G1 Therapeutics Provides Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

February 24, 2021

- G1's COSELA™ (trilaciclib) Approved by FDA as First and Only Therapy to Decrease the Incidence of Chemotherapy-Induced Myelosuppression; Commercial Availability Expected in Early March -

- Launch Underway, including Medical Affairs, Promotional, and Educational Activities to Introduce COSELA to Oncologists and Oncology Nurses and Build Awareness of Myelosuppression -

- On-track to Initiate Three Additional Clinical Trials in 1H2021 to Assess the Potential Myeloprotection and/or Anti-Tumor Efficacy Benefit of COSELA in Multiple Cancers -

- Management to Host Webcast and Conference Call today at 4:30 PM ET -

RESEARCH TRIANGLE PARK, N.C., Feb. 24, 2021 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the fourth quarter and full-year ended December 31, 2020.

"With the recent approval of COSELA, we have a tremendous opportunity to introduce an effective and innovative therapy to proactively address chemotherapy-induced myelosuppression in patients with extensive-stage small cell lung cancer," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "The launch is underway with our partners at Boehringer Ingelheim, and the initial interest among medical oncologists and oncology nurses is extremely promising. COSELA has a broad mechanism of action, and as such, we are taking a tumor-agnostic approach to the development of COSELA as we advance it into and through multiple Phase 2 and registrational studies. We are confident in the potential for COSELA and look forward to delivering on our goal of improving the lives of as many people living with cancer as possible."

Fourth Quarter 2020 and Recent Highlights

Commercial

- **COSELA Approved by U.S. Food and Drug Administration (FDA)**: On February 12, 2021, the FDA approved COSELA for injection 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 (ES-SCLC). It is the first and only therapy designed to help protect bone marrow (myeloprotection) when administered prior to the start of chemotherapy. COSELA is expected to be commercially available through G1's specialty distributor partner network in early March. (Press release here)

Clinical

- **Initiated Pivotal Trial of COSELA in Patients with First Line Colorectal Cancer in the Fourth Quarter of 2020:** Patient enrollment has begun in a ~300 patient randomized, double-blind placebo-controlled pivotal registrational trial of COSELA in colorectal cancer. The primary endpoint is myelosuppression; secondary endpoints include progression free survival, overall survival, and patient reported outcomes. The data readout is expected in the first half of 2023.
- **Announced New Upcoming Registrational Trial of COSELA in First-line / Second Line Metastatic Triple-Negative Breast Cancer (mTNBC); Initiation Expected in First Half of 2021:** The Company expects to initiate a randomized, double-blind placebo-controlled registrational trial of COSELA in mTNBC in the first half of 2021. The trial is expected to enroll approximately 250 participants, with approximately 170 in the first line cohort. The trial will enroll patients who are both PD-L1-positive and PD-L1-negative in the first-line cohort. The primary endpoint is overall survival; secondary endpoints include patient-reported outcomes measures, safety/tolerability, myeloprotective measures, and progression-free survival. (Press release here)
- **Announced Two Upcoming Phase 2 Trials of COSELA in First-Line Metastatic Bladder Cancer (mUC) and Second Line / Third Line Non-Small Cell Lung Cancer (NSCLC); Initiation Expected in the First Half of 2021:** The Company expects to initiate Phase 2 trials of COSELA in first-line treatment of locally advanced or metastatic bladder cancer (locally advanced or metastatic urothelial carcinoma, or mUC) and second- and third-line treatment of NSCLC, both of which are known immunogenic tumors, in the first half of 2021. Both trials are designed to evaluate the anti-tumor efficacy of COSELA.
- **Entered into Clinical Trial Collaboration for Upcoming First-Line Locally Advanced or Metastatic Bladder Cancer (mUC) Trial:** G1 has entered into a clinical trial collaboration with the alliance between Merck KGaA, Darmstadt, Germany and Pfizer whereby the alliance will contribute clinical supply of the checkpoint inhibitor avelumab to the G1-sponsored and funded first-line mUC trial.

- **Presented Final Data from the Randomized Phase 2 Trial of COSELA in mTNBC at the 2020 San Antonio Breast Cancer Symposium (SABCS):** New data presented at the SABCS meeting showed that COSELA significantly improved overall survival (OS) in patients with mTNBC treated with COSELA prior to administration of a chemotherapy regimen of gemcitabine/carboplatin (GC) compared with GC alone, and that COSELA enhanced immune system function. Compared to GC alone (Group 1), statistically significant improvements in OS were achieved in both COSELA arms (Group 2: HR=0.31, p=0.0016; Group 3: HR=0.40, p=0.0004). As of the data cutoff of July 17, 2020, the median OS was 12.6 months in patients receiving GC alone, not yet reached for Group 2, and 17.8 months in Group 3. The median OS for Groups 2 and 3 combined was 19.8 months (HR=0.37, p<0.0001). Patients with both PD-L1-positive and PD-L1-negative tumors treated with COSELA and GC demonstrated improvement in OS compared to patients receiving GC alone, with the PD-L1-positive subset achieving statistically significant improvement. Data from T-cell clonality analysis suggest that administering COSELA prior to chemotherapy enhanced immune system function. (Poster here)
- **Presented Updated Results from Phase 1b Monotherapy Trial of Rintodestrant in ER+, HER2- Breast Cancer at the 2020 SABCS:** In a heavily pre-treated patient population, G1's oral selective estrogen receptor degrader (SERD) rintodestrant showed evidence of clinical activity as monotherapy, including a clinical benefit rate of 30%. Safety and tolerability findings across all doses, including the 600 mg and 1,000 mg expansion cohorts, were consistent with previously reported data. These findings supported the Company's decision to move the 800mg dose into the ongoing 40-patient Phase 2 combination trial with CDK4/6 inhibitor palbociclib. The data readout is expected in the second quarter of 2021. (Poster here)

Corporate

- **On February 23, 2021, the Board of Directors adopted the G1 Therapeutics, Inc. 2021 Inducement Equity Incentive Plan (the "Plan").** There are 500,000 shares of our common stock reserved under the Plan to be used exclusively for grants of awards to individuals that were not previously employees or directors of G1, as an inducement material to the individual's entry into employment with G1 within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Plan was approved by Board of Directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Plan are substantially similar to G1's stockholder-approved 2017 Equity Incentive Plan, as amended.

Fourth Quarter and Full Year 2020 Financial Results

As of December 31, 2020, cash and cash equivalents totaled $207.3 million, compared to $269.2 million as of December 31, 2019.

Subsequent to December 31, 2020, between January 14th, 2021 and February 9th, 2021, we sold 3,513,027 shares of common stock pursuant to our 2018 sales agreement for "at the market offerings" with Cowen and Company, LLC, resulting in $86.4 million in net proceeds. This ATM offering is now closed. In addition, the Company now has access to $30 million of the remaining $80M of our debt financing facility with Hercules Capital upon achievement of the FDA approval of COSELA milestone.

License revenue for the fourth quarter of 2020 was $16.5 million, primarily related to an upfront payment for our license agreement with Simcere recognized following the transfer of the related technology and know-how which occurred during the period. In addition, we recognized revenue for existing inventory transfers related to our license agreements with Genor and EQRx, as well as revenue for reimbursable clinical trial costs due from EQRx. License revenue for the full-year 2020 was $45.3 million.

Operating expenses for the fourth quarter of 2020 were $40.6 million, compared to $36.6 million for the fourth quarter of 2019. GAAP operating expenses include stock-based compensation expense of $4.8 million for the fourth quarter of 2020, compared to $4.5 million for the fourth quarter of 2019. Operating expenses for the full-year 2020 were $141.8 million, compared to $129.0 million for the prior year. Stock-based compensation expense for the full-year 2020 was $18.8 million, compared to $16.4 million for the prior year.

Research and development (R&D) expenses for the fourth quarter of 2020 were $16.4 million, compared to $24.5 million for the fourth quarter of 2019. The decrease in R&D expenses was primarily due to decreases in clinical program costs, external costs related to discovery and preclinical development, and costs for manufacturing pharmaceutical active ingredients. R&D expenses for the full-year 2020 were $73.3 million, compared to $89.0 million for the prior year.

General and administrative (G&A) expenses for the fourth quarter of 2020 were $24.3 million, compared to $12.1 million for the fourth quarter of 2019. The increase in G&A expenses was largely due to an increase in compensation due to increases in headcount, pre-commercialization activities, medical affairs costs, and professional fees and other administrative costs necessary to support our operations. G&A expenses for the full-year 2020 were $68.5 million, compared to $40.0 million for the prior year.

The net loss for the fourth quarter of 2020 was $25.3 million, compared to $35.4 million for the fourth quarter of 2019. Net loss for the full-year 2020 was $99.3 million, compared to a net loss of $122.4 million for the prior year. The basic and diluted net loss per share for the fourth quarter of 2020 was $(0.67) compared to $(0.94) for the fourth quarter of 2019. The basic and diluted net loss per share for the full-year 2020 was $(2.62) compared to $(3.27) for the full-year 2019.

Financial Guidance

The Company expects its current financial position to be sufficient to fund its operations and capital expenditures into 2023.

Webcast and Conference Call

G1 will host a webcast and conference call at 4:30 p.m. ET today to provide a corporate and financial update for the fourth quarter and full-year 2020

ended December 31, 2020. The live call may be accessed by dialing (866) 763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 5267698. 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

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

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis and Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.

- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).

- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).

- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.

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

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

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

Please see full Prescribing Information here

For more information about COSELA, please call 1-800-790-G1TX (1-800-790-4189)

About G1 Therapeutics
G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the discovery, development and delivery 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 evaluating targeted cancer therapies 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.

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 timing and commercial launch and availability of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib) and rintodestrant, COSELA's (trilaciclib) possibility to improve patient outcomes across multiple indications, rintodestrant's potential as an oral SERD, our reliance on partners to develop and commercial licensed products, and the impact of pandemics such as COVID-19 (coronavirus), 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 a successful commercial launch for COSELA (trilaciclib); the company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates other than 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 development-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)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 207,306	$ 269,208
Working Capital	$ 192,949	$ 251,234
Total Assets	$ 228,552	$ 284,831
Accumulated deficit	$ (436,107)	$ (336,853)
Total stockholders' equity	$ 177,351	$ 255,527

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

	Three months ended December 31,		Twelve months ended December 31,	
	2020	2019	2020	2019
License revenue	$ 16,546	$ -	$ 45,285	$ -
Operating expenses:				

Research and development	16,374	24,492	73,271	89,002
General and administrative	24,260	12,061	68,490	40,039
Total operating expenses	40,634	36,553	141,761	129,041
Loss from operations	(24,088)	(36,553)	(96,476)	(129,041)
Other income (expense):				
Interest Income	30	1,111	952	6,579
Interest Expense	(756)	-	(1,778)	-
Other income (expense)	(54)	1	(542)	15
Total other income (expense), net	(780)	1,112	(1,368)	6,594
Loss before income taxes	(24,868)	(35,441)	(97,844)	(122,447)
Income tax expense	479	-	1,410	-
Net loss	$ (25,347)	$ (35,441)	$ (99,254)	$ (122,447)
Net loss per share, basic and diluted	$ (0.67)	$ (0.94)	$ (2.62)	$ (3.27)
Weighted average common shares outstanding, basic and diluted	38,053,609	37,586,218	37,878,026	37,499,256

Source: G1 Therapeutics