G1 Therapeutics Provides Corporate Update at the 42nd Annual J.P. Morgan Healthcare Conference

January 8, 2024 at 6:45 AM EST

- Initial Data from the Ongoing Phase 2 Trial in Combination with the Antibody-Drug Conjugate (ADC) Sacituzumab Govitecan (SG) Suggest a Potentially Meaningful Improvement in Overall Survival (OS) for Patients Receiving Trilaciclib -

- COSELA® (trilaciclib) Vial Volume Growth Accelerated in the Fourth Quarter of 2023 with 19% Growth Over Prior Quarter -

- Interim OS Analysis of Pivotal 1L Triple Negative Breast Cancer (TNBC) for Trilaciclib is Expected in the First Quarter of 2024 -

- Cash Runway Expected into 2025 -

RESEARCH TRIANGLE PARK, N.C., Jan. 08, 2024 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced new clinical, commercial and corporate updates, including encouraging preliminary overall survival (OS) data from the Company's ongoing Phase 2 trial of trilaciclib in combination with the ADC sacituzumab govitecan (SG) in patients with TNBC. This update is now available in a new corporate presentation which will be used during the 42nd Annual J.P. Morgan Healthcare Conference and can be accessed here.

"We have entered 2024 with strong momentum across our business, including compelling preliminary overall survival data from our ADC combination study in metastatic TNBC, accelerating COSELA sales volume in the most recent quarter, and awaiting near-term data from our 1L TNBC pivotal study for trilaciclib," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "We believe the initial OS results from our ADC trial may serve as proof-of-concept for the potential of trilaciclib to improve overall survival in combination with the growing class of TROP2 ADCs across TNBC indications and beyond. More imminently, we look forward to the interim OS analysis of our pivotal 1L TNBC trial, which has the potential to transform treatment for women living with this aggressive and difficult-to-treat cancer."

The update includes the following:

Clinical

- **Initial efficacy results from ongoing Phase 2 ADC trial suggest improved OS among patients receiving trilaciclib in combination with a TROP2 ADC:** Preliminary data from the ongoing Phase 2 trial of trilaciclib in combination with the ADC sacituzumab govitecan (SG) in metastatic TNBC patients suggests clinically meaningful improvements in OS among patients receiving trilaciclib in combination with SG compared to SG alone based on historical data from the ASCENT trial, including (1) current median OS of 17.9 months with trilaciclib vs 12.1 months for SG alone and (2) estimated 12-month survival of 59% of patients receiving trilaciclib in combination with SG, which would be a ~20% improvement over SG alone. The Company expects to provide updated OS data from this study mid-2024.
- **Interim OS analysis of ongoing 1L TNBC pivotal trial expected in 1Q24:** This Phase 3 trial builds upon the clinically meaningful and statistically significant OS results demonstrated in the previous Phase 2 TNBC trial. Achievement of the OS endpoint would enable global regulatory submissions.
- **OS continues to improve over time for Phase 2 TNBC patients receiving subsequent anti-cancer therapy (SACT):** Among patients receiving SACT after conclusion of study drug in the previous Phase 2 TNBC trial, the OS benefit in the trilaciclib arm increased over time as patients received SACT. Patients in the trilaciclib arms receiving subsequent 2L+ chemotherapy exhibited a median OS of 14.0 months from start of SACT, compared to patients in the chemotherapy arm receiving subsequent 2L+ chemotherapy of 5.8 months (p=0.001). The median OS of 14.0 months in the trilaciclib arms also compares favorably to historical 2L+ benchmarks for chemotherapy and SG of 6.7 months and 12.1 months in the ASCENT trial, respectively.

Commercial

- **Strong COSELA® (trilaciclib) volume growth in 4Q23:** COSELA vial volume grew 19% in 4Q23 over the prior quarter as platinum-based chemotherapy shortages began to abate. COSELA vial volume in October, November, and December 2023 represented the highest volume months since launch.
- **High levels of satisfaction with COSELA:** Up to 91% of prescribing oncologists and nurse practitioners / physician assistants rate satisfaction with COSELA as “very high” primarily driven by fewer hospitalization and protection of multiple cell lineages, which is also supported by real-world evidence.

Corporate

- **Global opportunities in TNBC expected to be pursued through partnerships:** If positive, the Phase 3 1L TNBC OS results would be expected to support regulatory submissions and enable reimbursement in territories outside of the U.S. to drive global expansion through future partnerships.
- **Cash runway to extend into 2025:** The Company expects approximately $82M in cash, cash equivalents, and marketable securities as of December 31, 2023, and a >30% decrease in 2023 operating expenses compared to that of 2022.

About G1 Therapeutics
G1 Therapeutics, Inc. is a commercial-stage oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company’s first commercial product, COSELA® (trilaciclib). The Company is also evaluating therapies in combination with cytotoxic therapies and/or immunotherapy in areas of high unmet need including triple-negative breast cancer and extensive stage small cell lung cancer. G1’s goal is to provide innovative therapeutic advances for people living with cancer. G1 is based in Research Triangle Park, N.C. For additional information, please visit http://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," “could”, “believe,” “goal”, “projections,” "estimate," "intend," “indicate,” “potential,” “opportunity,” “suggest,” 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 expectations for the commercial success of COSELA® (trilaciclib), our ability to further develop and expand the use of COSELA in the treatment of extensive-stage small cell lung cancer, that the initial OS results from the ADC trial serve as proof-of-concept for the potential of trilaciclib to improve overall survival in combination with the growing class of TROP2 ADCs, that achievement of OS endpoint in ongoing PRESERVE 2 Phase 3 clinical trial would provide the potential to transform treatment for women living with this aggressive and difficult-to-treat cancer and is expected to enable global regulatory submissions, and that G1’s cash runway is expected to extend into 2025, 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; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. 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
Communications Officer
Vice President, Investor Relations and Corporate Communications
(919) 907-1944
wroberts@g1therapeutics.com

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