



G1 Therapeutics Provides Third Quarter 2022 Financial Results and Operational Highlights

November 2, 2022

- Achieved \$23.6 million in Total Revenue in the Third Quarter of 2022 Including \$8.3 million in Net Revenue from Sales of COSELA® (trilaciclib) -
- Provided Encouraging Initial Data from Phase 2 Trial Demonstrating Potential of Trilaciclib to Reduce (>50%) the Rates of Adverse Events (AEs) Related to an Antibody-Drug Conjugate (ADC) -
 - Completed Patient Enrollment in Pivotal Phase 3 Trial of Trilaciclib in Metastatic Triple Negative Breast Cancer (mTNBC) (PRESERVE 2) -
 - Completed Patient Enrollment in Phase 2 Clinical Trial of Trilaciclib in Combination with Chemotherapy and Avelumab in Patients with Bladder Cancer (mUC) (PRESERVE 3) -
- Announced Acceptance of Abstract of Initial Results from Phase 2 Trilaciclib Mechanism of Action (MOA) Trial for Poster Presentation at the 2022 San Antonio Breast Cancer Symposium (SABCS) -
 - Management to Host Webcast and Conference Call today at 8:30 AM ET -

RESEARCH TRIANGLE PARK, N.C., Nov. 02, 2022 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the third quarter ended September 30, 2022.

"During the third quarter of 2022, we demonstrated continued execution on our clinical programs, but also experienced lower COSELA sales momentum versus what we achieved in the second quarter," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "Regarding the former, today we provided encouraging initial safety data from our ongoing Phase 2 trial of trilaciclib in combination with an ADC showing its potential to reduce the rates of adverse events associated with the ADC sacituzumab govitecan-hziy, including myelosuppression, diarrhea, and potentially alopecia. We also completed enrollment in our pivotal Phase 3 mTNBC trial and in our Phase 2 bladder cancer and mechanism of action trials. Regarding the latter, we are actively working through variability in the ES-SCLC market at certain times of the year due to patient flow and account staffing, and have recently put in place a variety of actions that we believe will enable us to drive growth over the coming months. G1's mission is to improve the lives of those affected by cancer by effectively developing trilaciclib and by ensuring broad access to COSELA, and we remain dedicated to excellence in both areas."

Third Quarter 2022 and Recent Highlights

Financial

- **Achieved \$8.3 million in Net COSELA Revenue:** G1 recognized total revenues of \$23.6 million in the third quarter of 2022, including \$8.3 million in net product revenue from sales of COSELA.
- **Ended the Third Quarter 2022 with Cash, Cash Equivalents, and Marketable Securities of \$123.0 million.**

Clinical

- **Announced Initial Safety Data from Phase 2 Trial of Trilaciclib in Combination with an Antibody-Drug Conjugate; Additional Results Including Initial Efficacy Expected in 1H23:** Initial Phase 2 safety data suggest on-target effect of trilaciclib to reduce (>50%) the rates of adverse events associated with the ADC sacituzumab govitecan-hziy, including myelosuppression, diarrhea and potentially alopecia due to the presence of CDK4/6-expressing cells in the intestinal crypt and hair follicles, relative to the previously published sacituzumab govitecan-hziy single agent safety profile. The Company anticipates disclosure of a more comprehensive data set including safety and initial efficacy results at a medical meeting in

the second quarter 2023.

- **Completed Enrollment in Pivotal Phase 3 Clinical Trial of Trilaciclib in Patients with mTNBC:** Enrollment in PRESERVE 2 is complete at 187 patients receiving first line trilaciclib or placebo prior to gemcitabine and carboplatin (GC). The primary endpoint is to evaluate the effect of trilaciclib on overall survival (OS) compared with placebo in patients receiving first-line GC. Key secondary endpoints include assessment of the effect of trilaciclib on patients' quality of life compared with placebo, myeloprotection measures, progression free survival (PFS), and overall rate of response (ORR). G1 expects the interim OS analysis to be conducted by its data monitoring committee at 70% of events in the second half of 2023. If the trial meets the interim analysis stopping rule, it will terminate, and G1 will report the topline results. If it does not, the trial will continue to the final analysis. (Press release [here](#))
- **Completed Enrollment in Phase 2 Clinical Trial of Trilaciclib in Combination with Chemotherapy and the Checkpoint Inhibitor Avelumab in Patients with Bladder Cancer (mUC):** Enrollment is complete at 92 patients in PRESERVE 3. The primary endpoint is PFS. Key secondary endpoints include overall survival, overall response rate, duration of response, and myeloprotection. Initial safety and response data are expected in the fourth quarter of 2022 followed by data on the primary endpoint of progression free survival in 2023.
- **Confirmed that Initial Data from Pivotal Phase 3 Trial of Trilaciclib in Patients with Metastatic Colorectal Cancer (mCRC) (PRESERVE 1) Are Expected in the First Quarter of 2023:** G1 has reiterated that it expects to release initial data, including results from the primary endpoint, in the first quarter of 2023. The primary endpoint is myeloprotection as measured by duration of severe neutropenia (DSN) in cycles 1-4 and the occurrence of severe neutropenia (SN) during induction. Key secondary endpoints include the effects of trilaciclib on PFS, OS, and patients' quality of life compared with placebo. If the data from the primary endpoint are positive, G1 will work closely with the FDA to expedite our filing for regulatory approval in this indication. (Press release [here](#))
- **Announced Acceptance of Abstract for Poster Presentation of Initial Results from Phase 2 Trial Confirming the MOA of Trilaciclib:** This 24 patient Phase 2 trial in early stage TNBC is designed to confirm the MOA of trilaciclib in modulating the anti-tumor immune response. The primary endpoints will assess the immune-based MOA, including the impact of trilaciclib on CD8+ T cells and regulatory T cells, or Tregs, in the tumor microenvironment. Secondary endpoints include pathological complete response (pCR), immune response, and profiling measures. Initial results from the primary endpoint will be presented as a poster presentation during the 2022 SABCS.
- **Announced Acceptance of Two Abstracts for Poster Presentation during the Society for Immunotherapy of Cancer (SITC) 2022 Annual Meeting:** G1 will present two posters during the SITC meeting: "Transient inhibition of cyclin-dependent kinase 4/6 with trilaciclib enhances inhibitory receptor immunotherapy to improve antitumor efficacy" (abstract #471) and "Trilaciclib, an intravenous cyclin-dependent kinase 4/6 inhibitor, enhances antitumor responses by modulating T cells" (abstract #1314).

Medical

- **Presented Data at the 2022 Precision Oncology Summit Demonstrating that Trilaciclib Reduces Severe Hematologic Adverse Events and Supportive Care Needs in Patients with Extensive-Stage Small Cell Lung Cancer (ES-SCLC) When Administered Prior to Chemotherapy:** In real- world practice, trilaciclib is used in a heterogeneous population of ES-SCLC patients with variability in timing of trilaciclib initiation, chemotherapeutic backbone, and presence of hematological toxicity before trilaciclib initiation. Despite this heterogeneity, trilaciclib showed consistent potential to reduce occurrence of myelosuppression, supportive care utilization, chemotherapy dose decrease, and treatment delay. (Poster [here](#))

Corporate

- **Conducted Virtual R&D Day, "Innovations in Oncology: The Science of Trilaciclib":** On September 15, 2022, G1 conducted an R&D Day to review the development and expansion strategy for trilaciclib. Included in the agenda was a presentation of new preclinical data supporting potential of trilaciclib to work synergistically with other anti-cancer therapies, including by enhancing the cancer immunity cycle by enhancing T-cell activation, favorably altering the tumor microenvironment, and improving long term immune surveillance. (Webcast of event [here](#))

Third Quarter 2022 Financial Results

As of September 30, 2022, cash and cash equivalents and marketable securities totaled \$123.0 million, compared to \$221.2 million as of December 31, 2021.

Total revenues for the third quarter of 2022 were \$23.6 million, including \$8.3 million in net product sales of COSELA and license revenue of \$15.3 million, compared to total \$4.9 million of total revenue in the third quarter of 2021. This license revenue in the current quarter is primarily related to

revenue recognized from two development milestones in the Simcere license agreement, including a \$13 million milestone related to the approval of COSELA in China.

Operating expenses for the third quarter of 2022 were \$45.1 million, compared to \$46.0 million for the third quarter of 2021. GAAP operating expenses include stock-based compensation expense of \$4.8 million for the third quarter of 2022, compared to \$5.5 million for the third quarter of 2021.

Cost of goods sold expense for the third quarter of 2022 was \$1.1 million compared to \$0.6 million for the third quarter of 2021, primarily due to an increase in product sales.

Research and development (R&D) expenses for the third quarter of 2022 were \$19.6 million, compared to \$21.1 million for the third quarter of 2021. The decrease in R&D expenses was primarily due to a decrease in costs for manufacturing of active pharmaceutical ingredients and drug product to support clinical trials.

Selling, general, and administrative (SG&A) expenses for the third quarter of 2022 were \$24.4 million, compared to \$24.3 million for the third quarter of 2021. The increase in SG&A expenses was due to increases in personnel costs due to increased headcount and administrative costs. The increase is offset by a decrease in medical affairs costs, commercialization costs, and professional and technology costs.

The net loss for the third quarter of 2022 was \$25.3 million, compared to \$42.5 million for the third quarter of 2021. The basic and diluted net loss per share for the third quarter of 2022 was \$(0.59) compared to \$(1.00) for the third quarter of 2021.

Webcast and Conference Call

G1 will host a webcast and conference call at 8:30 a.m. ET today to provide a corporate and financial update for the third quarter ended September 30, 2022.

Please note that there is a new process to access the call via telephone. To register and receive a dial in number and unique PIN to access the live conference call, please [follow this link to register online](#). While not required, it is recommended that you join 10 minutes prior to the start of the event. A live and archived webcast will be available on the [Events & Presentations](#) page of the company's website: www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

About COSELA[®] (trilaciclib) for Injection

COSELA (trilaciclib) was approved by the U.S. Food and Drug Administration on February 12, 2021.

Indication

COSELA[®] (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

Important Safety Information

COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

Warnings and precautions include injection-site reactions (including phlebitis and thrombophlebitis), acute drug hypersensitivity reactions, interstitial lung disease (pneumonitis), and embryo-fetal toxicity.

The most common adverse reactions (>10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

This information is not comprehensive. Please click here for full Prescribing Information. <https://www.g1therapeutics.com/cosela/pi/>

To report suspected adverse reactions, contact G1 Therapeutics at 1-800-790-G1TX or call FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

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 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 expectations for the commercial sales of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib), our ability to generate data to maximize trilaciclib's applicability to future treatment paradigms, our ability to obtain approvals for and commercialize additional indications of COSELA (trilaciclib), and our reliance on partners to develop licensed products. If we are not in compliance with our monthly net revenue covenants or the minimum cash covenant, we may be subject to the acceleration clauses in our loan agreement, and the lender may call the debt, resulting in our immediate need for additional funds. In addition, COSELA (trilaciclib) may fail to achieve the degree of market acceptance for commercial success, and the impact of pandemics such as COVID-19 (coronavirus). Each of these forward-looking statements is based on the company's expectations and assumptions as of the date of this press release and 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 a successful commercialize COSELA (trilaciclib); the company's ability to complete clinical trials for, obtain approvals for and commercialize additional indications of COSELA (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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G1 Therapeutics, Inc.
Balance Sheet Data
(in thousands)

	September 30, 2022	December 31, 2021
Cash and cash equivalents and Marketable securities	\$ 122,982	\$ 221,186
Working Capital	\$ 120,331	\$ 215,952
Total Assets	\$ 166,573	\$ 254,094
Accumulated deficit	\$ (698,369)	\$ (584,459)
Total stockholders' equity	\$ 45,965	\$ 143,541

G1 Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues				
Product sales, net	\$ 8,269	\$ 3,576	\$ 22,467	\$ 6,717
License revenue	15,307	1,282	18,584	18,963
Total revenues	23,576	4,858	41,051	25,680
Operating expenses				
Cost of goods sold	1,111	591	2,756	1,642
Research and development	19,581	21,143	66,729	56,435
Selling, general and administrative	24,432	24,268	76,857	72,474
Total operating expenses	45,124	46,002	146,342	130,551
Loss from operations	(21,548)	(41,144)	(105,291)	(104,871)
Other income (expense)				
Interest income	211	7	270	35
Interest expense	(2,764)	(934)	(7,436)	(2,609)
Other income (expense)	48	(76)	(234)	(208)
Total other income (expense), net	(2,505)	(1,003)	(7,400)	(2,782)
Loss before income taxes	(24,053)	(42,147)	(112,691)	(107,653)
Income tax expense	1,219	321	1,219	679
Net loss	\$ (25,272)	\$ (42,468)	\$ (113,910)	\$ (108,332)
Net loss per share, basic and diluted	\$ (0.59)	\$ (1.00)	\$ (2.67)	\$ (2.60)
Weighted average common shares outstanding, basic and diluted	42,799,342	42,383,573	42,731,826	41,740,911



Source: G1 Therapeutics