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Evoke Accelerates New Drug Application Process by Engaging Regulatory Experts

NDA Preparation Initiates as EVK-001 Nears Phase 3 Study Completion

SOLANA BEACH, Calif., March 03, 2016 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ:EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has engaged Regulatory Professionals, Inc. (RPI) to provide additional personnel and expertise to the Company in connection with the preparation and submission of its New Drug Application (NDA) for metoclopramide nasal spray (EVK-001) to the U.S. Food and Drug Administration (FDA).

RPI has been providing full service regulatory affairs assistance to pharmaceutical companies in accordance with FDA standards for more than 15 years. Evoke has been preparing the needed documentation for the NDA and with this relationship is now able to accelerate the process. RPI has been engaged to assist Evoke with strategic and tactical regulatory services for an NDA submission as well as with preparation for a pre-NDA meeting with the FDA. The data from Evoke's ongoing Phase 3 clinical trial of EVK-001, which is expected to complete enrollment in the second quarter of 2016, will be included in the submission. RPI previously assisted Evoke with the planning process for the EVK-001 NDA, and together they are now initiating synthesis of documents required for the NDA.

Marilyn Carlson, D.M.D, M.D., RAC, Chief Medical Officer of Evoke, commented, "RPI has a seasoned team with many years of experience helping companies successfully compile their data into a comprehensive NDA for submission to the FDA. By engaging the firm at this point in our process, we are preparing to move to a pre-NDA meeting rapidly after completion of our Phase 3 trial. Furthermore, the FDA has agreed we can submit a 505(b)(2) NDA which allows us to reference existing data from the literature as well as studies used to approve oral and intravenous metoclopramide formulations to support our application. We expect that this will also help to improve the efficiency of the NDA submission and review process for EVK-001."

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 EVK-001, 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. EVK-001 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 enrollment completion of Evoke's ongoing Phase 3 clinical trial of EVK-001 and the timing of the submission of an NDA for EVK-001 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 risk and uncertainties inherent in Evoke's business, including, without limitation: the inherent risks of clinical development of EVK-001, including delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; Evoke will require substantial additional funding to potentially commercialize EVK-001, as well as

to finance additional development requirements, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; the 505(b)(2) regulatory approval pathway may take longer, cost more or entail greater complications and risks than anticipated, and may not be successful; 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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