Evoke Announces Agreement with Mallinckrodt to Amend Milestone Payments

March 26, 2018

Cash runway extended to January 2019

SOLANA BEACH, Calif., March 26, 2018 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has amended the Company's agreement with Mallinckrodt, ARD Inc. to defer development and approval milestone payments for Gimoti™, the Company's nasal delivery formulation of metoclopramide for the treatment of symptoms associated with gastroparesis in women. The amended agreement defers the amount and timing of two milestone payments due upon U.S. Food and Drug Administration (FDA) acceptance for review of the New Drug Application (NDA) and final product marketing approval into a single milestone payment due one year after FDA approval of the Gimoti NDA.

"We continue to focus our current resources on the NDA submission and commercial preparation of Gimoti and appreciate Mallinckrodt's support of Evoke and our intent to bring Gimoti to market. This deferral provides us additional available capital. We have now improved our cash runway to January of next year and remain on track to submit the Gimoti NDA next quarter," 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; the potential timing of FDA approval, if any, of the 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: 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 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.

Investor Contact:
The Ruth Group
Tram Bui
Tel: 646-536-7035
tbui@theruthgroup.com

Primary Logo

Source: Evoke Pharma, Inc.