The European Commission Grants Orphan Drug Designation to Temferon™ for Treatment of Glioma

June 29, 2023

MILAN, Italy and NEW YORK, June 29, 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 **European Commission has granted Orphan Drug Designation (ODD) to Temferon ™for the treatment of glioma**. Glioblastoma Multiforme (GBM) is the first clinical indication of Temferon.

ODD is granted by the European Commission for medicines in development to treat rare conditions affecting no more than five in 10,000 people in the European Union (EU), provided there is no other satisfactory treatment option or the medicine can be of significant benefit to those affected by the condition. Sponsors of with ODD designation can benefit from a number of incentives in the EU; for example, ODD medicines benefit from ten years of market exclusivity once they receive a marketing authorization in the EU.

"European Medicine Agency's Committee reviewed Genenta's ODD application for Temferon and agreed on the potential significant benefit that Temferon could contribute to patients suffering from GBM if approved. The ODD designation supports and facilitates the development of our cell therapy-based technology platform for solid tumors," said **Pierluigi Paracchi**, **Chief Executive Officer** at Genenta. "The EMA ODD designation follows the orphan drug designation granted by the **US Food and Drug Administration** to Temferon for the treatment of GBM in March 2023. The preliminary interim results of Genenta's ongoing phase 1/2a trials in newly diagnosed patients with unmethylated MGMT gene promoter reviewed by EMA included an Overall Survival at two years, which is longer than the median Overall Survival described in published reports," continued **Pierluigi Paracchi**.

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.

Temferon is Genenta's product at the most advanced stage of development and consists of the patient's own stem progenitor cells modified with Genenta's platform to express interferon alpha (IFNa) within solid tumors. IFNa is a well-known immunomodulatory protein that has been used in the clinic for decades for the treatment of a variety of cancers, but with limited current use because of the systemic toxicity. Genenta's platform is designed to avoid systemic toxicity and selectively deliver therapeutic activity within the solid tumor. From pre-clinical experiments, it has been observed that **Temferon breaks tumor-induced tolerance, thus allowing the immune system to recognize the tumor and mount a durable immune response**.

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, 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 Genenta's Annual Report on Form 20-F for the year ended December 31, 2022 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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