



New Real-World Data Show Potential of Trilaciclib to Reduce the Substantial Burden of Myelosuppression in Patients with Extensive-Stage Small-Cell Lung Cancer Treated with Chemotherapy

March 31, 2022

Data being presented at the National Comprehensive Cancer Network (NCCN) 2022 Annual Conference

RESEARCH TRIANGLE PARK, N.C., March 31, 2022 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: [GTHX](#)), a commercial-stage oncology company, today announced results of a retrospective, observational study describing the substantial burden of myelosuppression and its impact on healthcare resource utilization (HCRU) in 3,277 patients being treated with chemotherapy for extensive-stage small-cell lung cancer (ES-SCLC). The study also described patient outcomes from 21 patients receiving trilaciclib prior to chemotherapy; of these, 17 received commercial trilaciclib in the real-world setting, and four received trilaciclib in clinical trials.

Results showed that the use of trilaciclib prior to chemotherapy was associated with a 50% reduction in the percent of patients with grade ≥ 3 myelosuppressive hematologic adverse events (HAE) in at least one blood cell lineage and a 74% reduction in the percent of all-cause hospitalizations (days 1 to 21 after treatment), compared to patients who received chemotherapy alone. The analyses were derived using structured, real-world, de-identified clinical patient level data from the Integra Connect oncology warehouse. Findings are being presented in a poster session at the Annual Conference of the National Comprehensive Cancer Network (NCCN), held from March 31 to April 2, 2022.

The poster titled, "Burden of Myelosuppression Among Patients with Extensive-Stage Small Cell Lung Cancer Treated with Chemotherapy in a Community Oncology Setting" is available in the [scientific publications section](#) of G1's website.

"The real-world burden of myelosuppressive hematologic adverse events among patients receiving chemotherapy, and the resulting hospitalizations, are routinely underestimated in the community oncology setting," said Jeffrey Scott, M.D., Chief Medical Officer of Integra Connect and lead author of the study. "In this retrospective analysis, nearly 60% of patients receiving chemotherapy alone had a grade ≥ 3 myelosuppressive HAE in at least one lineage, with a sizeable proportion having multilineage (≥ 2 lineages) myelosuppression. Importantly, these data also capture the first real-world experience of using trilaciclib prior to chemotherapy. Among those patients, the use of trilaciclib nearly eliminated not only grade ≥ 3 HAEs associated with multilineage myelosuppression but also all-cause hospitalizations."

In the study, the researchers conducted a primary analysis of 3,277 patients who received chemotherapy alone and a secondary analysis from 21 patients who received trilaciclib prior to chemotherapy, including 17 who received commercial trilaciclib in the real-world setting. Utilizing data from the Integra Connect Database, the researchers quantified the prevalence and frequency of grade ≥ 3 myelosuppressive HAEs and associated healthcare resource utilization (including supportive care such as G-CSFs, ESAs, and blood transfusions), and all-cause hospitalizations.

Key findings included:

Myelosuppressive HAEs

- Grade ≥ 3 myelosuppressive HAEs were observed across all regimens in chemotherapy-treated patients (no trilaciclib) with ES-SCLC
- Patients treated with chemotherapy alone (no trilaciclib):
 - 57.4% had at least one grade ≥ 3 myelosuppressive HAE
 - 33.3% had grade ≥ 3 thrombocytopenia, 34.0% had grade ≥ 3 anemia, and 44.6% had grade ≥ 3 neutropenia
 - 19.6% had both grade ≥ 3 anemia and grade ≥ 3 thrombocytopenia
 - 20.3% had both grade ≥ 3 neutropenia and grade ≥ 3 anemia
 - 23.0% had both grade ≥ 3 neutropenia and grade ≥ 3 thrombocytopenia
 - 14.5% had grade ≥ 3 HAEs in all three lineages
- Patients treated with trilaciclib prior to chemotherapy:
 - 28.6% had at least one grade ≥ 3 myelosuppressive HAE
 - 4.8% had grade ≥ 3 thrombocytopenia, 14.3% had grade ≥ 3 anemia, and 19.0% had grade ≥ 3 neutropenia
 - 0% had both grade ≥ 3 anemia and grade ≥ 3 thrombocytopenia
 - 4.8% had both grade ≥ 3 neutropenia and grade ≥ 3 anemia
 - 4.8% had both grade ≥ 3 neutropenia and grade ≥ 3 thrombocytopenia
 - No patients had grade ≥ 3 HAEs in all three lineages

Healthcare Resource Utilization (HCRU) for HAE Management:

- Patients treated with chemotherapy alone (no trilaciclib):
 - 7.4% were hospitalized between days 8 and 16 after initiation of chemotherapy, and 18.8% were hospitalized between days 1 and 21 after initiation
 - 83.9% received a G-CSF (61.1% within three days after treatment), 10.7% received RBC transfusions, and 2.4%

received platelet transfusions at any time after initiation

- Patients treated with trilaciclib prior to chemotherapy:
 - No patients were hospitalized between days 8 and 16 after initiation of chemotherapy, and one was hospitalized between days 1 and 21 after initiation
 - 71.4% received a G-CSF (47.6% within three days after treatment), 4.8% received RBC transfusions, and none received platelet transfusions at any time after initiation

The researchers noted that future studies using data from larger patient populations are recommended to enable a more robust comparison between patients treated with trilaciclib prior to chemotherapy and patients treated with chemotherapy without trilaciclib.

“The myelotoxic impacts of chemotherapy in patients with ES-SCLC — including \geq grade 3 neutropenia, anemia, and thrombocytopenia — pose a considerable burden to both patients and to the healthcare system at large in terms of associated healthcare resources required to treat them,” said Huan Huang, Director of Health Economics and Outcomes Research at G1 Therapeutics and co-author of the study. “While the numbers in the trilaciclib dataset are small, these new data add to a growing body of real-world data cataloguing the extent of this burden in patients with ES-SCLC and the need for innovative therapies, such as trilaciclib, to reduce them.”

The results add to data recently published in the *Journal of Medical Economics* showing the use of trilaciclib prior to first-line chemotherapy resulted in cost savings due to fewer myelosuppressive adverse events and their associated treatment costs in patients with extensive-stage small-cell lung cancer. The data showed that the use of trilaciclib in this setting resulted in a 78% overall reduction in the number of myelosuppressive adverse events and an estimated cost savings per patient were \$18,840 from a U.S. payer perspective compared to chemotherapy alone. The findings were derived from a cost-effectiveness analysis based on published literature on myelosuppression and data from the pivotal Phase 2 trilaciclib trial. This manuscript is also available in the [scientific publications section](#) of the G1’s website.

About the Integra Connect dataset

Integra Connect, LLC., a value-based, precision medicine company, is powered by industry-leading clinical and financial data and technologies. For this study, the company applied a sophisticated, data-driven algorithm to its dataset and identified patient lives for analysis based on disease parameters, treatment regimens, and timeframe. The data was provided from community oncology settings across the US, an important view given the majority of cancer patients seek care in these types of practices. Integra Connect believes that life sciences and biopharmaceutical organizations have an opportunity to harness real-world patient data as a way to optimize their research, treatment, and business decisions. **For additional** information, please visit www.integraconnect.com.

G1 Therapeutics

G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of next generation therapies that improve the lives of those affected by cancer. G1 has a deep clinical pipeline and is executing a tumor-agnostic development plan evaluating trilaciclib in a variety of solid tumors, including colorectal, breast, lung, and bladder cancers. G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit www.g1therapeutics.com and follow us on Twitter [@G1Therapeutics](https://twitter.com/G1Therapeutics).

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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 press release include, but are not limited to, those relating to the therapeutic potential of trilaciclib. Forward-looking statements are based on the company’s 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 the company’s actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in the company’s filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the company’s ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates other than trilaciclib; the company’s initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a commercial-stage company; and market conditions. Except as required by law, the company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

G1 Therapeutics Contact:

Will Roberts
Vice President, Investor Relations & Corporate Communications
919-907-1944
wroberts@g1therapeutics.com

Rebecca Levine
Director, Corporate Communications and Public Relations
(919) 667-8711
rlevine@g1therapeutics.com



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