Genenta Progresses to Higher Dosing Cohort in Temferon™ Phase 1/2a Clinical Trial in Glioblastoma Multiforme

May 4, 2022

No dose limiting toxicity observed in previous three dose level cohorts
Represents a 50% higher dose than highest prior level
Update of guidance for trial

MILAN, Italy and NEW YORK, May 04, 2022 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a clinical-stage biotechnology company pioneering the development of hematopoietic stem progenitor cell immuno-gene therapy for cancer, announces that its ongoing trial of Temferon™ in glioblastoma multiforme patients who have an unmethylated MGMT gene promoter (uMGMT-GBM) has escalated to the next planned dose. With no drug-limiting toxicities observed at lower doses, Genenta has now dosed the first patient in a new cohort (cohort 6) with 3.0 x 10^6 Temferon cells per kilogram, 50% higher than the next highest prior level. One further-escalated dosing level is planned for the Phase 1 segment of the Phase 1/2a trial (cohort 7). Genenta now expects to complete the enrollment and dosing of patients in cohorts 6 and 7 by the end of the first half of 2023.

Pierluigi Paracchi, Chief Executive Officer at Genenta Science, said: “This is a highly important step for Genenta. Temferon has so far been well tolerated without systemic toxicities and has generated positive preliminary signals of immune activity. The data provide preliminary clinical confirmation of Temferon’s mechanism of action. We are now increasing the dose significantly to raise the level of peripheral Temferon cells over time and to help define the optimal dose.”

To date in the Phase 1/2a study, Genenta has dosed Temferon at 0.5, 1.0 and 2.0 x10^6 cells/kg with no observation of drug-limiting toxicity, and without reaching a maximum tolerated dose. The first part of the ongoing Phase1/2a study aims to define the dose of Temferon that can be administered safely and to assess the therapeutic impact to a range of patients where variability in intrinsic tumor biology, immune status and prior treatments may affect their response to therapy.

The Phase 1/2a study is a multi-center, open-label, dose escalation study in newly diagnosed uMGMT-GBM patients, designed to assess the tolerability, safety and efficacy of Temferon at varying dose levels.

About Genenta Science

Genenta (www.genenta.com) is a clinical-stage biotechnology company pioneering 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 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 based on our platform technology which is designed to reach solid tumors, induce a durable immune response not restricted to pre-selected tumor antigens nor type, and avoid systemic toxicity, 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. (GNTA) undertakes no duty to update such information except as required under applicable law.

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