Genenta Secures Approval for Innovative Trial for Metastatic Renal Cell Cancer

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Glioblastoma study achieves milestone with successful dose escalation, setting stage for Phase 2

MILAN and NEW YORK, Oct. 02, 2024 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a pioneer in immuno-oncology and a leader in cell-based therapeutics, is pleased to announce that the Agenzia Italiana del Farmaco (AIFA) has approved a new Phase 1 clinical trial for metastatic Renal Cell Cancer (mRCC), marking a significant expansion of the potential applications for Genenta's flagship product, Temferon™. This approval by AIFA is in line with the standards that are harmonized across European regulatory frameworks established by the European Medicines Agency (EMA).

From the CEO's Desk: Pierluigi Paracchi, CEO and Co-founder of Genenta, stated: "This approval to initiate a Phase 1 trial in metastatic renal cell carcinoma marks another significant milestone for Genenta, leverages the encouraging results from treating Glioblastoma Multiforme (GBM), and underscores our platform's potential versatility and effectiveness in other solid tumor indications. We believe Temferon will offer a new experimental treatment to patients with late-stage mRCC, a patient population with no currently available treatment options. The insights gained from our uMGMT Glioblastoma Multiforme (TEM-GBM) studies continue to inform and enhance our understanding, demonstrating Temferon's potential to reprogram the tumor microenvironment and activate the immune system across diverse oncology landscapes."

Clinical Progress: Genenta's ongoing TEM-GBM development program is progressing having completed a Phase 1 dose-ranging trial that confirmed the absence of dose-limiting toxicities across 24 patients. Temferon-derived cells remained detectable in the peripheral blood for over two years post-infusion. The treatment has been associated with a median survival of 16.8 months, showing a 25% increase in the 2 years overall survival, setting the stage for our decision to advance to Phase 2 of the study.

Metastatic disease is evident in 25% of newly diagnosed patients with mRCC. The newly approved mRCC trial, expected to commence in Q4 2024, targets a high-risk patient population whose median overall survival is currently less than 2 years after multiple lines of therapy. IFNα, the therapeutic payload delivered by Temferon, has demonstrated benefits across a range of solid tumors, including those involving the urinary tract. This trial aims to leverage similar immune response mechanisms against renal cell cancer.

Preclinical Update: Prof. **Luigi Naldini**, Co-founder of Genenta, noted: "Our recent preclinical studies demonstrate synergy between Temferon and other immunotherapy treatments, specifically in the context of solid tumors. This innovative approach leverages Temferon's ability to reprogram the tumor microenvironment, fostering a cell-mediated immune response. These findings are pivotal as they lay the groundwork for new therapeutic strategies that could significantly improve outcomes for patients with solid tumors."

Upcoming Engagements: Genenta will showcase these developments at several upcoming events, including Maxim Group's 2024 Healthcare Virtual Summit (October 15-17) and at the Society for Neuro-Oncology (SNO) Annual Meeting (November 21-24, Houston, Texas).

About Genenta and Temferon
Genenta (www.genenta.com) is a clinical-stage biotechnology company engaged in the development of a proprietary hematopoietic stem cell therapy for the treatment of a variety of solid tumor cancers. Temferon™ is based on ex-vivo gene transfer into autologous Tie2+ hematopoietic stem/progenitor cells (HSPCs) to deliver immunomodulatory molecules directly via tumor-infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). Temferon is currently under investigation in a clinical trial for newly diagnosed Glioblastoma Multiforme patients with an unmethylated MGMT gene promoter (uMGMT-GBM) and expects to commence a Phase 1 clinical trial for metastatic Renal Cell Carcinoma (mRCC). Temferon is designed to reach solid tumors, induce a durable immune response not restricted to pre-selected tumor antigens nor type, and avoid systemic toxicity, which are some of the main unresolved challenges in immuno-oncology.

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.

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