# G1 Therapeutics Provides Fourth Quarter and Full-Year 2019 Corporate and Financial Update

February 26, 2020

*New Drug Application (NDA) submission for trilaciclib in small cell lung cancer on track for 2Q20*
*Trilaciclib selected for inclusion in I-SPY 2 breast cancer trial*
*Rintodestrant (G1T48) combination trial with palbociclib expected to initiate in 2Q20*
*Management to host webcast and conference call today at 4:30 p.m. ET*

RESEARCH TRIANGLE PARK, N.C., Feb. 26, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the fourth quarter and full-year ended December 31, 2019.

"We achieved significant clinical and regulatory milestones across our pipeline in 2019. In 2020, our primary focus is the execution of our U.S. and European regulatory filings for trilaciclib for patients with small cell lung cancer and preparation for its commercial launch in the U.S.," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "We believe trilaciclib has the potential to improve outcomes for patients receiving chemotherapy across a broad range of tumor types. In 2020, we will initiate a Phase 3 trial in colorectal cancer and evaluate trilaciclib in the I-SPY 2 breast cancer trial."

**Fourth Quarter Regulatory, Clinical and Corporate Highlights**

- **Initiated rolling NDA submission for trilaciclib in small cell lung cancer (SCLC) in 4Q19 and expect to complete the filing in 2Q20.** Certain portions of the NDA, including preclinical data, were submitted to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019. The company plans to complete the filing in the second quarter of 2020.

- **Trilaciclib included in I-SPY 2 neoadjuvant breast cancer trial based on compelling overall survival (OS) findings in Phase 2 triple-negative breast cancer (TNBC) trial.** At the European Society for Medical Oncology (ESMO) 2019 Congress, the company presented preliminary data from its randomized, open-label Phase 2 trial of trilaciclib in TNBC showing that the addition of trilaciclib to chemotherapy resulted in a significant increase in OS compared to chemotherapy alone (press release here). These findings contributed to trilaciclib being selected for inclusion in the ongoing Phase 2 I-SPY 2 TRIAL™. Two new investigational treatment arms of the trial will evaluate trilaciclib in neoadjuvant treatment of locally advanced breast cancer. The study will generate data that will allow the company to evaluate trilaciclib in combination with several broadly-used chemotherapy classes, an anti-PD-1 immunotherapy, and a range of breast cancer subtypes (press release here).

- **Findings from Phase 1/2a rintodestrant monotherapy trial in patients with ER+, HER2- breast cancer support initiation of combination trials with CDK4/6 inhibitors.** The company announced preliminary safety, tolerability and efficacy data on rintodestrant (formerly G1T48), its oral selective estrogen receptor degrader (SERD), at the 2019 European Society of Medical Oncology Congress in September (press release here). Based on these findings, G1 plans to initiate an additional arm of its ongoing Phase 1/2a trial in the second quarter of 2020 to explore the combination regimen of rintodestrant and the CDK4/6 inhibitor Ibrance® (palbociclib) as a treatment for ER+, HER2- breast cancer. Palbociclib will be provided by Pfizer Inc. under a non-exclusive clinical supply agreement.

- **Reported additional data from Phase 1b/2a clinical trial of lerociclib in combination with fulvestrant for the treatment of ER+, HER2- breast cancer.** Updated findings presented at the 2019 San Antonio Breast Cancer Symposium showed lerociclib, dosed without a drug holiday, has a differentiated safety and tolerability profile than observed in clinical trials with currently marketed CDK4/6 inhibitors. Preliminary efficacy findings were consistent with other CDK4/6 inhibitors used in combination with fulvestrant. Additional safety and efficacy data are expected in the third quarter of 2020.

**Fourth Quarter/Full-Year 2019 Financial Highlights and 2020 Guidance**

- **Cash Position:** Cash and cash equivalents totaled $269.2 million as of December 31, 2019, compared to $369.3 million as of December 31, 2018.
- **Operating Expenses:** Operating expenses were $36.6 million for the fourth quarter of 2019, compared to $26.1 million for the fourth quarter of 2018. GAAP operating expenses include stock-based compensation expense of $4.5 million for the fourth quarter of 2019, compared to $3.3 million for the fourth quarter of 2018. Operating expenses for the full-year 2019 were $129.0 million, compared to $89.3 million for the prior year. Stock-based compensation expense for the full-year 2019 was $16.4 million, compared to $10.2 million for the prior year.
- **Research and Development Expenses:** Research and development (R&D) expenses for the fourth quarter of 2019 were $24.5 million, compared to $19.1 million for the fourth quarter of 2018. R&D expenses for the full-year 2019 were $89.0 million, compared to $70.7 million for the prior year. The increase in R&D expenses was primarily due to an increase in

clinical program costs, costs for manufacturing pharmaceutical active ingredients, and personnel costs due to additional headcount.

- **General and Administrative Expenses:** General and administrative (G&A) expenses for the fourth quarter of 2019 were $12.1 million, compared to $7.0 million for the fourth quarter of 2018. G&A expenses for the full-year 2019 were $40.0 million, compared to $18.6 million for the prior year. The increase in G&A expenses was largely due to an increase in compensation due to additional headcount, increase in pre-commercialization activities, increase in medical affairs costs, and an increase in professional fees and other administrative costs necessary to support our operations.
- **Net Loss:** G1 reported a net loss of $35.4 million for the fourth quarter of 2019, compared to $24.1 million for the fourth quarter of 2018. Net loss for the full-year 2019 was $122.4 million, compared to a net loss of $85.3 million for the prior year.
- **2020 Guidance:** The company expects to end 2020 with $110-$130 million in cash and cash equivalents, prior to the consideration of potential proceeds from partnerships, collaboration activities, and/or other sources of capital. The company expects year-end 2019 cash and cash equivalents of $269.2 million to be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2021.

**Key Anticipated 2020 Milestones**

- Complete NDA submission for trilaciclib in SCLC in 2Q20 and Marketing Authorization Application to the European Medicines Agency in 4Q20.
- Begin enrollment in I-SPY 2 clinical trial of trilaciclib in neoadjuvant breast cancer in 2Q20.
- Initiate additional arm of rintodestrant Phase 1/2a trial to evaluate combination with Ibrance® (palbociclib) in 2Q20; additional Phase 1/2a monotherapy data expected in 4Q20.
- Initiate Phase 3 clinical trial of trilaciclib in colorectal cancer in 4Q20.

**Webcast and Conference Call**

The management team 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 2019 ended December 31, 2019. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 4188787. 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 G1 Therapeutics**

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs. Trilaciclib is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation from the FDA; a rolling NDA submission for small cell lung cancer is expected to be completed in the second quarter of 2020. Rintodestrant (formerly G1T48) is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies.

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 news release include, but are not limited to, those relating to the therapeutic potential of trilaciclib, rintodestrant and lerociclib, the timing of marketing applications in the U.S. and Europe for trilaciclib in SCLC, the planned initiation of the additional arm of the rintodestrant trial to evaluate combination with Ibrance® (palbociclib), and lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors and 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; 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, 2019 | December 31, 2018 |
|---|---|---|
| Cash and cash equivalents | $ 269,208 | $ 369,290 |
| Working capital | $ 251,234 | $ 357,771 |
| Total assets | $ 284,831 | $ 371,270 |
| Accumulated deficit | $ (336,853) | $ (214,406) |
| Total stockholders' equity | $ 255,527 | $ 358,820 |

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue | $ — | $ — | $ — | $ — |
| Operating expenses | | | | |
| Research and development | 24,492 | 19,077 | 89,002 | 70,683 |
| General and administrative | 12,061 | 7,009 | 40,039 | 18,603 |
| Total operating expenses | 36,553 | 26,086 | 129,041 | 89,286 |
| Operating loss | (36,553) | (26,086) | (129,041) | (89,286) |
| Other income (expense) | | | | |
| Other income | 1,112 | 1,994 | 6,594 | 3,998 |
| Total other income, net | 1,112 | 1,994 | 6,594 | 3,998 |
| Net loss | $ (35,441) | $ (24,092) | $ (122,447) | $ (85,288) |
| Net loss per share, basic and diluted | $ (0.94) | $ (0.65) | $ (3.27) | $ (2.56) |
| Weighted average common shares outstanding, basic and diluted | 37,586,218 | 37,203,233 | 37,499,256 | 33,316,719 |

Source: G1 Therapeutics