

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): November 5, 2019



GENOCEA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36289
(Commission File Number)

51-0596811
(IRS Employer
Identification No.)

**Cambridge Discovery Park
100 Acorn Park Drive, 5th Floor
Cambridge, MA 01240**
(Address of principal executive offices, including zip code)
(Registrant's telephone number, including area code): **(617) 876-8191**

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-2 of 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 November 5, 2019, Genocea Biosciences, Inc. issued a press release announcing the presentation of preclinical and clinical data demonstrating that ATLAS™ can identify relevant neoantigens and exclude inhibitory neoantigens that suppress anti-tumor immune responses at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), taking place from November 6 - 10, 2019 in National Harbor, Maryland. A copy of the press release, dated November 5, 2019, 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

99.1

[Press Release issued by Genocea Biosciences, Inc. on November 5, 2019](#)

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: November 5, 2019



Investor Contact:

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Genocea Presents Preclinical Research that Shows Inhibitory Neoantigens Stifle Protective Anti-Tumor Immune Responses at Society for Immunotherapy of Cancer (SITC)

Proportions of inhibitory neoantigens found in cancer patients with the ATLAS™ biology-driven platform may also predict patient responses to immunotherapy

Confirm positive GEN-009 clinical immunogenicity results

CAMBRIDGE, Mass., November 5, 2019 - [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today announced preclinical and clinical data demonstrating that ATLAS™ can identify relevant neoantigens and exclude inhibitory neoantigens that suppress anti-tumor immune responses at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), taking place from November 6 – 10, 2019 in National Harbor, Maryland. ATLAS is Genocea's unique platform that profiles each patient's T cell responses to every candidate neoantigen to select those driving pre-existing anti-tumor responses. Additional data will also be presented, demonstrating that inhibitory neoantigen profiles may predict if a patient will respond to immunotherapy and confirming broad immune response data for the company's novel neoantigen therapy GEN-009.

"Our preclinical findings represent exciting and powerful new discoveries in the role that inhibitory neoantigens play in response to immunotherapies," said Tom Davis, M.D., Chief Medical Officer, Genocea. "Through these data, we demonstrate the power of the ATLAS platform to identify and target only those neoantigens with a high propensity to drive anti-tumor responses while excluding inhibitory, immunosuppressive antigens. We are also pleased to share additional GEN-009 results, which round out the GEN-009 clinical immunogenicity data set from our initial patient cohort and confirm the relevance of these preclinical findings in advancing patient treatment."

The following posters will be located in Prince George's Exhibition Halls AB. Odd-numbered posters will be presented on Friday, November 8th from 12:30 – 2:00 p.m. ET and 6:30 – 8:00 p.m. ET, and even-numbered posters will be presented on Saturday, November 9th from 12:35 – 2:05 p.m. ET and 7:00 – 8:30 p.m. ET.

Summary of Poster #P678 – Vaccine neoantigens empirically identified through the *ex vivo* ATLAS™ platform promote potent therapeutic responses to cancer in mice

- ATLAS screening of mutations from B16F10 melanoma identified approximately 4 percent of mutations as neoantigens, and 3.5 percent of mutations as eliciting potentially deleterious inhibitory T cell responses; the majority were not algorithm-predicted.
- When an ATLAS-identified stimulatory neoantigen was combined in a vaccine formulation and therapeutically administered as monotherapy into tumor-bearing mice, tumor growth was either significantly delayed or completely abrogated in all mice.
- Vaccination with inhibitory neoantigens suppresses anti-tumor immune responses.

Summary of Poster #P417 – ATLAS™ identifies relevant neoantigens for therapeutic anti-tumor vaccination and may serve as a biomarker for efficacy of immunotherapy of solid tumors

- In an analysis of the first six patients who participated in the GEN-009 phase 1/2a study, ATLAS identified neoantigens by recalling both stimulatory and inhibitory neoantigen-specific T cell responses; many of which were not predicted using *in silico* approaches.
- Post-vaccination predicted neoantigens were not more immunogenic than not predicted neoantigens.
- In a separate analysis including non-vaccinated subjects, the proportion of inhibitory to stimulatory neoantigen-specific responses may be a biomarker of immunotherapy success.

Summary of Poster #P420 – Broad immunogenicity from GEN-009, a neoantigen vaccine using ATLAS™, an autologous immune assay, to identify immunogenic and inhibitory tumor neoantigens

- GEN-009-101 is a phase 1/2a study testing safety, immunogenicity and clinical activity in immune responsive tumors (NCT03633110).
- The vaccine was well-tolerated with only grade 1/2 adverse events reported.
- With data from patients enrolled (n=5), vaccination elicited both CD8⁺ and CD4⁺ T cell responses in all subjects, as measured by *ex vivo* and *in vitro* stimulation fluorospot assays, and confirms broad immune responses generated against 98 percent of all immunized neoantigens with a range of tumor types.

About Genocea Biosciences, Inc.

Genocea is a biopharmaceutical company developing personalized cancer immunotherapies. Our unique ATLAS™ technology platform allows us to identify targets based on each person's tumor antigen-specific T cell responses. Using ATLAS, we can both optimize neoantigens for inclusion in our immunotherapies and exclude inhibitory antigens that exert an immunosuppressive effect on anti-tumor immune responses. We are advancing complementary programs

built from ATLAS insights: GEN-009, our neoantigen vaccine candidate for which we are conducting a Phase 1/2a clinical trial across a variety of solid tumor types, and GEN-011, our neoantigen-specific adoptive T cell therapy, for which we intend to file an Investigational New Drug Application in the first half of 2020. To learn more, please visit www.genoclea.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. Genoclea 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 Genoclea's Annual Report on Form 10-K for the year ended December 31, 2018 and any subsequent SEC filings. These forward-looking statements speak only as of the date of this press release and Genoclea assumes no duty to update forward-looking statements, except as may be required by law.