G1 Therapeutics and Pepper Bio Announce Global (Excluding Asia-Pac) License Agreement for Lerociclib

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- Pepper Bio will Gain Exclusive Rights for the Clinical Development, Regulatory Submissions, and Commercialization of Lerociclib in the US, Europe, Japan, and All Other Global Markets Excluding Asia-Pacific -

RESEARCH TRIANGLE PARK, N.C. and BOSTON, May 01, 2024 (GLOBE NEWSWIRE) -- G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, and Pepper Bio, the world's first transomics drug discovery and development company, announced a global licensing agreement (excluding the Asia-Pacific region) for lerociclib for all indications except for certain radioprotectant uses. As Pepper Bio's first in-licensed therapeutic, lerociclib is a potent and selective inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6). The therapeutic has previously demonstrated impressive efficacy in clinical studies across various cancer types, including two completed Phase 3 clinical trials in HR+/Her2- metastatic breast cancer.

Today, the most common type of liver cancer, hepatocellular carcinoma (HCC), is the third leading cause of all cancer-related deaths. Using Pepper Bio's transomics platform, COMPASS, the company was able to identify CDK4 and CDK6 as potentially important targets in treating HCC. Pepper Bio then tested lerociclib in preclinical models, which showed superior efficacy over standard of care during and after dosing. With this in-licensing deal, lerociclib will be Pepper Bio's first therapeutic on its way to Phase 2 clinical trials.

Pepper Bio's platform, COMPASS, translates layers of biological maps, including genomics (genes), transcriptomics (RNA), proteomics (proteins), and phosphoproteomics (function of proteins), to offer researchers a complete picture of how diseases impact biology. Setting Pepper Bio apart from other drug discovery platforms is its unprecedented ability to look at the real-time function of proteins in a biological system, as opposed to the current methods of only measuring the presence, type, and quantity of proteins. COMPASS unveils the intricate functions of these proteins, which significantly impact how drugs are built and developed.

"Liver cancer is a real and devastating diagnosis for hundreds of thousands of patients each year. Adding lerociclib into our pipeline is a significant step forward in our mission to find treatments for untreatable diseases," said Jon Hu, Chief Executive Officer and co-founder of Pepper Bio. "Lerociclib holds tremendous promise as a cornerstone of our oncology portfolio, and we are excited to leverage its potential to bring life-saving treatments to those in need."

Pepper Bio will gain exclusive rights to develop, manufacture, and commercialize lerociclib for all indications except for certain radioprotectant uses in the US, Europe, Japan, and all other global markets, excluding the Asia-Pacific region, which G1 has already licensed to Genor Biopharma. G1 Therapeutics and Pepper Bio will collaborate closely to ensure a seamless transition and advance the development of lerociclib through clinical trials and regulatory approval processes.

This news follows Pepper Bio's oversubscribed seed funding round, led by NFX, Silverton Partners, Merck Digital Sciences Studio, and others. Pepper Bio is now poised to initiate clinical development programs for lerociclib, with the ultimate goal of obtaining regulatory approvals and making lerociclib available to patients as quickly as possible.

Under the terms of the agreement, G1 is expected to receive upfront payments totaling mid-single-digit millions within 12 months and is eligible to receive a maximum of $135M upon achievement of development and commercial milestones in up to three indications. In addition, Pepper Bio will pay G1 a double-digit royalty on aggregate annual net sales of lerociclib.

"Pepper Bio's commitment to innovation makes them the right partner for advancing lerociclib through the next stages of clinical development," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "This agreement is consistent with our corporate strategy to form partnerships that enable global access to our promising oncology therapies; with Pepper Bio, we look forward to the opportunity to realize the full therapeutic potential of lerociclib across new oncology indications."

For more information about G1 Therapeutics, please visit www.g1therapeutics.com. For more information about Pepper Bio and its drug development pipeline, please visit pepper.bio

About Lerociclib
Lerociclib is a differentiated oral CDK4/6 inhibitor based on its unique attributes, including its increased selectivity and potency for CDK 4 and CDK 6 and shorter half-life. Preliminary clinical data in hormone receptor-positive, HER2-negative (HR+, HER2-) breast cancer have demonstrated proof-of-concept of the differentiated clinical profile of continuously dosed lerociclib versus currently marketed CDK4/6 inhibitors, with improved tolerability and less neutropenia while maintaining robust clinical activity. Lerociclib has been licensed to Genor Biopharma in the Asia-Pacific region (excluding Japan) and is under National Medical Products Administration review in China for 1L and 2L HR+/HER2- breast cancer.

About Pepper Bio
Pepper Bio is the world's first transomics drug discovery company, leveraging its proprietary transomics database and analytics to identify promising first-in-class therapies, rediscover new uses for existing therapeutics, and rescue drugs in development on a path toward failure. Founded in 2020 and based in Boston, Massachusetts, Pepper Bio is led by co-founder and Chief Executive Officer, Jon Hu, and co-founder and Chief Science Officer, Samantha Dale Strasser, Ph.D. For more information about Pepper Bio and its drug development pipeline, please visit pepper.bio.

About G1 Therapeutics
G1 Therapeutics, Inc. is a commercial-stage oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA® (trilaciclib). The Company is also evaluating therapies in combination with cytotoxic therapies and/or immunotherapy in areas of high unmet need including triple-negative breast cancer and extensive stage small cell lung cancer. G1's goal is to provide innovative therapeutic advances for people living with cancer. G1 is based in Research Triangle Park, N.C. For additional information, please visit http://www.g1therapeutics.com and follow us on X (formerly known as Twitter) @G1Therapeutics and LinkedIn.

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," "could", "believe," "goal", "projections," "estimate," "intend," "indicate," "potential," "promising," "opportunity," "suggest," 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, statements regarding the anticipated benefits of the licensing agreement between Pepper Bio and G1 Therapeutics, the potential of lerociclib as a treatment for cancer, and the anticipated development and commercialization plans for lerociclib, 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 dependence on the commercial success of COSELA (trilaciclib); the development and commercialization of new drug products is highly competitive; 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 commercial-stage company; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. 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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