Genenta Provides First Half 2022 Business Update and Financial Results

October 24, 2022

- Current dose escalation study data shows a median overall survival of 17 months
- Adding cohort to Phase 1/2a trial in GBM to assess additional conditioning regimen
- Cash and cash equivalents of €34.7 million as of June 30, 2022, providing a cash runway until the end of 2024
- €1.8 million unrealized foreign exchange gain

MILAN, Italy and NEW YORK, Oct. 24, 2022 (GLOBE NEWSWIRE) -- Genenta Science (Nasdaq: GNTA), ("Genenta" or the "Company"), 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, provides business and financial results for the six months ended June 30, 2022.

Pierluigi Paracchi, CEO, said: "Genenta made substantial clinical progress through the first part of 2022, following the successful closing of our upsized initial public offering (IPO) in December 2021, which raised gross proceeds of $37.2 million. Genenta presented clinical data from the Phase 1/2a dose-escalation study of Temferon™ at several prestigious scientific congresses through the early part of the year (including AACR, ASGCT, ASCO) which confirms biological activity in line with Temferon's mechanism of action.

We have also reinforced the company leadership with two senior appointments, Mark A. Sirgo, PharmD, as Chairman of the Board and Timothy J. Obara as Vice President, Business Development. We are delighted to welcome Mark and Tim, who bring significant and highly relevant expertise to our operations as we continue the exciting development of Genenta and our cell-based technology."

Carlo Russo, Chief Medical Officer and Head of Development said: "The data generated so far in our Phase 1/2a trial of Temferon provide preliminary evidence of Temferon's mechanism of action's ability to avoid the systemic toxicity of the delivered antitumor payload (interferon-alpha), its local expression within the tumor microenvironment, and the presence of engineered TEMs (TIE2-expressing monocytes) at more than 18 months after treatment, suggesting a potential durable effect. Current data shows the median overall survival is 17 months.

This ongoing trial has escalated to the next planned dose. The study has been testing escalating doses of Temferon along with different conditioning regimens, used as a pre-treatment to prepare patients for therapy. We are adding another cohort to assess an additional conditioning regimen that aims to further maximize effective engraftment, reduce risks of severe immunosuppression, and facilitate the expansion of our hematopoietic based technology platform to a broad number of solid cancer indications as a stand-alone or combination product. We expect to complete the enrollment and dosing of patients in the second half of 2023."

Business Update

- The ongoing Phase 1/2a trial of Temferon in glioblastoma multiforme patients with an unmethylated MGMT gene promoter (uMGMT-GBM), escalated to the next planned dose. With no drug-limiting toxicities observed at lower doses, Genenta has now dosed patients in a new cohort (cohort 6) with 3.0 x 10^6 Temferon cells per kilogram, 50% higher than the prior cohort.
- Preliminary findings from the Phase 1/2a trial of Temferon in the treatment of patients with glioblastoma multiforme provided initial evidence of its potential for modulating the tumor microenvironment, and signs of biological activity. The findings also showed good tolerability and an absence of systemic toxicity of Temferon. The findings were given as an oral presentation at the 25th annual meeting of the American Society of Gene and Cell Therapy (ASGCT).
- The Company presented clinical data from the Phase 1/2a dose-escalation study of Temferon at the annual meetings of the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO). Data from 15 treated patients provided initial evidence of successful engraftment of Temferon-derived cells and evidence of biological activity in tumors resected in patients with uMGMT-GBM undergoing 2nd surgery.
- The Company appointed Mark A. Sirgo, PharmD, an executive leader with over 35 years of pharmaceutical industry experience, as its new Chairman of the Board. Dr. Sirgo founded and was CEO of the specialty pharmaceutical company Biodelivery Sciences, Inc. (Nasdaq:BDSI) for 13 years prior to its sale to Collegium in April of this year.
- The Company also appointed Tim Obara, a highly seasoned commercial healthcare executive with significant experience across a broad range of therapeutic areas and with global responsibility, as Vice President, Business Development. He joined from the University of Pennsylvania's Gene Therapy Program, where he was Executive Director of Research Operations.

Financial Results for the Six Months Ended June 30, 2022

For the six months ended June 30, 2022, and June 30, 2021, the Company reported a net loss of €2.1 million and €4.0 million, or a net loss of €0.12 per share and €0.27 per share, respectively. The decrease in net loss for the six months ended June 30, 2022,

compared with the same period in 2021, resulted primarily from: i) a €1.8 million unrealized foreign exchange gain due to a strong US Dollar and weak Euro, since most of the Company's IPO proceeds in December 2021 were raised in US Dollars, even though the Company reports in Euros and the large majority of the Company's expenses are in Euros. On December 17, 2021 (the time of the Company's IPO), the Euro-to-USD exchange rate was 1.133; and, on June 30, 2022, the exchange rate was at 1.039; ii) a €1.6 million decrease in research and development expense, in part due to changes in the scheduling of patient treatment in the Company's Phase 1/2a clinical trial, the mix of therapy treatments to which patients in the trial were subjected, changes in manufacturing, and the greater compensation benefit derived from the tax credit from the Italian Revenue Agency for research and development expenses; and, iii) a €1.7 million increase in general and administrative costs due to an expansion of the Company's infrastructure to manage its operating activities, mainly related to compliance, administration, and corporate governance.

There were no revenues for the six-months ended June 30, 2022, or June 30, 2021. Research and development expenses were €1.6 million and €3.2 million for the six-months ended June 30, 2022, and June 30, 2021, respectively. General and administrative expenses were €2.5 million and €0.8 million for the six-months ended June 30, 2022, and June 30, 2021, respectively. Unrealized exchange rate gain was €1.8 million and €0 for the six-months ended June 30, 2022, and June 30, 2021, respectively.

As of June 30, 2022, the Company had €34.7 million in cash and cash equivalents, as compared to €37.2 million of cash and cash equivalents as of December 31, 2021. The Company expects these funds to be sufficient to fund operations through the end of 2024.

About Genenta Science

Genenta (www.genenta.com) is 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. Our platform is not tumor type nor target antigen restricted and should provide sustained targeted expression of therapeutic payload(s) inside the tumor micro-environment. Genenta's lead product candidate, Temferon, is aimed at precisely targets the delivery of interferon-alpha to the tumor micro-environment, minimizing systemic toxicity while breaking tumor-induced immune tolerance. Our treatments are designed as one-time monotherapies, but with the additional potential, when used in combination, to significantly enhance the efficacy of other approved therapeutics.

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 Company's 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 press release are made as of the date of this release, and the Company undertakes no duty to update such information except as required under applicable law.

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