
**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 17, 2018

G1 THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38096
(Commission
File Number)

26-3648180
(IRS Employer
Identification No.)

79 T.W. Alexander Drive
4501 Research Commons, Suite 100
Research Triangle Park, NC
(Address of principal executive offices)

27709
(zip code)

Registrant's telephone number, including area code: (919) 213-9835

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01 Other Events.

On September 17, 2018, G1 Therapeutics, Inc. issued a press release announcing that it is expediting analyses of myelopreservation data from its randomized Phase 2 trial of trilaciclib in combination with chemotherapy and Tecentriq® (atezolizumab) in first-line small cell lung cancer. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 [PressRelease of G1 Therapeutics, Inc., dated September 17, 2018.](#)

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 thereunto duly authorized.

G1 THERAPEUTICS, INC.

By: /s/ Mark A. Velleca
Mark A. Velleca, M.D., Ph.D.
President and Chief Executive Officer

Date: September 17, 2018



G1 Therapeutics to Report Myelopreservation Data from Randomized Phase 2 Trial of Trilaciclib/Chemotherapy/Tecentriq® in Small Cell Lung Cancer in Fourth Quarter 2018

- Management to host webcast and conference call today at 8:30 a.m. ET

RESEARCH TRIANGLE PARK, NC, September 17, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced that it is expediting analyses of myelopreservation data from its randomized Phase 2 trial of trilaciclib in combination with chemotherapy and Tecentriq® (atezolizumab) in first-line small cell lung cancer (SCLC). Myelopreservation results from the trial will be reported in the fourth quarter of 2018.

“We elected to make myelopreservation the primary outcome of the randomized trilaciclib/chemotherapy/Tecentriq trial based on the strength of the first-line small cell lung cancer myelopreservation results from our randomized Phase 2 trilaciclib/chemotherapy trial, which we reported in March,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, Research and Development. “This protocol amendment, which we have discussed with U.S. and European regulatory authorities, enables us to accelerate analyses of mature myelopreservation data collected from the trilaciclib/chemotherapy/Tecentriq trial. The trial will remain blinded to investigators and participants, with no impact on our timeline to report overall survival data.”

This randomized, double-blind Phase 2 trial enrolled 107 patients to receive trilaciclib or placebo in combination with chemotherapy (carboplatin + etoposide) and Tecentriq as first-line treatment for SCLC. The trial is evaluating the myelopreservation potential of trilaciclib. Myelopreservation is the ability to preserve hematopoietic stem and progenitor cell function, as well as immune system function, during chemotherapy. Anti-tumor efficacy measures including overall response rate, progression-free survival and overall survival are also being evaluated. Under the revised protocol, myelopreservation results are now the primary outcome and overall survival is being assessed as a secondary outcome. The trial completed enrollment in February 2018.

“Data from the trilaciclib/chemotherapy/Tecentriq trial have the potential to confirm the myelopreservation results observed in our randomized Phase 2 trial of trilaciclib in combination with chemotherapy. Both trials evaluated trilaciclib in first-line small cell lung cancer using the same chemotherapy backbone,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “By the end of the year we will have myelopreservation data from all four randomized Phase 2 trials of trilaciclib, including three in small cell lung cancer and one in triple negative breast cancer. In these trials, trilaciclib was used in first-, second- and third-line settings in combination with a variety of chemotherapy regimens. We plan to discuss the totality of the data, which includes approximately three hundred participants who received trilaciclib, with U.S. and European regulatory authorities in the first half of 2019.”

Webcast and Conference Call

The G1 management team will host a webcast and conference call at 8:30 a.m. ET today to discuss the trilaciclib clinical development program. The live call may be accessed by dialing 866-763-6020



(domestic) or 210-874-7713 (international) and entering the conference code: 3892548. A live and archived webcast will be available on the [Events & Presentations](#) page of the company's website: www.g1therapeutics.com.

About Trilaciclib

Trilaciclib is a first-in-class myelopreservation therapy designed to preserve hematopoietic stem and progenitor cell function, as well as immune system function, during chemotherapy. Trilaciclib is a short-acting intravenous CDK4/6 inhibitor administered prior to chemotherapy and has the potential to significantly improve treatment outcomes.

Trilaciclib is being evaluated in four randomized Phase 2 clinical trials. In March 2018, G1 announced positive Phase 2 data showing myelopreservation benefits in newly diagnosed, treatment-naïve small cell lung cancer (SCLC) patients ([NCT02499770](#)). Additional results from this trial will be reported at the European Society for Medical Oncology (ESMO) 2018 Congress being held October 19-23. The company plans to report data from three other randomized Phase 2 trials in 2018: a trial in combination with chemotherapy and Tecentriq® in first-line SCLC, ([NCT03041311](#)), a trial in combination with chemotherapy in previously treated SCLC ([NCT02514447](#)), and a trial in combination with chemotherapy in triple-negative breast cancer ([NCT02978716](#)).

About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs, [trilaciclib](#), [lerociclib](#) and [G1T48](#), that are designed to enable more effective combination treatment strategies and improve patient outcomes across multiple oncology indications.

G1 is based in Research Triangle Park, NC. For additional information, please visit www.g1therapeutics.com and follow us on Twitter @G1Therapeutics.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release include, but are not limited to, the therapeutic potential of trilaciclib, lerociclib and G1T48, and are based on G1 Therapeutics’ expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause G1 Therapeutics’ actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in G1 Therapeutics’ filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” sections contained therein and include, but are not limited to, G1 Therapeutics’ ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; G1 Therapeutics’ initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; G1 Therapeutics’ development of a CDK4/6 inhibitor to reduce



chemotherapy-induced myelosuppression is novel, unproven and rapidly evolving and may never lead to a marketable product; and market conditions. Except as required by law, G1 Therapeutics assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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