

# Celsion Corporation Establishes Wholly Owned Subsidiary to Manage Investigator-Sponsored Development of ThermoDox®

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Celsion GmbH will manage current and future cancer studies with ThermoDox®

Celsion continues its strategic focus on the development of GEN-1 and PLACCINE

LAWRENCEVILLE, N.J., June 23, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, announces that its new wholly owned subsidiary, Celsion GmbH, will manage all current and future investigator-sponsored development of ThermoDox<sup>®</sup>, the Company's proprietary heat-activated liposomal encapsulation of doxorubicin. Andreas Voss, M.D., a leading oncology researcher, has been named Managing Director of Celsion GmbH and will step down from Celsion's board of directors later this year to head the subsidiary, which is based in Zug, Switzerland.

Establishing Celsion GmbH allows Celsion's management to focus solely on GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase I/II development for the treatment of advanced ovarian cancer, and PLACCINE T, its nucleic acid vaccine platform. In addition to clinical and regulatory advice, Celsion's ongoing investment in ThermoDox will be limited to providing clinical drug supply and modest financial support.

ThermoDox® is currently under investigator-sponsored development for several cancer indications, including:

- A Phase I study led by the University Medical Center Utrecht in the Netherlands to determine the safety, tolerability and feasibility of ThermoDox<sup>®</sup> in combination with Magnetic Resonance Guided High Intensity Focused Ultrasound hyperthermia and cyclophosphamide therapy for the local treatment of the primary tumor in metastatic breast cancer.
- A Phase I study led by Oxford University in the UK to assess intravenous delivery of ThermoDox® in combination with High Intensity Focused Ultrasound in pancreatic cancer.
- A clinical project at the National Institutes of Health to evaluate ThermoDox® plus the chemotherapy drug mitomycin in bladder cancer.

Commenting on his new role in leading Celsion GmbH, Dr. Voss said, "I am excited to spearhead this effort and to work with investigators around the world who are interested in pursuing further clinical development of ThermoDox<sup>®</sup>. Building upon encouraging preclinical results in several cancer indications, we have been fielding numerous requests from investigators to conduct their own studies. We know that doxorubicin is one of the most active cytotoxic drugs with no known specific resistance mechanism. Furthermore, the ability of ThermoDox<sup>®</sup> to deliver high doses into tumor tissue is proven and its mechanism of action is well understood. Celsion GmbH's long-term objective is to seek partnerships that will maximize the potential of ThermoDox<sup>®</sup>, ultimately providing value to the parent company."

Michael H. Tardugno, Celsion's chairman, president and chief executive officer, said, "Despite the bitter disappointment and surprise with our Phase III OPTIMA study of ThermoDox® in primary liver cancer, many investigators are undaunted by various anomalies related to that data and see value in the drug's continued study. We owe patients and the scientific community the opportunity to investigate ThermoDox® while removing the financial obligation from our stockholders. Celsion is now solely focused on the significant opportunity we face with GEN-1 and PLACCINE in advanced ovarian cancer and SARS-CoV-2 vaccines, respectively. I am delighted that Celsion GmbH is in the experienced hands of Dr. Voss, who will pursue other collaborations and partnerships with the intent to monetize this asset."

Andreas Voss, M.D. joined Celsion's board of directors in 2015. Dr. Voss has more than 25 years of research and drug development expertise. He previously served as Vice President of Clinical Affairs for Europe at Caris Life Sciences, a biotechnology company focused on implementing personalized medicine in oncology through its liquid biopsy technology. Prior to joining Caris in 2010, he was responsible for the global clinical development of Avastin<sup>®</sup> and was a member of the Corporate Drug Safety Board at F. Hoffmann-La Roche. Before joining Roche in 2006, he was Medical Director for the Lung Cancer Disease Area at AstraZeneca, and from 2000 to 2003 he was Medical Director for Anti-infectives and Oncology at Bayer GmbH. From 1996 to 2000, Dr. Voss was Head of Medical Research, Oncology at Asta Medica AG. Dr. Voss received his M.D. from the University of Hamburg Medical School and was a postdoctoral fellow at the University of California San Diego.

## **About Celsion Corporation**

Celsion is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative cancer treatments, including immunotherapies and DNA-based therapies; and a platform for the development of nucleic acid vaccines currently focused on SARS-CoV2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. ThermoDox <sup>®</sup>, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. Celsion also has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit www.celsion.com

#### **Forward-Looking Statements**

Forward-looking statements in this news 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, statements relating to the offering and the use of proceeds therefrom, 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 or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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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