September 7, 2016

Evoke Pharma Announces Positive Non-Clinical Pre-NDA Meeting with FDA for Gimoti

SOLANA BEACH, Calif., Sept. 07, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (Nasdaq:EVOK) (the "Company"), a specialty pharmaceutical company focused on treatments for gastrointestinal diseases, today announced that it has completed a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding its lead product candidate, Gimoti™, its patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. The focus of this pre-NDA meeting with the FDA was the content of the regulatory, chemistry, manufacturing, and control (CMC), and non-clinical sections of the Company's planned 505(b)(2) NDA for Gimoti.

Prior to the pre-NDA meeting, Evoke submitted an information package describing the proposed content and format of the regulatory, CMC, and non-clinical sections of the Gimoti NDA. The subsequent face-to-face pre-NDA meeting afforded Evoke the opportunity to gain further understanding of the FDA's expectations regarding these key sections of the NDA.

Based on the FDA's response to the information package and the pre-NDA meeting discussion, Evoke believes it now has the information needed to complete these sections of the NDA in a manner that will be acceptable for the FDA's review of the complete package.

"We are pleased to have begun discussions with the Agency regarding our proposed NDA submission for Gimoti utilizing the 505(b)(2) pathway. We had a very productive meeting and this portion of our data package was well-received," Dave Gonyer, R.Ph., President and CEO, stated. "Additionally, it was agreed that Evoke will request to meet with the FDA again in the near future to discuss the clinical data that will comprise the remaining sections of the NDA."

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," "or 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: potential NDA submission and regulatory pathway for Gimoti, including Evoke's belief that the sections of the NDA regarding the regulatory, CMC and non-clinical information will be acceptable to the FDA; the timing, if any, of an additional pre-NDA meeting with the FDA to discuss the clinical sections of the NDA; and the potential for regulatory approval and commercialization of 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 risk and uncertainties inherent in Evoke's business, including, without limitation: additional analyses of data from the Phase 3 trial may produce negative or inconclusive results and may not serve as the basis for an NDA submission or regulatory approval; the final FDA minutes may be inconsistent with Evoke's understanding of the FDA's position on the matters addressed at the meeting, or may be inconsistent with previously announced topline results; 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 conduct additional trials of Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; Evoke will require substantial additional funding to continue to develop and 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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