UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 4, 2021**

GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36289**	**51-0596811**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Acorn Park Drive, 5th Floor

Cambridge, MA 02140

(Address of principal executive offices, including zip code)

(617) 876-8191

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	GNCA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2of the Securities Exchange Act of 1934 (§ 240 12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by a check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 4, 2021, Genocea Biosciences, Inc. issued a press release announcing long-term immunogenicity and clinical response data from its GEN-009 neoantigen vaccine Phase 1 clinical trial. A copy of the press release, dated June 4, 2021, is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, is being furnished and shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release issued by Genocea Biosciences, Inc. on June 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GENOCEA BIOSCIENCES, INC.

By: /s/ DIANTHA DUVALL
Diantha Duvall
Chief Financial Officer
(Principal Financial Officer)

Date: June 4, 2021

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Genocea Presents Promising Long-term Results from GEN-009 Neoantigen Vaccine Phase 1 Trial at ASCO 2021

Four of nine checkpoint inhibitor-sensitive patients experienced RECIST responses post vaccination; median duration without disease progression after initial GEN-009 vaccination was 15 months

Two of seven CPI-refractory patients experienced stable disease for up to 10 months after initial GEN-009 vaccination

In the monotherapy cohort, six of eight patients with no measurable disease continue without recurrence for a median duration of 25 months after initial GEN-009 vaccination

Augmented T cell responses to ATLAS™-identified vaccine neoantigens were durable for at least 6 months post first GEN-009 vaccination

CAMBRIDGE, Mass., June 4, 2021 - Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, presents updated immunogenicity and clinical response data from the GEN-009 Phase 1 trial that continue to validate the company's unique and differentiated approach to identifying clinically meaningful immunotherapy targets through the proprietary ATLAS selection process. Data on the neoantigen vaccine combined with PD-1 inhibition in advanced solid tumors will be shared by Maura Gillison, M.D., Ph.D., Lead Investigator, MD Anderson Cancer Center, during a poster presentation (Abstract #2613) at the virtual 2021 American Society of Clinical Oncology (ASCO) Annual Meeting from June 4-8, 2021. The poster is available for on-demand viewing on the ASCO website and also posted to the Scientific Resources section of the Genocea website at https://www.genocea.com/science.

Long-term results demonstrate that GEN-009 continues to generate broad immune responses against neoantigens that can lead to sustained clinical responses. In Part A of the study, designed to measure safety and immunogenicity only, eight patients with no measurable disease were vaccinated with GEN-009 as a monotherapy. Six of the eight patients continue without recurrence with a median follow up of 25 months post start of the vaccination. Notably, as previously reported, GEN-009 elicited T cell immune responses to 99% of the ATLAS-selected neoantigens, the highest seen across neoantigen vaccine programs.

In Part B, patients were enrolled at the initiation of a PD-1 checkpoint inhibitor (CPI)-based standard of care (SOC) regimen for advanced or metastatic disease; patients who were controlled on SOC and did not require alternate therapy are labeled CPI-sensitive, patients who required alternate therapy before vaccination are labeled CPI-refractory. Of the nine CPI-sensitive patients, the latest data show four patients experienced novel reduction in tumor volume post-GEN-009 dosing and achieved independent RECIST responses after vaccination, including three partial responses (PRs) and one complete response (CR). This is an increase from the two PRs and one CR previously reported at SITC 2020. The remaining five CPI-sensitive patients all achieved disease stabilization. Across the CPI-sensitive cohort, the median duration without disease progression after initial GEN-009 vaccination was 15 months. Of the seven CPI-refractory patients, two achieved stable disease after initial GEN-009 vaccination for up to 10 months. GEN-009 has been well tolerated with only mild adverse events associated with the vaccine adjuvant.

Expanded immunogenicity data from Part B of the study revealed that vaccine-specific T cell responses were detected *ex vivo* after the first dose of the vaccine and continued to rise with each subsequent dose. Vaccine-specific T cell responses remained significantly elevated over baseline and post-CPI, pre-vaccine timepoints for at least 6 months, showing persistence of the vaccine response. CPI-sensitive subjects had a greater number of neoantigens identified with ATLAS at baseline compared with patients in the CPI-refractory cohort, and also had evidence of epitope spread for $CD8^+$ T cells post-dosing. Additionally, the magnitude of $CD4^+$ T cell responses were greater for the CPI-refractory than CPI-sensitive subjects, despite a reduced proportion of peptides to which $CD4^+$ T cell responses were measured, suggesting that the breadth and not the magnitude of response could be associated with favorable outcomes.

“We are very encouraged that GEN-009 can generate broad and diverse immune responses through ATLAS-selected neoantigens” said Thomas Davis, M.D., Chief Medical Officer of Genocea. “The deepened and durable responses in the CPI-sensitive patients and durable disease control in refractory patients are notable. We believe the cumulative long-term GEN-009 data continues to support our unique approach to identifying clinically meaningful immunotherapy targets and provides a strong foundation for our novel cell therapy candidate, GEN-011, which can target up to 30 ATLAS selected neoantigens and is currently in the clinic.”

ASCO POSTER SESSION: Developmental Therapeutics – Immunotherapy

Abstract 2613: https://meetinglibrary.asco.org/record/196014/abstract

Title: *Long term results from a phase 1 trial of GEN-009, a personalized neoantigen vaccine, combined with PD-1 inhibition in advanced solid tumors*

GEN-009 is an adjuvanted personalized neoantigen vaccine being evaluated in eligible patients with advanced cancer who received standard-of-care (SOC) PD-1 checkpoint inhibitor (CPI) +/- chemotherapy during vaccine manufacturing and received 5 vaccine doses over 6 months along with continuation of PD-1 CPI. Genocea’s proprietary ATLAS™ platform selects tumor neoantigens for synthesis into GEN-009 peptides and identifies each patient’s own peripheral blood T cells and antigen-presenting cells. Patients who progressed prior to vaccination could receive alternate therapy followed by GEN-009 alone or in combination with a salvage regimen, as well as accelerated vaccine dosing. The contributions from GEN-009 are assessed using each patient as their own control based upon changes in tumor volume pre- versus post-vaccination.

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 advancing two ATLAS-enabled programs: GEN-009, our neoantigen vaccine for which we are conducting a Phase 1/2a clinical trial and GEN-011, our adoptive T cell therapy comprising neoantigen-targeted peripheral cells for which we are conducting a Phase 1/2a clinical trial. 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 related to GEN-009, GEN-011 and research updates 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, 2020 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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