Immune Analysis from Phase 2 Triple Negative Breast Cancer Trial Demonstrates Trilaciclib Enhanced Patients' T Cell Immune Function When Administered Prior to Chemotherapy

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- Exploratory Analysis Investigated Immune Mechanisms Underlying The Significant Improvement In Overall Survival Shown In The Phase 2 TNBC Trial, Results Of Which Were Presented At 2020 San Antonio Breast Cancer Symposium -

- Responders Showed Increased T Cell Function as Measured by Greater Cytokine Production -

- Responders Had Fewer Immune-Suppressing Cells Known as Myeloid-Derived Suppressor Cells -

RESEARCH TRIANGLE PARK, N.C., Nov. 12, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced results from an immunologic analysis of Phase 2 study data showing that trilaciclib enhances both CD4 and CD8 T cell function in certain patients with metastatic triple negative breast cancer (mTNBC) when administered prior to chemotherapy. Patients receiving placebo prior to chemotherapy did not demonstrate enhanced T cell function. Results of the immunologic analysis are being presented in a poster session at the 36th Annual Meeting of The Society for Immunotherapy of Cancer (SITC), Nov. 10-14, 2021. The poster is available in the scientific publications section of the G1's website.

"The Phase 2 immunologic data analysis suggests that administering trilaciclib prior to chemotherapy may enhance antitumor efficacy by modulating the composition and response of immune cell subsets," said John Yi, PhD, Director of Translational Medicine at G1 Therapeutics.

In the exploratory analysis, researchers sought to investigate the immune mechanisms underlying the improved rate of overall survival shown in the 2020 Phase 2 trial of TNBC patients receiving trilaciclib in combination with gemcitabine/carboplatin (GCb) compared with GCb alone. The researchers evaluated tumor samples and peripheral blood samples from patients at baseline and after trilaciclib/GCb administration or after placebo/GCb administration to identify differential gene expression and changes in immune function between the two groups. Further, they measured qualitative and quantitative differences between patients who did respond or did not respond to trilaciclib plus GCb. Response to treatment was defined as partial or complete response, while nonresponse was defined as stable or progressive disease.

Among the findings in the poster titled, "Immune Profiling to Investigate Improved Survival in Patients with Metastatic Triple-Negative Breast Cancer Receiving Trilaciclib Prior to Chemotherapy":

- Patients who received trilaciclib prior to GCb showed increased T cell function as measured by greater production of inflammatory cytokines
- Patients who received trilaciclib had fewer immune suppressing cells known as myeloid-derived suppressor cells (MDSCs) than patients who received GCb alone, whether they were responders or non-responders to treatment
- Non-responders to trilaciclib/GCb had a reduction in circulating CD4 and CD8 T cells and a decreased production of inflammatory cytokines

"It is critical that we fully understand the underlying immune mechanisms that contributed to the overall survival improvement that was seen in the Phase 2 mTNBC trials, and to identify biomarkers that will clearly distinguish between trilaciclib responders and non-responders," said Dr. Yi. "We are further investigating the impact of trilaciclib on changes to the tumor-infiltrating immune response in our Phase 3 PRESERVE 2 trial in patients with mTNBC and in a planned mechanism-of-action trial in the neoadjuvant TNBC setting."

About Triple Negative Breast Cancer (TNBC)
According to the American Cancer Society, nearly 300,000 new cases of invasive breast cancer are diagnosed annually in the U.S. Triple-negative breast cancer makes up approximately 15% to 20% of such diagnosed breast cancers. TNBC is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. Because TNBC cells lack key growth-signaling receptors, patients do not respond well to medications that block estrogen, progesterone, or HER2 receptors. Instead, treating TNBC typically involves chemotherapy, radiation, and surgery. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer. In general, survival rates tend to be lower with TNBC compared to other forms of breast cancer, and TNBC is also more likely than some other types of breast cancer to return after it has been treated, especially in the first few years after treatment. It also tends to be higher grade than other types of breast cancer.

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.

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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 that administering trilaciclib prior to chemotherapy may enhance antitumor efficacy by modulating the composition and response of immune cell subsets), and the therapeutic potential of trilaciclib, which has not been approved for and is not commercially available for any use described in this press release. 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.

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