Genocea Presents Updated Long-term Safety, Immunogenicity and Durability Data from GEN-009 Neoantigen Vaccine Phase 1/2a Trial Part A at Virtual ASCO 2020

May 29, 2020

Data show immune responses occur rapidly after only two vaccinations and can be sustained for more than one year

Part B is exploring the vaccine's ability to reduce tumor size beyond the standard-of-care therapy alone

CAMBRIDGE, Mass., May 29, 2020 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today presents updated durability, safety and immunogenicity clinical data from Part A of its ongoing Phase 1/2a trial for GEN-009, the company's lead neoantigen vaccine candidate. Data will be shared by Roger Cohen, M.D., University of Pennsylvania Abramson Cancer Center, during a video poster presentation (Abstract #3107) at the virtual 2020 American Society of Clinical Oncology (ASCO) Annual Meeting on May 29, 2020 from 8:00 – 11:00 am EDT.

ASCO POSTER SESSION: Developmental Therapeutics – Immunotherapy
Abstract 3107

Title: ***GEN-009, a neoantigen vaccine containing ATLAS-selected neoantigens, to generate broad sustained immunity against immunogenic tumor mutations and avoid inhibitory peptides.***

The analysis evaluates eight patients from Part A of the trial who were vaccinated with GEN-009 as adjuvant therapy, focusing on the onset and duration of induced immunity and clinical outcomes. Seven out of the eight patients enrolled have continued without progression with a median follow up of over one year. All patients received dosing as planned, with five doses given over a six-month period with immune responses occurring rapidly after only two vaccinations. No significant adverse side effects were reported with the administration of GEN-009, with only mild symptoms associated with the vaccine adjuvant. In addition, there are several notable patient outcomes:

- Prior to the GEN-009 trial, one patient diagnosed with melanoma (low PDL-1) had progressed after treatment with a PD-1 antibody, an experimental vaccine and a CTLA-4 inhibitor. After GEN-009, the patient continues in remission for more than 12 months.
- A patient diagnosed with squamous cell cancer of the head and neck had experienced successively shorter remissions but is now exceeding previous remissions and approaching nine months progression free with GEN-009.

"The fact that seven of eight patients continue without progression is encouraging. The vaccine has been well tolerated with only mild injection site reactions. Vaccinated patients have generated both $CD4^+$ and $CD8^+$ *ex vivo* immune responses with immunogenicity manifested to 99% of the vaccinated antigens," said Dr. Cohen.

Both $CD8^+$ and $CD4^+$ responses were measured in both *ex vivo* and *in vitro* assays and were detected as early as day 29 extending as far as 12 months.

The Part B trial continues with patients diagnosed with advanced disease who are receiving GEN-009 in combination with standard of care regimens, including immune checkpoint inhibitors. This cohort will explore the vaccine's ability to reduce tumor size beyond the standard of care therapy alone.

"Together, these data suggest that ATLAS-identified neoantigens generate broad, sustained T cell responses starting after only 4 weeks and lasting for up to 6 months after the last vaccination," said Thomas Davis, M.D., Chief Medical Officer of Genocea. "We look forward to advancing the GEN-009 Phase 1/2a Part B trial and reporting those results, and additional Part A results, later in 2020."

About Genocea Biosciences, Inc.
Genocea's mission is to conquer cancer by developing personalized cancer immunotherapies in multiple tumor types. Our unique ATLAS™ platform comprehensively profiles each patient's T cell responses to potential targets, or antigens, on the tumor. ATLAS enables us to optimize the neoantigens for inclusion in our immunotherapies and exclude inhibitory antigens that can exert an immunosuppressive effect. We are advancing two ATLAS-enabled programs: GEN-009, our neoantigen vaccine for which we are conducting a Phase 1/2a clinical trial and expect preliminary clinical results in the third quarter of 2020, and GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood, for which we intend to file an Investigational New Drug Application in the second quarter of 2020. To learn more, please visit www.genocea.com.

Forward-Looking Statements
This press release includes forward-looking statements, including statements relating to GEN-009 and GEN-011, within the meaning of the Private Securities Litigation Reform Act. 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. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Genocea's Annual Report on Form 10-K for the year ended December 31, 2019 and any subsequent SEC filings. 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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