Celsion's GEN-1 Immunotherapy Receives Orphan Drug Designation from the European Medicines Agency

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Approval Adds 10 Years of Market Exclusivity Following Marketing Authorization in Europe

LAWRENCEVILLE, N.J., March 23, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. GEN-1 previously received orphan designation from the U.S. Food and Drug Administration and is currently being evaluated in a Phase I/II clinical trial (the OVATION 2 Study) for the treatment of newly diagnosed patients with Stage III and IV ovarian cancer.

The OVATION 2 Study combines GEN-1 with the standard of care for the treatment of newly diagnosed patients with Stage III and IV ovarian cancer who will undergo standard neoadjuvant chemotherapy followed by interval debulking surgery. The OVATION 2 Study is a randomized Phase I/II study designed to evaluate the safety of 100 mg/m² of GEN-1 in the Phase I portion, followed by a continuation at the safe dose in the Phase II portion in an open-label, 1:1 randomized design.

"EMA's orphan drug designation for GEN-1 recognizes the urgent need for new therapies to treat ovarian cancer, an aggressive, rapidly progressing disease with few effective treatment options," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We are pleased to receive a positive opinion from EMA COMP as this Designation carries multiple benefits and represents another important milestone for our clinical program to treat late-stage ovarian cancer."

As established by the EMA, Orphan Medicinal Product Designation (the "Designation") by the European Commission provides for scientific advice and certain regulatory assistance during the product development phase, direct access to centralized marketing authorization and certain financial incentives for companies developing new therapies intended for the treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 people in the European Union (EU).

Benefits for the Designation are manifold and include:

- 10 years of market exclusivity (in which other industry sponsors are prevented from entering the market with a similar product for the same therapeutic indication);
- EMA protocol assistance for sponsors on the conduct of the tests and trials necessary to demonstrate their quality, safety and efficacy, or regulatory assistance;
- EMA advice will be free or given in return for reduced fees;
- Access to a centralized procedure allowing immediate marketing authorization in all Member States and facilitating the availability of medicines to all patients in the EU;
- Eligibility for a reduction of regulatory fees associated with pre-authorization inspections, as well as, marketing authorization application fees and certain other fees for qualifying companies.

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 cancer. 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. (CLSN-G1 CLSN-OV)

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; 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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