Evoke Granted Gender Specific Patent for Gimoti™ in Mexico

May 10, 2018

First North American patent for Gimoti with expiry in 2032

SOLANA BEACH, Calif., May 10, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that the Mexican Institute of Industrial Property has issued a Notice that it intends to grant Mexican Patent Application MX/a/2014/002125 for Gimoti, covering uses of metoclopramide for intranasal delivery for the treatment of symptoms associated with diabetic gastroparesis specifically for women.

“This is the second allowance from our estate of international patent applications directed toward female specific intellectual property in gastroparesis,” commented Dave Gonyer, President and CEO. “The studies we have conducted have shown significant differences in how to treat patients with gastroparesis. As a result of the gender differences we have found in our clinical program, we are focused on developing Gimoti specifically for women so we can provide the best possible treatment option to patients suffering from this debilitating disease.”

Gastroparesis, which often compromises the ability for oral medications to pass through the stomach to allow predictable absorption, remains a significant burden on patients, 80% of whom are women. Through Evoke’s extensive gastroparesis research, the Company has developed Gimoti, its nasal formulation of metoclopramide, to deliver an effective medication while bypassing the dysfunctional stomach. This non-oral treatment is an important improvement in relieving symptoms of this debilitating disease, where approximately 4 million prescriptions of oral metoclopramide are written each year in the United States.

The company is currently preparing to submit its 505(b)(2) New Drug Application (NDA) for Gimoti to the U.S. Food and Drug Administration (FDA) within the second quarter 2018.

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: the anticipated expiration date of the Mexican patent; Evoke’s plans to continue development of Gimoti specifically for women; anticipated timing to submit an NDA for Gimoti; and the potential timing of FDA approval, if any, of the 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: Evoke may spend its available cash faster than it anticipates; 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 may not be able to obtain, maintain and enforce its patents and other intellectual property rights, and it may be prohibitively difficult or costly to protect such rights; the scope of the patent to be issued by the Mexican Institute of Industrial Property may not provide the protections we expect; 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, 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.