



November 9, 2017

Evoke Pharma Signs Commercial Agreement with Thermo Fisher Scientific

SOLANA BEACH, Calif., Nov. 09, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced the selection of the Patheon division of Thermo Fisher Scientific, Inc., as the commercial manufacturing partner for Gimoti™, Evoke's nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis. Thermo Fisher is a leading global contract development and manufacturing organization (CDMO) with specialized capabilities for the preparation, fill and finish of nasal spray products. Under the five-year agreement, Thermo Fisher will manufacture Gimoti for Evoke's potential commercial efforts.

"We are very pleased to announce the selection of Thermo Fisher as our commercial manufacturing partner, which will supply Gimoti in accordance with FDA standards for chemistry, manufacturing and controls (CMC) as we move closer toward a potential approval of Gimoti. We believe that Thermo Fisher's recent acquisition of Patheon, a CDMO who we have worked closely with since 2008, provides additional expertise in the manufacturing of nasal spray products and makes them an ideal partner," stated Dave Gonyer, R.Ph. President and CEO. "The partnership is another critical step for the Company as we continue to move closer to the commercialization of Gimoti and we are working diligently to prepare and finalize our NDA submission by next quarter."

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 metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal administration. 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: Thermo Fisher's capability of manufacturing Gimoti in accordance with Food and Drug Administration (FDA) standards; Evoke's plans to have Thermo Fisher manufacture Gimoti for its commercial efforts; and the timing of the submission of a new drug application (NDA) for Gimoti. 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 risks and difficulties of complying with FDA's manufacturing standards; risks associated with FDA review of the final results from the recently completed comparative exposure pharmacokinetic (PK) trial; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings; the inherent risks of clinical development of Gimoti; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing Gimoti; Evoke's dependence on third parties for the manufacture of Gimoti as well as the analysis of the PK trial results; Evoke may require additional funding to complete the analysis of the PK trial results and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; 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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