



Genenta Science and AGC Biologics Enter Development and Manufacturing Service Agreement

February 7, 2023

MILAN, N.Y., Feb. 07, 2023 (GLOBE NEWSWIRE) -- Genenta Science (NASDAQ: GNTA), a clinical-stage biotechnology company engaged in the development of hematopoietic stem progenitor cell immuno-gene therapy for cancer, has entered into a development and manufacturing service agreement (MSA) with AGC Biologics S.p.A. to manufacture cell therapy lentivirus-based product for Genenta's ongoing clinical programs. AGC Biologics offers end-to-end global [viral vector](#) and [cell therapy](#) development, manufacturing and quality/regulatory services, supported by scientists with 30 years of knowledge and experience.

"The expansion of our existing relationship with AGC Biologics underscores the progress of our platform's clinical development. Based on results from Phase 1 of the ongoing Phase 1/2 clinical trial, we are scaling up the manufacturing process to be ready for Phase 2 of the trial," said Pierluigi Paracchi, Chief Executive Officer of Genenta. "This investment in manufacturing represents a significant step forward based on our expectation that our treatment has the potential to impact the tumor micro-environment and break immune tolerance in solid tumors."

Genenta had an existing manufacturing services agreement with Molecular Medicine S.p.A.'s facility in Milan, which was subsequently acquired by AGC Biologics in 2020. The Milan site has been manufacturing lentiviral vectors (LVV) and drug product for Genenta's ongoing programs since 2016, starting with the initial process development steps. The services provided under this existing agreement are in addition to the services that will be provided under the AGC Biologics MSA.

"This is the next step in our partnership with Genenta and we are proud to be supporting this innovative product and technology, and helping it reach the next phase of trials. It has been inspiring to watch this once small Italian biotech company reach new heights as they work to bring important treatments to patients around the world," said Luca Alberici, General Manager, AGC Biologics Milan. "This collaboration highlights the strength of AGC Biologics' viral vector services, our scientific expertise and the decades of scientific GMP manufacturing knowledge we have here in Milan."

About Genenta Science

Genenta (www.genenta.com) is a clinical-stage biotechnology company engaged in 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 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.

About AGC Biologics

AGC Biologics is a leading global biopharmaceutical Contract Development and Manufacturing Organization (CDMO) with a strong commitment to delivering the highest standard of service as we work side-by-side with our clients and partners, every step of the way. We provide world-class development and manufacture of mammalian and microbial-based therapeutic proteins, plasmid DNA (pDNA), messenger RNA (mRNA), viral vectors, and genetically engineered cells. Our global network spans the U.S., Europe, and Asia, with cGMP-compliant facilities in Seattle, Washington; Boulder and Longmont, Colorado; Copenhagen, Denmark; Heidelberg, Germany; Milan, Italy; and Chiba, Japan and we currently employ more than 2,000 employees worldwide. Our commitment to continuous innovation fosters the technical creativity to solve our clients' most complex challenges, including specialization in fast-track projects and rare diseases. AGC Biologics is the partner of choice.

To learn more, visit www.agcbio.com.

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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