

Evoke Pharma Reports Fourth Quarter and Full Year 2019 Financial Results

March 12, 2020

Gimoti[™] Prescription Drug User Fee Act (PDUFA) decision date set for June 19, 2020

SOLANA BEACH, Calif., March 12, 2020 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the fourth quarter and full year ended December 31, 2019.

"Over the course of 2019, we worked diligently to address the regulatory requests from the U.S. Food and Drug Administration (FDA) that culminated in the resubmission and acceptance for filing of our Gimoti NDA. We look forward to the June 19th PDUFA date and will continue to work with FDA throughout the review process," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. "During this FDA review process, we are actively working with our commercial partner, Eversana, to prepare for the potential commercialization of Gimoti. Our partnership allows us to leverage Eversana's integrated suite of capabilities, including highly experienced personnel with proficiency in all key facets of pharmaceutical product commercialization including sales. This partnership has allowed us to continue to maximize our resources and we expect our current cash to support our operations into the third quarter of 2020, excluding the \$5 million Eversana line of credit that becomes available if FDA approves the Gimoti NDA."

Fourth Quarter and Full Year 2019 Financial Review

For the fourth quarter of 2019, the net loss was approximately \$1.4 million, or \$0.06 per share, compared to a net loss of approximately \$1.8 million, or \$0.10 per share for the fourth quarter of 2018. For the year ended December 31, 2019, the net loss was approximately \$7.1 million, or \$0.32 per share. This compares to a net loss of approximately \$7.6 million, or \$0.46 per share for the full year of 2018.

Research and development expenses totaled approximately \$0.6 million for the fourth quarter of 2019 compared to approximately \$0.7 million for the fourth quarter of 2018. For the full year of 2019, research and development expenses were approximately \$3.4 million compared to approximately \$4.1 million in the prior year.

For the fourth quarter of 2019, general and administrative expenses were approximately \$0.8 million compared to approximately \$1.1 million for the fourth quarter of 2018. For the year ended December 31, 2019, general and administrative expenses were approximately \$3.7 million versus approximately \$3.9 million for the full year of 2018.

Total operating expenses for the fourth quarter of 2019 were approximately \$1.4 million compared to total operating expenses of approximately \$1.8 million for the same period of 2018. For the year ended December 31, 2019, total operating expenses were approximately \$7.2 million compared to approximately \$8.0 million for the full year of 2018.

As of December 31, 2019, the Company's cash and cash equivalents were approximately \$5.7 million.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The Company is developing Gimoti, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Metoclopramide is currently available only in oral and injectable formulations and is the only drug currently approved in the United States to treat gastroparesis. Visit <u>www.EvokePharma.com</u> for more information.

Safe Harbor Statement

Evoke cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding: the potential timing of FDA action on the NDA and potential approval and product launch for Gimoti; Evoke's belief that it can leverage Eversana's capabilities to prepare for potential commercialization of Gimoti; and Evoke's projected cash runway. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Evoke's business, including, without limitation: the potential for the FDA to delay the PDUFA target goal date due to the FDA's internal resource constraints or other reasons; Evoke may be unable to timely and successfully address the deficiencies raised in the Complete Response Letter (CRL) regarding Gimoti, including as a result of adverse findings from a root cause analysis or data from the newly manufactured product batches not fully addressing issues raised by the FDA in the CRL and type A meeting; FDA may not agree with Evoke's conclusion of the results from the manufacturing testing or the root cause analysis, or may require Evoke to conduct additional studies;

the inherent risks of clinical development and regulatory approval of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the manufacturing data; Evoke's depending on EVERSANA to prepare for commercialization and launch commercial sales of Gimoti, if approved; Evoke is entirely dependent on the success of Gimoti; Evoke will require substantial additional funding to continue its operations, and may be unable to raise capital or obtain funds when needed, including to fund ongoing operations; Evoke could face significant additional costs due to litigation or other events; and other risks detailed in Evoke's prior press releases and in the periodic reports it files with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Evoke undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Evoke Pharma, Inc.

Balance Sheets

	D	ecember 31, 2019		2018
Assets				
Current Assets:				
Cash and cash equivalents	\$	5,663,833		\$ 5,319,004
Prepaid expenses		581,706		329,218
Total current assets		6,245,539		5,648,222
Operating lease right-of-use asset		138,538		—
Other assets		11,551		11,551
Total assets	\$	6,395,628		\$ 5,659,773
Liabilities and stockholders' equity				
Current Liabilities:				
Accounts payable and accrued expenses	\$	1,033,383		\$ 476,202
Accrued compensation		843,162		1,158,251
Operating lease liability		138,538		—
Total current liabilities		2,015,083		1,634,453
Commitments and contingencies				
Stockholders' equity:				
Preferred stock		_		_
Common stock		2,443		1,743
Additional paid-in capital		90,108,492		82,628,312
Accumulated deficit		(85,730,390)	(78,604,735
Total stockholders' equity		4,380,545		4,025,320
Total liabilities and stockholders' equity	\$	6,395,628		\$ 5,659,773

Evoke Pharma, Inc.

Statements	ot	Operations

	Year Ended December 31,			
	2019	2018		
Operating expenses:				
Research and development	\$ 3,416,466	\$ 4,095,014		
General and administrative	3,737,987	3,919,671		
Total operating expenses	7,154,453	8,014,685		
Loss from operations	(7,154,453) (8,014,685)		
Other income:				
Interest income	28,798	15,213		
Gain from change in fair value of warrant liability	_	433,392		
Total other income	28,798	448,605		
Net loss	\$ (7,125,655) \$ (7,566,080)		
Net loss per share of common stock, basic and diluted	\$ (0.32) \$ (0.46)		
Weighted-average shares used to compute basic and diluted net loss per share	22,296,089	16,602,422		

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Tram Bui Tel: 646-536-7035 tbui@theruthgroup.com



Source: Evoke Pharma, Inc.