

## Celsion Corporation's ThermoDox® HEAT Study Findings Reviewed at the International Liver Cancer Association (ILCA) 2013 Annual Conference in Washington, D.C. on September 14, 2013

## Updated Overall Survival in Large Subgroup Continues to Show Positive Clinical Benefit Company Sponsors Symposium on Directions in Early-Intermediate HCC

LAWRENCEVILLE, N.J., Sept. 16, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN) announced today that Ronnie T.P. Poon, MD, MS, PhD, FRCS (Edin), FACS, Professor of Surgery at the University of Hong Kong and Lead Asia Pacific Principal Investigator for Celsion's Phase III HEAT Study of ThermoDox® in hepatocellular carcinoma (HCC) reviewed the official clinical trial results from the HEAT Study including findings from the HEAT Study post-hoc analysis at the International Liver Cancer Association 7<sup>th</sup> Annual Conference held on September 13-15, 2013 in Washington D.C. Following Professor Poon's presentation on September 14, 2013, the Company sponsored a symposium of leading liver cancer experts to discuss new directions in the treatment of early-intermediate HCC.

Professor Poon's oral presentation, titled "Phase 3 Randomized, Double-Blind, Dummy Controlled Trial of Radiofrequency Ablation (RFA) + Lyso-Thermosensitive Liposomal Doxorubicin for Hepatocellular Carcinoma (HCC) Lesions 3-7 cm," was held on September 14, 2013 at 12:00 p.m. (local time) during the Plenary Session. Professor Poon's presentation also included the most recent Overall Survival data from the HEAT Study post-hoc analysis which continues to suggest positive progression-free survival (PFS) and Overall Survival (OS) in ThermoDox® treated patients when heating cycles from the radiofrequency ablation (RFA) procedure were optimized.

The data from the HEAT Study post-hoc analysis presented by Professor Poon demonstrate that ThermoDox® markedly improves Overall Survival, when compared to the control group, in patients if their lesions undergo RFA for 45 minutes or more. These findings apply to single HCC lesions (63% of the HEAT Study population) from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a subgroup of approximately 300 patients (42% of the patients in the HEAT Study).

- In the patient subgroup treated in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes and was completed within 90 minutes (40% of single lesion patients) Overall Survival improved by 71% (Hazard Ratio of 0.585) when compared to the control arm of RFA treatment only.
- In the patient subgroup treated in the ThermoDox® arm whose RFA procedure lasted longer than 90 minutes (23% of single lesion patients), Overall Survival improved by similar 71% (Hazard Ratio of 0.584) when compared to the control arm of RFA treatment only.
- When combined, these two subgroups show clinical results that indicate a 61% improvement in Overall Survival, a Hazard Ratio of 0.623 and a P-value = 0.058.
- In contrast, the patient subgroup treated with ThermoDox® whose RFA procedure lasted less than 45 minutes in duration (37% of single lesion patients) indicated that the control arm had a slightly improved Overall Survival benefit when compared to the ThermoDox® arm.
- The Hazard Ratio reported above should be viewed with caution since they are not statistically significant and the HEAT Study has not reached its median point for Overall Survival analysis. Celsion continues to follow all patients in the HEAT Study to the secondary endpoint, Overall Survival, and will update the subgroup analysis based on RFA heating duration.

Celsion also sponsored a symposium in conjunction with the ILCA conference moderated by Professor Riccardo Lencioni, MD, FSIR, EBIR, the Director of the Division of Diagnostic Imaging and Intervention at Pisa University School of Medicine in Italy. Â Participants included Professor Josep Llovet, MD, PhD, Professor of Medicine and Director, Mount Sinai Liver Cancer Program, Mount Sinai School of Medicine; Ghassan K. Abou-Alfa MD, PhD, Associate Attending Memorial Sloan-Kettering Cancer Center, New York, NY, Associate Professor, Weill Medical College at Cornell University, New York, NY, and Associate Professor, Gastrointestinal Oncology Service, Memorial Sloan-Kettering Cancer Center, New York, NY; and Professor Ronnie T.P. Poon, MD, PhD. The discussion focused on new developments in the treatment of early-intermediate HCC including the updated data from the Company's HEAT Study post-hoc analysis as well as computer modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

- Results from a finite element method model that simulates temperature, perfusion contours with RFA treatments and allow prediction of drug deposition contour maps with the combined use of RFA and ThermoDox®, show a direct correlation with heating time and amount of drug deposited to the tumor margin, where both adequate heat and tissue perfusion exist.
- Results from recently completed large animal studies (21 subject porcine study) demonstrate that longer RFA heating (dwell) time results in higher local tissue concentrations of ThermoDox® in the surrounding ablation zone. Â

Professor Riccardo A. Lencioni commented, "After reviewing the complete and subgroup analysis of the Phase III HEAT Study as well as the recently completed porcine study, I am convinced ThermoDox® demonstrates clinical activity in a highly responsive population of single lesion patients. The duration of heat from the RFA procedure is an important factor in a successful clinical outcome when combined with ThermoDox® as demonstrated by the growing body of clinical and non-clinical data generated by the Company. These findings build a solid scientific foundation of understanding that increased perfusion and longer heating duration are key factors for ensuring that the heat-sensitive liposomes are activated to deposit high concentrations of doxorubicin in the tumor and the surrounding liver tissue."

ILCA has selected the HEAT Study presentation to be webcast as part of an online educational program of the ILCA 2013 Annual Conference. Professor Poon's presentation will also be available on Celsion's website at <a href="http://investor.celsion.com/events.cfm">http://investor.celsion.com/events.cfm</a>.

The International Liver Cancer Association is the only international organization devoted exclusively to liver cancer research for experts from all related disciplines — medical, interventional and surgical oncology as well as hepatology. ILCA's Executive Committee consists of Dr. Josep M. Llovet (President); Professor Riccardo Lencioni and Dr. Morris Sherman. Celsion notes that Professors Lencioni and Poon and Dr. Sherman are principal investigators on the HEAT Study.

## **About Celsion Corporation**

Celsion is dedicated to the development and commercialization of innovative cancer drugs, including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology. Celsion has research, license or commercialization agreements with leading institutions, including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford. For more information on Celsion, visit our website: http://www.celsion.com.

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; the significant expense, time, and risk of failure of conducting clinical trials; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; termination of the Technology Development Contract or collaboration between Celsion and HISUN at any time; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion 's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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