Celsion and Hainan Poly Pharm Sign Agreement to Manufacture Celsion's DNA-based Vaccine

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Expands GEN-1 Program Collaboration to Add Clinical and Commercial Batches of Investigational Vaccine

LAWRENCEVILLE, N.J. and HAINAN, China, Sept. 17, 2021 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage company focused on DNA-based immunotherapy and next-generation vaccines, and Hainan Poly Pharm Co. Ltd. (Shenzhen Stock Exchange 300630.SZ), a generics manufacturer dedicated to providing therapeutic-value products and services to patients and customers around the world, today announced an amendment to their existing contract manufacturing agreement to include development work for Celsion's investigational DNA-based COVID-19 vaccine. Under the terms of the amended agreement, Poly Pharm will manufacture clinical batches and, if approved for use, will also manufacture commercial batches for Celsion's vaccine based on its TheraPlas technology. TheraPlas underlies Celsion's GEN-1 product and its PLACCINE vaccine technology platform.

Poly Pharm is experienced with chemistry, manufacturing and controls (CMC), process development and good manufacturing processes (cGMP), including process optimization and manufacturing services to help customers advance new drug development projects. Its sites and pharmaceutical compounds have been approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), China's National Medical Products Administration (NMPA) and the World Health Organization (WHO).

Madame Fang, chief executive officer of Hainan Poly Pharm said, "Poly Pharm is a fully-integrated specialty pharmaceutical company with rich CDMO experience. Poly Pharm and Celsion have a successful cooperation on GEN-1 and have been successfully manufacturing clinical batches of GEN-1 to support Celsion's OVATION 2 Study in advanced ovarian cancer. The GEN-1 collaboration and the DNA-based COVID-19 vaccine program demonstrate our expertise in highly cost-effective manufacturing of nucleic acid based finished drugs. We are glad that a DNA-based vaccine can be our second cooperative project. Celsion's DNA vaccine technology platform is a promising platform as it may address global vaccine storage and distribution needs. We are pleased that Celsion has recognized Poly Pharm's skills and dependability, especially with difficult-to-manufacture products, and we are looking forward to helping address the global COVID-19 pandemic."

Commenting on the agreement, Michael Tardugno, chairman, president and chief executive officer of Celsion said, "This is the second plasmid DNA-based investigational new drug project with Hainan Poly Pharm. Our first collaboration is GEN-1, which incorporates a DNA plasmid encoding IL-12 into a unique nanoparticle delivery system. GEN-1 immunotherapy is being evaluated in the Phase I/II OVATION 2 Study in combination with chemotherapy for patients with newly diagnosed advanced ovarian cancer. We have enjoyed a productive working relationship with Poly Pharm delivering quality product efficiently and are delighted to expand our contract manufacturing agreement with them."

About the PLACCINE platform

PLACCINE is Celsion's proprietary plasmid and DNA delivery technology and the subject of a provisional patent application that covers a broad range of next-generation DNA vaccines. An adaptation of the Company's TheraPlas technology, PLACCINE is a DNA vaccine technology platform characterized by a single plasmid DNA with multiple coding regions. The plasmid vector is designed to express multiple pathogen antigens along with a potent immune modifier. It is delivered via a synthetic delivery system and has the potential to be easily modified to create vaccines against a multitude of infectious diseases, addressing:

- **Viral Mutations**: PLACCINE may offer broad-spectrum and mutational resistance (variants) by targeting multiple antigens on a single plasmid vector.
- **Enhanced Efficacy**: The potent immune modifiers such as cytokines and chemokines may improve humoral and cellular responses to viral antigens and can be incorporated in the plasmid.
- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that can result in durable antigen exposure and a robust vaccine response to viral antigens.
- **Storage & Distribution**: PLACCINE allows for stability that is compatible with manageable vaccine storage and distribution.
- **Dosing & Administration**: PLACCINE is a synthetic delivery system that should require a simple injection that does not require viruses or special equipment to deliver its payload.

About Hainan Poly Pharm

Hainan Poly Pharm. Co. Ltd. a Chinese generics manufacturer dedicated to providing therapeutic-value products and services to patients and customers around the world, including R&D, manufacturing and marketing. Poly Pharm is one of the few listed biopharmaceutical companies which meet the EU and US cGMP standard in China. Poly Pharm not only has manufacturing capacity from API to finished products, but it also provides CDMO service for customers in the area of ophthalmic preparation, topical preparation, vaccines, and anti-cancer biological drugs, including the production from clinical batches to commercial batches.

Founded in 1992, Poly has built a product portfolio including active pharmaceutical ingredients (API) and finished products and has earned a

reputation for high-quality products. Poly Pharm initiated its international registration program in 2005. Since 2012, Poly Pharm has received inspections from various global authorities including the FDA, EMA, NMPA and WHO with positive outcomes that validate its cGMP compliance and quality control.

With the approval of products for marketing by the EMA and US FDA, and the distribution of its products to EU markets, Poly Pharm has entered the global market. In 2017, Poly Pharm successfully completed an initial public offering and listed its shares on the Shenzhen Stock Exchange (300630.SZ).

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-CoV-2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. ThermoDox®, 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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