the potential to precisely and non-invasively target lesions with acoustic energy, creating sufficient heat to activate ThermoDox(R) and preferentially release high concentrations of the drug doxorubicin. This Celsion-Philips combinational treatment approach may change the paradigm for addressing a broad range of cancers.

Prominent experts in the field of MR-HIFU cancer treatment, including Dr. Bradford Wood of the National Institutes of Health Clinical Center, Dr. Chrit Moonen of the CNRS/University Victor Segalen Bordeaux, and Dr. Kullervo Hynynen of Sunnybrook Health Sciences Centre are participating in the Celsion-Philips research program. Under the leadership of Dr. Wood, these researchers will be conducting pre-clinical studies to assess doxorubicin drug delivery and to optimize MR-HIFU performance in this application. An IND (Investigational New Drug) submission is planned for early 2010, following successful completion of the pre-clinical studies.

The companies' joint research is focused on the treatment of pancreatic cancer and cancer metastases in bone.

Pancreatic cancer is an aggressive cancer with an extremely high mortality rate. There are 37,000 annual incidences in the U.S., which ranks pancreatic cancer as the fourth leading cause of cancer deaths. Curative surgical resection (also known as the 'Whipple' procedure) is indicated in fewer than 20% of patients, while chemotherapeutic approaches provide modest, if any, patient survival benefit. These factors illustrate the high unmet need for better treatments and the potential significance of MR-HIFU mediated, targeted delivery of doxorubicin.

For bone metastases, ThermoDox(R) combined with MR-HIFU will be investigated both for tumor control as well as for palliative pain treatment. Cancer progresses to bone metastases in a majority of patients with late-stage breast, prostate or lung cancer, with estimates of between 300,000 - 500,000 cases annually in the U.S. Patients typically experience excruciating and unrelenting pain, often treated with opiate drugs and NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) with modest benefit. External beam radiation therapy has been used for tumor control, but does not provide significant pain relief for many patients.

"The drug/device combination of ThermoDox and MR-HIFU has great synergy with the potential to provide an innovative non-invasive therapy for patients with aggressive and life-threatening cancers," said Falko Busse, vice president and general manager MR-HIFU for Philips Healthcare. "We are excited about our continued collaboration with Celsion because the combination of our technologies could provide a more effective treatment for pancreatic cancer and bone metastases."

"Since the beginning of the collaboration in 2008, Philips and Celsion have made excellent progress to develop ThermoDox and MR-HIFU," added Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Initial feasibility work suggests that a combination of these technologies has the potential to significantly expand the market for ThermoDox; providing promise to thousands of patients with difficult to treat disease."

Philips and Celsion will both be in attendance at the upcoming International Symposium on Therapeutic Ultrasound held in Aix-en-Provence (France) from September 23-26. The companies will be pleased to answer questions regarding the technologies at the Philips conference booth.

### **About ThermoDox<sup>(R)</sup>**

ThermoDox in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. ThermoDox is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers including breast cancer. Localized mild hyperthermia (40-42 degrees Celsius)

releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox is being evaluated in a 600-patient global Phase 3 study at 40 clinical sites under an FDA Special Protocol Assessment. The primary endpoint for the study is progression-free survival and enrollment is expected to be completed in 2010. For recurrent chest wall breast cancer, ThermoDox is being evaluated in a Phase I/II open-label, dose-escalating trial that is designed to measure durable local complete response at the tumor site. Celsion expects to enroll approximately 100 patients across the United States and to complete the study by the first half of 2010. Additional information on these ThermoDox clinical studies may be found at <http://www.clinicaltrials.gov>.

*ThermoDox(R) is a registered trademark of Celsion Corporation*

### **About Philips' MRI Guided High Intensity Focused Ultrasound (MR-HIFU)**

MRI-guided High Intensity Focused Ultrasound, or MR-HIFU, is a new non-invasive technique with the potential to provide local tumor control and improve quality of life. The Philips MR-HIFU system combines the HIFU capability of non-invasively heating tissue deep inside the human body with the excellent soft tissue contrast, 3D imaging capabilities, and non-invasive temperature measurement techniques provided by MRI to plan, guide and monitor the treatment.

The Philips MR-HIFU system offers a unique technique called Volumetric Heating. With this technique, essential for localized mild hyperthermia, the ultrasound focus is moved electronically over the volume to be heated and is monitored with real-time temperature sensitive MR images to create a uniform temperature distribution.

For the treatment of uterine fibroids, a prevalent condition in women of childbearing age, the Philips MR-HIFU system is currently being evaluated in a global multi-center clinical trial involving centers in North America, Europe and Asia.

For more information about Philips' MR-HIFU email: [mr-hifu.info@philips.com](mailto:mr-hifu.info@philips.com).

### **About Celsion Corporation**

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Philips Healthcare to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. Celsion has research, license, or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, Cleveland Clinic, and the North Shore Long Island Jewish Health System. For more information on Celsion, visit our website: <http://www.celsion.com>

### **About Royal Philips Electronics**

Royal Philips Electronics of the Netherlands (NYSE: PHG, AEX: PHI) is a diversified Health and Well-being company, focused on improving people's lives through timely innovations. As a world leader in healthcare, lifestyle and lighting, Philips integrates technologies and design into people-centric solutions, based on fundamental customer insights and the brand promise of "sense and simplicity". Headquartered in the Netherlands, Philips employs approximately 128,000 employees in more than 60 countries worldwide. With sales of USD 42 billion (E27 billion) in 2007, the company is a market leader in cardiac care, acute care and home healthcare, energy efficient lighting solutions and new lighting applications, as well as lifestyle products for personal well-being and pleasure with strong leadership positions in flat TV, male shaving and grooming, portable entertainment and oral healthcare. News from Philips is located at [www.philips.com/newscenter](http://www.philips.com/newscenter).

*Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.*

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