Genenta Demonstrated Reprogramming of the Tumor Microenvironment in GBM Patients, Paving the Way for Innovative Treatments of Solid Tumors

February 8, 2024

Based on Preliminary Data from Ongoing Dose Ranging Stage of the Phase 1/2 Clinical Trial

MILAN, Italy and NEW YORK, Feb. 08, 2024 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a clinical-stage immuno-oncology (I/O) 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:

We have successfully dosed the first of three patients in Cohort 8 (Temferon™ at 4x10^6/kg), the last cohort of the Phase 1 dose-ranging part of the Phase 1/2 clinical trial in newly diagnosed uMGMT Glioblastoma Multiforme (TEM-GBM) patients. The second patient has been enrolled and the treatment is planned.

- Thus far, the preliminary data indicate **no dose-limiting toxicities** related to Temferon have been detected in any of **22 treated patients**.
- Temferon-derived differentiated cells were evident within the peripheral blood 14 days after infusion and were still detectable at **more than 24 months**.
- As of December 2023, preliminary data in uMGMT patients, the most aggressive form of GBM, show a **2-year Overall Survival (OS) of 25%**; the historically reported data observed in uMGMT and methilated patients undergoing current standard of care is approximately 14% to 18%, respectively.
- We expect reporting top line Phase 1 dose-ranging data by the end of 2Q24.

Dr. **Luigi Naldini**, co-founder of Genenta and Director at the San Raffaele - Telethon Institute for Gene Therapy, stated, “Several techniques, including RNA single-cell analysis, suggest that Temferon can reprogram the Tumor Microenvironment (TME) in patients similarly to what we had demonstrated in preclinical models and activate the immune cell infiltration towards mounting immune responses against the tumor.”

“We had a patient who, albeit anecdotal, survived for over three years with Temferon and second line treatment, with a stable tumor during that period,” reported **Carlo Russo**, CMO and Head of Development. “We believe our preliminary data generated so far, including the duration of the cell presence in the patients, combined with our pre-clinical data showing the agnostic efficacy, open up intriguing possibilities for the use of Temferon in a variety of solid tumors.”

“The absence of limiting toxicity observed so far suggests the ability of our technology to prevent systemic toxicity in humans commonly associated with powerful anti-tumor proteins,” noted **Pierluigi Paracchi**, CEO of Genenta.

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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