Evoke Pharma Completes Manufacturing of Commercial Scale Registration Batches of Gimoti™

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SOLANA BEACH, Calif., Sept. 17, 2019 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has completed manufacturing commercial scale batches of its product candidate Gimoti (metoclopramide nasal spray) with its partner Thermo Fisher Scientific, a leading global contract development and manufacturing organization that specializes in the preparation, fill and finish of nasal spray products.

Evoke plans to collect Chemistry, Manufacturing and Controls (CMC) data from these registration batches, which were requested in the complete response letter (CRL) from the U.S. Food and Drug Administration (FDA). These data will be used to support the proposed acceptance criteria for performance characteristics and device quality control and will be included in Evoke's planned resubmission of the 505(b)(2) New Drug Application (NDA) for Gimoti.

"We are pleased to complete another step toward commercial readiness with manufacturing at commercial scale while addressing regulatory requests," stated Dave Gonyer, President and CEO. "Based on the meeting minutes from our recent Type A meeting with FDA, we are now focused on collecting data from these batches to support our NDA resubmission. Simultaneously, we continue to prepare the root cause analysis and patient experience data as requested in the CRL. We remain on track to resubmit a comprehensive NDA package for Gimoti in the fourth quarter of this year."

About Gastroparesis
Gastroparesis is a debilitating, episodic condition that disproportionately affects adult women and is characterized by slow or delayed gastric emptying of the stomach's contents after meals, often resulting in flares of symptoms that include nausea, vomiting, abdominal pain and bloating. Vomiting and gastric emptying delays can cause unpredictable absorption of food and oral medications, which complicate glucose control and can lead to dehydration and malnutrition. These clinical manifestations of gastroparesis also potentially render existing oral drug treatment options ineffective. If approved, Gimoti would be the first non-oral outpatient drug treatment for symptoms associated with acute and recurrent diabetic gastroparesis in adult women and would represent the first significant advancement in the treatment of gastroparesis in 40 years.

About Evoke Pharma, Inc.
Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat Gastrointestinal (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 plans to use the CMC data from the registration batches to support the resubmission of the Gimoti NDA; the addressability of the approvability issues cited by FDA in the CRL, including with respect to the performance characteristics and root cause analysis regarding the pharmacokinetic variability; and the potential for an NDA resubmission in the fourth quarter. 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 CMC data from the registration batches may not support the acceptance criteria for droplet size distribution and other performance characteristics and device quality control; Evoke may be unable to timely and successfully address the deficiencies raised in the CRL, including as a result of adverse findings from a root cause analysis or data from the completed registration manufactured product batches; FDA may not agree with Evoke's conclusion of the root cause analysis or analysis of the CMC data from the registration batches or may require Evoke to conduct additional studies; the inherent risks of clinical development of Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti and analysis of the PK data; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that FDA will accept or approve an NDA resubmission for Gimoti; Evoke will require substantial additional funding to address the deficiencies raised in the CRL, 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; Evoke's ability to maintain the continued listing of its common stock on the Nasdaq Capital Market; 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.

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