Genocea Presents Encouraging Initial Data from GEN-011 Phase 1/2a Trial at AACR 2022

April 8, 2022

GEN-011 shows consistent pattern of activity in first five heavily pre-treated, checkpoint-refractory patients with advanced solid tumors and progressive disease

Dose escalation continues toward potentially more effective regimen

Initial translational data corroborate clinical findings

PLANET™ manufacturing process is highly reliable and continues to improve; patients next to be dosed to receive GEN-011 with substantially boosted yields, neoantigen specificity and potency

Investor webcast at 4:30 pm ET today to further discuss data

CAMBRIDGE, Mass., April 08, 2022 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, presents clinical, preclinical, and manufacturing data at the American Association for Cancer Research (AACR) Annual Meeting 2022 beginning today in New Orleans and virtually. The presentations include promising initial data from the TiTAN™ clinical trial for the neoantigen-targeted peripheral T cell (NPT) therapy product candidate GEN-011, results demonstrating successful production of GEN-011 using Genocea's PLANET™ manufacturing process, and new preclinical data on Inhibigens™, antigens of suppressive immune responses uniquely identifiable by Genocea's ATLAS™ platform.

The Phase 1/2a TiTAN trial investigates the safety, tolerability, T cell persistence and proliferation, and clinical activity of GEN-011 in patients with refractory solid tumors. The study includes two dosing cohorts. Cohort A patients (n=2) received a lower intensity regimen without lymphodepletion with fractional GEN-011 doses monthly, and with post-infusion intermediate dose interleukin-2 (IL-2) (125K IU/kg daily s.c.). In Cohort B, patients (n=3) received GEN-011 as a single infusion after lymphodepletion, followed by IL-2. This Cohort includes one of three escalating lymphodepletion and IL-2 dose regimens, and patients have not yet been dosed at the highest regimen.

The early results presented at AACR show anti-tumor activity despite the lower intensity regimens and heavily pretreated tumors. Stable disease was seen at the initial Day 57 scan in four of the five patients. While all patients had progressive disease (PD) at their Day 113 scan, three of the five experienced clear biologic changes after infusion. These included palpable improvement in peripheral nodal disease and resolution of severe neuropathy causing arm paralysis and pain in patients with refractory SCCHN. A patient with metastatic non-small cell lung cancer (NSCLC) experienced a 10% reduction in tumor diameters (approx. 30% reduction in volume), also with resolution of tumor associated cough. The potential for drug product proliferation and persistence for months is supported by translational assays, and clinical activity is associated with declines in detectable circulating tumor DNA (ctDNA) after treatment in some patients.

None of the initial patients have experienced dose-limiting toxicities, with no evidence of self-reactivity or autoimmune toxicity. Overall, the range of Grade 2 and Grade 3 treatment emergent adverse events (TEAEs) align with expected toxicity from cell therapy regimens. The poster presentation and additional context are available in the Scientific Resources section of the Genocea website.

Genocea has had a 100% success rate in manufacturing GEN-011 through its PLANET process to date. Of the 17 patient samples entering PLANET, 100% have either successfully yielded a released drug product (14) or are continuing in process (3). Significantly, as a result of continuous process improvements, the next six patients will be dosed with drug products that have a median two-fold increase in cell dose and greater neoantigen specificity and potency.

"Using peripherally derived T cells and our ATLAS bioassay to target specific neoantigens for inclusion or Inhibigen exclusion in GEN-011 is yielding promising early results in patients," said Thomas Davis, MD, Chief Medical Officer of Genocea. "This activity in low intensity regimens shows that the neoantigen targeted cells are recognizing and engaging with the tumor, which is a very encouraging sign of the potential for greater clinical activity in more intense regimens. Additionally, the continued improvements to our PLANET manufacturing process could lead to more clinically meaningful results in this patient population with high unmet need. We are grateful to our trial participants and are excited for more results to come in Q4 this year."

Additional data presented at AACR highlights ongoing work characterizing inhibitory antigens, or Inhibigens - putatively pro-tumor antigens that are uniquely identifiable by ATLAS and present in nearly every cancer patient profiled by Genocea. With the benefit of ATLAS, Genocea excludes T cells to Inhibigens from GEN-011. A preclinical poster presented at the meeting demonstrates how detrimental these Inhibigens are to the efficacy of cancer therapeutics in mouse models of melanoma and pancreatic cancer.

Genocea is hosting an investor webcast with live Q&A at 4:30 pm ET on Friday, April 8. Dr. Melissa Johnson, Program Director of Lung Cancer Research and the Solid Tumor Immune Effector Cellular Therapy Program at the Sarah Cannon Cancer Institute, will join Genocea leadership to discuss the GEN-011 clinical results and other data being presented at AACR. The live webcast will be available on the Events & Presentations page of the Genocea website, with the recording and poster presentations in the Scientific Resources section immediately following the event.

AACR POSTER SESSION CATEGORY: Phase 1 Adult Clinical Trials
Abstract #CT153
Title: ***TiTAN: a phase 1 study of GEN-011, a neoantigen-targeted peripheral blood-derived T cell therapy with broad neoantigen targeting***
Presenter: Maura Gillison, MD, PhD, MD Anderson Cancer Center
Date: Monday, April 11, 2022
Time: 1:30 p.m. – 5:00 p.m. CT

Clinical Results from 5 initial patients show no dose limiting toxicities and proliferation and persistence of desired effector memory T cells for at least 36 days. As expected from a non-exhausted peripherally-derived T cell product, this persistence supports the biological activity of GEN-011.

AACR POSTER SESSION CATEGORY: Inflammation, Immunity, and Cancer
Abstract #2088
Title: *The PLANET manufacturing process reproducibly generates high-quality neoantigen-targeted peripheral T cells (NPTs) for adoptive T cell therapy in the TiTAN clinical trial*
Presenter: Harshal Zope, PhD, Genocea Biosciences
Date: Monday, April 11, 2022
Time: 1:30 p.m. – 5:00 p.m. CT
Results of the PLANET manufacturing process show 100% success in the production of a customized drug product for patients, each including exclusively T cells covering 90% of the intended neoantigen targets. The resulting neoantigen-targeted peripheral T cells are non-exhausted, broadly reactive, and include up to 30 characterized neoantigen targets.

AACR POSTER SESSION CATEGORY: Clinical Research Excluding Trials
Abstract #2745
Title: *ATLAS-identified Inhibigen-specific responses accelerate tumor growth in mouse melanoma and pancreatic cancer*
Presenter: Jessica Flechtner, PhD, Genocea Biosciences
Date: Tuesday, April 12, 2022
Time: 9:00 a.m. – 12:30 p.m. CT
Inhibigens, regardless of antigen type, disrupt an otherwise protective vaccine in mouse models of melanoma. Furthermore, Inhibigens also promote tumor growth in pancreatic cancer models, demonstrating the effect is not cancer type-specific. Transplanting T cells into nude mice confirms that Inhibigen-specific T cells exert this pro-tumor effect.

About GEN-011
GEN-011 is a neoantigen-targeted peripherally derived T cell therapy candidate comprised of autologous CD4+ and CD8+ T cells that are specific for up to 30 ATLAS-identified neoantigens to limit tumor escape. NPTs have minimal bystander, non-tumor-specific cells, and are devoid of Inhibigen-specific cells which may be detrimental to clinical response.

About the GEN-011 TiTAN clinical trial
TiTAN is an open-label, multi-center Phase1/2a trial evaluating safety, tolerability, T cell persistence and proliferation and clinical efficacy of GEN-011. The TiTAN clinical trial is testing two cohorts. Cohort A patients receive a fractionated lower dose regimen of GEN-011 without lymphodepletion and an intermediate IL-2 regimen to maximize the tumor-killing potential of the infused cells. Cohort B patients receive a single high dose administration of GEN-011, along with one of three escalating regimens of lymphodepletion and IL-2.

About Genocea Biosciences, Inc.
Genocea's mission is to identify the right tumor targets to develop life-changing immunotherapies for people suffering from cancer. Our proprietary ATLAS™ platform can comprehensively profile each patient's T cell responses to potential targets, or antigens, on that patient's tumor. ATLAS zeroes in on both antigens that activate anti-tumor T cell responses and inhibitory antigens, Inhibigens™, that drive pro-tumor immune responses. We are conducting a Phase 1/2a clinical trial for GEN-011, our investigational adoptive T cell therapy comprising neoantigen-targeted peripheral cells. We continue to monitor patients in our phase 1/2a clinical trial for GEN-009, our investigational neoantigen vaccine. In addition to our two clinical programs, we are conducting research in several areas where we believe ATLAS could be a key tool in optimizing antigen selection for therapies across a number of diseases. To learn more, please visit https://www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act, including statements related to GEN-011 and the anticipated timing of additional results from its Phase 1/2a clinical trial, the PLANET manufacturing process and research efforts, including with regard to ATLAS and Inhibigens. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time. These factors include, but are not limited to, risks related to our substantial dependence on GEN-011 where any failure to successfully develop GEN-011, or any significant delays in doing so, will have a material adverse effect on Genocea; the potential failure of GEN-011, which is in an early stage of clinical development; potential delays in enrolling patients in the GEN-011 study; our reliance on third parties to conduct technical development, non-clinical studies and clinical trials for our product candidates; our reliance on third parties to conduct some or all aspects of our product manufacturing; that GEN-011 is uniquely manufactured for each patient and the potential difficulties in production, particularly with respect to scaling our manufacturing capabilities; our ability to obtain or protect intellectual property rights related to our product candidates; the potential impacts of COVID-19 on our business and financial results; changes in law, regulations, or interpretations and enforcement of regulatory guidance; our need for additional financing and the risks listed under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2021 and any subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements, except as may be required by law.

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