FDA Grants Orphan Drug Designation to Temferon for Treatment of Glioblastoma Multiforme

March 2, 2023

MILAN and NEW YORK, March 02, 2023 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a clinical-stage immuno-oncology company developing a cell-based platform harnessing the power of hematopoietic stem cells to provide durable and safe treatments for solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Temferon™ for the treatment of glioblastoma multiforme (GBM).

"We expect that the FDA's decision to grant Orphan Drug Designation to Temferon will enhance the development of our cell therapy, which we believe has the potential to address the unmet medical need of patients and strengthen our clinical program," said **Pierluigi Paracchi, Chief Executive Officer** of Genenta. "The Orphan Drug Designation program highlights the significant need for an efficacious therapy for patients suffering from glioblastoma multiforme."

Temferon is a proprietary cell therapy designed to reprogram the tumor microenvironment by delivering immunomodulatory molecules directly to tumors. Genenta is testing Temferon in an ongoing Phase 1/2a clinical trial in newly diagnosed patients with GBM who have an unmethylated MGMT gene promoter (uMGMT-GBM).

GBM is the most common malignant primary brain tumor and the most aggressive diffuse glioma, with unmethylated MGMT promoter status identified in approximately 60% of the GBM population.

The ODD program supports the development of treatments that address diseases affecting fewer than 200,000 people in the United States (which equates to approximately 6 cases per 10,000 population). Incentives that come with the designation include eligibility for federal grants, tax credits for qualified clinical trials, prescription drug user fee exemptions, and a seven-year marketing exclusivity period upon FDA approval.

About Genenta Science
Genenta (www.genenta.com) is a clinical-stage biotechnology company engaged in the development of a proprietary hematopoietic stem cell gene 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™, which is under investigation in a phase 1/2a clinical trial in newly diagnosed Glioblastoma Multiforme patients who have an unmethylated MGMT gene promoter (uMGMT-GBM), 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 the phase 1/2a clinical trial or any studies relating to the treatment of glioblastoma multiforme patients who have an unmethylated MGMT gene promoter (uMGMT-GBM). 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 the Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Genenta Science S.p.A. undertakes no duty to update such information except as required under applicable law.

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