# Real World Data Indicate That Trilaciclib Reduces Hospitalizations and Myelosuppressive Events and May Improve Survival in Patients with Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

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**Multiple Analyses Also Describe Significant Burden of Chemotherapy-Induced Myelosuppression and Impact on Healthcare Resource Utilization in ES-SCLC**

RESEARCH TRIANGLE PARK, N.C., Oct. 27, 2023 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced the presentation of four posters that provide new-real world evidence indicating that trilaciclib administered prior to platinum-based chemotherapy in patients with extensive-stage small cell lung cancer (ES-SCLC) lowers the rate of hospitalization and cytopenia events and may improve survival. In addition, multiple real-world analyses indicate the consistent impact of chemotherapy-induced myelosuppressive events, including severe neutropenia, thrombocytopenia, and anemia, on patients with ES-SCLC being treated with platinum-based chemotherapy as well as the resulting impact on healthcare resource utilization. The posters are being presented at the 2023 American Society of Clinical Oncology (ASCO) Quality Care Symposium, held October 27th and 28th in Boston, MA. A copy of the posters will be made available on the G1 Therapeutics website following the presentations here.

“The burden of chemotherapy-induced myelosuppression not only puts patients at risk for serious adverse events but can also stress the healthcare system,” said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. “Findings from these real-world analyses demonstrate the need to protect patients from the harmful side effects of chemotherapy so that they can continue their treatment. Trilaciclib offers the potential to transform the treatment experience, and these new data underscore the results we’ve seen across multiple analyses showing the positive impact of proactive treatment with trilaciclib.”

The poster presentations include:

**Myelosuppression and Healthcare Utilization Among Patients with Chemotherapy-Treated Extensive-Stage Small Cell Lung Cancer (ES-SCLC) with and without Trilaciclib from Community Oncology Practices (Gajra, A. *et al.*)**

This observational study compared cytopenia-related outcomes and HRU between patients with ES-SCLC who received trilaciclib prior to chemotherapy vs. those who did not in a real-world setting. Using the EMOL Health’s database, which includes >7 million patients from >500 U.S. community oncology practices, structured electronic medical records (EMRs) from January 2020 to April 2023 were examined for this study, supplemented by chart review. Descriptive analyses were performed for patient baseline characteristics and outcomes between the two matched cohorts. Adjusted analyses were conducted to evaluate grade ≥3 myelosuppression in ≥1, ≥2, and all three lineages, as well as all-cause hospitalization.

Results of this retrospective study suggest that patients receiving trilaciclib prior to chemotherapy (n=77) in cycles 1-4 had lower rates of grade ≥3 myelosuppressive HAEs and cytopenia-related HRU compared to the matched comparison cohort (n=77) not treated with trilaciclib:

- 11.2% of trilaciclib-treated patients had grade ≥3 HAEs in ≥1 lineage compared to 30.7% of patients in the comparison cohort.
- 1.2% of trilaciclib-treated patients had grade ≥3 HAEs in ≥2 lineages compared to 13.5% of patients in the comparison cohort.
- 0.4% of trilaciclib-treated patients had grade ≥3 HAEs in 3 lineages compared to 4.9% of patients in the comparison cohort.

G-CSF administered any time during the cycle was reduced by 60.7% in patients receiving trilaciclib compared to those not receiving trilaciclib in the comparison cohort (25.6% vs. 65.2%). Similarly, RBC transfusions and erythropoiesis-stimulating agent (ESA) use were reduced by 84.4% (1.7% vs. 10.9%) and 42.2% (3.7% vs. 6.4%), respectively, in patients receiving trilaciclib compared to those that did not.

After adjusting for age, sex, index line of therapy, and number of chemotherapy cycles receiving trilaciclib, the odds of developing an event of grade ≥3 myelosuppression in ≥1, ≥2, and 3 lineages were reduced by 70%, 90%, and 96%, respectively, with trilaciclib use. All results were statistically significant. The odds of all-cause hospitalization were reduced by 51% with trilaciclib use, though not statistically significant.

**Assessment of Hospitalizations and Cytopenia Events Among Patients with Extensive Stage Small Cell Lung Cancer (ES-SCLC) Receiving Chemotherapy with Trilaciclib (Huang, H. *et al.*)**

The goal of this study was to evaluate real-world rates of hospitalizations and cytopenia-related outcomes in patients with ES-SCLC treated with chemotherapy and trilaciclib, compared to patients who did not receive trilaciclib. This retrospective study used data from the 100% Medicare Fee-for-Service and the Inovalon MORE$^2$ closed claims databases between February 2020 and September 2023. Included in the study were 132 patients who received trilaciclib prior to chemotherapy (and did not receive prophylactic G-CSF) and 11,940 patients who did not receive trilaciclib.

Hospitalization Outcomes

- Patients receiving trilaciclib had a lower rate of all-cause per patient per month (PPPM) hospitalizations during follow-up (0.14±0.25 vs. 0.19±0.27; $p<0.01$) and were less likely to be hospitalized within 90 days post-chemotherapy initiation (21.2% vs. 32.1%; $p<0.01$), compared to the patients who did not receive trilaciclib.

Cytopenia Related Outcomes

- Compared to patients who did not receive trilaciclib, patients receiving trilaciclib prior to their chemotherapy had a statistically significantly lower risk of febrile neutropenia (relative risk 15.5%, $p$=0.03) and numerically lower risk of anemia, neutropenia and thrombocytopenia in the 90-day post-index period.

Survival Outcomes

- Patients receiving trilaciclib had a numerically higher rate of survival at six months (84.1%) compared to the non-trilaciclib group (72.3%) and a survival hazard ratio of 0.63 (95% CI: 0.35-1.14, $p=0.13$) compared to patients not receiving trilaciclib.

This real-world study suggests that trilaciclib administered prior to chemotherapy was associated with lower rates of hospitalizations and cytopenia events, along with an early trend toward improved survival. Trilaciclib is an effective proactive intervention to prevent adverse events associated with treatment for ES-SCLC.

**Burden of Myelosuppression in Extensive-Stage Small-Cell Lung Cancer Patients Receiving Chemotherapy: Retrospective Analysis of Real-World Data from Tennessee Oncology (Blakely, L.J. *et al.*)**

Using data from Tennessee Oncology (TNO), one of the largest community-based cancer care specialists in the U.S., this study evaluated the burden of myelosuppression as assessed by hematologic adverse events (HAEs), including anemia, neutropenia, and thrombocytopenia among patients with ES-SCLC treated with chemotherapy (no trilaciclib). Additionally, it assessed cytopenia-related and all-cause healthcare resource use (HRU) among the same population.

The retrospective analysis followed 152 ES-SCLC patients who received chemotherapy (with or without immunotherapy) but did not receive trilaciclib at any point in their therapy. Among these patients, the prevalence of single and multi-lineage myelosuppression during follow up period (10 month average follow-up period after initiation of chemotherapy) was as follows:

- 63.8% had grade ≥ 3 myelosuppressive HAE in ≥ 1 lineage.
    - 49.3% had grade ≥ 3 neutropenia, 29.0% had grade 3 anemia, and 28.3% had grade ≥ 3 thrombocytopenia.
- 32.2% had grade ≥3 HAEs in ≥2 lineages.
- 10.5% had grade ≥3 HAEs in 3 lineages.

Cytopenia-related and all-cause healthcare resource use (HRU) during follow up period included:

- 76.3% of patients received granulocyte colony-stimulating factor (G-CSF) administration at any time during follow-up.
- 30.3% received a red blood cell (RBC) transfusion.
- 57.9% experienced at least one inpatient admission.
- 67.8% experienced at least one emergency room visit.
- 100% experienced at least one outpatient visit.

These results suggest that, consistent with other published studies, there is high patient burden associated with traditional management of myelosuppression in patients with ES-SCLC in a community oncology practice like TNO, indicating an unmet need in this population. Therapies that protect bone marrow from myelosuppression have potential to reduce such burden.

**Patient Characteristics Associated with Myelosuppression Among Patients with Extensive-Stage Small Cell Lung Cancer Treated with Chemotherapy in The Community Oncology Setting (Goldschmidt, J. *et al.*)**

This retrospective observational study examined the association between patient attributes and the risk of chemotherapy-induced myelosuppression in patients with ES-SCLC, utilizing real-world data from the U.S. Oncology Network's iKnowMed (iKM) electronic health record system.

This study found that all patients with ES-SCLC are at a similar risk of myelosuppressive events, irrespective of patient characteristics (age, sex, race, ECOG performance status) and baseline lab values (hemoglobin, ANC, or platelet count), which were not found to be risk factors for myelosuppressive events for ES-SCLC patients receiving chemotherapy. Chemotherapy intensity and prophylactic management had a more

prominent role in risk of myelosuppression. Additionally, the study found that treatment delays and holds are associated with a higher risk of myelosuppressive events. These findings suggest that how patients present in their initial visits are not necessarily predictive of myelosuppressive events.

**About Small Cell Lung Cancer**
In the United States, approximately 30,000 small cell lung cancer patients are treated annually. SCLC, one of the two main types of lung cancer, accounts for approximately 14% of all lung cancers. SCLC is an aggressive disease and tends to grow and spread faster than NSCLC. It is usually asymptomatic; once symptoms do appear, it often indicates that the cancer has spread to other parts of the body. About 70% of people with SCLC will have cancer that has metastasized at the time they are diagnosed. The severity of symptoms usually increases with increased cancer growth and spread. From the time of diagnosis, the general 5-year survival rate for people with SCLC is 6%. The five-year survival rates for limited-stage (the cancer is confined to one side of the chest) SCLC is 12% to 15%, and for extensive stage (cancer has spread to the other lung and beyond), survival rates are less than 2%. Chemotherapy is the most common treatment for ES-SCLC.

**About 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, including the Company's first commercial product, COSELA® (trilaciclib). G1 has a deep clinical pipeline and is executing a development plan evaluating trilaciclib in a variety of solid tumors, including 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 X (formerly known as Twitter) @G1Therapeutics and LinkedIn.



**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, the need to protect patients from the harmful side effects of chemotherapy and the potential of trilaciclib to transform the treatment experience 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 dependence on the commercial success of COSELA (trilaciclib); the development and commercialization of new drug products is highly competitive; the company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; 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 Contacts:**

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

Source: G1 Therapeutics