G1 Therapeutics Provides First Quarter 2023 Financial Results and Operational Highlights

May 3, 2023

- Drove 18% Quarterly Net Revenue Growth of COSELA® (trilaciclib) Over the Fourth Quarter of 2022; Grew Quarterly Vial Volume by 21% Over Prior Quarter -

- Provided Updated Timing for Interim Overall Survival (OS) Analysis of Pivotal Phase 3 Trial in Metastatic Triple Negative Breast Cancer (TNBC); Analysis Now Expected in the First Quarter of 2024 -

- Completed Enrollment in Phase 2 Trial of Trilaciclib in Combination with an Antibody Drug Conjugate (ADC) in Patients with Metastatic TNBC -

- Announced Acceptance of Additional Results from Phase 2 ADC and Neoadjuvant TNBC Trials for Presentation at the ESMO Breast Cancer 2023 Annual Congress and the ASCO 2023 Annual Meeting, Respectively -

- Strengthened Balance Sheet Through Monetization of Future Royalties and Milestones from Simcere, Providing Additional Near-Term Capital to Extend Cash Runway Beyond Important Clinical Trial Readouts Expected in Early 2024 -

- Management to Host Webcast and Conference Call today at 8:30 AM ET -

RESEARCH TRIANGLE PARK, N.C., May 03, 2023 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the first quarter ended March 31, 2023.

“Since the start of 2023, we've focused efforts on our three core priorities of driving significant growth in sales of COSELA, executing on our four ongoing clinical trials of trilaciclib, and efficiently managing our cash runway through each of our data readouts,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “We made good progress on all fronts during the first quarter of this year. The commercial team executed well, driving net COSELA sales growth of 18% quarter-over-quarter, and vial volume growth of 21%, as we work towards our guidance of between $50 million and $60 million in product revenue this year. Regarding the clinical pipeline, we've continued to move each of our trials forward, including our two Phase 2 trials in TNBC from which data are expected later this quarter, followed by results from our pivotal Phase 3 trial in TNBC which are now expected in the first quarter of next year."

First Quarter 2023 and Recent Highlights

Financial

- **Recognized $10.5 million in Net COSELA Revenue:** Results represent an 18% increase in net sales over the fourth quarter of 2022. G1 recognized total revenues of $12.9 million for the first quarter of 2023.
- **Achieved 21% COSELA Vial Volume Growth Over the Fourth Quarter of 2022.**
- **Ended the First Quarter 2023 with Cash, Cash Equivalents, and Marketable Securities of $116.3 million.**
- **Strengthened Balance Sheet Through Non-Equity Dilutive Monetization of Simcere Milestones and Royalties:** In the second quarter of 2023, G1 and Simcere reached agreement whereby Simcere will buy out the remaining milestones and royalties on sales of COSELA (trilaciclib hydrochloride for injection) in Greater China for up to $48 million, with $30 million received within the second quarter of 2023, providing additional non-equity dilutive financing that secures G1’s cash runway beyond its clinical trial readouts. All other aspects of the strategic collaboration remain in place including participation and cost-sharing in global clinical trials. G1 retains the rights to trilaciclib throughout the rest of the world,

other than Greater China.

Clinical

- **Provided Updated Timing for Initial Results from Pivotal Phase 3 Clinical Trial of Trilaciclib in Patients with mTNBC; Interim OS Analysis Now Expected in the First Quarter of 2024:** The primary endpoint of PRESERVE 2 is to evaluate the effect of trilaciclib on OS compared with placebo in patients receiving first-line gemcitabine/carboplatin. G1 now expects the interim OS analysis to be conducted by its data monitoring committee at 70% of events in the first quarter of 2024. If the trial meets the interim analysis stopping rule, it will terminate, and G1 will report the top line results. If it does not, the trial will continue to the final analysis.

- **Completed Enrollment in Phase 2 Trial of Trilaciclib in Combination with the ADC Sacituzumab Govitecan-Hziy:** Enrollment is complete at 30 patients in this exploratory Phase 2, multicenter, open-label, single arm study evaluating the safety and efficacy of trilaciclib administered prior to sacituzumab in patients with unresectable, locally advanced or metastatic TNBC.

- **Announced Upcoming Poster Presentation of Results from Trilaciclib Phase 2 ADC Combination Trial:** Additional results from this trial in metastatic TNBC have been accepted for poster presentation during the European Society for Medical Oncology (ESMO) Breast Cancer 2023 Annual Congress. The abstract (201P) will be presented during the poster session on May 12, 2023 from 12:15PM to 1:00PM Central European Summer Time (CEST). G1 currently expects to reach the OS endpoints for this study in the first quarter of 2024. Initial Phase 2 safety data presented in November 2022 suggested an on-target effect of trilaciclib to reduce the rates of adverse events associated with sacituzumab govitecan (SG), including myelosuppression and diarrhea, relative to the previously published SG single agent safety profile. (Press release here)

- **Announced Upcoming Poster Presentation of Results from Phase 2 Mechanism of Action Trial of Trilaciclib in Patients with Neoadjuvant TNBC:** Additional results from this trial have been accepted for poster presentation during the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting. The abstract (603) will be presented during the poster session on June 4, 2023 from 8:00AM to 11:00AM CDT. Initial Phase 2 safety data showed favorable alterations in the tumor microenvironment from a single dose of trilaciclib monotherapy as measured by increases in the proportions of CD8+ T cells compared to T regulatory cells (Tregs) in patients with early-stage triple negative breast cancer (TNBC). (Press release here)

- **Confirmed that Initial Results Including the Primary Endpoint of Progression Free Survival from the Phase 2 Bladder Cancer Trial of Trilaciclib (PRESERVE 3) Are Anticipated Midyear 2023:** G1 has reiterated that additional safety and efficacy results, including results from the primary endpoint of Progression Free Survival, are expected from PRESERVE 3 midyear 2023. The Company currently expects to reach the OS endpoints for this study in the first quarter of 2024.

First Quarter 2023 Financial Results

As of March 31, 2023, cash and cash equivalents and marketable securities totaled $116.3 million, compared to $145.1 million as of December 31, 2022. This includes $52.0 million in net proceeds from a fourth quarter 2022 underwritten public offering of its common stock at a public offering price of $6.50 per share. Cowen and Raymond James acted as joint book-running managers for the offering. Needham & Company and Wedbush PacGrow acted as lead managers for the offering.

Total revenues for the first quarter of 2023 were $12.9 million, including $10.5 million in net product sales of COSELA and license revenue of $2.5 million, related to supply and manufacturing services with Simcere, royalty revenue from Simcere, and clinical trial reimbursements from EQRx and Simcere, compared to $6.9 million in total revenues in the first quarter of 2022.

Operating expenses for the first quarter of 2023 were $38.7 million, compared to $53.7 million for the first quarter of 2022. GAAP operating expenses include stock-based compensation expense of $3.8 million for the first quarter of 2023, compared to $5.8 million for the first quarter of 2022.

Cost of goods sold expense for the first quarter of 2023 was $1.5 million compared to $0.7 million for the first quarter of 2022, primarily due to an increase in product sales.

Research and development (R&D) expenses for the first quarter of 2023 were $15.5 million, compared to $26.3 million for the first quarter of 2022. The decrease in R&D expenses was primarily due to a decrease in the Company's clinical program costs.

Selling, general, and administrative (SG&A) expenses for the first quarter of 2023 were $21.8 million, compared to $26.7 million for the first quarter of 2022. The decrease in SG&A expenses was primarily due to decreases in commercialization activities, personnel costs, and professional fees.

The net loss for the first quarter of 2023 was $27.6 million, compared to $49.2 million for the first quarter of 2022. The basic and diluted net loss per share for the first quarter of 2023 was $(0.53) compared to $(1.15) for the first quarter of 2022.

2023 Financial Guidance

G1 today reiterated its full year 2023 net revenue guidance. The Company expects to generate between $50 million and $60 million in COSELA net revenue in 2023. G1's product revenue guidance was initially provided in its fourth quarter and full year 2022 financial results and business update, and is based on expectations for continued acceleration of sales performance of COSELA in the U.S.

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 first quarter ended March 31, 2023.

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 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 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 full year 2023 financial guidance, 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 with our debt facility, 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.
Condensed Balance Sheet Data (unaudited)
(in thousands)

	March 31, 2023	December 31, 2022
Cash and cash equivalents and Marketable securities	$116,317	$145,070
Working Capital	$120,275	$143,912
Total Assets	$161,957	$187,965
Accumulated deficit	$(759,613)	$(732,018)
Total stockholders' equity	$44,988	$68,747

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

	Three Months Ended March 31,	
	2023	2022
Revenues		
Product sales, net	$ 10,492	$ 5,480
License revenue	2,454	1,422
Total revenues	12,946	6,902
Operating expenses		
Cost of goods sold	1,459	669
Research and development	15,480	26,305
Selling, general and administrative	21,753	26,709
Total operating expenses	38,692	53,683
Loss from operations	(25,746)	(46,781)
Other income (expense)		
Interest income	716	9
Interest expense	(3,089)	(2,265)
Other income (expense)	524	(155)
Total other income (expense), net	(1,849)	(2,411)
Loss before income taxes	(27,595)	(49,192)
Income tax expense	—	—
Net loss	$ (27,595)	$ (49,192)
Net loss per share, basic and diluted	$ (0.53)	$ (1.15)
Weighted average common shares outstanding, basic and diluted	51,647,934	42,687,201

Source: G1 Therapeutics