FDA Exempts Evoke from Requirement for Human Factor Validation Study

Company reaffirms NDA submission by year end 2017

SOLANA BEACH, Calif., Feb. 15, 2017 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal diseases, today announced that it has received a letter from FDA exempting its late stage product, Gimoti™ from a Human Factors (HF) Validation study requirement prior to submission of a New Drug Application (NDA).

In February 2016, FDA published new guidance entitled “Applying Human Factors and Usability Engineering to Medical Devices”, which requires drug products classified as a drug/device combination, such as Gimoti, undergo evaluation that may require an HF Validation study as described in FDA’s Guidance.

To comply with this new Guidance, Evoke evaluated the need for an HF Validation study and submitted an HF assessment report to FDA for Gimoti using a Failure Mode and Effects Analysis risk analysis taking into account the intended uses, users, use environments, product-user interface, and associated medical factors. In their written response, FDA stated Evoke had adequately considered the risks associated with the proposed Gimoti nasal spray and determined that an HF Validation study is not needed at this time. The favorable FDA response helps reduce potential risks and saves additional resources in the development process including NDA preparation.

“We are very pleased with the continued FDA communication and their agreement that an HF Validation study is not needed. This is another step closer to a potential NDA submission which our entire team remains focused to deliver this year," commented Dave Gonyer R.Ph., President and CEO. Mr. Gonyer continued, “Given FDA agreement at a recent pre-NDA meeting to conduct a comparative exposure trial in healthy subjects, we are finalizing procedures to initiate that trial as soon as possible. We intend to pursue an NDA submission by the end of the year and plan to update our investors in the near term with more specific timelines on these efforts.”

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: the FDA’s decision to exempt Evoke from conducting an HF Validation study prior to submitting the NDA for Gimoti; the timing of the initiation of the comparative exposure trial in healthy subjects; and the timing of Evoke’s submission of the NDA for Gimoti to the FDA. 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 FDA may determine based on further review to require Evoke to complete an HF Validation study prior to submitting the NDA for Gimoti; risks associated with successfully commencing and receiving favorable results from the planned comparative exposure trial in healthy subjects; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings, including that the FDA will not accept selected data from our Phase 3

clinical trial; the FDA may change its recommendations regarding evaluation of drugs for the treatment of gastroparesis; 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 new formulations of Gimoti for use in the PK trial; Evoke's dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK trial 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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