Genenta Strengthens Agreement with AGC Biologics to Boost Cell Therapy Manufacturing

January 9, 2025

Sharing Insights at the 'Italy on the Move' Event and Engaging Investors at Biotech Showcase During JPM Healthcare Week in San Francisco

MILAN and NEW YORK, Jan. 09, 2025 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a pioneer in immuno-oncology and a leader in cell-based therapeutics, is pleased to announce that it has strengthened its partnership with AGC Biologics, a global contract development and manufacturing organization (CDMO), by amending their Development and Master Services Agreement. This amendment introduces an **exclusive GMP suite at the AGC Biologics Cell and Gene Center of Excellence in Milan, dedicated to the manufacturing of Genenta's cell therapy product, ensuring compliance with cGMP standards**. This strategic move enhances Genenta's production capabilities, potentially improving efficiency and reliability in its manufacturing processes.

The newly approved methastatic Renal Cell Cancer (mRCC) Phase 1/2a trial began in Q4 2024, and Genenta expects to treat **six patients by the end of the first half of 2025**, while continuing progress with the Glioblastoma Multimforme (GBM) study. In total, Genenta projects manufacturing **27 autologous drug products** in 2025.

"*Our strengthened partnership with AGC Biologics represents our unwavering commitment to patients participating in our GBM and mRCC trials*," said **Pierluigi Paracchi**, CEO and Co-founder of Genenta. "*This enhanced capacity ensures that we can treat a larger number of patients and further validate our therapeutic approach, bringing us closer to our vision of transforming cancer treatment through cell-based therapies.*"

Prof. **Luigi Naldini**, Co-founder of Genenta, noted: "*Our recent preclinical and clinical studies underscore Temferon's unique potential to reprogram the tumor microenvironment, inhibiting myeloid cell-induced immune suppression and fostering T-cell responses. This approach not only enhances the potential efficacy of Temferon as a monotherapy but also suggests promising synergies when combined with various immunotherapeutic strategies, including immune checkpoint inhibitors and CAR-T cell therapies. These findings provide a strong foundation for advancing therapeutic strategies targeting solid tumors and bring us closer to open up new cancer treatments.*"

Upcoming Engagements during **JPM Healthcare Week**: Genenta will participate in **Biotech Showcase 2025**, taking place **January 13–15**, **2025**, in San Francisco to present its innovative technology for treating solid tumors through genetically modified cell therapy. Pierluigi Paracchi will also speak at ***"Italy on the Move"***, a flagship biotech event organized by the Italian Ministry of Foreign Affairs and International Cooperation. The event, aimed at promoting Italy's life sciences sector and fostering international investments, will be held on **January 15**, **2025**, at INNOVIT – Italian Innovation and Culture Hub in San Francisco. Notable speakers include Karthic Jayaraman, Partner and Co-Head of Global Healthcare at TPG Capital, and Frederick Beddingfield, CEO of Rubedo Life Sciences. The event will be moderated by Audrey Greenberg, Co-Founder and Executive Managing Director of the Center for Breakthrough Medicines.

About Genenta

Genenta (Nasdaq: GNTA) is a clinical stage immuno-oncology company developing a proprietary hematopoietic stem cells therapy for the treatment of a variety of solid tumor cancers. Genenta's first in class product candidate is Temferon™, which is designed to allow the expression of immune-therapeutic payloads within the tumor microenvironment by bone marrow derived myeloid cells and enable a durable and targeted response. Genenta has completed a Phase 1 trial for newly diagnosed Glioblastoma Multiforme patients with an unmethylated MGMT gene promoter, which suggests the potential reprogramming of the tumor microenvironment and inhibiting of myeloid induced tolerance, while allowing the induction of T cell responses, potentially breaking immune tolerance. Genenta has initiated in Q4 2024 a Phase 1/2a metastatic Renal Cell Carcinoma study that will also include combination with immune checkpoint inhibitors. Our treatments are designed as one-time monotherapies, but with the additional potential, when used in combination, to significantly enhance the efficacy of other approved therapeutics.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "suggest," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Genenta's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict,

including risks related to the completion and timing of its ongoing clinical trial for newly diagnosed GBM patients with uMGMT-GBM, its expected clinical trial for metastatic RCC or any related studies, as well as Genenta's ability to fund its research and development plans. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Genenta's Annual Report on Form 20-F for the year ended December 31, 2023 filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of the date of this announcement, and Genenta undertakes no duty to update such information except as required under applicable law.

This press release discusses product candidates that are under preclinical or clinical evaluation and that have not yet been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority. Until finalized in a clinical study report, clinical trial data presented herein remain subject to adjustment as a result of clinical site audits and other review processes. No representation is made as to the safety or effectiveness of these product candidates or the use for which such product candidates are being studied. Temferon™ is an investigational product candidate for which the effectiveness and safety have not been established. In addition, Temferon™ is not approved for use in any jurisdiction.

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Source: GENENTA SCIENCE SPA