Genenta Announces Ongoing Clinical Trial Progress and Proposed Expansion in Solid Tumor Treatments

July 28, 2023

Company Selects Refractory Advanced Genitourinary Malignancies including Renal Cell Cancer as Second Indication

Company Selects Refractory Advanced Genitourinary Malignancies including Renal Cell Cancer as **Second Indication**

MILAN, Italy and NEW YORK, July 28, 2023 (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:

1. the Phase 1 dose-ranging clinical trial in Glioblastoma Multiforme (TEM[1]-GBM) is progressing in line with the development program.
    - All the patients assigned to Cohort 7 (3x10E/kg Temferon™) are dosed.
    - Enrollment of the patients in Cohort 8 (4x10E/kg) is completed.
    - No dose-limiting toxicity has been observed at this point.
    - The median Overall Survival (OS) is currently equal to 17 months.
2. We have selected Refractory Advanced Genitourinary Malignancies including Renal Cell Cancer (RCC) as the second solid tumor indication for Temferon. Late-stage RCC is considered an orphan disease with an unfavorable prognosis for Stage IV RCC patients.
    - The median OS in high-risk patients is only 6 months with the current standard of care.
    - 20% of newly diagnosed patients have metastatic disease.
    - Targeted release of IFN-α (Interferon alpha), which is the anti-tumor payload of our platform, we believe the use of a cell-based delivery mechanism is an innovative and clinically relevant approach to modulating the immune microenvironment in patients with immunogenic malignancies, such as metastatic RCC or Urogenital Cancer (UC).
    - IFN efficacy has been established in UC and immunotherapy is also now well established in this type of cancer, offering the potential opportunity of using Temferon in combination with other I/O products such as checkpoint inhibitors.

“We believe the clinical data we are observing in the GBM trial on safety, tolerability, and biological activity allow us to progress the expansion of our platform,” said **Pierluigi Paracchi**, **Chief Executive Officer** of Genenta. "The use of Temferon for the treatment of Urogenital Cancer patients is an important step for validating in humans the agnostic nature of our product that has already been demonstrated in several tumor animal models”, continued **Pierluigi Paracchi**.

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 (IFN-α) within solid tumors. IFN-α 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.

Genenta Media
Tiziana Pollio
+39 348 23 15 143
tiziana.pollio@genenta.com

[1] Tie2 Expressing Monocytes

Source: GENENTA SCIENCE SPA