Evoke Pharma to Resubmit Gimoti™ NDA Based on FDA Meeting Minutes and Announces Second Quarter 2019 Financial Results

August 8, 2019

NDA resubmission anticipated in fourth quarter 2019

SOLANA BEACH, Calif., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that following receipt of U.S. Food and Drug Administration (FDA) minutes from a type A meeting held on July 25, 2019, the Company intends to resubmit its New Drug Application (NDA) for Gimoti™ in the fourth quarter of 2019. The Company also announced its financial results for the second quarter ended June 30, 2019.

The purpose of the type A meeting was to obtain the Agency's feedback and agreement on the Company's plan to address deficiencies cited in the April 2019 Complete Response Letter (CRL) in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

Based on FDA feedback and the meeting minutes, the Company will include its root cause analysis and previously collected patient use and experience information in its resubmission package. The Company also agreed to provide an analysis of pump performance characteristics of the nasal spray devices used in the comparative bioavailability study and 3-month stability data from commercial scale batches of Gimoti which the Company initiated manufacturing in June 2019. FDA did not request additional human clinical trials be completed for resubmission.

"We are very pleased with the outcome of our meeting with FDA and appreciate their thoughtful approach in considering the totality of the data from our previously submitted NDA, along with a root cause analysis summary and additional quality data that will be referenced in our planned resubmission," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma, Inc. "We now have the clarity required to resubmit our Gimoti NDA in the fourth quarter of 2019, and we believe we have sufficient funds to support our operations into the second quarter of 2020."

Second Quarter 2019 Financial Review

For the second quarter of 2019, net loss was approximately $2.1 million, or $0.09 per share, compared to a net loss of approximately $2.3 million, or $0.14 per share for the second quarter of 2018.

Research and development expenses totaled approximately $1.2 million for the second quarter of 2019, compared to approximately $1.4 million for the second quarter of 2018. Research and development expenses were primarily related to responding to requests for additional information from FDA and manufacturing registration batches of Gimoti.

For the second quarter of 2019, general and administrative expenses were approximately $0.9 million compared to approximately $0.9 million for the second quarter of 2018.

Total operating expenses for the second quarter of 2019 were approximately $2.1 million, compared to total operating expenses of approximately $2.3 million for the second quarter of 2018.

As of June 30, 2019, the Company's cash and cash equivalents were approximately $7.4 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 www.EvokePharma.com 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: Evoke's plan to resubmit the Gimoti NDA in the fourth quarter of 2019; Evoke's specific plans on the inclusion of certain analysis and date in the

resubmission; and Evoke's belief that it can address the approvability issues raised by the FDA in the CRL and during the Type a meeting. 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: FDA may disagree that the root cause analysis and additional patient data will address the PK variability or droplet size distribution issues raised by FDA; the stability data from the commercial scale batches manufactured in June 2019 may not address the FDA's concerns or support approval of the NDA; later developments with FDA that may be inconsistent with the already completed meetings, and the risk that the resubmitted NDA may still not be accepted by the FDA; FDA may not agree with Evoke's interpretation of the results of clinical trials of Gimoti; the inherent risks of clinical development of Gimoti; Evoke may still incur significant additional expenses prior to the Gimoti NDA resubmission which could significantly shorten our projected cash runway; Evoke's reliance on a third party, Novos Growth Partners (NGP), for critical aspects of the commercialization of Gimoti; Evoke's ability to timely secure a contract sale organization; Evoke could face unexpected costs due to additional regulatory requests, litigation or other events; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will approve the NDA for Gimoti or that Evoke and NGP will successfully commercialize Gimoti; Evoke may require substantial additional funding, and may be unable to raise capital or obtain funds under the working capital loan or line of credit when needed, including to fund ongoing operations; 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.

(Financial Statements to Follow)

Evoke Pharma, Inc.

Condensed Balance Sheets

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 7,440,079	$ 5,319,004
Prepaid expenses	109,739	329,218
Other current assets	11,551	—
Total current assets	7,561,369	5,648,222
Operating lease right-of-use asset	69,795	—
Other assets	—	11,551
Total assets	$ 7,631,164	$ 5,659,773
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 407,517	$ 476,202
Accrued compensation	807,706	1,158,251
Operating lease liability	69,795	—
Total current liabilities	1,285,018	1,634,453
Stockholders' equity:		
Common stock	2,411	1,743
Additional paid-in capital	89,027,832	82,628,312
Accumulated deficit	(82,684,097)	(78,604,735)
Total stockholders' equity	6,346,146	4,025,320
Total liabilities and stockholders' equity	$ 7,631,164	$ 5,659,773

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 1,205,599	$ 1,388,791	$ 1,952,481	$ 2,774,157
General and administrative	918,139	917,305	2,141,152	1,949,550

Total operating expenses	2,123,738	2,306,096	4,093,633	4,723,707
Loss from operations	(2,123,738)	(2,306,096)	(4,093,633)	(4,723,707)
Other income:				
Interest income	9,642	2,902	14,271	4,335
Gain from change in fair value of warrant liability	—	—	—	433,392
Total other income	9,642	2,902	14,271	437,727
Net loss	$ (2,114,096)	$ (2,303,194)	$ (4,079,362)	$ (4,285,980)
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.14)	$ (0.20)	$ (0.27)
Weighted-average shares used to compute basic and diluted net loss per share	23,258,567	16,425,468	20,371,442	15,926,253

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Source: Evoke Pharma, Inc.