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): **September 22, 2020**

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 September 22, 2020, Genocea Biosciences, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) Application for GEN-011, an adoptive T cell therapy targeting neoantigens. A copy of the press release, dated September 22, 2020, 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 Current Report on Form 8-K, including Exhibit 99.1 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, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by Genocea Biosciences, Inc. on September 22, 2020

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: September 22, 2020

Investor Contact:
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Genocea Announces FDA Acceptance of GEN-011 IND Application

Novel adoptive T cell therapy targets checkpoint-refractory solid tumors with neoantigen-specific T cells from peripheral blood

CAMBRIDGE, Mass., September 22, 2020 – Genocea Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company developing next-generation neoantigen immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) Application for GEN-011, an adoptive T cell therapy targeting neoantigens and designed to improve upon the limitations of TIL and TCR therapies. The IND allows Genocea to initiate a Phase 1/2a clinical study of GEN-011 in patients who have failed standard-of-care checkpoint inhibitor therapy. The trial will evaluate safety, T cell proliferation and persistence as well as clinical activity.

"GEN-011 builds on the power of our ATLAS™ platform, as demonstrated in our GEN-009 clinical trial, to identify the relevant neoantigens which drive robust anti-tumor T cell responses in patients, regardless of HLA type," said Chip Clark, President and Chief Executive Officer of Genocea. "Using a patient's peripheral T cells, already programmed to kill cancer cells with relevant neoantigens, enables this non-engineered therapy to rapidly scale. We therefore believe GEN-011 may eventually offer efficacy, accessibility and cost advantages to patients and providers."

Genocea plans to enroll up to 24 patients across several tumor types in the Phase 1/2 trial. In one cohort, patients will receive multiple low doses of GEN-011 with low-dose IL-2 and without lymphodepletion. In the other cohort, patients will receive a single GEN-011 dose after lymphodepletion and a high dose of IL-2.

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 GEN-011, our neoantigen-specific cell therapy using T cells derived from peripheral blood for which we are commencing a Phase 1/2a clinical trial. To learn more, please visit www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements, including statements relating 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.