

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

June 23, 2020

Date of Report (Date of earliest event reported)

MARKER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37939

(Commission File Number)

45-4497941

(IRS Employer Identification No.)

**3200 Southwest Freeway
Suite 2240**

Houston, Texas

(Address of principal executive offices)

77027

(Zip Code)

(713) 400-6400

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K 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, par value \$0.001 per share | MRKR | The Nasdaq Stock Market LLC |

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 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 23, 2020, Marker Therapeutics, Inc. (the “**Company**”) announced that it has received approval from the United States Adopted Names Council for the use of “zelenoleucel” as the nonproprietary (generic) name for MT-401. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today’s date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|--|
| 99.1 | Press release, dated June 23, 2020 |

SIGNATURES

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

Marker Therapeutics, Inc.

Dated: June 23, 2020

By: /s/ Anthony Kim
Anthony Kim
Chief Financial Officer



Marker Therapeutics Receives USAN Approval for “zelenoleucel” as Nonproprietary Name for MT-401, Multi-Tumor-Associated Antigen Targeted T Cell Product for Acute Myeloid Leukemia

Houston, TX – June 23, 2020 – Marker Therapeutics, Inc. (Nasdaq:MRKR), a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications, announced today that the United States Adopted Names (USAN) Council has approved “zelenoleucel” as the nonproprietary (generic) name for MT-401, a multi-tumor-associated antigen (MultiTAA)-specific T cell product candidate for the treatment of patients with acute myeloid leukemia (AML) following allogeneic stem cell transplant in both adjuvant and active disease settings.

“The USAN approval of zelenoleucel as the generic name for MT-401 is another step forward for continued advancement of our therapy,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “MT-401, which received Orphan Drug designation from the U.S. FDA in April, has shown clinical benefit in patients with acute myeloid leukemia post stem cell transplant in an investigator-sponsored trial. We are excited about the continued clinical development of zelenoleucel and look forward to initiating our Company-sponsored Phase 2 study in patients with AML following transplant.”

About USAN

The United States Adopted Names (USAN) Council is responsible for selecting simple, informative and unique nonproprietary (generic) drug names. The USAN Council establishes logical nomenclature classifications based on pharmacological and/or chemical relationships. In addition to one member-at-large and a Food and Drug Administration (FDA) liaison, the council consists of one representative from each of the following: The American Medical Association, United States Pharmacopeia (USP) and the American Pharmacists Association.

About MultiTAA-Specific T Cell Therapy

Marker’s Multi-Tumor-Associated Antigen Targeted (MultiTAA) platform is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient’s blood capable of recognizing a broad range of tumor antigens. In early clinical trials, the multi-antigen approach has been well-tolerated and shown to enhance tumor destroying capability of T cells. It is one of the first therapies to consistently demonstrate epitope-spreading – inducing the patient’s own T cells to expand, potentially contributing to a lasting anti-tumor effect. Unlike other cell therapies which require pre-conditioning regimens and hospitalization, MultiTAA-specific T cells are designed to be administered in an outpatient setting.

About Marker Therapeutics, Inc.

Marker Therapeutics, Inc. is a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. Marker’s cell therapy technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens (i.e. tumor targets) and kill tumor cells expressing those targets. This population of T cells is designed to attack multiple tumor targets following infusion into patients and to activate the patient’s immune system to produce broad spectrum anti-tumor activity. Because Marker does not genetically engineer its T cell therapies, we believe that our product candidates will be easier and less expensive to manufacture, with reduced toxicities, compared to current engineered CAR-T and TCR-based approaches, and may provide patients with meaningful clinical benefit. As a result, Marker believes its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

To receive future press releases via email, please visit: <https://www.markertherapeutics.com/email-alerts>

Forward-Looking Statement Disclaimer

This release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements in this news release concerning the Company's expectations, plans, business outlook or future performance, and any other statements concerning assumptions made or expectations as to any future events, conditions, performance or other matters, are "forward-looking statements." Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to our non-engineered multi-tumor antigen specific T cell therapies; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the potential benefits of orphan drug designation; and the timing and success of our clinical trials, as well as clinical trials conducted by our collaborators. Forward-looking statements are by their nature subject to risks, uncertainties and other factors which could cause actual results to differ materially from those stated in such statements. Such risks, uncertainties and factors include, but are not limited to the risks set forth in the Company's most recent Form 10-K, 10-Q and other SEC filings which are available through EDGAR at www.sec.gov. The Company assumes no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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