January 18, 2018

Celsion Corporation Provides Corporate Update and 2018 Outlook

Company Advances ThermoDox® for Treatment of Primary Liver Cancer Following Independent Data Monitoring Committee's Unanimous Recommendation to Continue Phase III OPTIMA Study

OPTIMA Study Enrollment Reached 74% Enrollment at Year-End, With Enrollment Completion Expected in Third Quarter 2018

Initiation of Enrollment of Phase I Portion of OVATION II Study of GEN-1 for Treatment of Ovarian Cancer Anticipated in the First Half of 2018

Cash Position of $25.5 Million at Year-End 2017 Provides Runway to Advance Development Priorities into Third Quarter of 2019

LAWRENCEVILLE, N.J., Jan. 18, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today provided a year-end 2017 corporate review and announced clinical progress for two of its development programs: ThermoDox®, a proprietary, heat-activated liposomal encapsulation of doxorubicin, which is in Phase III development for treatment of primary liver cancer; and GEN-1, an IL-12 DNA plasmid vector encased in a nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein, and which is in Phase I development for the localized treatment of ovarian cancer.

"In 2017, Celsion achieved our key development goals for our two lead programs, ThermoDox® and GEN-1. We expect to build upon this success in 2018 as we work toward advancing our pipeline of clinical and preclinical development programs, which hold the potential to enhance the power of proven chemotherapy and immunotherapy platforms," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "After successful and highly efficient financings in the second half of 2017, we have capital sufficient to complete enrollment of our Phase III OPTIMA Study and advance development through the first pre-planned efficacy analysis, which is expected in the first quarter of 2019. We further expect that our current cash position will allow us to make meaningful progress in our open-label, randomized, 86-patient Phase I/II study of GEN-1 in newly diagnosed patients with stage III and IV ovarian cancer. We are well positioned to execute on our clinical development plans to achieve meaningful milestones in the next year, and I look forward to sharing our progress."

Clinical Developments

ThermoDox®

OPTIMA Study Update. The Company announced that, as of year-end 2017, enrollment in the OPTIMA Study reached 74% of the 550 patients necessary to ensure that its primary endpoint, overall survival, can be evaluated with statistical significance. The OPTIMA Study is currently enrolling at 69 sites in North America, Europe, China and the Asia-Pacific region. The statistical plan for the OPTIMA Study calls for two interim efficacy analyses by the independent Data Monitoring Committee (DMC).

On August 7, 2017, the Company announced that the DMC completed a planned interim analysis of the first 50% of patients randomized in the trial. The DMC unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout, based on the risk-to-benefit analysis conducted by the Committee. The DMC's role is to review study data at regular intervals, with the primary responsibilities of ensuring the safety of all patients enrolled in the study and monitoring the quality and overall conduct of the trial, including each site's compliance with the minimum radiofrequency ablation (RFA) heating time of 45 minutes specified in the study protocol.

Published HEAT Study Data Support the Phase III OPTIMA Study. A manuscript titled "Phase III HEAT Study Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients with Unresectable Hepatocellular Carcinoma Lesions," was published in the high impact, peer-reviewed medical journal, *Clinical Cancer Research*, in November 2017. The article detailed learnings from the Company's 701 patient HEAT Study of ThermoDox® in the treatment of primary liver cancer, including overall survival data from a well-balanced subgroup of 285 patients supporting the OPTIMA Study.

- The final overall survival (OS) analysis from the HEAT study demonstrated that in a large, well-bounded subgroup of

patients (n=285 patients, 41% of the previous 701 patient HEAT Study), treatment with a combination of ThermoDox® and standardized RFA provided an average 58% improvement in OS compared to standardized RFA alone. The Hazard Ratio (HR) was 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198. In this large subgroup, median OS for the ThermoDox® plus standardized RFA group translated into a 25.4-month (more than 2.1 years) survival benefit over the standardized RFA-only group, totaling approximately 80 months (6-1/2 years, which is considered a curative treatment for HCC) for the ThermoDox® plus standardized RFA group, versus 53 months for the standardized RFA-only group.

Conclusions from the publication were further supported by results from a 2016 independent retrospective analysis of the HEAT Study conducted by the National Institutes of Health. The NIH findings are consistent with Celsion's own analysis of the HEAT Study data, which demonstrated that over a 3.5-year period, there was a statistically significant survival benefit in patients treated with ThermoDox® plus optimized RFA over the optimized RFA only group.

R&D Day. Lead investigators (Asia-Pacific and Europe) from the OPTIMA study, representing multiple medical disciplines (hepatology, interventional radiology and surgery), presented their past and current clinical experiences with ThermoDox® as a potential treatment for HCC at a Company-hosted R&D Day event in October 2017.

GEN-1 Immunotherapy

OVATION Study Update. In October 2017, the Company announced completion of enrollment and final clinical and translational research data from its OVATION Study, a Phase Ib dose-escalating clinical trial combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. GEN-1 is an IL-12 DNA plasmid vector formulated as a nanoparticle in a non-viral delivery system to cause the sustained local production and secretion of the Interleukin-12 (IL-12) protein loco-regionally to the tumor site.

The Company further reported encouraging clinical data from the first fourteen patients who completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose-limiting toxicities and promising dose-dependent efficacy signals, which correlate well with successful surgical outcomes as summarized below:

- Of the fourteen patients treated in the entire study, two (2) patients demonstrated a complete response, ten (10) patients demonstrated a partial response and two (2) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one (1) complete response and four (4) partial responses.
- Fourteen patients had successful resections of their tumors, with nine (9) patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection.
- All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.

Key translational research findings from all evaluable patients in the study were consistent with the earlier reports from partial analysis of the data and are summarized below:

- The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose-dependent increases in IL-12 and Interferon-gamma (IFN-g) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism.
- Consistent with the previous partial reports, the effects observed in the IHC analysis were pronounced decreases in the density of immunosuppressive T-cell signals (Foxp3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment.
- The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients, suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival.
- These translational research findings demonstrate that GEN-1 in ovarian cancer patients is biologically active and creates a shift in the primary tumor and in the surrounding tumor environment in the peritoneal cavity that promotes a pro-immune T-cell population dynamic and conversion of tumor naïve T-cell into cytotoxic effector T-cells in the tumor microenvironment.

Progression-Free Survival for Patients Treated per Protocol in the Phase IB OVATION Study Continues to be

Followed. Of the thirteen patients who received GEN-1 treatment in all four dose-escalating cohorts, only four patients' cancer have progressed as of January 15, 2018. This compares favorably to the historical median progression-free survival of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Summarized below are the latest PFS results for all patients treated per protocol in the Phase IB OVATION Study:

- Cohort 1 (36 mg/m²) - All patients have progressed; Average PFS was 19.25 months; Longest progression-free patient in 1st cohort was 24.8 months.
- Cohort 2 (47 mg/m²) - No patients have progressed after 21 months.
- Cohort 3 (61 mg/m²) - One patient has progressed after 14 months; Two other patients in 3rd cohort are progression free over 18 months
- Cohort 4 (79 mg/m²) - No patients have progressed; Average PFS for these five patients in 4th cohort is 15 months.

Advisory Board Recommendation and FDA Submission Enable OVATION II Study Enrollment Initiation, Expected in First Half of 2018. The Company held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the OVATION Study in order to determine the next steps forward for GEN-1. With the endorsement and recommendations from the Advisory Board, the Company filed a next phase protocol with U.S. Food and Drug Administration (FDA) in November 2017.

In January 2018, the Company announced that after a two-month review period, the FDA accepted the Company's submission without comment, providing clearance for the OVATION II Study, the Company's planned Phase I/II clinical trial of GEN-1, its DNA-based immunotherapy for the localized treatment of ovarian cancer. Since then, the Company did receive minor comments from the FDA focusing primarily on the role of the Data Safety Monitoring Board and the need for a 3 + 3 evaluation of the single phase I cohort and full evaluation of the maintenance treatment at the highest dose prior to initiation of the Phase II portion of the trial. The Company agrees with FDA's comments and is modifying the protocol accordingly. The Company continues to expect to initiate enrollment in the study in the first half of 2018.

The Phase I/II trial was developed with extensive input from the Company's Medical Advisory Board. The OVATION II Study builds on the highly promising clinical and translational research data from the Phase IB dose-escalating OVATION Study where enrolled patients received escalating weekly doses of GEN-1, from levels beginning at 36mg/m², to 47mg/m², 61mg/m² and 79mg/m² weekly for 8 treatments in total, in combination with neoadjuvant chemotherapy, followed by interval debulking surgery.

The OVATION II Study is designed with a single dose escalation phase to 100 mg/m², followed by a continuation at the selected dose in Phase II in an open label, 1:1 randomized design up to 90 patients with Stage III/IV ovarian cancer at up to fifteen U.S. centers. The study is powered to show a 33% improvement in the primary endpoint, progression-free survival (PFS), when comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

Corporate Development

Raised Approximately $28.6 Million in Gross Proceeds in the Second Half of 2017. Equity offerings totaling approximately $28.6 million in gross proceeds strengthened the Company's balance sheet, providing additional capital to advance its ThermoDox® and GEN-1 clinical programs through the second quarter of 2019.

In October 2017, the Company raised $17.0 million in gross proceeds through the exercise of outstanding common stock warrants. In addition, the Company completed an underwritten equity offering of shares of common stock and warrants to purchase common stock with Oppenheimer & Co. The gross proceeds of the offering were approximately $6.6 million.

Financial Guidance/Unaudited Cash and Investments

Celsion had approximately $25.5 million in cash and investments at the beginning of 2018, which the Company expects will be sufficient to complete the following anticipated milestones:

ThermoDox®

- Complete enrollment of Phase III pivotal OPTIMA Study for primary liver cancer
  - First pre-planned efficacy analysis in first half of 2019
  - Second pre-planned efficacy analysis expected in the second half of 2019

GEN-1 Immunotherapy

- Initiate Phase I portion of OVATION II Study in the first half of 2018
  - Data from Phase I portion of trial in second half of 2018

- Initiate Phase II randomized portion of OVATION II Study in second half of 2018
  - Data from Phase II randomized portion of OVATION II Study to be reported throughout 2019 (Open Label Design)

About the OPTIMA Study

The Phase III OPTIMA Study is expected to enroll up to 550 patients in up to 75 clinical sites in the United States, Europe, China and the Asia-Pacific region, and will evaluate ThermoDox® in combination with optimized radiofrequency ablation (RFA), which will be standardized to a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for the trial is Overall Survival, which is supported by post-hoc analysis of data from the Company's 701 patient HEAT Study, where optimized RFA has demonstrated the potential to significantly improve survival when combined with ThermoDox®. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

About GEN-1 Immunotherapy

GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer (NK) cell proliferation. The Company has previously reported positive safety and encouraging Phase I results with GEN-1 given as monotherapy in patients with peritoneally metastasized ovarian cancer, and a Phase Ib trial of GEN-1 in combination with PEGylated doxorubicin in patients with platinum-resistant ovarian cancer.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

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 uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in 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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