G1 Therapeutics Provides Second Quarter 2020 Corporate and Financial Update

August 5, 2020

- Submitted New Drug Application (NDA) for trilaciclib in small cell lung cancer (SCLC)
- Co-promotion agreement with Boehringer Ingelheim for U.S. trilaciclib launch
- Partnership for trilaciclib in China and global out-licensing of lerociclib net a combined $40 million in upfront payments, up to $486 million in milestone payments, plus potential royalties
- Secured $100 million credit facility to support trilaciclib development and commercialization
- Increasing cash guidance for FY 2020 to $185-$200 million at year end
- Management to host webcast and conference call today at 5:00 p.m. ET

RESEARCH TRIANGLE PARK, N.C., Aug. 05, 2020 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the second quarter ended June 30, 2020.

"We made substantial progress on a number of fronts in the first half of 2020, and sharpened our focus on bringing trilaciclib to patients in 2021. By forging four strategic collaborations and securing a flexible credit facility, we have achieved three important objectives: positioning G1 for a strong commercial launch of trilaciclib in the United States, providing global access to our therapies, and securing non-dilutive capital to support the continued development of trilaciclib in additional indications," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "We are now executing a comprehensive launch strategy for trilaciclib designed to raise awareness of the burden that chemotherapy-induced myelosuppression places on patients and the healthcare system, as well as implementing a robust development plan to evaluate the benefits of trilaciclib in additional tumor types and chemotherapy regimens."

Regulatory, Clinical and Corporate Highlights

- **NDA for trilaciclib in small cell lung cancer (SCLC) submitted in June 2020.** Pending acceptance, the company expects to receive a PDUFA date assignment by the U.S. Food and Drug Administration (FDA) in August 2020. Trilaciclib has been assigned Breakthrough Therapy Designation by the FDA.
- **Entered into co-promotion agreement with Boehringer Ingelheim for trilaciclib in SCLC in the United States and Puerto Rico.** Under the terms of the three-year agreement, G1 and Boehringer Ingelheim will collaborate on the commercialization of trilaciclib for its first potential indication in SCLC. G1 will lead marketing, market access and medical engagement initiatives, with Boehringer Ingelheim leading sales force engagement initiatives. G1 will book revenue and retain development and commercialization rights to trilaciclib (press release here).
- **Partnered with Simcere to develop and commercialize trilaciclib in Greater China.** The company entered into an exclusive agreement with Simcere Pharmaceuticals Group for the development and commercialization of trilaciclib for all indications in Greater China (mainland China, Hong Kong, Macau, and Taiwan). Under the terms of the agreement, G1 received a $14 million upfront payment and is eligible to receive sales-based royalties and up to $156 million in potential milestone payments (press release here). As part of this agreement, the company will collaborate with Simcere on future clinical trials. G1 and Simcere will be responsible for all development and commercialization costs in their respective territories.
- **I-SPY 2 neoadjuvant breast cancer trial including trilaciclib initiated in 2Q20.** Trilaciclib was selected for inclusion in the ongoing Phase 2 I-SPY 2 TRIAL™, based on compelling overall survival findings in a Phase 2 triple-negative breast cancer (TNBC) trial (press release here). The I-SPY trial will generate data across a range of breast cancer subtypes that will allow the company to evaluate trilaciclib in combination with several broadly-used chemotherapy classes and an anti-PD-1 immunotherapy.
- **Rintodestrant and Ibrance combination trial initiated in 2Q20.** The company previously announced preliminary safety, tolerability and efficacy data on rintodestrant, its oral selective estrogen receptor degrader (SERD) (press release here) as monotherapy treatment for ER+, HER2- breast cancer. Based on these findings, G1 initiated an additional arm of its ongoing Phase 1/2a trial to evaluate the combination regimen of rintodestrant and the CDK4/6 inhibitor Ibrance® (palbociclib). Palbociclib is being provided by Pfizer Inc. under a non-exclusive clinical supply agreement.
- **Out-licensed global development and commercialization rights to lerociclib.** The company entered into separate, exclusive agreements with EQRx (rights for U.S., Europe, Japan, and all markets outside Asia-Pacific) and Genor Biopharma (rights for Asia-Pacific, excluding Japan) for the development and commercialization of lerociclib in all indications. Combined, these agreements provided $26 million in upfront payments to G1, along with sales-based royalties and up to $330 million in potential milestone payments (see press releases on EQRx agreement and Genor agreement). EQRx and Genor are responsible for all costs related to the development and commercialization of lerociclib in their respective territories.
- **Out-licensed global development and commercialization rights to preclinical CDK2 inhibitor compounds.** The company entered into an exclusive license agreement with ARC Therapeutics for global development and

commercialization rights to its preclinical CDK2 inhibitor compounds. Under the terms of the agreement, G1 received an upfront payment and equity in ARC with an aggregate value of approximately $2.1 million. The company is also entitled to receive an additional milestone payment and sales-based royalties, and has right of first negotiation to re-acquire these assets.

- **Secured flexible credit financing for up to $100 million.** The company announced it had entered into a debt financing agreement for up to $100 million with Hercules Capital, Inc. G1 has accessed $20 million to support the development and commercialization of trilaciclib (press release here).

Second Quarter 2020 Financial Highlights and 2020 Guidance

- **Cash Position:** Cash and cash equivalents totaled $234.3 million as of June 30, 2020, compared to $269.2 million as of December 31, 2019.
- **License Revenue:** License revenues were $2.1 million for the second quarter of 2020, related to the license of CDK2 inhibitor compounds to ARC Therapeutics.
- **Operating Expenses:** Operating expenses were $33.0 million for the second quarter of 2020, compared to $32.6 million for the second quarter of 2019. GAAP operating expenses include stock-based compensation expense of $4.4 million for the second quarter of 2020, compared to $3.7 million for the second quarter of 2019.
- **Research and Development Expenses:** Research and development (R&D) expenses for the second quarter of 2020 were $18.5 million, compared to $23.5 million for the second quarter of 2019. The decrease in R&D expenses was primarily due to a decrease in clinical program costs of $3.4 million and regulatory filing reimbursement received during the second quarter of 2020 for $3.0 million, offset by an increase in costs for manufacturing active pharmaceutical ingredients.
- **General and Administrative Expenses:** General and administrative (G&A) expenses for the second quarter of 2020 were $14.4 million, compared to $9.1 million for the second quarter of 2019. 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 $31.2 million for the second quarter of 2020, compared to $30.7 million for the second quarter of 2019.
- **2020 Guidance:** The company is increasing its previous financial guidance and expects to end 2020 with $185-$200 million in cash and cash equivalents, up from previous guidance of $110-$130 million. This guidance includes receipt of upfront payments from recent agreements, but does not include consideration of potential additional proceeds from partnerships, collaboration activities, and/or other sources of capital.

Key Anticipated 2020 Milestones

- NDA acceptance/PDUFA date assignment for trilaciclib in SCLC in August 2020.
- Initiate Phase 3 clinical trial of trilaciclib in colorectal cancer in 4Q20.
- Presentation of Phase 2 data of trilaciclib in triple-negative breast cancer in 4Q20.
- Presentation of additional rintodestrant monotherapy data in 4Q20.

Webcast and Conference Call

The management team will host a webcast and conference call at 5:00 p.m. ET today to provide a corporate and financial update for the second quarter 2020 ended June 30, 2020. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 4648036. 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 FDA-designated Breakthrough Therapy designed to improve outcomes for patients being treated with chemotherapy. Rintodestrant 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 press 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, trilaciclib's possibility to improve patient outcomes across multiple indications, rintodestrant's potential to be best-in-class oral SERD, lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors, 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 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)

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 234,267	$ 269,208
Working capital	$ 218,167	$ 251,234
Total assets	$ 253,597	$ 284,831
Accumulated deficit	$ (399,086)	$ (336,853)
Total stockholders' equity	$ 203,845	$ 255,527

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
License revenue – related party	$ 2,140	$ —	$ 2,140	$ —
Operating expenses:				
Research and development	18,531	23,489	38,965	41,569
General and administrative	14,431	9,094	25,818	16,896
Total operating expenses	32,962	32,583	64,783	58,465
Loss from operations	(30,822)	(32,583)	(62,643)	(58,465)
Other income (expense):				
Interest income	91	1,893	872	3,809
Interest expense	(265)	—	(265)	—
Other income (expense)	(214)	—	(197)	14
Total other income (expense), net	(388)	1,893	410	3,823
Net loss	$ (31,210)	$ (30,690)	$ (62,233)	$ (54,642)
Net loss per share, basic and diluted	$ (0.83)	$ (0.82)	$ (1.65)	$ (1.46)
Weighted average common shares outstanding, basic and diluted	37,786,208	37,470,926	37,722,965	37,434,156

Source: G1 Therapeutics