



FDA Approves PDUFA Fee Waiver for Gimoti™ New Drug Application

March 5, 2018

Cash runway updated into October 2018

SOLANA BEACH, Calif., March 05, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the U.S. Food and Drug Administration (FDA) granted its request for a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee of approximately \$2.4 million for the 505(b)(2) New Drug Application (NDA) for Evoke's Gimoti™, nasal delivery formulation of metoclopramide for the treatment of symptoms associated with gastroparesis in women. The Company remains on track to file the Gimoti NDA next quarter.

"FDA's grant of the PDUFA fee waiver enables us to continue to focus our resources on finalizing the Gimoti NDA filing. As we review our 2018 budget, we are able to extend our cash runway into October 2018. We continue to remain conservative with our expenditures and with a projected NDA filing next quarter, we look forward to a potential U.S. product launch in 2019," commented Dave Gonyer, President and CEO.

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: anticipated timing to submit an NDA for Gimoti and Evoke's projected cash runway. 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 disagree that the existing safety database is sufficient to allow an NDA submission and approval; risks associated with FDA review of the final results from the comparative exposure pharmacokinetic (PK) trial, including the FDA may not agree with Evoke's interpretation of such results; later developments with the FDA that may be inconsistent with the already completed pre-NDA meetings and most recent correspondence; 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; Evoke will require substantial additional funding to conduct any new safety trials required by the FDA prior to NDA submission, and may be unable to raise capital 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.

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Source: Evoke Pharma, Inc.